As filed with the Securities and Exchange Commission on October 28, 2019

Registration No. 333-234174

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

Amendment No. 1
to
FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

89bio, Inc.
(Exact name of registrant as specified in its charter)

Delaware	2834	36-4946844
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

535 Mission Street, 14th Floor
San Francisco, CA 94105
(415) 500-4614
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Rohan Palekar
Chief Executive Officer
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Approximate date of commencement of proposed sale to the public: As soon as practicable after this registration statement becomes effective.

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. ☐

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act. ☐

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be Registered(1)	Proposed Maximum Offering Price Per Share(2)	Proposed Maximum Aggregate Offering Price(2)	Amount of Registration Fee(3)
Common Stock, par value $0.001 per share	5,031,250	$17.00	$85,531,250	$11,102

(1) Includes 656,250 additional shares that the underwriters have the option to purchase from the registrant, if any. See "Underwriting."
(2) Estimated solely for purposes of calculating the registration fee in accordance with Rule 457(a) under the Securities Act of 1933, as amended.
(3) The registrant previously paid filing fees of $9,086 in connection with a previous filing of its registration statement on Form S-1 (File No. 333-234174), which registration statement contemplated a proposed maximum offering price of $70,000,000.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to such Section 8(a), may determine.

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to Completion
Preliminary Prospectus dated October 28, 2019

PROSPECTUS

4,375,000 Shares

Common Stock

This is 89bio, Inc.'s initial public offering. We are selling 4,375,000 shares of our common stock.

We expect the public offering price to be between $15.00 and $17.00 per share. Currently, no public market exists for the shares. After pricing of the offering, we expect that the shares will trade on The Nasdaq Global Market under the symbol "ETNB."

We are an "emerging growth company" as defined under the federal securities laws and, as such, we have elected to comply with certain reduced public company reporting requirements for this prospectus and may elect to do so in future filings.

Investing in the common stock involves risks that are described in the "Risk Factors" section beginning on page 10 of this prospectus.

	Per Share	Total
Public offering price	$	$
Underwriting discounts and commissions(1)	$	$
Proceeds, before expenses, to us	$	$

(1) See the section titled "Underwriting" for additional information regarding compensation payable to the underwriters.

The underwriters may also exercise their option to purchase up to an additional shares from us, at the public offering price, less the underwriting discount, for 30 days after the date of this prospectus.

Our existing stockholders affiliated with our directors have indicated an interest in purchasing an aggregate of up to approximately $40 million of shares of our common stock in this offering at the initial public offering price per share and on the same terms as the other purchasers in this offering. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, fewer or no shares of common stock to any of these potential purchasers, and any of these potential purchasers could determine to purchase more, fewer or no shares of common stock in this offering. The underwriters will receive the same underwriting discount and commissions on these shares of common stock as they will on any other shares of common stock sold to the public in this offering.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The shares will be ready for delivery on or about , 2019.

BofA Securities **SVB Leerink** **RBC Capital Markets**

Oppenheimer & Co.

The date of this prospectus is , 2019.

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Neither we nor the underwriters have authorized anyone to provide you with information other than that contained in this prospectus or in any free writing prospectus prepared by or on behalf of us or to which we have referred you. We and the underwriters take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We and the underwriters are offering to sell, and seeking offers to buy, common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus or any free writing prospectus is accurate only as of its date, regardless of its time of delivery or of any sale of shares of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside of the United States: We have not, and the underwriters have not, done anything that would permit this offering, or possession or distribution of this prospectus, in any jurisdiction where action for that purpose is required, other than the United States. Persons outside of the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of our common stock and the distribution of this prospectus outside of the United States.

PROSPECTUS SUMMARY

This summary highlights selected information contained elsewhere in this prospectus. This summary does not contain all of the information that you should consider before deciding to invest in our common stock. You should read the entire prospectus carefully, including "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and notes to those consolidated financial statements included elsewhere in this prospectus, before making an investment decision. Some of the statements in this summary constitute forward-looking statements, see "Special Note Regarding Forward-Looking Statements." In this prospectus, unless the context requires otherwise, references to "we," "us," "our," "89bio" or the "company" refer to (i) 89Bio Ltd. for the periods prior to the Reorganization (as defined below) and (ii) 89bio, Inc. for the periods after completion of the Reorganization, in each case together with its consolidated subsidiaries.

Our Company

Overview

We are a clinical-stage biopharmaceutical company focused on the development and commercialization of innovative therapies for the treatment of liver and cardio-metabolic diseases. Our lead product candidate, BIO89-100, a specifically engineered glycoPEGylated analog of fibroblast growth factor 21 ("FGF21"), is currently being developed for the treatment of nonalcoholic steatohepatitis ("NASH"). NASH is a severe form of nonalcoholic fatty liver disease ("NAFLD"), characterized by inflammation and fibrosis in the liver that can progress to cirrhosis, liver failure, hepatocellular carcinoma ("HCC") and death. There are currently no approved products for the treatment of NASH. FGF21 is a clinically-validated mechanism that has been shown in humans to reduce liver fat (steatosis) and address cardio-metabolic dysregulation. We believe BIO89-100 may be a differentiated FGF21 therapy based on its robust and durable biological effects and a favorable tolerability profile, as well its potential for a longer dosing interval. Combining these characteristics with the ability to address the key liver pathologies in NASH, as well as the underlying metabolic dysregulation in NASH patients, BIO89-100 has the potential to become a mainstay of NASH therapy. We successfully completed a Phase 1a, first-in-human, single ascending dose ("SAD") clinical trial with 58 healthy volunteers. The magnitude and significance of BIO89-100's biological effects after a single dose on lipid parameters were robust and durable. In July 2019, we initiated our proof of concept ("POC") Phase 1b/2a clinical trial in patients with NASH or patients with NAFLD and a high risk of NASH and we expect to report topline data in the second half of 2020.

The prevalence of NAFLD, which affects approximately 25% of the global population, and NASH, which develops in approximately 20% to 25% of NAFLD patients, is growing and is driven primarily by the worldwide obesity epidemic. The critical pathophysiologic mechanisms underlying the development and progression of NASH include reduced ability to handle lipids, increased insulin resistance, injury to hepatocytes and liver fibrosis in response to hepatocyte injury. Patients with NASH frequently have other significant metabolic co-morbidities such as obesity, hyperglycemia, dyslipidemia and systemic hypertension (a constellation of which is commonly referred to as metabolic syndrome) and these further contribute to the risk of cardiovascular disease. The number of NASH cases in the United States is projected to expand from 16.5 million in 2015 to 27 million in 2030, with similar prevalence growth expected in Europe. Diet and exercise are currently the standard of care for NAFLD and NASH, but adherence to this treatment regimen is poor and there remains a high unmet need in the treatment of NASH.

We also intend to develop BIO89-100 for the treatment of severe hypertriglyceridemia ("SHTG"), a condition identified by severely elevated levels of triglycerides ("TG") (greater than or equal to 500 mg/dL), which is associated with an increased risk of NASH, cardiovascular events and acute pancreatitis. SHTG accounts for up to 10% of all acute pancreatitis episodes. It is estimated that there are 2.5 million to 4 million patients in the United States with TG ³ 500 mg/dL and up to 50% of SHTG patients treated with certain

approved drugs are refractory to current standard of care. We expect to initiate our Phase 2 trial in SHTG patients in the first half of 2020 in order to evaluate the ability of BIO89-100 to reduce fasting plasma triglyceride levels compared to baseline levels and to report topline data in the first half of 2021. At this stage, we have not sought a Special Protocol Assessment or other agreement with the FDA on the required clinical trials needed to support an application for approval of BIO89-100 in SHTG. However, based on FDA guidance for the development of SHTG treatments, as well as the regulatory path followed by other companies that have successfully developed SHTG therapies, we believe that a combination of smaller clinical trials and shorter development timelines could mean that SHTG potentially represents a quicker path to market for BIO89-100.

We believe BIO89-100 has the potential to address multiple drivers underlying metabolic dysregulation, which would make it an ideal candidate for selected liver and cardio-metabolic diseases.

Our Lead Product Candidate, BIO89-100

BIO89-100 is a specifically engineered FGF21 analog that we believe has the potential to address the critical pathophysiologic mechanisms underlying NASH. FGF21 is a metabolic hormone that regulates energy expenditure and glucose and lipid metabolism. FGF21 has been clinically shown to reduce liver fat (steatosis). It is also thought to exert effects on liver fibrosis by improving metabolic regulation, which reduces ongoing liver injury thus giving the liver time to heal. FGF21 also generates an on-target effect to increase adiponectin, a hormone released from adipose tissue that, among other functions, can suppress development and progression of hepatic fibrosis. However, FGF21 in its native form suffers from a short half-life and a tendency to aggregate in solution, both of which impact its suitability as a viable drug. To address these challenges, we have specifically engineered BIO89-100 to maintain the clinical benefits of FGF21, while extending half-life in vivo, protecting against proteolysis, reducing renal clearance, minimizing susceptibility to aggregate in solution and optimizing potency.

BIO89-100 has been evaluated in seven animal studies of NASH, diabetes and obesity, including studies in mice and non-human primates. Each study was customized to assess endpoints relevant to liver and metabolic diseases and conducted according to standard practices at experienced contract research organizations (“CROs”). In these preclinical studies, consistent beneficial effects across a range of endpoints were observed, including improvements in hepatic steatosis, injury and fibrosis in a diet-induced NASH study of 50 mice (see “Business—BIO89-100—Results of DIN Mouse Studies” Figure 11 which illustrates that statistically significant mean changes with respect to hepatic steatosis and fibrosis were each observed and Figure 12 which illustrates that statistically significant mean changes with respect to injury were observed) and improved glycemic control and lipid handling in a study of 24 spontaneously diabetic obese cynomolgus monkeys with elevated triglycerides (see “Business—BIO89-100—Results of Spontaneously Diabetic Obese Cynomolgus Monkey Studies” Figures 20 and 21, respectively which illustrate that statistically significant mean changes with respect to glycemic control and lipid handling were each observed).

In May 2019, we announced positive topline data from our Phase 1a, first-in-human, SAD clinical trial of BIO89-100 in 58 healthy volunteers. In this SAD study, BIO89-100 demonstrated a favorable tolerability profile in the 43 volunteers who received BIO89-100 with a half-life of 55 to 100 hours. At single doses of 9.1 mg and higher, BIO89-100 demonstrated significant improvements in key lipid parameters measured at Day 8 and Day 15 after dosing on Day 1. The mean changes versus baseline include reductions in triglycerides (up to 51%) and LDL-C (up to 37%) and increase in HDL-C (up to 36%) despite the baseline values being in the normal range. As compared to placebo treatment, these mean changes were all statistically significant ($p < 0.001$). BIO89-100 demonstrated rapid (beginning from Day 2), sustained and durable improvements in lipid parameters for two weeks or more after single dose administration. Based on these findings and results from our animal studies, we believe such a lengthy duration of effect may confer longer dosing intervals to BIO89-100. We are currently enrolling our POC Phase 1b/2a trial with 83 total patients randomized to receive once weekly or

once every two weeks subcutaneous dosing of either BIO89-100 or placebo, in each case, for up to 12 weeks. This trial is designed to assess the safety, tolerability and pharmacokinetic ("PK") properties of BIO89-100, as well as changes in liver steatosis and key biomarker assessments.

We also intend to develop BIO89-100 for the treatment of SHTG. In diabetic obese cynomolgus monkeys with elevated triglycerides, BIO89-100 showed significant effects on triglycerides at doses as low as 0.1 mg/kg/week, with a 78% reduction from baseline observed at the highest dose level of 1.0 mg/kg/week. In our Phase 1a SAD study, BIO89-100 showed a significant reduction in triglycerides of up to 51% after a single dose in healthy volunteers. While currently approved SHTG therapies decrease TG levels, they generally do not have broader metabolic benefits. To the extent that we are able to show in subsequent human clinical trials that BIO89-100 significantly decreases both TG and LDL-C levels and improves other metabolic parameters, we believe that BIO89-100 could be a differentiated therapy in this indication. We expect to initiate our Phase 2 trial in SHTG patients in the first half of 2020 in order to evaluate the ability of BIO89-100 to reduce fasting plasma triglyceride levels compared to baseline levels and to report topline data in the first half of 2021.

BIO89-100 Patent Rights

We retain exclusive worldwide rights to BIO89-100. BIO89-100 is protected by a family of issued patents with claims directed to composition of matter and methods of use. The first of our patents for BIO89-100 are projected to expire in the United States in 2028, with the final composition-of-matter patent projected to expire in the United States in 2038, in each case, without patent term extensions. Because BIO89-100 is a biologic drug, marketing approval is also expected to provide 12 years of market exclusivity in the United States from the approval date of a biologics license application ("BLA").

Our Team

Our management team has extensive drug development, manufacturing and commercialization experience, having brought many successful drugs to market, including biologic agents. We are also supported by a group of directors and leading investors whose collective experience will assist us in realizing our corporate strategy. Our existing investors include OrbiMed, Longitude Capital, RA Capital and Pontifax.

Strategy

Our goal is to become a leading biopharmaceutical company focused on the development and commercialization of innovative therapies for the treatment of liver and cardio-metabolic diseases. The key components of our strategy are to:

- Rapidly advance BIO89-100 through clinical development for the treatment of NASH.
- Expand the breadth of indications for BIO89-100 with an initial focus on SHTG.
- Scale-up and optimize the manufacturing of BIO89-100.
- Establish a commercial infrastructure in key geographies.
- Construct a diversified multi-asset pipeline of novel therapies.

Risks Associated with our Business

Our business is subject to a number of risks that you should be aware of before making an investment decision. You should carefully consider all of the information set forth in this prospectus and, in particular, you

should evaluate the specific factors set forth under "Risk Factors" in deciding whether to invest in our common stock. Among these important risks are the following:

- We are a clinical-stage biopharmaceutical company with a limited operating history and no products approved for commercial sale. We have incurred net losses since our inception, we expect to incur significant and increasing operating losses and we may never be profitable. Our stock is a highly speculative investment.
- Even if this offering is successful, we will require substantial additional capital to finance our operations, which may not be available to us on acceptable terms, or at all. As a result, we may not complete the development and commercialization of BIO89-100 or develop new product candidates.
- Our financial condition raises substantial doubt as to our ability to continue as a going concern.
- Our business depends on the success of BIO89-100, our only product candidate under clinical development, which is in the early stages of clinical development and has not completed a pivotal trial. If we are unable to obtain regulatory approval for and successfully commercialize BIO89-100 or other future product candidates, or we experience significant delays in doing so, our business will be materially harmed.
- Clinical drug development involves a lengthy and expensive process with uncertain timelines and uncertain outcomes, and the results of prior preclinical or clinical trials are not necessarily predictive of our future results. Our clinical trials may fail to adequately demonstrate the safety and efficacy of BIO89-100 or any future product candidates.
- We are initially developing BIO89-100 for the treatment of NASH, an indication for which there are no approved products. This makes it difficult to predict the timing and costs of the clinical development of BIO89-100 in NASH.
- BIO89-100 and any future product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval or limit the commercial profile of an approved label.
- We face substantial competition, which may result in others discovering, developing or commercializing competing products before or more successfully than us.
- Lack of efficacy, adverse events or undesirable side effects may emerge in clinical trials conducted by third parties developing FGF product candidates, which could adversely affect our stock price, our ability to attract additional capital and our development program.
- We have relied on, and expect to continue to rely on, third-party manufacturers to produce BIO89-100 or any future product candidates. Any failure by a third-party manufacturer to produce acceptable product candidates for us pursuant to our specifications and regulatory standards may delay or impair our ability to initiate or complete our clinical trials, obtain and maintain regulatory approvals or commercialize approved products.
- We rely on third parties to conduct our clinical trials and some aspects of our research and preclinical testing, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research or testing.
- Our success depends upon our ability to obtain and maintain intellectual property protection for our products and technologies.

- We rely on a license from Teva Pharmaceutical Industries Ltd. ("Teva") and a sublicense from ratiopharm GmbH ("ratiopharm"), a Teva affiliate, to patents and know-how related to glycoPEGylation technology that are used in the development, manufacture and commercialization of BIO89-100. Any termination or loss of significant rights, including the right to glycoPEGylation technology, or breach, under these agreements or any future license agreement related to our product candidates, would materially and adversely affect our ability to continue the development and commercialization of the related product candidates.

Corporate Information

We were incorporated in January 2018 in Israel under the name 89Bio Ltd. 89bio, Inc., the registrant whose name appears on the cover page of this prospectus, was incorporated in June 2019 for the purpose of an internal reorganization transaction. In September 2019, all of the equity holders of 89Bio Ltd. exchanged 100% of the equity of 89Bio Ltd. for 100% of the equity of 89bio, Inc. Following this exchange (the "Reorganization"), 89Bio Ltd. became a wholly owned subsidiary of 89bio, Inc. and 89bio, Inc. owns the business described and for which historical financial information is included elsewhere in this prospectus. Shares of the common stock of 89bio, Inc. are being offered by this prospectus.

Our principal executive offices are located at 535 Mission Street, 14th Floor, San Francisco, California 94105 and our telephone number is (415) 500-4614. Our website is *www.89bio.com*. The information on, or that can be accessed through, our website is not part of this prospectus and is not incorporated by reference herein.

Implications of Being an Emerging Growth Company

We are an emerging growth company, as defined in Section 2(a) of the Securities Act of 1933, as amended (the "Securities Act"), as modified by the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"), and we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including relief from the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, less extensive disclosure obligations regarding executive compensation in our registration statements, periodic reports and proxy statements, exemptions from the requirements to hold a nonbinding advisory vote on executive compensation, and exemptions from stockholder approval of any golden parachute payments not previously approved. We may also elect to take advantage of other reduced reporting requirements in future filings. As a result, our stockholders may not have access to certain information that they may deem important and the information that we provide to our stockholders may be different than, and not comparable to, information presented by other public reporting companies. We could remain an emerging growth company until the earlier of (1) the last day of the year following the fifth anniversary of the completion of this offering, (2) the last day of the year in which we have total annual gross revenue of at least $1.07 billion, (3) the last day of the year in which we are deemed to be a "large accelerated filer" as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), which would occur if the market value of our common stock held by non-affiliates exceeded $700.0 million as of the last business day of the second fiscal quarter of such year or (4) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

In addition, the JOBS Act also provides that an emerging growth company may take advantage of the extended transition period provided in the Securities Act for complying with new or revised accounting standards. An emerging growth company may therefore delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption and, as a result, will not be subject to the same implementation timing for new or revised accounting standards as are required of other public companies that are not emerging growth companies, which may make comparison of our consolidated financial information to those of other public companies more difficult.

The Offering

Common stock offered by us	4,375,000 shares.
Option to purchase additional shares of common stock	The underwriters have a 30-day option to purchase up to 656,250 additional shares of our common stock.
Common stock to be outstanding immediately after this offering	12,063,592 shares (or 12,719,842 shares if the underwriters exercise in full their option to purchase additional shares of our common stock).
Use of proceeds	We expect that our net proceeds from this offering will be approximately $62.7 million (or approximately $72.5 million if the underwriters exercise in full their option to purchase 656,250 additional shares), assuming an initial public offering price of $16.00 per share, the midpoint of the price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds from this offering, together with our existing cash and cash equivalents, to fund the development of BIO89-100 for the treatment of NASH and SHTG, for the manufacture of BIO89-100 and scale up, to evaluate potential new indications for BIO89-100 and for working capital and other general corporate purposes. See “Use of Proceeds” for additional information.
Risk factors	You should carefully read and consider the information set forth in the “Risk Factors” section of this prospectus together with all of the other information set forth in this prospectus, before deciding whether to invest in shares of our common stock.
Proposed Nasdaq Global Market trading symbol	“ETNB”

The number of shares of common stock to be outstanding following this offering (i) is based on 611,226 shares of our common stock and 42,826,389 shares of our convertible preferred stock outstanding as of June 30, 2019, (ii) includes 1,173,611 shares of our convertible preferred stock issued in July 2019, (iii) gives effect to the Reorganization and the automatic conversion immediately prior to the completion of this offering of all outstanding shares of our convertible preferred stock into 7,077,366 shares of our common stock, and (iv) excludes the following:

- 721,079 shares of our common stock issuable upon the exercise of stock options outstanding as of June 30, 2019 under our 2019 Equity Incentive Plan (as amended and restated, the “2019 Plan”) at a weighted-average exercise price of $1.93 per share;
- 583,080 options to purchase shares of our common stock granted subsequent to June 30, 2019 at a weighted-average exercise price of $4.26 per share;
- 343,083 shares of our common stock reserved for future issuance under our 2019 Plan as of June 30, 2019 and 396,727 and 1,383,302 additional shares of common stock reserved for future

issuance on July 28, 2019 and October 24, 2019, respectively, as well as any automatic increase in the number of shares of common stock reserved for future issuance thereunder; and

- 225,188 shares of our common stock to be reserved for future issuance under our 2019 Employee Stock Purchase Plan, which we expect to enter into and which will become effective immediately prior to the completion of this offering, as well as any automatic increase in the number of shares of common stock reserved for future issuance thereunder.

Except as otherwise noted, we have presented the information in this prospectus based on the following assumptions:

- completion of the Reorganization;
- the conversion of all shares of our convertible preferred stock outstanding into 7,077,366 shares of our common stock, which conversion will occur immediately prior to the completion of this offering;
- the one-for-6.217 reverse stock split for our common stock and a proportional adjustment to the conversion ratio of our convertible preferred stock effected on October 25, 2019;
- no exercise by the underwriters of their option to purchase additional shares of our common stock in this offering;
- no exercise of outstanding stock options after June 30, 2019; and
- the filing and effectiveness of our second amended and restated certificate of incorporation (the "Amended Certificate") with the Secretary of State of the State of Delaware, and the adoption of our second amended and restated bylaws (the "Amended Bylaws"), each of which will occur immediately prior to the completion of this offering. See "Description of Capital Stock—Anti-Takeover Effects of Our Amended Certificate, Amended Bylaws and Delaware Law."

Our existing stockholders affiliated with our directors have indicated an interest in purchasing an aggregate of up to approximately $40 million of shares of our common stock in this offering at the initial public offering price per share and on the same terms as the other purchasers in this offering. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, fewer or no shares of common stock to any of these potential purchasers, and any of these potential purchasers could determine to purchase more, fewer or no shares of common stock in this offering. The underwriters will receive the same underwriting discount and commissions on these shares of common stock as they will on any other shares of common stock sold to the public in this offering.

Summary Consolidated Financial Data

The following summary consolidated statement of operations data for the period from January 18, 2018 (inception) to December 31, 2018 are derived from our audited consolidated financial statements included elsewhere in this prospectus. The following summary consolidated statement of operations data for the period from January 18, 2018 (inception) to June 30, 2018 and the six months ended June 30, 2019 and summary consolidated balance sheet data as of June 30, 2019 are derived from our unaudited interim condensed consolidated financial statements included elsewhere in this prospectus. Our unaudited interim condensed consolidated financial statements were prepared on the same basis as our audited consolidated financial statements and, in our opinion, reflect all adjustments, consisting only of normal recurring adjustments, that are necessary for the fair statement of our unaudited interim condensed consolidated financial statements. Our historical results presented below are not necessarily indicative of the results to be expected for any future period, and our interim results are not necessarily indicative of the results to be expected for the full year or any future period. You should read this information in conjunction with the information in "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Selected Consolidated Financial Data" and our consolidated financial statements and the related notes included elsewhere in this prospectus.

	Period from January 18, 2018 (inception) to December 31, 2018	Period from January 18, 2018 (inception) to June 30, 2018	Six Months Ended June 30, 2019
	(in thousands, except share and per share amounts)		
Consolidated Statement of Operations Data:			
Operating expenses:			
Research and development	$ 13,681	$ 6,700	$ 7,474
General and administrative	1,481	268	1,357
Total operating expenses	15,162	6,968	8,831
Loss from operations	15,162	6,968	8,831
Other (income) expenses, net	986	405	10,552
Net loss before tax	16,148	7,373	19,383
Income tax expense	28	—	29
Net loss and comprehensive loss	$ 16,176	$ 7,373	$ 19,412
Net loss per share, basic and diluted(1)	$ 36.45	$ 26.95	$ 31.76
Weighted-average shares used to compute net loss per share, basic and diluted(1)	443,767	273,532	611,226
Pro forma net loss per share, basic and diluted (unaudited) (1)	$ 7.60		$ 4.24
Weighted-average shares used to compute pro forma net loss per share, basic and diluted (unaudited)(1)	2,127,190		4,583,692

(1) See Notes 2 and 11 to our audited consolidated financial statements and Notes 2 and 10 to our unaudited interim condensed consolidated financial statements included elsewhere in this prospectus for an explanation of the calculations of our net loss per share, basic and diluted, and the weighted-average number of shares used in the computation of per-share amounts.

	As of June 30, 2019		
	Actual	Pro Forma(1)	Pro Forma As Adjusted(2)
		(in thousands)	
Consolidated Balance Sheet Data:			
Cash and cash equivalents	$ 21,919	$ 23,093	$ 85,793
Total assets	22,347	23,521	86,017
Total current liabilities	9,537	9,537	9,333
Convertible preferred shares	48,168	—	—
Accumulated deficit	(35,588)	(35,588)	(35,588)
Total shareholders' (deficit) equity	(35,358)	13,984	76,684

(1) The pro forma column reflects (i) the issuance in July 2019 of 1,173,611 shares of our convertible preferred stock and (ii) the automatic conversion of all outstanding shares of our convertible preferred stock into an aggregate of 7,077,366 shares of our common stock immediately prior to the completion of this offering.

(2) The pro forma as adjusted column reflects $62.7 million in estimated proceeds from the issuance and sale of shares of our common stock in this offering, assuming an initial public offering price of $16.00 per share, the midpoint of the price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each $1.00 increase (decrease) in the assumed initial public offering price would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents, total assets, total current liabilities and total shareholders' (deficit) equity by $4.1 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each increase (decrease) of 1,000,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents, total assets, total current liabilities and total shareholders' (deficit) equity by $14.9 million, assuming no change in the assumed initial public offering price per share and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

RISK FACTORS

An investment in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below before deciding whether to purchase shares of our common stock. You should also refer to the other information contained in this prospectus, including our audited consolidated financial statements and related notes included elsewhere in this prospectus and "Management's Discussion and Analysis of Financial Condition and Results of Operations." Our business, financial condition, results of operations and prospects could be materially and adversely affected by any of these risks or uncertainties. In any such case, the trading price of our common stock could decline, and you could lose all or part of your investment.

Risks Related to Our Business and Industry

We are a clinical-stage biopharmaceutical company with a limited operating history and no products approved for commercial sale. We have incurred net losses since our inception, we expect to incur significant and increasing operating losses and we may never be profitable. Our stock is a highly speculative investment.

We are a clinical-stage biopharmaceutical company with a limited operating history that may make it difficult to evaluate the success of our business to date and to assess our future viability. We commenced operations in 2018, and to date, our operations have been limited to organizing and staffing our company, business planning, raising capital, acquiring our initial product candidate, BIO89-100 and licensing certain related technology, conducting research and development activities, including preclinical studies and early clinical trials, and providing general and administrative support for these operations. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect and/or an acceptable safety profile, gain regulatory approval and become commercially viable. We have no products approved for commercial sale, we have not generated any revenue from product sales to date and we continue to incur significant research and development and other expenses related to our ongoing operations. We have limited experience as a company conducting clinical trials and no experience as a company commercializing any products.

We are not profitable and have incurred net losses since our inception. As of June 30, 2019, we had an accumulated deficit of $35.6 million. Consequently, predictions about our future success or viability may not be as accurate as they would be if we had a longer operating history or a history of successfully developing and commercializing pharmaceutical products. We have spent, and expect to continue to spend, significant resources to fund research and development of, and seek regulatory approvals for, BIO89-100 and any future product candidates. We expect to incur substantial and increasing operating losses over the next several years as our research, development, preclinical testing and clinical trial activities increase. As a result, our accumulated deficit will also increase significantly. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our shareholders' (deficit) equity and working capital. The net losses we incur may fluctuate significantly from quarter-to-quarter such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. Even if we eventually generate product revenue, we may never be profitable and, if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

We currently have no source of product revenue and may never become profitable.

BIO89-100 is in the early stages of development. To date, we have not generated any revenue from the licensing or commercialization of BIO89-100. We will not be able to generate product revenue unless and until BIO89-100 or any future product candidate, alone or with future partners, successfully completes clinical trials,

receives regulatory approval and is successfully commercialized. As BIO89-100 is in the early stages of development, we do not expect to receive revenue from it for a number of years, if ever. Although we may seek to obtain revenue from collaboration or licensing agreements with third parties, we currently have no such agreements that could provide us with material, ongoing future revenue and we may never enter into any such agreements. Our ability to generate future product revenue from BIO89-100 or any future product candidates also depends on a number of additional factors, including our or our future partners' ability to:

- successfully complete research and clinical development of BIO89-100 and any future product candidates;
- establish and maintain supply and manufacturing relationships with third parties, and ensure adequate and legally compliant manufacturing of bulk drug substances and drug products to maintain that supply;
- launch and commercialize future product candidates for which we obtain marketing approval, if any, and, if launched independently, successfully establish a sales force, marketing and distribution infrastructure;
- demonstrate the necessary safety data post-approval to ensure continued regulatory approval;
- obtain coverage and adequate product reimbursement from third-party payors, including government payors;
- achieve market acceptance for our or our future partners' products, if any;
- establish, maintain, protect and enforce our intellectual property rights; and
- attract, hire and retain qualified personnel.

In addition, because of the numerous risks and uncertainties associated with pharmaceutical product development, including that our product candidates may not advance through development or achieve the endpoints of applicable clinical trials, we are unable to predict the timing or amount of increased expenses, or if or when we will achieve or maintain profitability. In addition, our expenses could increase beyond expectations if we decide, or are required by the U.S. Food and Drug Administration (the "FDA") or comparable foreign regulatory authorities, to perform studies or trials in addition to those that we currently anticipate. Even if we complete the development and regulatory processes described above, we anticipate incurring significant costs associated with launching and commercializing these products.

Even if we generate revenue from the sale of any of our product candidates that may be approved, we may not become profitable and may need to obtain additional funding to continue operations. If we fail to become profitable or do not sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce our operations.

Even if this offering is successful, we will require substantial additional capital to finance our operations, which may not be available to us on acceptable terms, or at all. As a result, we may not complete the development and commercialization of BIO89-100 or develop new product candidates.

As a clinical-stage biopharmaceutical company, our operations have consumed significant amounts of cash since our inception. We expect our research and development expenses to increase substantially in connection with our ongoing activities, particularly as we conduct our Phase 1b/2a clinical trial of BIO89-100 and seek regulatory approvals for BIO89-100.

We believe that the net proceeds from this offering, together with our existing cash and cash equivalents and the funds available from the first tranche of the potential term loan discussed under the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources", will fund our projected operating requirements into the second half of 2021. Our forecast of the period of time through which our financial resources will adequately support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this "Risk Factors" section. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Our future funding requirements, both short and long-term, will depend on many factors, including:

- the initiation, progress, timing, costs and results of preclinical and clinical studies for BIO89-100 and any future product candidates we may develop;
- the outcome, timing and cost of seeking and obtaining regulatory approvals from the FDA and comparable foreign regulatory authorities, including the potential for such authorities to require that we perform more studies than those that we currently expect or change their requirements on studies that had previously been agreed to;
- the cost to establish, maintain, expand, enforce and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with licensing, preparing, filing, prosecuting, defending and enforcing of any patents or other intellectual property rights;
- the effect of competing technological and market developments;
- market acceptance of any approved product candidates, including product pricing and product coverage and adequate reimbursement by third-party payors;
- the cost of acquiring, licensing or investing in additional businesses, products, product candidates and technologies;
- the cost and timing of selecting, auditing and potentially validating a manufacturing site for commercial-scale manufacturing of BIO89-100; and
- the cost of establishing sales, marketing and distribution capabilities for BIO89-100 and any future product candidates for which we may receive regulatory approval and that we determine to commercialize ourselves or in collaboration with our future partners.

We will require additional capital to discover, develop, obtain regulatory approval for and commercialize BIO89-100 and any future product candidates. We do not have any committed external source of funds. We expect to finance future cash needs through public or private equity or debt offerings or product collaborations. Additional capital may not be available in sufficient amounts or on reasonable terms, if at all. If we do not raise additional capital, we may not be able to expand our operations or otherwise capitalize on our business opportunities, our business and financial condition will be negatively impacted and we may need to:

- significantly delay, scale back or discontinue research and discovery efforts and the development or commercialization of any product candidates or cease operations altogether;
- seek strategic alliances for research and development programs when we otherwise would not, or at an earlier stage than we would otherwise desire or on terms less favorable than might otherwise be available; or
- relinquish, or license on unfavorable terms, our rights to technologies or any product candidates that we otherwise would seek to develop or commercialize ourselves.

In addition, if BIO89-100 receives approval and is commercialized, we will be required to make milestone and royalty payments to Teva, from whom we acquired certain patents and intellectual property relating to BIO89-100, and from whom we licensed patents and know-how related to glycoPEGylation technology that is used in the manufacture of BIO89-100. For additional information regarding this license agreement, please see "Business—Agreements with Teva."

Raising additional capital may cause dilution to stockholders purchasing shares in this offering, restrict our operations or require us to relinquish rights to our technologies.

Stockholders purchasing shares in this offering could suffer dilution or be negatively affected by fixed payment obligations we may incur if we raise additional funds through the issuance of additional equity securities or debt, such as the potential term loan discussed under the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources". Furthermore, these securities may have rights senior to those of our common stock and could contain covenants or protective rights that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we need to secure additional financing, such additional fundraising efforts may divert our management and research efforts from our day-to-day activities, which may adversely affect our ability to develop and commercialize BIO89-100 and any future product candidates.

To the extent we obtain additional funding through product collaborations, these arrangements would generally require us to relinquish rights to some of our technologies, product candidates or products, and we may not be able to enter into such agreements, on acceptable terms, if at all. If we are unable to obtain additional funding on a timely basis, we may be required to curtail or terminate some or all of our development programs or product candidates.

Our financial condition raises substantial doubt as to our ability to continue as a going concern.

Our consolidated financial statements have been prepared assuming that we will continue to operate as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. Based on our current forecast, and without accounting for the proceeds from this offering or any other offering, we do not have sufficient resources for at least the next year following the date that the consolidated financial statements appearing elsewhere in this prospectus were issued. To date, we have not generated revenues from our activities and have incurred substantial operating losses. We expect that we will continue to generate substantial operating losses for the foreseeable future until we complete development of BIO89-100 or our other product candidates and seek regulatory approvals to market such product candidates. We will continue to fund our operations primarily through utilization of our current financial resources and additional raises of capital.

These conditions raise substantial doubt about our ability to continue as a going concern. Additionally, our independent registered public accounting firm has included in its audit opinion for the period from January 18, 2018 (inception) to December 31, 2018 an explanatory paragraph that there is substantial doubt as to our ability to continue as a going concern. We plan to address these conditions by raising funds from our current investors as well as potential outside investors. However, there is no assurance that such funding will be available to us, will be obtained on terms favorable to us or will provide us with sufficient funds to meet our objectives. The reaction of investors to the inclusion of a going concern statement by our auditors and our potential inability to continue as a going concern may materially adversely affect our share price and our ability to raise new capital or enter into partnerships. If we become unable to continue as a going concern, we may have to liquidate our assets and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our consolidated financial statements.

Our business depends on the success of BIO89-100, our only product candidate under clinical development, which is in the early stages of clinical development and has not completed a pivotal trial. If we are unable to obtain regulatory approval for and successfully commercialize BIO89-100 or other future product candidates, or we experience significant delays in doing so, our business will be materially harmed.

To date, the primary focus of our product development has been BIO89-100 for the treatment of patients with NASH. Currently, BIO89-100 is our only product candidate under clinical development. This may make an investment in our company riskier than similar companies that have multiple product candidates in active development and that therefore may be able to better sustain a failure of a lead candidate. Successful continued development and ultimate regulatory approval of BIO89-100 for the treatment of NASH or other indications, including SHTG, is critical to the future success of our business. We have invested, and will continue to invest, a significant portion of our time and financial resources in the clinical development of BIO89-100. If we cannot successfully develop, obtain regulatory approval for and commercialize BIO89-100, we may not be able to continue our operations. The future regulatory and commercial success of BIO89-100 is subject to a number of risks, including the following:

- we may not have sufficient financial and other resources to complete the necessary clinical trials for BIO89-100, including, but not limited to, the clinical trials needed to obtain drug approval;
- the mechanism of action of BIO89-100 is complex, and we do not know the degree to which it will translate into a therapeutic benefit, if any, in NASH or any other indication, and we do not know the degree to which the complex mechanism of action may contribute to long-term safety issues or adverse events, if any, when BIO89-100 is taken for prolonged periods such as in the treatment of NASH or any other indication;
- we may not be able to obtain adequate evidence from clinical trials of efficacy and safety for BIO89-100 for the treatment of NASH or other indications;
- in our clinical trials for BIO89-100, we may need to adjust our clinical trial procedures and may need additional clinical trial sites, which could delay our clinical trial progress;
- the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA or comparable foreign regulatory authorities for marketing approval;
- patients in our clinical trials may suffer serious adverse effects for reasons that may or may not be related to BIO89-100, which could delay or prevent further clinical development;
- the standards implemented by clinical or regulatory agencies may change at any time and we cannot be certain what efficacy endpoints the FDA or foreign clinical or regulatory agencies may require in pivotal clinical trials with respect to NASH or any other indication for the approval of BIO89-100;
- the results of later stage clinical trials may not be as favorable as the results we have observed to date in our preclinical studies and Phase 1a clinical trial;
- if we obtain accelerated approval of BIO89-100 or any other product candidate based on a surrogate endpoint, we may be required to conduct a post-approval clinical outcomes trial to confirm the clinical benefit of the product candidate; if any such post-approval trial is not successful we may not be able to continue marketing the product;
- we cannot be certain of the number and type of clinical trials and non-clinical studies that the FDA or other regulatory agencies will require in order to approve BIO89-100 for the treatment of NASH or any other indication, including SHTG;

- if approved for NASH or SHTG, BIO89-100 will likely compete with products that may reach approval for the treatment of NASH prior to BIO89-100, products that are currently approved for the treatment of SHTG and the off-label use of currently marketed products for NASH and SHTG; and

- we may not be able to obtain, maintain or enforce our patents and other intellectual property rights.

Of the large number of drugs in development in the pharmaceutical industry, only a small percentage results in the submission of a new drug application or a new BLA to the FDA and even fewer are approved for commercialization. Furthermore, even if we do receive regulatory approval to market BIO89-100, any such approval may be subject to limitations on the indicated uses or patient populations for which we may market the products. Accordingly, even if we are able to obtain the requisite financing to continue to fund our development programs, we may be unable to successfully develop or commercialize BIO89-100. If we or any of our future development collaborators are unable to develop, or obtain regulatory approval for, or, if approved, successfully commercialize BIO89-100, we may not be able to generate sufficient revenue to continue our business.

Clinical drug development involves a lengthy and expensive process with uncertain timelines and uncertain outcomes, and the results of prior preclinical or clinical trials are not necessarily predictive of our future results. Our clinical trials may fail to adequately demonstrate the safety and efficacy of BIO89-100 or any future product candidates.

BIO89-100 and any future product candidates will be subject to rigorous and extensive clinical trials and extensive regulatory approval processes implemented by the FDA and comparable foreign regulatory authorities before obtaining marketing approval from these regulatory authorities. The drug development and approval process is lengthy and expensive, and approval is never certain. Investigational new drugs, such as BIO89-100, may not prove to be safe and effective in clinical trials. We have no direct experience as a company in conducting later stage clinical trials required to obtain regulatory approval. We may be unable to conduct clinical trials at preferred sites, enlist clinical investigators, enroll sufficient numbers of participants or begin or successfully complete clinical trials in a timely fashion, if at all. In addition, the design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. Because we have limited experience as a company designing clinical trials, we may be unable to design and execute a clinical trial to support regulatory approval. Even if our current clinical trial is successful, it will be insufficient to demonstrate that BIO89-100 is safe or effective for registration purposes.

There is a high failure rate for drugs and biologic products proceeding through clinical trials. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of BIO89-100 or any future product candidate may not be predictive of the results of later-stage clinical studies or trials and the results of studies or trials in one set of patients or line of treatment may not be predictive of those obtained in another. In fact, many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late stage clinical trials even after achieving promising results in preclinical studies and earlier stage clinical trials. In addition, data obtained from preclinical and clinical activities is subject to varying interpretations, which may delay, limit or prevent regulatory approval. It is impossible to predict when or if BIO89-100 or any future product candidate will prove effective or safe in humans or will receive regulatory approval. Owing in part to the complexity of biological pathways, BIO89-100 or any future product candidate may not demonstrate in patients the biochemical and pharmacological properties we anticipate based on laboratory studies or earlier stage clinical trials, and they may interact with human biological systems or other drugs in unforeseen, ineffective or harmful ways. The number of patients exposed to product candidates and the average exposure time in the clinical development programs may be inadequate to detect rare adverse events or findings that may only be detected once a product candidate is administered to more patients and for greater periods of time. To date, our Phase 1a clinical trial has involved a small patient population of healthy volunteers and, because of the small sample size in such trial, the results of this clinical trial may be subject to substantial

variability and may not be indicative of either future interim results or final results in patients with liver or cardio-metabolic diseases. If we are unable to successfully demonstrate the safety and efficacy of BIO89-100 or other future product candidates and receive the necessary regulatory approvals, our business will be materially harmed.

If we experience delays in clinical testing, our commercial prospects will be adversely affected, our costs may increase and our business may be harmed.

Conducting clinical studies for any product candidates for approval in the United States requires filing an investigational new drug ("IND") application and reaching agreement with the FDA on clinical protocols, finding appropriate clinical sites and clinical investigators, securing approvals for such studies from the institutional review board at each such site, manufacturing clinical quantities of product candidates and supplying drug product to clinical sites. Currently, we have an active IND with the FDA in the United States for BIO89-100. Because our IND is with the gastrointestinal division of the FDA, we may be required to file an additional IND with another division for any future indications, including SHTG. If any such future IND is not approved by the FDA, our clinical development timeline may be negatively impacted and any future clinical programs may be delayed or terminated.

We cannot guarantee that we will be able to successfully accomplish required regulatory activities or all of the other activities necessary to initiate and complete clinical trials. As a result, our preclinical studies and clinical trials may be extended, delayed or terminated, and we may be unable to obtain regulatory approvals or successfully commercialize our products. We do not know whether any other clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Our product development costs will increase if we experience delays in clinical testing. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize BIO89-100 and any future product candidates or allow our competitors to bring products to market before we do, which would impair our ability to successfully commercialize BIO89-100 or any future product candidates and may harm our business, results of operations and prospects. Events that may result in a delay or unsuccessful completion of clinical development include:

- delays in reaching agreement on acceptable terms with prospective CROs and clinical trial sites;
- ongoing discussions with the FDA or comparable foreign authorities regarding the scope or design of our clinical trials;
- deviations from the trial protocol by clinical trial sites and investigators, or failures to conduct the trial in accordance with regulatory requirements;
- the need to repeat clinical trials as a result of inconclusive or negative results or poorly executed testing or changes in required endpoints by the FDA or comparable foreign authorities;
- unfavorable FDA inspection and review of a clinical trial site or records of any clinical or preclinical investigation;
- the placement of a clinical hold on a clinical trial by the FDA or comparable foreign authorities;
- delays in obtaining, or the inability to obtain, required approvals from institutional review boards or other governing entities at clinical sites selected for participation in our clinical trials;
- failure of third parties, such as CROs, to satisfy their contractual duties to us or meet expected deadlines;

- delays in the testing, validation, manufacturing and delivery of the product candidates to the clinical sites;
- insufficient supply or deficient quality of product candidate materials or other materials necessary to conduct our clinical trials;
- for clinical trials in selected patient populations, delays in identification and auditing of central or other laboratories and the transfer and validation of assays or tests to be used to identify selected patients;
- delays in enrolling participants into our clinical trials;
- delays in patients completing a trial or returning for post-treatment follow-up;
- delays caused by patients dropping out of a trial due to side effects, disease progression or otherwise;
- serious and unexpected drug-related adverse effects experienced by participants in our clinical trials;
- implementation of new, or changes to, guidance or interpretations from the FDA or comparable foreign authorities with respect to approval pathways for any product candidates we are pursuing, such as the draft guidance documents from the FDA and the European Medicines Agency for the development of NASH that were issued in 2018 and 2019;
- withdrawal of clinical trial sites from our clinical trials as a result of changing standards of care or the ineligibility of a site to participate in our clinical trials; or
- changes in government regulations or administrative actions or lack of adequate funding to continue the clinical trials.

Our or our future collaborators' inability to timely complete clinical development could result in additional costs to us as well as impair our ability to generate product revenue, continue development, commercialize BIO89-100 and any future product candidates, reach sales milestone payments and receive royalties on product sales. In addition, if we make changes to a product candidate, we may need to conduct additional nonclinical studies or clinical trials to bridge or demonstrate the comparability of our modified product candidate to earlier versions, which could delay our clinical development plan or marketing approval for our current product candidate and any future product candidates.

If we encounter difficulties in enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

The timely completion of clinical trials largely depends on patient enrollment. We may encounter delays in enrolling, or be unable to enroll, a sufficient number of patients to complete any of our clinical trials, and even once enrolled, we may be unable to retain a sufficient number of patients to complete any of our trials. Furthermore, as a result of the inherent difficulties in diagnosing NASH, which can currently only be definitively diagnosed through a liver biopsy, and the significant competition for recruiting NASH patients in clinical trials, we or our future collaborators may be unable to enroll the patients we need to complete clinical trials on a timely basis, or at all.

Many factors affect patient enrollment, including:

- the size and nature of the patient population, which may be limited due to diagnostic requirements;

- the number and location of clinical sites;
- competition with other companies for clinical sites or patients;
- the availability and amount of any patient stipend;
- the eligibility and exclusion criteria for the trial, including any potential requirement for a biopsy;
- the design of the clinical trial;
- inability to obtain and maintain patient consents;
- significant adverse events or other side effects observed, if any;
- risk that enrolled participants will drop out before completion; and
- competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies (oral versus injectables, like BIO89-100), including any new drugs that may be approved for the indications we are investigating.

In addition, our competitors, some of whom have significantly greater resources than we do, are conducting clinical trials for the same indications and seek to enroll patients in their studies that may otherwise be eligible for our clinical studies or trials, which could lead to slow recruitment and delays in our clinical programs. Further, since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which could further reduce the number of patients who are available for our clinical trials in these sites.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. If we are unable to enroll a sufficient number of patients that will complete clinical testing, we will be unable to seek or gain marketing approval for BIO89-100 and any future product candidates and our business will be harmed. Even if we are able to enroll a sufficient number of patients in our clinical studies or trials, delays in patient enrollment may result in increased costs or may affect the timing or outcome of our clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of BIO89-100 and any future product candidates.

We are initially developing BIO89-100 for the treatment of NASH, an indication for which there are no approved products. This makes it difficult to predict the timing and costs of the clinical development of BIO89-100 for the treatment of NASH.

Our current research and development efforts are focused on developing BIO89-100 for the treatment of NASH, an indication for which there are no approved products. The regulatory approval process for novel product candidates such as BIO89-100 can be more expensive and take longer than for other, better known or extensively studied product candidates. As other companies are in later stages of clinical trials for their potential NASH therapies, we expect that the path for regulatory approval for NASH therapies may continue to evolve in the near term as these other companies refine their regulatory approval strategies and interact with regulatory authorities. Such evolution may impact our future clinical trial designs, including trial size and endpoints, in ways that we cannot predict today. Our anticipated development costs would likely increase if development of BIO89-100 or any future product candidate is delayed because we are required by the FDA to perform studies or trials in addition to, or different from, those that we currently anticipate. Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to predict the timing or amount of any increase in our anticipated development costs.

BIO89-100 and any future product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval or limit the commercial profile of an approved label.

Undesirable side effects caused by BIO89-100 or any future product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authorities. Additional clinical studies may be required to evaluate the safety profile of BIO89-100 or any future product candidates. While no serious adverse events were reported in our Phase 1a clinical trial of BIO89-100, the following treatment-related adverse events were reported in at least two subjects in the treatment cohort: injection site reactions and headaches.

Future results of our trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. In such an event, we could suspend or terminate our trials or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of BIO89-100 or any future product candidates for any or all targeted indications. Drug-related side effects could affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Any of these occurrences could materially and adversely affect our business, financial condition, results of operations and prospects.

It may be difficult to discern whether certain events or symptoms observed during our clinical trials or by patients using our approved products are related to BIO89-100 or any future product candidates or approved products or some other factor. As a result, we and our development programs may be negatively affected even if such events or symptoms are ultimately determined to be unlikely related to BIO89-100 or any future product candidates or approved products. We cannot assure you that additional or more severe adverse side effects related to BIO89-100 or any future product candidates will not be observed in our clinical trials or in the commercial setting. Further, we expect that BIO89-100 will require multiple administrations vis subcutaneous injection in the course of a clinical trial, and this chronic administration increases the risk that our clinical drug development programs may not uncover all possible adverse events that may eventually be experienced by patients treated with BIO89-100, such as rare adverse events or chance findings that may only be detected once product candidates are administered to ore patients or for greater periods of time. If observed, such adverse side effects could delay or preclude regulatory approval of BIO89-100 or any future product candidates, limit commercial use or result in the withdrawal of previously granted marketing approvals. If we or others identify undesirable or unacceptable side effects caused by BIO89-100 or any future product candidates or products:

- we may be required to modify, suspend or terminate our clinical trials;
- we may be required to modify or include additional dosage and administration instructions, warnings and precautions, contraindications, boxed warnings, limitations, restrictions or other statements in the product label for our approved products, or issue field alerts to physicians and pharmacies;
- we may be required to conduct costly additional clinical trials;
- we may be subject to limitations on how we may promote our approved products;
- sales of our approved products may decrease significantly;
- regulatory authorities may require us to take our approved products off the market;
- we may be subject to regulatory investigations, government enforcement actions, litigation or product liability claims; and
- our products may become less competitive or our reputation may suffer.

Any of these results could decrease or prevent any sales of our approved product or substantially increase the costs and expenses of commercializing and marketing our product.

We face substantial competition, which may result in others discovering, developing or commercializing competing products before or more successfully than us.

The biopharmaceutical industry is intensely competitive and subject to rapid innovation and significant technological advancements. We believe the key competitive factors that will affect the development and commercial success of BIO89-100 and any future product candidates are efficacy, safety and tolerability profile, reliability, convenience of dosing, price, the level of generic competition and reimbursement. Our competitors include multinational pharmaceutical companies, specialized biotechnology companies, universities and other research institutions. A number of biotechnology and pharmaceutical companies are pursuing the development or marketing of pharmaceuticals that target the same diseases that we are targeting. Smaller or earlier-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Given the high incidence of NASH and SHTG, it is likely that the number of companies seeking to develop products and therapies for the treatment of liver and cardio-metabolic diseases, such as NASH and SHTG, will increase. For additional information regarding our competition, please see “Business—Competition.”

There are no currently approved therapies for the treatment of NASH. Although there are no approved therapies that specifically target the signaling pathways that BIO89-100 is designed to affect, there are numerous currently approved therapies for treating diseases other than NASH and some of these currently approved therapies may exert effects that could be similar to BIO89-100. Many of these approved drugs are well-established therapies or products and are widely accepted by physicians, patients and third-party payors. Some of these drugs are branded and subject to patent protection, and others are available on a generic basis. Insurers and other third-party payors may also encourage the use of generic products or specific branded products. We expect that if BIO89-100 or any future product candidates are approved, they will be priced at a significant premium over competitive generic products, including branded generic products. This may make it difficult for us to differentiate our products from currently approved therapies, which may adversely impact our business strategy. In addition, many companies are developing new therapeutics, and we cannot predict what the standard of care will be as BIO89-100 or any future product candidates progress through clinical development. In addition, to the extent BIO89-100 or any future product candidates are approved for cardio-metabolic indications, such as SHTG, the commercial success of our products will also depend on our ability to demonstrate benefits over the then-prevailing standard of care, including diet, exercise and lifestyle modifications.

Further, if BIO89-100 or any future product candidates are approved for the treatment of SHTG, we will compete with currently approved therapies and therapies further along in development. Our competitors both in the United States and abroad include large, well-established pharmaceutical and generic companies with significantly greater name recognition. Our competitors may be able to charge lower prices than we can, which may adversely affect our market acceptance. Many of these competitors have greater resources than we do, including financial, product development, marketing, personnel and other resources. Clinical trials for the treatment of SHTG may be relatively costly and time consuming. The requirements for approval by the FDA and comparable foreign regulatory authorities may change over time and this may require changes to ongoing or future clinical trial designs that could impact timelines and cost.

If our competitors market products that are more effective, safer or cheaper than our products or that reach the market sooner than our products, we may not achieve commercial success. In addition, the biopharmaceutical industry is characterized by rapid technological change. Because our research approach integrates many technologies, it may be difficult for us to stay abreast of the rapid changes in other technologies. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our technologies, products or product candidates obsolete, less competitive or not economical.

Many of our competitors have substantially greater financial, technical, human and other resources than we do and may be better equipped to develop, manufacture and market technologically superior products. In addition, many of these competitors have significantly longer operating histories and greater experience than we have in undertaking nonclinical studies and human clinical trials of new pharmaceutical products and in obtaining regulatory approvals of human therapeutic products. Many of our competitors have established distribution channels for the commercialization of their products, whereas we have no such channel or capabilities. In addition, many competitors have greater name recognition and more extensive collaborative relationships.

As a result, our competitors may obtain regulatory approval of their products more rapidly than we do or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidate or any future product candidates. Our competitors may also develop and succeed in obtaining approval for drugs that are more effective, more convenient, more widely used and less costly or have a better safety profile than our products and these competitors may also be more successful than we are in manufacturing and marketing their products. If we are unable to compete effectively against these companies, then we may not be able to commercialize our product candidate or any future product candidates or achieve a competitive position in the market. This would adversely affect our ability to generate revenue. Our competitors also compete with us in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical trial sites and enrolling patients for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our inability to compete effectively in any of these aspects of our business could harm our business, financial condition, results of operations and prospects.

Lack of efficacy, adverse events or undesirable side effects may emerge in clinical trials conducted by third parties developing FGF product candidates, which could adversely affect our stock price, our ability to attract additional capital and our development program.

Lack of efficacy, adverse events or undesirable side effects may emerge in clinical trials conducted by third parties developing FGF product candidates like ours. For example, Bristol-Myers Squibb Company and Akero Therapeutics, Inc. are also developing FGF21 product candidates for the treatment of NASH. We have no control over their clinical trials or development program, and lack of efficacy, adverse events or undesirable side effects experienced by subjects in their clinical trials could adversely affect our stock price, our ability to attract additional capital and our development of BIO89-100 or even the viability of BIO89-100 as a product candidate, including by creating a negative perception of FGF therapeutics by healthcare providers or patients.

Interim, topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary or topline data from our clinical trials, which are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our clinical trials. In addition, we may report interim analyses of only certain endpoints rather than all endpoints. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available.

In addition, adverse changes between interim data and final data could significantly harm our business and prospects. Additional disclosure of interim data by us or by our competitors in the future could also result in volatility in the price of our common stock after this offering. Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular drug, drug candidate or our business. If the topline data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, BIO89-100 or any future product candidates may be harmed, which could harm our business, financial condition, results of operations and prospects.

We may encounter difficulties in managing our growth, which could adversely affect our operations.

We are in the early stages of building the full management team and employee base that we anticipate we will need to complete the development BIO89-100 and other future product candidates. As of June 30, 2019, we had 14 employees, some of whom are based in the United States and some of whom are based in Israel. As we advance our preclinical and clinical development programs for product candidates, seek regulatory approval in the United States and elsewhere and increase the number of ongoing product development programs, we anticipate that we will need to increase our product development, scientific and administrative headcount. We will also need to establish commercial capabilities in order to commercialize any product candidates that may be approved. Such an evolution may impact our strategic focus and our deployment and allocation of resources. Our management, personnel and systems may experience difficulty in adjusting to our growth and strategic focus.

Our ability to manage our operations and growth effectively depends upon the continual improvement of our procedures, reporting systems and operational, financial and management controls. We may not be able to implement administrative and operational improvements in an efficient or timely manner and may discover deficiencies in existing systems and controls. If we do not meet these challenges, we may be unable to execute our business strategies and may be forced to expend more resources than anticipated addressing these issues.

We may acquire additional technology and complementary businesses in the future. Acquisitions involve many risks, any of which could materially harm our business, including the diversion of management’s attention from core business concerns, failure to effectively exploit acquired technologies, failure to successfully integrate the acquired business or realize expected synergies or the loss of key employees from either our business or the acquired businesses.

In addition, in order to continue to meet our obligations as a public company and to support our anticipated long-term growth, we will need to increase our general and administrative capabilities. Our management, personnel and systems may not be adequate to support this future growth.

If we are unable to successfully manage our growth and the increased complexity of our operations, our business, financial position, results of operations and prospects may be materially and adversely affected.

We must attract and retain highly skilled employees in order to succeed. If we are not able to retain our current senior management team and our scientific advisors or continue to attract and retain qualified scientific, technical and business personnel, our business will suffer.

We may not be able to attract or retain qualified personnel and consultants due to the intense competition for such individuals among in the biotechnology and pharmaceutical industries. If we are not able to

attract and retain necessary personnel and consultants to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development and commercial objectives, our ability to raise additional capital and our ability to implement our business strategy.

Our industry has experienced a high rate of turnover of management personnel in recent years. We are highly dependent on the development, regulatory, commercialization and business development expertise of the members of our executive team, as well as other key employees and consultants. If we lose one or more of our executive officers or other key employees or consultants, our ability to implement our business strategy successfully could be seriously harmed. Any of our executive officers or other key employees or consultants may terminate their employment at any time and replacing such individuals may be difficult and time-consuming because of the limited number of individuals in our industry with the necessary breadth of skills and experience. Competition to hire and retain employees and consultants from this limited pool is intense, and we may be unable to hire, train, retain or motivate such individuals. Additionally, we do not currently maintain "key person" life insurance on the lives of our executives or any of our employees. This lack of insurance means that we may not receive adequate compensation for the loss of the services of these individuals. If we are unable to continue to attract and retain high-quality personnel, the rate and success with which we can discover and develop product candidates and our business will be limited.

We have relied on, and expect to continue to rely on, third-party manufacturers to produce BIO89-100 or any future product candidates. Any failure by a third-party manufacturer to produce acceptable product candidates for us pursuant to our specifications and regulatory standards may delay or impair our ability to initiate or complete our clinical trials, obtain and maintain regulatory approvals or commercialize approved products.

The manufacturing of biologic drugs such as BIO89-100 is complex and the process of identifying the qualifying suppliers takes a significant investment of time and money. We do not own or operate manufacturing facilities for the production of clinical or commercial quantities of our product candidates, and we lack the resources and the capabilities to do so. As a result, we currently rely, and expect to rely for the foreseeable future, on third-party manufacturers to supply us with BIO89-100 and any future product candidates.

We currently have a sole source relationship with Northway Biotechpharma ("BTPH") pursuant to which they supply us with BIO89-100. If there should be any disruption in our supply arrangement with BTPH, including any adverse events affecting BTPH, it could have a negative effect on the clinical development of BIO89-100 and other operations while we work to identify and qualify an alternate supply source.

We do not have a long-term supply agreement with any third-party manufacturer. Reliance on third-party manufacturers entails risks to which we would not be subject if we manufacture product candidates or products ourselves. For example, if we do not maintain our key manufacturing relationships, we may fail to find replacement manufacturers or develop our own manufacturing capabilities in a timely manner or at all, which could delay or impair our ability to obtain regulatory approval for our products and substantially increase our costs or deplete profit margins, if any. If we do find replacement manufacturers, we may not be able to enter into agreements with them on terms and conditions favorable to us, and there could be a substantial delay before new facilities could be qualified and registered with the FDA and other comparable foreign regulatory authorities. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the possible failure of the third party to manufacture product candidates according to our schedule, or at all, including if our third-party contractors give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreements between us and them;

- the possible breach of the manufacturing agreement by the third party because of factors beyond our control (including a failure to manufacture product candidates in accordance with our product specifications);
- the possible mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active drug or placebo not being properly identified;
- the possibility of clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how;
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us; and
- reliance on the third party for regulatory compliance, quality assurance and safety and pharmacovigilance reporting.

Certain raw materials necessary for the manufacture of BIO89-100 under our current manufacturing process, such as reagents that are needed for the glycoPEGylation, are available only from a single supplier. In April 2018, we entered into a Reagent Supply and Technology Transfer Agreement with Teva under which Teva agreed to supply us several reagents required for the glycoPEGylation process until December 31, 2022 and transfer the know-how required for our production of these reagents. We expect the manufacture of these reagents will be transferred to a new supplier prior to expiration of the agreement with Teva. Any complications arising under our agreement with Teva, with the subsequent transfer of know-how to us, or any difficulties securing a new supplier could considerably delay the manufacture of BIO89-100. Any significant delay in the acquisition or decrease in the availability of these raw materials from Teva or any new supplier could considerably delay the manufacture of BIO89-100, which could adversely impact the timing of any planned trials or the regulatory approvals of BIO89-100.

The FDA and other comparable foreign regulatory authorities require manufacturers to register manufacturing facilities. The FDA and other comparable foreign regulatory authorities also inspect these facilities to confirm compliance with current good manufacturing practices ("cGMP"). Contract manufacturers may face manufacturing or quality control problems causing drug substance production and shipment delays or a situation where the contractor may not be able to maintain compliance with the applicable cGMP requirements. We may have little to no control regarding the occurrence of third-party manufacturer incidents. Any failure to comply with cGMP requirements or other FDA or comparable foreign regulatory requirements could adversely affect our clinical research activities and our ability to develop BIO89-100 or any future product candidates and market our products following approval. Our sole source supplier, BTPH, has not yet manufactured a commercial product, and as a result, has not been subject to inspection by the FDA and other comparable foreign regulatory authorities.

If BIO89-100 or any future product candidates are approved by the FDA or other comparable foreign regulatory authorities for commercial sale, we may need to manufacture such product candidate in larger quantities. We intend to use third-party manufacturers for commercial quantities of BIO89-100 to the extent we advance this product candidate and other product candidates. Our manufacturers may not be able to successfully increase the manufacturing capacity for any of our product candidates in a timely or efficient manner, or at all. If we are unable to successfully increase the manufacturing capacity for a product candidate, the regulatory approval or commercial launch of that product candidate may be delayed or there may be a shortage in the supply of the product candidate.

In addition, the operations of our third-party manufacturers may be subject to earthquakes, power shortages, telecommunications failures, failures or breaches of information technology systems, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics, and other natural or man-made disasters or business interruptions. Damage or extended periods of interruption to our facilities due to fire, natural disaster, power loss, communications failure, unauthorized entry or other events could cause us to cease or delay development of some or all of our product candidates. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

Our current and anticipated future dependence upon others for the manufacture of our product candidates may adversely affect our future profit margins and our ability to develop our product candidates and commercialize any products that receive regulatory approval on a timely basis.

In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer, we may have difficulty transferring such skills or technology to another third party and a feasible alternative many not exist. These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to have another third party manufacture our product candidates. If we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. For example, in the event that we need to switch our third-party manufacturer of BIO89-100 from BTPH, which is our sole manufacturing source for BIO89-100, we anticipate that the complexity of the glycoPEGylation manufacturing process may materially impact the amount of time it may take to secure a replacement manufacturer. The delays associated with the verification of a new manufacturer, if we are able to identify an alternative source, could negatively affect our ability to develop product candidates in a timely manner or within budget.

The manufacture of biologic products is complex and we are subject to many manufacturing risks, any of which could substantially increase our costs and limit supply of our products.

To date, BIO89-100 has been manufactured by a single third-party manufacturer, BTPH, solely for preclinical studies and clinical trials. This manufacturer may not be able to scale production to the larger quantities required for large clinical trials and to commercialize BIO89-100. The process of manufacturing BIO89-100 is complex, highly regulated and subject to several risks, including:

- the process of manufacturing biologics is susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error and improper storage conditions. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our products or in the manufacturing facilities in which our products are made, the manufacturing facilities may need to be closed for an extended period of time to investigate and eliminate the contamination;

- the manufacturing facilities in which our products are made could be adversely affected by equipment failures, labor and raw material shortages, financial difficulties of our contract manufacturers, natural disasters, power failures, local political unrest and numerous other factors; and

- any adverse developments affecting manufacturing operations for our products may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls or other interruptions in the supply of our products. We may also have to record inventory write-offs and incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts or seek costlier manufacturing alternatives.

The manufacture of biologic products, and in particular, the glycoPEGylation process, is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of biologic products often encounter difficulties in production, particularly in scaling up and validating initial production and ensuring the avoidance of contamination. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, operator error and shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. We cannot assure you that any stability or other issues relating to the manufacture of BIO89-100 will not occur in the future.

We have limited process development capabilities and have access only to external manufacturing capabilities. We do not have and we do not currently plan to acquire or develop the facilities or capabilities to manufacture bulk drug substance or filled drug product for use in human clinical trials or commercialization. Any delay or interruption in the supply of clinical trial materials, including as a result of breach by us or BTPH of our agreement with BTPH, or our inability to agree to the terms of supply or related services in any statement of work, could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely.

We plan to develop a new drug product formulation for BIO89-100 and we may be unsuccessful. Any changes in methods of product candidate manufacturing or formulation may result in the need to perform new clinical trials, which would require additional costs and cause delay.

We plan to develop a new drug product formulation of BIO89-100 for late stage clinical trials and commercialization. Our current drug product is stored as a frozen liquid and is therefore not well-suited to larger clinical trials or commercialization. We have engaged a formulation development company to explore both a new refrigerated liquid formulation and a freeze-dried, or lyophilized formulation. We also plan to begin development of a pen-type autoinjector for the new drug product formulation. There is no assurance that we will be successful in developing a new drug product formulation or an autoinjector on a timely basis or at all, which could impede our development and commercialization strategy for BIO89-100. The FDA or other comparable foreign regulatory authorities could require nonclinical studies or clinical trials to support introduction of any new formulation and autoinjector, which could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase our clinical trial costs, delay approval of BIO89-100 and jeopardize our ability to commence product sales and generate revenue from BIO89-100, if approved.

We rely on third parties to conduct our clinical trials and some aspects of our research and preclinical testing, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research or testing.

We currently rely on, and expect to continue to rely on, third parties, such as CROs, clinical data management organizations, medical institutions, consultants and clinical investigators, to conduct our clinical trials and certain aspects of our research and preclinical testing. Any of these third parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements, it would delay our product development activities and such alternative arrangements may not be available on terms acceptable to us.

Our reliance on these third parties for research and development activities will reduce our control over these activities, but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as current Good Clinical Practices, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. We also are required to register ongoing clinical trials and post the results of completed clinical

trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for BIO89-100 or any future product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our medicines.

We also expect to rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development, marketing approval and/or commercialization of BIO89-100 or any future product candidates, producing additional losses and depriving us of potential revenue.

In addition, while we have received the majority of the knowledge with regard to our current product candidate from Teva, we may still depend on Teva to provide information and documentation regarding certain aspects of BIO89-100 or any future product candidates. If Teva delays providing or fails to provide such information or documentation, we may also be delayed in our efforts to successfully commercialize BIO89-100 or any future product candidates. We also depend on Teva to support our efforts to transfer the manufacturing process to a contract manufacturer. If Teva is unable to or otherwise fails to support such transfer, we may incur significant delay and increased costs in commercializing BIO89-100 or any future product candidates.

We may not be able to obtain and maintain the third-party relationships that are necessary to develop, commercialize and manufacture some or all of our product candidates.

We expect to depend on collaborators, partners, licensees, clinical investigators, CROs, manufacturers and other third parties to support our discovery efforts, to formulate product candidates, to conduct clinical trials for some or all of our product candidates, to manufacture clinical and commercial scale quantities of our drug substance and drug product and to market, sell and distribute any products we successfully develop. Any problems we experience with any of these third parties could delay the development, commercialization and manufacturing of our product candidates, which could harm our results of operations.

We cannot guarantee that we will be able to successfully negotiate agreements for, or maintain relationships with, collaborators, partners, licensees, clinical investigators, CROs, manufacturers and other third parties on favorable terms, if at all. If we are unable to obtain or maintain these agreements, we may not be able to clinically develop, formulate, manufacture, obtain regulatory approvals for or commercialize BIO89-100 and any future product candidates, which will in turn adversely affect our business.

We expect to expend substantial management time and effort to enter into relationships with third parties and, if we successfully enter into such relationships, to manage these relationships. In addition, substantial amounts will be paid to third parties in these relationships. However, we cannot control the amount or timing of resources our future contract partners will devote to our research and development programs, product candidates or potential product candidates, and we cannot guarantee that these parties will fulfill their obligations to us under these arrangements in a timely fashion, if at all. In addition, while we manage the relationships with third parties, we cannot control all of the operations of and any outsourcing used by such third parties. We rely on third parties' knowledge regarding specific local laws and regulatory requirements in foreign jurisdictions, where applicable.

If we fail to develop and commercialize additional product candidates, we may be unable to grow our business.

Although the development and commercialization of BIO89-100 is currently our primary focus, as part of our longer-term growth strategy, we plan to evaluate the development and commercialization of other

therapies related to NASH and other liver and cardio-metabolic diseases. The success of this strategy depends primarily upon our ability to identify and validate new therapeutic candidates, and to identify, develop and commercialize new drugs and biologics. Our research efforts may initially show promise in discovering potential new drugs and biologics, yet fail to yield product candidates for clinical development for a number of reasons, including:

- we may need to rely on third parties to generate molecules for some of our product candidate programs;
- we may encounter product manufacturing difficulties that limit yield or produce undesirable characteristics that increase the cost of manufacturing our product candidates, cause delays or make our product candidates unmarketable;
- product candidates may cause adverse effects in patients or subjects, even after successful initial toxicology studies, which may make the product candidates unmarketable;
- product candidates may not demonstrate a meaningful benefit to patients or subjects; and
- our future collaboration partners may change their development profiles or plans for potential product candidates or abandon a therapeutic area or the development of a partnered product.

If any of these events occur, we may be forced to abandon our development efforts for one or more programs, which could have a material adverse effect on our business, operating results and prospects and could potentially cause us to cease operations. Future research programs to identify new product candidates may require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful.

Product candidates may require additional, time-consuming development efforts prior to commercial sale, including preclinical studies, clinical trials and approval by the FDA and/or comparable foreign regulatory authorities. All product candidates are prone to the risks of failure that are inherent in pharmaceutical product development, including the possibility that the product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot assure you that any such products that are approved will be manufactured or produced economically, be successfully commercialized, be widely accepted in the marketplace, or be more effective than other commercially available alternatives.

We may use our limited financial and human resources to pursue a particular research program or product candidate that is ultimately unsuccessful or less successful than other programs or product candidates that we may have forgone or delayed.

Because we have limited personnel and financial resources, we may forego or delay the development of certain programs or product candidates that later prove to have greater commercial potential than the programs or product candidates that we do pursue. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs for product candidates may not yield any commercially viable products. Similarly, our decisions to delay or terminate drug development programs may also be incorrect and could cause us to miss valuable opportunities. If we fail to accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through strategic collaboration, licensing or other arrangements or we may allocate our limited internal resources to that product candidate when it would have been more advantageous to enter into such an arrangement. Any such failure could have a material adverse effect on our business, financial condition, results of operations or prospects.

As we evolve from a company that is primarily involved in clinical development to a company that is also involved in commercialization, we may encounter difficulties in expanding our operations successfully.

As we advance our product candidates through clinical trials, we will need to expand our development, regulatory, manufacturing, and marketing and sales capabilities and may need to further contract with third parties to provide these capabilities, such as collaborators, distributors, marketers and additional suppliers. We currently have no experience as a company in or infrastructure for sales, marketing and distribution, and our operations are currently limited to clinical development activities and as our operations expand, we likely will need to manage additional relationships with such third parties.

If BIO89-100 or any future product candidate is approved, we intend either to establish a sales and organization with technical expertise and supporting distribution capabilities to commercialize BIO89-100 or any future product candidate or to outsource such functions to one or more third parties. Either of these options would be expensive and time-consuming. Some or all of these costs may be incurred in advance of any approval of BIO89-100 or any future product candidate. In addition, we may not be able to hire a sales force that is sufficient in size or has adequate expertise in the medical markets that we intend to target. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely affect the commercialization of BIO89-100 and other future product candidates.

Maintaining third-party relationships for these purposes will impose significant added responsibilities on members of our management and other personnel. We must be able to effectively manage our development efforts, recruit and train sales and marketing personnel, effectively manage our participation in the clinical trials in which our product candidates are involved and improve our managerial, development, operational and finance systems, all of which may impose a strain on our administrative and operational infrastructure.

If we enter into arrangements with third parties to perform sales, marketing or distribution services, any product revenues that we receive, or the profitability of these product revenues to us, are likely to be lower than if we were to market and sell any products that we develop without the involvement of these third parties. In addition, we may not be successful in entering into arrangements with third parties to sell and market our products or in doing so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our products.

We may seek to establish commercial collaborations for our product candidates, and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.

Our drug development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. We may decide to collaborate with other pharmaceutical and biotechnology companies for the development and potential commercialization of our product candidates.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator’s resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator’s evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or comparable foreign regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products and the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborators may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate.

Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

BIO89-100 and any future product candidates may not achieve adequate market acceptance among physicians, patients, healthcare payors and others in the medical community necessary for commercial success.

Even if our product candidates receive regulatory approval, they may not gain adequate market acceptance among physicians, patients, healthcare payors and others in the medical community. Given the number of drugs in development for the treatment of NASH, if we are unsuccessful in achieving a differentiated profile with BIO89-100 based on efficacy, safety and tolerability, dosing and administration, market acceptance will be limited. Efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may not be successful. Demonstrating the safety and efficacy of our product candidates and obtaining regulatory approvals will not guarantee future revenue. Our commercial success also depends on coverage and adequate reimbursement of our product candidates by third-party payors, including government payors, which may be difficult or time-consuming to obtain, may be limited in scope and may not be obtained in all jurisdictions in which we may seek to market our products. Governments and private insurers closely examine medical products to determine whether they should be covered by reimbursement and, if so, the level of reimbursement that will apply. We cannot be certain that third-party payors will sufficiently reimburse sales of our products, or otherwise enable us to sell our products at profitable prices. Similar concerns could also limit the reimbursement amounts that health insurers or government agencies in other countries are prepared to pay for our products. In many countries or regions where we may market our products, either directly or with collaborators, the pricing of prescription drugs is controlled by the government or regulatory agencies. Regulatory agencies in these countries could determine that the pricing for our products should be based on prices of other commercially available drugs for the same disease, rather than allowing us to market our products at a premium as new drugs. This may be particularly true for drugs that treat NASH or SHTG, which some healthcare providers and payors may deem to be a “lifestyle” disease that could be ameliorated by changes in diet and exercise. The degree of market acceptance of any of our approved product candidates will depend on a number of factors, including:

- the efficacy, safety and dosing profile of the product candidate as demonstrated in clinical trials;
- the timing of market introduction of the product candidate as well as competitive products;
- the clinical indications for which the product candidate is approved;
- acceptance of the product candidate as a safe and effective treatment by physicians and patients;
- the potential and perceived advantages of the product candidate over alternative treatments, including any similar generic treatments;
- the cost of treatment in relation to alternative treatments;

- the availability of coverage and adequate reimbursement and pricing by third parties and government authorities, including any requirements for biopsy-proven NASH prior to being approved for reimbursement;
- patients' willingness to pay out-of-pocket in the absence of coverage and/or adequate reimbursement from third-party payors;
- the relative convenience and ease of administration;
- the frequency and severity of adverse events;
- the effectiveness of sales and marketing efforts; and
- unfavorable publicity relating to the product candidate.

Sales of medical products also depend on the willingness of physicians to prescribe the treatment, which is likely to be based on a determination by these physicians that the products are safe, therapeutically effective and cost effective. In addition, the inclusion or exclusion of products from treatment guidelines established by various physician groups and the viewpoints of influential physicians can affect the willingness of other physicians to prescribe the treatment. We cannot predict whether physicians, physicians' organizations, hospitals, other healthcare providers, government agencies or private insurers will determine that our products are safe, therapeutically effective and cost effective as compared with competing treatments. If any product candidate is approved but does not achieve an adequate level of acceptance by such parties, we may not generate or derive sufficient revenue from that product candidate and may not become or remain profitable.

Even if we commercialize BIO89-100 or any future product candidate, we may face challenges to achieving profitability such as our products becoming subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which could harm our business.

The regulations that govern marketing approvals, pricing and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay or limit our commercial launch of the product, possibly for lengthy time periods, which could negatively impact the revenue we generate from the sale of the product in that particular country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval.

Our ability to commercialize any products successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from third-party payors, including government health care programs and private health insurers. Such third-party payors determine which medications they will cover and establish reimbursement levels. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that coverage and reimbursement will be available for any product that we or our future collaborators commercialize and, if reimbursement is available, what the level of reimbursement will be. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we or our future collaborators obtain marketing approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we and our future collaborators may not be able to successfully commercialize any product candidate for which marketing approval is obtained.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may only be temporary. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Our inability to promptly obtain coverage and profitable reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

To become and remain profitable, we or any potential future collaborator must develop and eventually commercialize BIO89-100 or any future product candidates with significant market potential at an adequate profit margin after cost of goods sold and other expenses. Commercialization of BIO89-100 or any future product candidates may entail a substantial cost of goods sold and there can be no assurance that we will be able to achieve a suitable gross margin with respect to sales of BIO89-100 or any future product candidates.

Healthcare reform in the United States may negatively impact our ability to profitably sell our product candidates, if approved, and to recoup the upfront investment needed to obtain regulatory approval of our product candidates.

Third-party payors, whether domestic or foreign, or governmental or commercial, are continually developing and advancing new methods of controlling healthcare costs. The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product for which we obtain marketing approval.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the “Affordable Care Act”) was enacted, which includes measures that have significantly changed the way health care is financed by both governmental and private insurers. Among the provisions of the Affordable Care Act of particular importance include:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents, which is apportioned among these entities according to their market share in certain government healthcare programs;
- a Medicare Part D coverage gap discount program, in which manufacturers must agree to offer point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer’s outpatient drugs to be covered under Medicare Part D;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- a methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;

- a licensure framework for follow-on biologic products;
- an extension of a manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research; and
- establishment of a Center for Medicare Innovation at the Centers for Medicare & Medicaid Services ("CMS") to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Some of the provisions of the Affordable Care Act have yet to be implemented, and there have been judicial and congressional challenges to certain aspects of the Affordable Care Act which could potentially void or significantly modify the Affordable Care Act in part or in whole. For example, since January 2017, President Trump signed two Executive Orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the Affordable Care Act. On December 22, 2017, President Trump signed into law The Tax Cuts and Jobs Act of 2017 (the "Tax Act"), which includes a provision repealing the individual mandate to maintain health insurance coverage under the Affordable Care Act effective January 1, 2019. Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain mandated fees under the Affordable Care Act, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans and the annual fee imposed on certain health insurance providers based on market share. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas ruled that the individual mandate is a critical and inseverable feature of the Affordable Care Act, and because it was repealed as part of the Tax Act, the remaining provisions of the Affordable Care Act are invalid as well. While neither the Texas District Court Judge, the Trump administration nor CMS have stated that the ruling will have an immediate effect, it is unclear how this decision, subsequent appeals, if any, and other efforts will impact the Affordable Care Act.

At the same time, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs. At the federal level, the Trump administration's budget proposals for fiscal years 2019 and 2020 contain further drug price control measures that could be enacted during the budget process or in other future legislation. The Trump administration released a "Blueprint," or plan, to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. We expect that the healthcare reform measures that have been adopted and may be adopted in the future may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product and could seriously harm our future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate product revenue, attain profitability or commercialize our products.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate product revenue, attain profitability, or commercialize our products. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for

which we may obtain regulatory approval and may affect our overall financial condition, including our ability to recoup the upfront investment needed to obtain regulatory approval for our product candidates.

Our international operations may expose us to business, regulatory, political, operational, financial, pricing and reimbursement risks associated with doing business outside of the United States.

Our use of our international facilities subject us to U.S. and foreign governmental trade, import and export, and customs regulations and laws. Compliance with these regulations and laws is costly and exposes us to penalties for non-compliance. Furthermore, if we succeed in developing any products, we intend to market them in other jurisdictions in addition to the United States. If approved, we may hire sales representatives and conduct physician and patient association outreach activities outside of the United States.

Doing business internationally potentially involves a number of risks, including but not limited to:

- multiple, conflicting and changing laws and regulations such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements, and other governmental approvals, permits and licenses;
- failure by us to obtain and maintain regulatory approvals for the use of our products in various countries;
- rejection or qualification of foreign clinical trial data by the competent authorities of other countries;
- additional potentially relevant third-party patent rights;
- complexities and difficulties in obtaining, maintaining, protecting and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations;
- a shortage of high-quality employees;
- laws and business practices favoring local companies;
- complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems;
- limits in our ability to penetrate international markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products and exposure to foreign currency exchange rate fluctuations;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions;
- the imposition of restrictions on the activities of foreign agents and representatives;
- certain expenses including, among others, expenses for travel, translation and insurance; and
- regulatory and compliance risks that relate to anti-corruption compliance and record-keeping that may fall within the purview of the U.S. Foreign Corrupt Practices Act, its accounting provisions or its anti-bribery provisions or provisions of anti-corruption or anti-bribery laws in other countries.

Any of these factors could harm our ongoing international clinical operations and supply chain, as well as any future international expansion and operations and, consequently, our business, financial condition, prospects and results of operations.

If we fail to comply with foreign regulatory requirements governing human clinical trials and marketing approval for drugs, we could be prevented from selling our product candidates in foreign markets, which may adversely affect our operating results and financial condition.

The requirements governing the conduct of clinical trials, product licensing, pricing, and reimbursement for marketing our product candidates outside the United States vary greatly from country to country and may require additional testing. We expect that our future clinical development of our product candidates will involve a number of clinical trials in foreign jurisdictions. We have no direct experience as a company in obtaining foreign regulatory approvals. The time required to obtain approvals outside the United States may differ from that required to obtain FDA approval. We may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not guarantee approval by comparable foreign regulatory authorities, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other countries or by the FDA. Failure to comply with these regulatory requirements or obtain required approvals could impair our ability to develop foreign markets for our product candidates and may have a material adverse effect on our results of operations and financial condition.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercialize any resulting products. Product liability claims may be brought against us by subjects enrolled in our clinical trials, patients, or others using our products. If we cannot successfully defend ourselves against claims that our product candidates or products that we may develop caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- product recalls or a change in the indications for which products may be used;
- termination of clinical trial sites or entire trial programs;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial subjects or patients;
- loss of revenue;
- diversion of management and scientific resources from our business operations; and
- the inability to commercialize any products that we may develop.

Our clinical trial liability insurance coverage may not adequately cover all liabilities that we may incur. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any

liability that may arise. Our inability to obtain product liability insurance at an acceptable cost or to otherwise protect against potential product liability claims could prevent or delay the commercialization of any products or product candidates that we develop. We intend to expand our insurance coverage for products to include the sale of commercial products if we obtain marketing approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. If we are sued for any injury caused by our products, product candidates or processes, our liability could exceed our product liability insurance coverage and our total assets. Claims against us, regardless of their merit or potential outcome, may also generate negative publicity or hurt our ability to obtain physician endorsement of our products or expand our business.

Our employees, contractors, vendors, principal investigators, consultants and future partners may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, contractors, vendors, principal investigators, consultants or future partners. Misconduct by these parties could include failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with federal and state healthcare fraud and abuse laws and regulations, to report financial information or data timely, completely or accurately, or to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Third-party misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. Although we intend to adopt a Code of Business Conduct and Ethics, which will be effective prior to the consummation of this offering, it is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us resulting from this misconduct and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions. If we or our future partners market products in a manner that violates fraud and abuse and other healthcare laws, or if we or our future partners violate government price reporting laws, we or our future partners may be subject to administrative civil and/or criminal penalties, among other sanctions.

Most states also have statutes or regulations similar to these federal laws, which may apply to items such as pharmaceutical products and services reimbursed by private insurers. We and/or our future partners may be subject to administrative, civil and criminal sanctions for violations of any of these federal and state laws. Pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of promotional and marketing activities, such as: providing free trips, free goods, sham consulting fees and grants and other monetary benefits to prescribers; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off-label promotion; and submitting inflated best price information to the Medicaid Rebate Program to reduce liability for Medicaid rebates. Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations.

Our business operations and relationships with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers are subject to broadly applicable healthcare regulatory laws, which could expose us to penalties.

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any product candidate for which we obtain regulatory approval. Our current and future arrangements may expose us to broadly applicable fraud and abuse and other healthcare laws that may constrain the business or financial arrangements and relationships through which we would market, sell and distribute our products. Even though we will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, federal and state healthcare laws pertaining to fraud and abuse are and will be applicable to our business. Such laws include, but are not limited to, the following:

- Federal false claims, false statements and civil monetary penalties laws, including the federal civil False Claims Act ("FCA"), which can be enforced through civil whistleblower or qui tam actions, prohibit, among others, any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, or causing to be made, a false statement to get a false claim paid.

- The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers, on the one hand, and prescribers, purchasers and formulary managers, on the other. Although there are several statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution, the exceptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. In addition, the intent standard under the federal Anti-Kickback Statute was amended by the Affordable Care Act to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Moreover, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA.

- The federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which prohibits, among other things, knowingly and willfully executing, or attempting to execute, a scheme or artifice to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private), willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious or fraudulent statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

- Patient data privacy and security regulation, including, in the United States, HIPAA, as amended by the Health Information Technology for Clinical Health Act of 2009 ("HITECH"), and their respective implementing regulations, which impose specified requirements on "covered entities," including healthcare providers, health plans, and healthcare clearinghouses, as well as their respective "business associates" that perform services for them that involve the use, or disclosure of, individually identifiable health information relating to the privacy, security and transmission of individually identifiable health information.

- The federal transparency requirements under the Physician Payments Sunshine Act, enacted as part of the Affordable Care Act, that require applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to track and annually report to CMS payments and other transfers of value provided to physicians and teaching hospitals and certain ownership and investment interests held by physicians or their immediate family members in the applicable manufacturer, and disclosure of such information will be made by CMS on a publicly available website.

- Analogous state, local or foreign laws, such as state anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state and local marketing and/or transparency laws applicable to manufacturers that may be broader in scope than the federal requirements; state laws that require biopharmaceutical companies to comply with the biopharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state and local laws that require licensure or registration by sales and marketing agents of a pharmaceutical company; state laws that require disclosure of information related to drug pricing; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect as HIPAA.

Pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of promotional and marketing activities, such as: providing free trips, free goods, sham consulting fees and grants and other monetary benefits to prescribers; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off-label promotion; and submitting inflated best price information to the Medicaid Rebate Program to reduce liability for Medicaid rebates. Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations.

The global data protection landscape is rapidly evolving, and we may be affected by or subject to new, amended or existing laws and regulations in the future, including as our operations continue to expand or if we operate in foreign jurisdictions. For example, in June 2018, California enacted the California Consumer Privacy Act of 2018 (the "CCPA"), which takes effect on January 1, 2020. The CCPA gives California residents the right to access and require deletion of their personal information, the right to opt out of certain personal information sharing, and the right to detailed information about how their personal information is collected, used and shared. The CCPA provides civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. Although the CCPA includes exemptions for certain clinical trials data, the law may increase our compliance costs and potential liability with respect to other personal information we collect about California residents. The CCPA has prompted a wave of proposals for new federal and state privacy legislation that, if passed, could increase our potential liability, increase our compliance costs and adversely affect our business. Several foreign jurisdictions, including the European Union (EU), its member states, the United Kingdom, Japan and Australia, among others, have adopted legislation and regulations that increase or change the requirements governing the collection, use, disclosure and transfer of the personal information of individuals in these jurisdictions. Additionally, certain countries have passed or are considering passing laws that require local data residency and/or restrict the international transfer of data. These laws have the potential to increase costs of compliance, risks of noncompliance and penalties for noncompliance.

If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, disgorgement, fines, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, additional oversight and reporting obligations, contractual damages, reputational harm, diminished

profits and future earnings, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, that person or entity may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

We depend on our information technology systems and those of our third-party collaborators, service providers, contractors or consultants. Our internal computer systems, or those of our third-party collaborators, service providers, contractors or consultants, may fail or suffer security breaches, disruptions, or incidents, which could result in a material disruption of our development programs or loss of data or compromise the privacy, security, integrity or confidentiality of sensitive information related to our business and have a material adverse effect on our reputation, business, financial condition or results of operations.

In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information and personal information. Our internal technology systems and infrastructure, and those of our current or future third-party collaborators, service providers, contractors and consultants are vulnerable to damage from computer viruses, unauthorized access or use resulting from malware, natural disasters, terrorism, war and telecommunication and electrical failures, denial-of-service attacks, cyber-attacks or cyber-intrusions over the Internet, hacking, phishing and other social engineering attacks, persons inside our organizations (including employees or contractors), loss or theft, or persons with access to systems inside our organization. Attacks on information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and they are being conducted by increasingly sophisticated and organized foreign governments, groups and individuals with a wide range of motives and expertise. In addition to extracting or accessing sensitive information, such attacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the security, confidentiality, integrity and availability of information. The prevalent use of mobile devices that access sensitive information also increases the risk of data security incidents which could lead to the loss of confidential information or other intellectual property. While to our knowledge we have not experienced any material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations or the operations of third-party collaborators, service providers, contractors and consultants, it could result in a material disruption of our development programs and significant reputational, financial, legal, regulatory, business or operational harm. The costs to us to mitigate, investigate and respond to potential security incidents, breaches, disruptions, network security problems, bugs, viruses, worms, malicious software programs and security vulnerabilities could be significant, and while we have implemented security measures to protect our data security and information technology systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service and other harm to our business and our competitive position.

For example, the loss of clinical trial data from completed, ongoing or planned clinical trials for our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any real or perceived security breach affects our systems (or those of our third-party collaborators, service providers, contractors or consultants), or results in the loss of or accidental, unlawful or unauthorized access to, use of, release of, or other processing of personally identifiable information or damage to our data or applications or other data or applications relating to our technology or product candidates, or inappropriate disclosure of confidential or proprietary information, we could incur liabilities and the further development of our product candidates could be delayed. Such a breach may require notification to governmental agencies, the media or individuals pursuant to various foreign, domestic (federal and state) privacy and security laws, if applicable, including HIPAA, as amended by HITECH, and its implementing rules and regulations, as well as regulations promulgated by the Federal Trade Commission and state breach notification laws. In addition, our liability insurance may not be sufficient in type or amount to cover us against claims related to security breaches, cyberattacks and other related incidents.

Any failure or perceived failure by us or any third-party collaborators, service providers, contractors or consultants to comply with our privacy, confidentiality, data security or similar obligations, or any data security

incidents or other security breaches that result in the accidental, unlawful or unauthorized access to, use of, release of, processing of, or transfer of sensitive information, including personally identifiable information, may result in negative publicity, harm to our reputation, governmental investigations, enforcement actions, regulatory fines, litigation or public statements against us, could cause third parties to lose trust in us or could result in claims by third parties, including those that assert that we have breached our privacy, confidentiality, data security or similar obligations, any of which could have a material adverse effect on our reputation, business, financial condition or results of operations. To the extent we maintain individually identifiable health information, we could be subject to fines and penalties (including civil and criminal) under HIPAA for any failure by us or our business associates to comply with HIPAA's requirements. Moreover, data security incidents and other security breaches can be difficult to detect, and any delay in identifying them may lead to increased harm. While we have implemented data security measures intended to protect our information, data, information technology systems, applications and infrastructure, there can be no assurance that such measures will successfully prevent service interruptions or data security incidents.

European data collection is governed by restrictive regulations governing the collection, use, processing and cross-border transfer of personal information.

We may collect, process, use or transfer personal information from individuals located in the European Economic Area in connection with our business, including in connection with conducting clinical trials in the European Economic Area (the "EEA"). Additionally, if any of our product candidates are approved, we may seek to commercialize those products in the European Economic Area. The collection and use of personal health data in the European Economic Area is governed by the provisions of the General Data Protection Regulation ((EU) 2016/679) (the "GDPR"), along with other European Union and country-specific laws and regulations. The United Kingdom and Switzerland have also adopted data protection laws and regulations. These legislative acts (together with regulations and guidelines) impose requirements relating to having legal bases for processing personal data relating to identifiable individuals and transferring such data outside of the European Economic Area, including to the United States, providing details to those individuals regarding the processing of their personal data, keeping personal data secure, having data processing agreements with third parties who process personal data, responding to individuals' requests to exercise their rights in respect of their personal data, reporting security breaches involving personal data to the competent national data protection authority and affected individuals, appointing data protection officers or corporate representatives, conducting data protection impact assessments and record-keeping. The GDPR imposes additional responsibilities and liabilities in relation to personal data that we process and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. Failure to comply with the requirements of the GDPR and related national data protection laws of the member states of the European Economic Area and other states in the European Economic Area may result in substantial fines, other administrative penalties and civil claims being brought against us, which could have a material adverse effect on our business, financial condition and results of operations. European data protection authorities may interpret the GDPR and national laws differently and may impose additional requirements, which adds to the complexity of processing personal data in or from the EEA or United Kingdom. Guidance on implementation and compliance practices are often updated or otherwise revised.

Our insurance policies are expensive and only protect us from some business risks, leaving us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter. We believe that we maintain insurance customary for businesses of our size and type, including clinical trial liability insurance. However, there are types of losses we may incur that cannot be insured against or that we believe are not economically reasonable to insure. Moreover, any loss incurred could exceed policy limits and policy payments made to us may not be made on a timely basis. Such losses could adversely affect our business prospects, results of operations, cash flows and financial condition. We do not know if our current levels of coverage are adequate or if we will be able to obtain insurance with adequate levels of coverage in the future, if at all. Any significant uninsured liability may require us to pay substantial amounts, which could materially and adversely affect our financial position and results of operations.

Disputes under key agreements or conflicts of interest with our scientific advisors or clinical investigators could delay or prevent development or commercialization of our product candidates.

Any agreements we have or may enter into with third parties, such as collaboration, license, formulation supplier, manufacturing, clinical research organization or clinical trial agreements, may give rise to disputes regarding the rights and obligations of the parties. Disagreements could develop over contract interpretation, rights to ownership or use of intellectual property, the scope and direction of research and development, the approach for regulatory approvals or commercialization strategy. We intend to conduct research programs in a range of therapeutic areas, but our pursuit of these opportunities could result in conflicts with the other parties to these agreements that may be developing or selling pharmaceuticals or conducting other activities in these same therapeutic areas. Any disputes or commercial conflicts could lead to the termination of our agreements, delay progress of our product development programs, compromise our ability to renew agreements or obtain future agreements, lead to the loss of intellectual property rights, result in increased financial obligations for us or result in costly litigation.

We work with outside scientific advisors and collaborators at academic and other institutions that assist us in our research and development efforts. Our scientific advisors are not our employees and may have other commitments that limit their availability to us. If a conflict of interest between their work for us and their work for another entity arises, we may lose their services.

If the market opportunities for any product that we or our strategic collaborators develop are smaller than we believe they are, our revenue may be adversely affected and our business may suffer.

We intend to initially focus our product candidate development on therapies for the treatment of liver and cardio-metabolic diseases. Our projections of addressable patient populations that have the potential to benefit from treatment with our product candidates are based on estimates. These estimates have been derived from a variety of sources, including the scientific literature, surveys of clinics, patient foundations or market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. The number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for our product candidates may not ultimately be amenable to treatment with our product candidates. Our market opportunity may also be limited by future competitor treatments that enter the market. If any of our estimates are inaccurate, the market opportunities for any of our product candidates could be significantly diminished and have an adverse material impact on our business.

Monitoring safety of patients receiving our product candidates is challenging, which could adversely affect our ability to obtain regulatory approval and commercialize.

For our ongoing clinical trial and planned clinical trials, we have and expect to contract with CROs and clinical trial sites experienced in the assessment and management of toxicities arising during clinical trials. Nonetheless, these CROs and clinical trial sites may have difficulty observing patients and treating toxicities, which may be more challenging due to personnel changes, inexperience, shift changes, house staff coverage or related issues. This could lead to more severe or prolonged toxicities or even patient deaths, which could result in us or the FDA delaying, suspending or terminating one or more of our clinical trials, and which could jeopardize regulatory approval. We also expect the centers using our product candidates, if approved, on a commercial basis could similarly have difficulty in managing adverse events. Medicines used at centers to help manage adverse side effects of our product candidates may not adequately control the side effects and/or may have a detrimental impact on the efficacy of the treatment. Use of these medicines may increase with new physicians and centers administering our product candidates.

Unstable market and economic conditions may have serious adverse consequences on our business and financial condition.

Global credit and financial markets have experienced extreme disruptions at various points over the last few decades, characterized by diminished liquidity and credit availability, declines in consumer confidence,

declines in economic growth, increases in unemployment rates and uncertainty about economic stability. If another such disruption in credit and financial markets and deterioration of confidence in economic conditions occurs, our business may be adversely affected. If the equity and credit markets were to deteriorate significantly in the future, it may make any necessary debt or equity financing more difficult to complete, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and share price and could require us to delay or abandon development or commercialization plans. In addition, there is a risk that one or more of our service providers, manufacturers or other partners would not survive or be able to meet their commitments to us under such circumstances, which could directly affect our ability to attain our operating goals on schedule and on budget.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations, which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties to sell our products sell our products outside the United States, to conduct clinical trials, and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

Changes in our effective income tax rate could adversely affect our results of operations.

We are subject to income taxes in the United States and various foreign jurisdictions. Various factors may have favorable or unfavorable effects on our effective income tax rate. These factors include, but are not limited to, interpretations of existing tax laws, changes in tax laws and rates, the accounting for stock options and other stock-based compensation, changes in accounting standards, future levels of research and development spending, changes in the mix and level of pre-tax earnings in different jurisdictions, the outcome of audits or other examinations by the U.S. Internal Revenue Service and tax regulators in other jurisdictions, the accuracy of our estimates for unrecognized tax benefits, the realization of deferred tax assets and changes to our ownership or capital structure. The impact of the above-mentioned factors and others on our effective income tax rate may be significant and could adversely affect our results of operations.

Risks Related to Regulatory Approvals

BIO89-100 has not received regulatory approval. If we are unable to obtain regulatory approvals to market BIO89-100 or any future product candidates, our business will be adversely affected.

We do not expect BIO89-100 or any future product candidate to be commercially available for several years, if at all. BIO89-100 is and any future product candidate will be subject to strict regulation by regulatory

authorities in the United States and in other countries. We cannot market any product candidate until we have completed all necessary preclinical studies and clinical trials and have obtained the necessary regulatory approvals. We do not know whether regulatory agencies will grant approval for BIO89-100 or any future product candidate. Even if we complete preclinical studies and clinical trials successfully, we may not be able to obtain regulatory approvals or we may not receive approvals to make claims about our products that we believe to be necessary to effectively market our products. Data obtained from preclinical studies and clinical trials is subject to varying interpretations that could delay, limit or prevent regulatory approval, and failure to comply with regulatory requirements or inadequate manufacturing processes are examples of other problems that could prevent approval. The regulatory authorities in the United States and the EU have not approved any products for the treatment of NASH, and while there are recent guidelines issued by the FDA for the development of drugs for the treatment of NASH and a FDA surrogate endpoint table for drug approval that includes SHTG, it is unclear whether the requirements for approval will change in the future. Any such changes may require us to conduct new trials that could delay our timeframe and increase the costs of our programs related to BIO89-100 or any future product candidate for the treatment of NASH or SHTG. While the FDA has approved reduction in triglycerides levels as a surrogate endpoint for the full approval of drugs for the treatment of SHTG, it is unclear whether this endpoint will apply to any product candidates that we develop. If such endpoint is not deemed to apply to our product candidates, it would delay our development timeline and increase the costs of our programs for the treatment of SHTG. We have not had any discussions with the FDA regarding a surrogate endpoint or accelerated approval regulations. However, we currently expect that our SHTG program would be subject to smaller clinical trials and that we may expect a relatively quick overall development timeline for this indication. These expectations are based on a published FDA surrogate endpoint table for drug approval that includes SHTG, as well as the development path followed by other companies that developed an SHTG therapy. However, we do not have a Special Protocol Assessment or other agreement with the FDA on the required clinical trials needed to support an application for approval of BIO89-100 in SHTG, and the overall clinical requirements and development timeline may be greater than expected. In addition, we may encounter delays or rejections due to additional government regulation from future legislation, administrative action or changes in the policies of the FDA or comparable foreign regulatory authorities. Even if the FDA or a comparable foreign regulatory authority approves a product, the approval will be limited to those indications covered in the approval.

Even if we are able to obtain regulatory approvals for BIO89-100 or any future product candidate, if they exhibit harmful side effects after approval, our regulatory approvals could be revoked or otherwise negatively impacted, and we could be subject to costly and damaging product liability claims.

Even if we receive regulatory approval for BIO89-100 or any future product candidates, we will have tested them in only a small number of patients during our clinical trials. If our applications for marketing are approved and more patients begin to use our product, new risks and side effects associated with our products may be discovered. As a result, regulatory authorities may revoke their approvals. We have not had any discussions with the FDA regarding a surrogate endpoint or accelerated approval regulations. However, based on recent guidelines issued by the FDA for the development of drugs for the treatment of NASH, if BIO89-100 is approved by the FDA based on a surrogate endpoint pursuant to section 506(c) of the Federal Food, Drug, and Cosmetic Act and the accelerated approval regulations (21 C.F.R. part 314, subpart H; 21 C.F.R. part 601, subpart E), consistent with FDA guidance, we will be required to conduct additional clinical trials establishing clinical benefit on the ultimate outcome of NASH. If BIO89-100 is approved by the FDA for the treatment of SHTG based on an endpoint of the reduction of triglycerides, the FDA may still require a cardiovascular outcomes study as part of a post-marketing authorization commitment. Such a study would be time consuming and costly and we cannot guarantee that we will see positive results, which could result in the revocation of the approval. Additionally, we may be required to conduct additional clinical trials, make changes in labeling of our product, reformulate our product or make changes and obtain new approvals for our and our suppliers' manufacturing facilities for BIO89-100 and any future product candidates. We might have to withdraw or recall our products from the marketplace. We may also experience a significant drop in the potential sales of our product if and when regulatory approvals for such product are revoked. As a result, we may experience harm to our reputation in the marketplace or become subject to

lawsuits, including class actions. Any of these results could decrease or prevent any sales of our approved product or substantially increase the costs and expenses of commercializing and marketing our product.

The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable. Our inability to obtain regulatory approval for BIO89-100 or any future product candidates would substantially harm our business.

Currently, we do not have any product candidates that have received regulatory approval. The time required to obtain approval from the FDA and comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of preclinical studies and clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's development and may vary among jurisdictions. It is possible that none of BIO89-100 or any future product candidates will ever obtain regulatory approval.

BIO89-100 or any future product candidate could fail to receive regulatory approval from the FDA or comparable foreign regulatory authorities for many reasons, including:

- disagreement with the design or implementation of our clinical trials;
- failure to demonstrate that a product candidate is safe and effective for its proposed indication;
- failure of clinical trials to meet the level of statistical significance required for approval;
- failure to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- disagreement with our interpretation of data from preclinical studies or clinical trials;
- the insufficiency of data collected from clinical trials of a product candidate to support the submission and filing of a BLA or other submission or to obtain regulatory approval;
- failure to obtain approval of the manufacturing processes or facilities of third-party manufacturers with whom we contract for clinical and commercial supplies; or
- changes in the approval policies or regulations that render our preclinical and clinical data insufficient for approval.

The FDA or comparable foreign regulatory authorities may require more information, including additional preclinical or clinical data to support approval, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program for other reasons. If we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may grant approval contingent on the performance of costly post-marketing clinical trials or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate.

Our failure to obtain regulatory approval in international jurisdictions would prevent us from marketing our product candidates outside the United States.

If we succeed in developing any products, we intend to market them in foreign jurisdictions in addition to the United States. In order to market and sell our products in other jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. We may not obtain foreign

regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions. Approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. If we fail to obtain approval of any of our product candidates by regulatory authorities in another country we will be unable to commercialize our product in that country, and the commercial prospects of that product candidate and our business prospects could decline. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, we must secure product reimbursement approvals before regulatory authorities will approve the product for sale in that country. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. Further, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries and regulatory approval in one country does not ensure approval in any other country, while a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others. Also, regulatory approval for any of our product candidates may be withdrawn if we fail to comply with regulatory requirements, if problems occur after the product candidate reaches the market or for other reasons. If we fail to comply with the regulatory requirements in international markets and fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed and our business will be adversely affected.

Even if BIO89-100 or any future product candidate receives regulatory approval, it may still face future development and regulatory difficulties.

Even if we obtained regulatory approval for a product candidate, it would be subject to ongoing requirements by the FDA and comparable foreign regulatory authorities governing the manufacture, quality control, further development, labeling, packaging, storage, distribution, safety surveillance, import, export, advertising, promotion, recordkeeping and reporting of safety and other post-market information. The FDA and comparable foreign regulatory authorities will continue to closely monitor the safety profile of any product even after approval. If the FDA, or comparable foreign regulatory authorities, become aware of new safety information after approval of any of our product candidates, it may require labeling changes or establishment of a risk evaluation and mitigation strategy or similar strategy, impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance.

In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP, regulations and standards. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, or undesirable side effects caused by such products are identified, a regulatory agency may:

- issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings about such product;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
- require that we conduct post-marketing studies;

- require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend marketing of, withdraw regulatory approval of or recall such product;
- suspend any ongoing clinical studies;
- refuse to approve pending applications or supplements to applications filed by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products, refuse to permit the import or export of products or require us to initiate a product recall.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our products and generate product revenue.

Advertising and promotion of any product candidate that obtains approval in the United States will be heavily scrutinized by the FDA, the Department of Justice, the Department of Health and Human Services' Office of Inspector General, state attorneys general, members of Congress and the public. Violations, including promotion of our products for unapproved (or off-label) uses, are subject to enforcement letters, inquiries and investigations, and significant civil and criminal sanctions by the government. In the United States, engaging in the impermissible promotion of our products for off-label uses can also subject us to false claims litigation under federal and state statutes, which can lead to significant civil and criminal penalties. Additionally, comparable foreign regulatory authorities will heavily scrutinize advertising and promotion of any product candidate that obtains approval outside of the United States.

The FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

Risks Relating to Intellectual Property

Our success depends upon our ability to obtain and maintain intellectual property protection for our products and technologies.

Our success will depend in significant part on our current or future licensors', licensees' or collaborators' ability to establish and maintain adequate protection of our owned and licensed intellectual property covering the product candidates we plan to develop, and the ability to develop these product candidates and commercialize the products resulting therefrom, without infringing the intellectual property rights of others. In addition to taking other steps to protect our intellectual property, we hold issued patents, we have applied for patents, and we intend to continue to apply for, patents with claims covering our technologies, processes and product candidates when and where we deem it appropriate to do so. We have filed numerous patent applications both in the United States and in certain foreign jurisdictions to obtain patent rights to inventions we have discovered, with claims directed to compositions of matter, methods of use and other technologies relating to our programs. There can be no assurance that any of these patent applications will issue as patents or, for those applications that do mature into patents, that the claims of the patents will exclude others from making, using or

selling our product candidates or products that compete with or are similar to our product candidates. In countries where we have not sought and do not seek patent protection, third parties may be able to manufacture and sell our product candidates without our permission, and we may not be able to stop them from doing so.

With respect to patent rights, we do not know whether any of the pending patent applications for any of our product candidates will result in the issuance of patents that effectively protect our technologies, processes and product candidates, or if any of our issued patents or our current or future licensors', licensees' or collaborators' issued patents will effectively prevent others from commercializing competitive technologies, processes and products. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or in some cases not at all, until they are issued as a patent. Therefore, we cannot be certain that we or our current or future licensors, licensees or collaborators were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we or our current or future licensors, licensees or collaborators were the first to file for patent protection of such inventions. For a description of our patent portfolio, see "Business—Intellectual Property."

Any changes we make to our BIO89-100 or any future product candidates to cause them to have what we view as more advantageous properties may not be covered by our existing patents and patent applications, and we may be required to file new applications and/or seek other forms of protection for any such altered product candidates. The patent landscape surrounding the technology underlying our product candidates is crowded, and there can be no assurance that we would be able to secure patent protection that would adequately cover an alternative to BIO89-100 or any future product candidates.

The patent prosecution process is expensive and time-consuming, and we and our current or future licensors, licensees or collaborators may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our current or future licensors, licensees or collaborators will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection for them. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain or enforce the patents, covering technology that we license from or license to third parties and may be reliant on our current or future licensors, licensees or collaborators to perform these activities, which means that these patent applications may not be prosecuted, and these patents enforced, in a manner consistent with the best interests of our business. If our current or future licensors, licensees or collaborators fail to establish, maintain, protect or enforce such patents and other intellectual property rights, such rights may be reduced or eliminated. If our current or future licensors, licensees or collaborators are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised.

Similar to the patent rights of other biotechnology companies, the scope, validity and enforceability of our owned and licensed patent rights generally are highly uncertain and involve complex legal and factual questions. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. In recent years, these areas have been the subject of much litigation in the industry. As a result, the issuance, scope, validity, enforceability and commercial value of our and our current or future licensors', licensees' or collaborators' patent rights are highly uncertain. Our and our current or future licensors', licensees' or collaborators' pending and future patent applications may not result in patents being issued that protect our technology or product candidates, or products resulting therefrom, in whole or in part, or that effectively prevent others from commercializing competitive technologies and products. The patent examination process may require us or our current or future licensors, licensees or collaborators to narrow the scope of the claims of pending and future patent applications, which would limit the scope of patent protection that is obtained, if any. Our and our current or future licensors', licensees' or collaborators' patent applications cannot be enforced against third parties practicing the technology that is currently claimed in such applications unless and until a patent issues from such

applications, and then only to the extent the claims that issue are broad enough to cover the technology being practiced by those third parties.

Furthermore, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after the resulting products are commercialized. As a result, our owned and in-licensed patents may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. We expect to seek extensions of patent terms for our issued patents, where available. This includes in the United States under the Hatch-Waxman Act, which permits a patent term extension of up to five years beyond the original expiration date of the patent as compensation for regulatory delays. However, such a patent term extension cannot lengthen the remaining term of a patent beyond a total of 14 years from the product's approval date. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. During the period of patent term extension, the claims of a patent are not enforceable for their full scope, but are instead limited to the scope of the approved product. In addition, the applicable authorities, including the FDA in the United States, and any comparable foreign regulatory authorities, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. In addition, we may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to the expiration of relevant patents or otherwise failing to satisfy applicable requirements. If this occurs, any period during which we have the right to exclusively market our product will be shorter than we would otherwise expect, and our competitors may obtain approval of and launch products earlier than might otherwise be the case.

We may not be able to protect our intellectual property rights throughout the world.

The legal protection afforded to inventors and owners of intellectual property in countries outside of the United States may not be as protective or effective as that in the United States and we may, therefore, be unable to acquire and enforce intellectual property rights outside the United States to the same extent as in the United States. Whether filed in the United States or abroad, our patent applications may be challenged or may fail to result in issued patents.

In addition, our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from practicing our technologies or from developing or commercializing competing products. Furthermore, others may independently develop or commercialize similar or alternative technologies or drugs, or design around our patents. Our patents may be challenged, invalidated, circumvented or narrowed, or fail to provide us with any competitive advantages. In many foreign countries, patent applications and/or issued patents, or parts thereof, must be translated into the native language. If our patent applications or issued patents are translated incorrectly, they may not adequately cover our technologies; in some countries, it may not be possible to rectify an incorrect translation, which may result in patent protection that does not adequately cover our technologies in those countries.

Filing, prosecuting, enforcing and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States are less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and certain state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with BIO89-100 or any future product candidates and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals. This could make it difficult for us to stop the infringement of our patents or the marketing of competing products in violation of our proprietary rights, generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could place our patent applications at risk of not issuing and could provoke third parties to assert claims against us or our collaborator. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful.

The requirements for patentability differ and certain countries have heightened requirements for patentability, requiring more disclosure in the patent application. In addition, certain countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we may have limited remedies if patents are infringed or if we are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. Accordingly, our efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license.

We rely on a license from Teva and a sublicense from ratiopharm to patents and know-how related to glycoPEGylation technology that are used in the development, manufacture and commercialization of BIO89-100. Any termination or loss of significant rights, including the right to glycoPEGylation technology, or breach, under these agreements or any future license agreement related to our product candidates, would materially and adversely affect our ability to continue the development and commercialization of the related product candidates.

In April 2018, we entered into an Asset Transfer and License Agreement (the "FGF21 Agreement") with Teva under which we acquired certain patents, intellectual property and other assets relating to Teva's glycoPEGylated FGF21 program, including BIO89-100. Under this agreement, we were granted a perpetual, non-exclusive (but exclusive as to BIO89-100), non-transferable, worldwide license to patents and know-how related to glycoPEGylation technology used in the development, manufacture and commercialization of BIO89-100 and products containing BIO89-100. The FGF21 Agreement also contains numerous covenants with which we must comply, including the utilization of commercially reasonable efforts to develop and ultimately commercialize BIO89-100, as well as certain reporting covenants and the obligation to make royalty payments, if and when BIO89-100 is approved for commercialization. Our failure to satisfy any of these covenants could result in the termination of the FGF21 Agreement. In addition, we entered into a Sublicense Agreement with ratiopharm (the "ratiopharm Sublicense"), under which we were granted a perpetual, exclusive, worldwide sublicense to patents and know-how related to glycoPEGylation technology used in the development, manufacture and commercialization of BIO89-100 and products containing BIO89-100. Termination of the FGF21 Agreement or the ratiopharm Sublicense will impact our rights under the intellectual property licensed to us by Teva and ratiopharm, respectively, including our license to glycoPEGylation technology, but will not affect our rights under the assets assigned to us.

Beyond this agreement, our commercial success will also depend upon our ability, and the ability of our licensors, to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. A third party may hold intellectual property rights, including patent rights, that are important or necessary to the development of our product candidates. As a result, we may enter into additional license agreements in the future. If we fail to comply with the obligations under these agreements, including payment and diligence obligations, our licensors may have the right to terminate these agreements, in which event we may not be able to develop, manufacture, market or sell any product that is

covered by these agreements or to engage in any other activities necessary to our business that require the freedom to operate afforded by the agreements, or we may face other penalties under the agreements.

Any of the foregoing could materially and adversely affect the value of the product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or amended agreements, which may not be available to us on equally favorable terms, or at all, or cause us to lose our rights under these agreements, including our rights to intellectual property or technology important to our development programs.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect BIO89-100 and any future product candidates.

As is the case with other biotechnology and pharmaceutical companies, our success is heavily dependent on intellectual property rights, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves technological and legal complexity, and obtaining and enforcing biopharmaceutical patents is costly, time-consuming and inherently uncertain. The U.S. Supreme Court in recent years has issued rulings either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations or ruling that certain subject matter is not eligible for patent protection. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by Congress, the federal courts, the USPTO and equivalent bodies in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce existing patents and patents we may obtain in the future.

Patent reform laws, such as the Leahy-Smith America Invents Act (the “Leahy-Smith Act”), as well as changes in how patent laws are interpreted, could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy-Smith Act made a number of significant changes to U.S. patent law. These include provisions that affect the filing and prosecution strategies associated with patent applications, including a change from a “first-to-invent” to a “first-inventor-to-file” patent system, and a change allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO-administered post-grant proceedings, including post-grant review, *inter partes* review and derivation proceedings. The USPTO has developed regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act and, in particular, the “first-inventor-to-file” provisions, became effective in 2013. The Leahy-Smith Act and its implementation may increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition and results of operations.

We may be unable to obtain intellectual property rights or technology necessary to develop and commercialize BIO89-100 and any future product candidates.

The patent landscape around our programs is complex, and we are aware of several third-party patents and patent applications containing subject matter that might be relevant to BIO89-100. Depending on what claims ultimately issue from these patent applications, and how courts construe the issued patent claims, as well as depending on the ultimate formulation and method of use of BIO89-100 or any future product candidates, we may need to obtain a license to practice the technology claimed in such patents. There can be no assurance that such licenses will be available on commercially reasonable terms, or at all. If a third party does not offer us a necessary license or offers a license only on terms that are unattractive or unacceptable to us, we might be unable to develop and commercialize one or more of our product candidates, which would have a material adverse effect on our business, financial condition and results of operations. Moreover, even if we obtain licenses to such intellectual property, but subsequently fail to meet our obligations under the relevant license agreements, or such

license agreements are terminated for any other reasons, we may lose our rights to the technologies licensed under those agreements.

The licensing or acquisition of third-party intellectual property rights is an area in which many companies operate that have interests that are in conflict with ours, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment, or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may become involved in lawsuits or other proceedings to protect or enforce our intellectual property, which could be expensive, time-consuming and unsuccessful and have a material adverse effect on the success of our business.

Third parties may infringe our patents or misappropriate or otherwise violate our intellectual property rights. In the future, we may initiate legal proceedings to enforce or defend our intellectual property rights, to protect our trade secrets or to determine the validity or scope of intellectual property rights we own or control. Also, third parties may initiate legal proceedings against us to challenge the validity or scope of intellectual property rights we own, control or to which we have rights. For example, generic or biosimilar drug manufacturers or other competitors or third parties may challenge the scope, validity or enforceability of our patents, requiring us to engage in complex, lengthy and costly litigation or other proceedings. These proceedings can be expensive and time-consuming and many of our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating intellectual property rights we own, control or have rights to, particularly in countries where the laws may not protect those rights as fully as in the United States. Litigation could result in substantial costs and diversion of management resources, which could harm our business and financial results. In addition, if we initiated legal proceedings against a third party to enforce a patent covering a product candidate, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States, defendants usually assert counterclaims alleging invalidity or unenforceability. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. In an infringement or declaratory judgment proceeding, a court may decide that a patent owned by or licensed to us is invalid or unenforceable, or may refuse to stop the other party from using the subject matter alleged to be infringing on the grounds that our patents do not cover that subject matter. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated, narrowed, held unenforceable or interpreted in such a manner that would not preclude third parties from entering the market with competing products.

Third-party pre-issuance submission of prior art to the USPTO, or opposition, derivation, revocation, reexamination, *inter partes* review or interference proceedings, or other pre-issuance or post-grant proceedings or other patent office proceedings or litigation in the United States or other jurisdictions provoked by third parties or brought by us, may be necessary to determine the inventorship, priority, patentability or validity of inventions with respect to our patents or patent applications. An unfavorable outcome could leave our technology or product candidates without patent protection, allow third parties to commercialize our technology or product candidates and compete directly with us, without payment to us, or could require us to obtain license rights from the prevailing party in order to be able to manufacture or commercialize our product candidates without infringing

third-party patent rights. Our business could be harmed if the prevailing party in such a case does not offer us a license on commercially reasonable terms, or at all. Even if we obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Even if we successfully defend such litigation or proceeding, we may incur substantial costs and our defense may distract our management and other employees.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, many foreign jurisdictions have rules of discovery that are different than those in the United States and that may make defending or enforcing our patents extremely difficult. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock.

Third parties may initiate legal proceedings against us alleging that we infringe their intellectual property rights or we may initiate legal proceedings against third parties to challenge the validity or scope of intellectual property rights controlled by third parties, the outcome of which would be uncertain and could have a material adverse effect on our business.

Our commercial success depends upon our ability to develop, manufacture, market and sell BIO89-100 and any future product candidates that we may develop and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and proprietary rights of third parties. The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. Third parties may initiate legal proceedings against us alleging that we infringe their intellectual property rights or we may initiate legal proceedings against third parties to challenge the validity or scope of intellectual property rights controlled by third parties, including in oppositions, interferences, revocations, reexaminations, *inter partes* review or derivation proceedings before the USPTO or its counterparts in other jurisdictions. These proceedings can be expensive and time-consuming and many of our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can.

We could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent of a third party. A finding of infringement could prevent us from commercializing our BIO89-100 or any future product candidates or force us to cease some of our business operations, which could materially harm our business.

We may not be aware of all third-party intellectual property rights potentially relating to BIO89-100 or any future product candidates and technologies. We are not aware of any facts that would lead us to conclude that the valid and enforceable claims of any third-party patents would reasonably be interpreted to cover our product candidates. As to pending third-party applications, we cannot predict with any certainty which claims will issue, if any, or the scope of such issued claims. Even if we believe third-party intellectual property claims are without merit, there is no assurance that a court would find in our favor on questions of infringement, validity, enforceability or priority. A court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, which could materially and adversely affect our ability to commercialize any product candidates we may develop and any other product candidates or technologies covered by the asserted third-party patents. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. If any such third-party patents (including those that may issue from such applications) were successfully asserted against us or other commercialization partners

and we were unable to successfully challenge the validity or enforceability of any such asserted patents, then we and other commercialization partners may be prevented from commercializing our product candidates, or may be required to pay significant damages, including treble damages and attorneys' fees if we are found to willfully infringe the asserted patents, or obtain a license to such patents, which may not be available on commercially reasonable terms, or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. Any of the foregoing would have a material adverse effect on our business, financial condition and operating results.

Although we have reviewed certain third-party patents and patent filings that we believe may be relevant to our therapeutic candidates or products, we have not conducted a freedom-to-operate search or analysis for any of our therapeutic candidates or products, and we may not be aware of patents or pending or future patent applications that, if issued, would block us from commercializing our therapeutic candidates or products. Thus, we cannot guarantee that our therapeutic candidates or products, or our commercialization thereof, do not and will not infringe any third party's intellectual property.

We may be subject to claims by third parties asserting misappropriation of intellectual property, or claiming ownership of what we regard as our own intellectual property.

Although we seek to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed confidential information or intellectual property, including trade secrets or other proprietary information, of any such employee's former employer, or that third parties have an interest in our patents as an inventor or co-inventor. Litigation may be necessary to defend against these claims. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or the services of personnel or sustain other damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms, or at all. Even if we successfully prosecute or defend against such claims, litigation could result in substantial costs and distract management.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations and prospects.

Our inability to protect our confidential information and trade secrets would harm our business and competitive position.

In addition to seeking patents for some of our technology and product candidates, we also rely substantially on trade secrets, including unpatented know-how, technology and other proprietary materials and information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. However, these steps may be inadequate, we may fail to enter into agreements with all such parties or any of these parties may breach the agreements and disclose our trade secrets and there may be no adequate remedy available for such breach of an agreement. We cannot assure you that our trade secrets will not be disclosed or that we can meaningfully protect our trade secrets. Enforcing a claim that a party illegally

disclosed or misappropriated a trade secret is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, some courts both within and outside the United States may be less willing, or unwilling, to protect trade secrets. If a competitor lawfully obtained or independently developed any technology or information that we protect as trade secret, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make products that are similar to BIO89-100 and any future product candidates we may develop or utilize similar technology but that are not covered by the claims of the patents that we exclusively license or may own in the future;
- we, or our future collaborators, might not have been the first to make the inventions covered by the issued patents and pending patent applications that we exclusively license or may own in the future;
- we, or our future collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or exclusively licensed intellectual property rights;
- it is possible that our pending patent applications or those that we may file in the future will not result in issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in major commercial markets in which we do not have sufficient patent rights to stop such sales;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may be asserted against our product candidates and technologies in a manner that harms our business; and
- we may choose not to file a patent application in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such trade secrets or know-how.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects.

If our trademarks and trade names are not maintained and adequately protected, we may not be able to build name recognition in our markets of interest, and our business may be adversely affected.

Failure to obtain trademark registrations in the future, could limit our ability to protect and enforce our trademarks and impede our marketing efforts in the countries in which we operate. We may not be able to protect our rights to trademarks and trade names which we may need to build name recognition with potential partners or

customers in our markets of interest. As a means to enforce any future trademark rights and prevent infringement, we may be required to file trademark claims against third parties or initiate trademark opposition proceedings. This can be expensive, and strain the financial resources of a company of our size, and time-consuming, and we may not be successful in enforcing our trademark rights. In addition, our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be infringing on other marks.

Future trademark applications in the United States and in other foreign jurisdictions where we may file may not be allowed or may subsequently be opposed. Even if these applications result in registration of trademarks, third parties may challenge our use or registration of these trademarks in the future. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected.

Risks Related to this Offering and Ownership of Our Common Stock

There is no existing market for our common stock and we do not know if one will develop, which may make it difficult for you to sell shares of our common stock. Even if a market does develop, the price of shares of our common stock in the market may not exceed the offering price.

Prior to this offering, there has not been a public market for our common stock or any of our equity interests. We cannot predict the extent to which investor interest in our company will lead to the development of an active trading market on The Nasdaq Global Market or how liquid that market may become. An active public market for our common stock may not develop or be sustained after this offering. If an active trading market does not develop or is not sustained, you may have difficulty selling any shares of our common stock that you buy. An inactive market may also impair our ability to raise additional capital or use our shares of common stock to acquire companies, products or technologies.

The initial public offering price for our common stock will be determined by negotiations among us and the representatives of the underwriters and may not be indicative of prices that will prevail in the open market following this offering. Consequently, you may not be able to sell shares of our common stock at prices equal to or greater than the price you pay in this offering.

The price of our common stock may be volatile, and you may lose all or part of your investment.

The market price of our common stock could fluctuate significantly, and you may not be able to resell your shares at or above the offering price. Those fluctuations could be based on various factors in addition to those otherwise described in this prospectus, including those described in these “Risk Factors.” Any of these factors may result in large and sudden changes in the volume and trading price of our common stock. In the past, following periods of volatility in the market price of a company’s securities, stockholders have often instituted securities class action litigation against that company. If we were involved in a class action suit, it could divert the attention of management, result in negative press reports and, if adversely determined, have a material adverse effect on our results of operations and financial condition.

In addition, the stock market, in general, and the stocks of many small healthcare and biotechnology companies, in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. Further, a decline in the broader financial markets and related factors beyond our control may cause the price of our common stock to decline rapidly and unexpectedly.

Future sales of our common stock, or the perception that such sales may occur, could depress the price of our common stock.

Sales of a substantial number of shares of our common stock in the public market, or the perception that such sales may occur, following this offering could depress the market price of our common stock. Our principal

stockholders, executive officers and directors and certain other equity holders have agreed with the underwriters not to offer, sell, dispose of or hedge any shares of our common stock or securities convertible into or exchangeable for shares of our common stock, subject to specified limited exceptions and extensions described elsewhere in this prospectus, during the period ending 180 days after the date of the final prospectus, except with the prior written consent of BofA Securities, Inc., SVB Leerink LLC and RBC Capital Markets, LLC.

Our Amended Certificate will authorize us to issue up to 100,000,000 shares of common stock, of which 12,063,592 shares will be outstanding after this offering (assuming no exercise of the underwriters' option to purchase additional shares) and 1,304,159 shares will be issuable upon the exercise of outstanding stock options. All of the shares sold in this offering will be freely tradable after the expiration date of the lock-up agreements, excluding any acquired by persons who may be deemed to be our affiliates. The remaining 7,688,592 shares are currently restricted as a result of securities laws or the lock-up agreements, but will be eligible for sale after this offering as described in the section titled "Shares Eligible for Future Sale." Shares of our common stock held by our affiliates will continue to be subject to the volume and other restrictions of Rule 144 under the Securities Act. BofA Securities, Inc., SVB Leerink LLC and RBC Capital Markets, LLC may, in their discretion and at any time without notice, release all or any portion of the shares subject to the lock-up. Sales of a substantial number of such shares upon expiration of the lock-up and market stand-off agreements, the perception that such sales may occur or early release of these agreements, could cause our market price to fall or make it more difficult for you to sell your common stock at a time and price that you deem appropriate. See "Underwriting."

Moreover, after this offering, holders of an aggregate of 7,077,366 shares of our common stock will have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders.

In addition, promptly following this offering, we intend to file a registration statement registering under the Securities Act the shares of our common stock reserved for issuance under our 2019 Plan, including shares issuable upon exercise of outstanding options. See "Shares Eligible for Future Sale" for a more detailed description of the shares that will be available for future sales upon completion of this offering. Once we register these shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and the lock-up agreements described above.

Further, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt or equity securities. If we issue common stock or securities convertible into our common stock, our common stockholders would experience additional dilution and, as a result, the price of our common stock may decline.

Our directors, executive officers and current holders of 5% or more of our capital stock will continue to have substantial control over our company after this offering, which could limit your ability to influence the outcome of matters subject to stockholder approval, including a change of control.

Without giving effect to any shares they may purchase in this offering, directors and executive officers will beneficially own approximately 25.4% of our outstanding common stock after this offering and other holders of 5% or more of our common stock will beneficially own approximately 63.2% of our outstanding common stock after this offering. Without giving effect to any shares they may purchase in this offering, our current directors, officers and stockholders who own greater than 5% of our outstanding common stock (on an as-converted basis), together with their affiliates, will beneficially own, in the aggregate, approximately 65.5% of our outstanding common stock after this offering. In addition, our existing stockholders affiliated with our directors have indicated an interest in purchasing an aggregate of up to approximately $40.0 million of shares of our common stock in this offering at the initial public offering price and on the same terms as the other purchasers in this offering. If such stockholders were to purchase all shares they have indicated an interest in purchasing, our current directors, officers and stockholders who own greater than 5% of our outstanding common stock (on an as-converted basis), together with their affiliates, would beneficially own approximately 86.2% of

our outstanding voting stock upon the closing of this offering (based on the assumed initial public offering price of $16.00 per share, the midpoint of the price range set forth on the cover page of this prospectus, and assuming no exercise of the underwriters' option to purchase additional shares and no exercise of outstanding options). As a result, after this offering, our executive officers, directors and other holders of 5% or more of our common stock, if they act, will be able to influence or control matters requiring approval by our stockholders, including the election of directors and the approval of mergers, acquisitions or other extraordinary transactions. In addition, our current directors, executive officers and other holders of 5% or more of our common stock, acting together, would have the ability to control the management and affairs of our company. They may also have interests that differ from yours and may vote in a way with which you disagree and that may be adverse to your interests. This concentration of ownership may have the effect of delaying, preventing or deterring a change of control of our company, could deprive our stockholders of an opportunity to receive a premium for their shares of our common stock as part of a sale of our company and could affect the market price of our common stock.

If securities or industry analysts do not publish research, or publish inaccurate or unfavorable research, about our stock or business, the price of our common stock and trading volume could decline.

The trading market for our common stock will depend, in part, on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts do not currently, and may never, publish research on our company. If no securities or industry analysts commence coverage of our company or if they cease to cover our company, the trading price for our stock would likely be negatively impacted. In the event that securities or industry analysts initiate coverage, if one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, demand for our common stock could decrease and the price of our common stock could decline. In addition, if our operating results fail to meet the forecast of analysts, the price of our common stock would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause the price of our common stock and trading volume to decline.

Participation in this offering by our existing stockholders would reduce the available public float for our shares.

Our existing stockholders affiliated with our directors, have indicated an interest in purchasing up to an aggregate of approximately $40.0 million of shares of our common stock in this offering at the initial public offering price. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters may determine to sell more, fewer or no shares of our common stock in this offering to these stockholders, or these stockholders may determine to purchase more, fewer or no shares of our common stock in this offering. To the extent these existing stockholders purchase any shares in this offering, such purchase could reduce the available public float for our shares because such stockholders may be restricted from selling the shares by restrictions under applicable securities laws. As a result, any purchase of shares by such stockholders in this offering may reduce the liquidity of our common stock relative to what it would have been had these shares been purchased by investors that were not existing stockholders.

We have identified material weaknesses in our internal control over financial reporting. If our remediation of the material weaknesses is not effective, or if we experience additional material weaknesses or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

Effective internal controls over financial reporting are necessary for us to provide reliable financial information and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 ("Section 404") of the Sarbanes-Oxley Act of 2002, as amended (the "Sarbanes-Oxley Act"), or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require

prospective or retroactive changes to our consolidated financial statements or identify other areas for further attention or improvement. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim consolidated financial statements will not be prevented or detected on a timely basis.

In connection with our financial statement close process for 2018, we identified material weaknesses in the design and operating effectiveness of our internal control over financial reporting.

These material weaknesses related to the following:

- We did not have an internal finance department. Consequently, we lacked sufficient personnel with an appropriate level of knowledge and requisite U.S. generally accepted accounting principles expertise to identify, evaluate and account for complex and non-routine transaction and an adequate supervisory review structure that is needed to comply with financial reporting requirements.

- We did not have an adequate assessment of risks that could significantly impact internal control over financial reporting and did not effectively design controls in response to the risks of material misstatement.

We are taking steps to remediate these material weaknesses through the implementation of appropriate segregation of duties, formalization of accounting policies and controls, hiring of our Chief Financial Officer and additional qualified accounting and finance personnel and engagement of financial consultants to enable the implementation of internal controls over financial reporting. We also plan to implement certain accounting systems to automate manual processes. However, we are still in the process of implementing these steps and cannot assure you that we will be successful in doing so or that these measures will significantly improve or remediate the material weaknesses described above. We, and our independent registered public accounting firm, were not required to perform an evaluation of our internal control over financial reporting as of December 31, 2018 in accordance with the provisions of the Sarbanes-Oxley Act. Accordingly, we cannot assure you that we have identified all material weaknesses or that there will not be additional material weaknesses or deficiencies that we will identify.

Upon becoming a public company, we will be required to comply with Section 404, which will require management to certify financial and other information in our quarterly and annual reports and provide an annual management report on the effectiveness of our internal control over financial reporting commencing with our second annual report. To achieve compliance with Section 404 within the prescribed period, we will need to continue to dedicate internal resources, outside consultants and continue to execute a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes, as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404 and material weaknesses may still exist. We also cannot assure you that there will not be additional material weaknesses or significant deficiencies in our internal controls in the future. In the event that we are not able to successfully remediate the existing material weaknesses in our internal control over financial reporting or demonstrate compliance with the Sarbanes-Oxley Act, that our internal control over financial reporting is perceived as inadequate or that we are unable to produce timely or accurate consolidated financial statements, investors may lose confidence in our operating results, the price of our common stock could decline and we may not be able to remain listed on The Nasdaq Global Market.

We will incur increased costs as a result of operating as a public company, and our management will devote substantial time to new compliance initiatives.

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company, and these expenses may increase even more after we are no longer an “emerging

growth company." As a public company, we will be subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Protection Act, as well as rules adopted, and to be adopted, by the SEC and Nasdaq. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, we expect these rules and regulations to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. The increased costs will increase our net loss. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be forced to accept reduced policy limits or incur substantially higher costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

We are an emerging growth company, as defined in the Securities Act, and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an emerging growth company, as defined in Section 2(a) of the Securities Act, as modified by the JOBS Act, and we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including relief from the auditor attestation requirements of Section 404 less extensive disclosure obligations regarding executive compensation in our registration statements, periodic reports and proxy statements, exemptions from the requirements to hold a nonbinding advisory vote on executive compensation, and exemptions from stockholder approval of any golden parachute payments not previously approved. As a result, our stockholders may not have access to certain information that they may deem important. We could be an emerging growth company for up to five years, although circumstances could cause us to lose that status earlier.

In addition, the JOBS Act also provides that an emerging growth company can take advantage of the extended transition period provided in the Securities Act for complying with new or revised accounting standards. An emerging growth company can therefore delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption and, as a result, will not be subject to the same implementation timing for new or revised accounting standards as for other public companies that are not emerging growth companies, which may make comparison of our consolidated financial statements to those of other public companies more difficult.

We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and the price of our common stock may be more volatile.

We have broad discretion as to the use of proceeds from this offering and may not use the proceeds effectively.

Our management will retain broad discretion as to the application of the proceeds of this offering and may spend these proceeds in ways in which you may not agree. You will not have the opportunity, as part of your investment decision, to assess whether we are using the proceeds appropriately. Our management might not apply our net proceeds in ways that ultimately increase the value of your investment. We cannot specify with certainty all of the particular uses for the net proceeds to be received upon the closing of this offering. Until the net proceeds are used, they may be placed in investments that do not produce significant income or that may lose value. The failure of our management to apply these funds effectively could result in unfavorable returns and uncertainty about our prospects, each of which could cause the price of our common stock to decline.

Because we do not expect to pay dividends in the foreseeable future, you must rely on price appreciation of our common stock for return on your investment.

We intend to retain most, if not all, of our available funds and earnings to fund the development and growth of our business. As a result, we do not expect to pay any cash dividends in the foreseeable future. Therefore, you should not rely on an investment in our common stock as a source for any future dividend income.

Our board of directors has significant discretion as to whether to distribute dividends and in what amounts. Even if our board of directors decides to declare and pay dividends, the timing, amount and form of future dividends, if any, will depend on, among other matters, our future results of operations and cash flow, our capital requirements and surplus, the amount of distributions, if any, received by us from our subsidiaries, our financial condition, contractual restrictions and other factors deemed relevant by our board of directors.

If you purchase shares of our common stock sold in this offering, you will incur immediate and substantial dilution.

If you purchase shares of our common stock in this offering, you will incur immediate and substantial dilution in the amount of $9.65 per share because the assumed initial public offering price of $16.00 per share, the midpoint of the price range set forth on the cover of this prospectus, is substantially higher than the as adjusted net tangible book value per share of our outstanding common stock. This dilution is due in large part to the fact that our earlier investors paid substantially less than the initial public offering price when they purchased their shares. In addition, you may also experience additional dilution upon future equity issuances or the issuance of stock options to purchase our common stock granted to our employees, directors and consultants under our stock option plan after this offering. To the extent we raise additional capital by issuing equity securities, our stockholders may experience additional dilution. In addition, as of June 30, 2019, we had outstanding stock options to purchase 721,079 shares of our common stock, all of which have exercise prices below the assumed initial offering price. To the extent these outstanding options are ultimately exercised, you will experience further dilution. See “Dilution.”

Our Amended Certificate, Amended Bylaws and Delaware law could prevent a third party from acquiring us (even if an acquisition would benefit our stockholders), may limit the ability of our stockholders to replace our management and limit the price that investors might be willing to pay for shares of our common stock.

Our Amended Certificate and our Amended Bylaws could have the effect of making it more difficult for a third party to acquire, or of discouraging a third party from attempting to acquire, control of us. These provisions could delay or prevent a change in control of the company and could limit the price that investors might be willing to pay in the future for shares of our common stock. These provisions, among other things:

- establish a staggered board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- authorize our board of directors to issue new series of preferred stock without stockholder approval and create, subject to applicable law, a series of preferred stock with preferential rights to dividends or our assets upon liquidation, or with superior voting rights to our existing common stock;
- eliminate the ability of our stockholders to call special meetings of stockholders;
- eliminate the ability of our stockholders to fill vacancies on our board of directors;
- establish advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted upon by stockholders at our annual stockholder meetings;

- permit our board of directors to establish the number of directors;
- provide that our board of directors is expressly authorized to make, alter or repeal our Amended Bylaws;
- provide that shareholders can remove directors only for cause and only upon the approval of not less than 66⅔ of all outstanding shares of our voting stock;
- require the approval of not less than 66⅔ of all outstanding shares of our voting stock to amend our bylaws and specific provisions of our certificate of incorporation; and
- limit the jurisdictions in which certain stockholder litigation may be brought.

As a Delaware corporation, we will be subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which prohibits a Delaware corporation from engaging in a business combination specified in the statute with an interested stockholder (as defined in the statute) for a period of three years after the date of the transaction in which the person first becomes an interested stockholder, unless the business combination is approved in advance by a majority of the independent directors or by the holders of at least two-thirds of the outstanding disinterested shares. The application of Section 203 of the Delaware General Corporation Law could also have the effect of delaying or preventing a change of control of us.

Our Amended Certificate provides that the Court of Chancery of the State of Delaware and the federal district courts of the United States will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our Amended Certificate to be in effect upon the completion of this offering provides that the Court of Chancery of the State of Delaware is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: any derivative action or proceeding brought on our behalf; any action asserting a breach of a fiduciary duty; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our Amended Certificate or our Amended Bylaws; or any action asserting a claim against us that is governed by the Delaware internal affairs doctrine. This provision would not apply to claims brought to enforce a duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Our Amended Certificate provides further that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, subject to and contingent upon a final adjudication in the State of Delaware of the enforceability of such exclusive forum provision. These choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees. If a court were to find the choice of forum provision contained in our Amended Certificate to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business. For example, under the Securities Act, federal courts have concurrent jurisdiction over all suits brought to enforce any duty or liability created by the Securities Act, and investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder, and the Court of Chancery of the State of Delaware recently determined that the exclusive forum provision of federal district courts of the United States for resolving any complaint asserting a cause of action arising under the Securities Act is not enforceable. However, this decision may be reviewed and ultimately overturned by the Delaware Supreme Court. If the Court of Chancery's decision were to be overturned, we would enforce the federal district court exclusive forum provision in our Amended Certificate.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains "forward-looking statements" within the meaning of the federal securities laws, which statements are subject to substantial risks and uncertainties and are based on estimates and assumptions. All statements, other than statements of historical facts included in this prospectus, including statements concerning our plans, objectives, goals, strategies, future events, future revenues or performance, financing needs, plans or intentions relating to product candidates, estimates of market size, business trends, the anticipated timing, costs, design and conduct of our planned clinical trials for BIO89-100, our only product candidate, the timing and likelihood of regulatory filings and approvals for BIO89-100, our ability to commercialize BIO89-100, if approved, the pricing and reimbursement of BIO89-100, if approved, the potential to develop future product candidates, our ability to scale up manufacturing, the potential benefits of strategic collaborations and our intent to enter into any strategic arrangements, the timing and likelihood of success, plans and objectives of management for future operations, future results of anticipated product development efforts and the anticipated use of the net proceeds from this offering, are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "may," "might," "will," "objective," "intend," "should," "could," "can," "would," "expect," "believe," "design," "estimate," "predict," "potential," "plan" or the negative of these terms, and similar expressions intended to identify forward-looking statements.

These statements involve known and unknown risks, uncertainties and other factors that could cause our actual results to differ materially from the forward-looking statements expressed or implied in this prospectus. Such risks, uncertainties and other factors include, among others, the factors disclosed in the sections in this prospectus entitled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this prospectus.

We caution you that the risks, uncertainties and other factors referred to above and elsewhere in this prospectus may not contain all of the risks, uncertainties and other factors that may affect our future results and operations. Moreover, new risks will emerge from time to time. It is not possible for our management to predict all risks. In addition, we cannot assure you that we will realize the results, benefits or developments that we expect or anticipate or, even if substantially realized, that they will result in the consequences or affect us or our business in the way expected. Forward-looking statements are not historical facts, and reflect our current views with respect to future events. Given the significant uncertainties, you should evaluate all forward-looking statements made in this prospectus in the context of these risks and uncertainties and not place undue reliance on these forward-looking statements as predictions of future events.

All forward-looking statements in this prospectus apply only as of the date made and are expressly qualified in their entirety by the cautionary statements included in this prospectus. We disclaim any intent to publicly update or revise any forward-looking statements to reflect subsequent events or circumstances, except as required by law.

INDUSTRY AND MARKET DATA

We obtained the industry, market and competitive position data used throughout this prospectus from our own internal estimates and research, as well as from industry and general publications, and research, surveys and studies conducted by third parties. Internal estimates are derived from publicly available information released by industry analysts and third-party sources, our internal research and our industry experience, and are based on assumptions made by us based on such data and our knowledge of the industry and market, which we believe to be reasonable. In addition, while we believe the industry, market and competitive position data included in this prospectus is reliable and based on reasonable assumptions, we have not independently verified any third-party information, and all such data involve risks and uncertainties and are subject to change based on various factors, including those discussed in "Risk Factors." These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us.

USE OF PROCEEDS

We estimate that we will receive net proceeds of approximately $62.7 million (or approximately $72.5 million if the underwriters' option to purchase additional shares is exercised in full) from the issuance and sale of the shares of common stock offered by us in this offering, assuming an initial public offering price of $16.00 per share, the midpoint of the price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Each $1.00 increase (decrease) in the assumed initial public offering price of $16.00 per share, the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the net proceeds to us from this offering by $4.1 million, assuming the number of shares of common stock offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of 1,000,000 shares in the number of shares of common stock offered by us, as set forth on the cover page of this prospectus, would increase (decrease) our net proceeds from this offering by $14.9 million, assuming the assumed initial public offering price remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

We intend to use the net proceeds of this offering, together with our existing cash and cash equivalents, primarily as follows:

- approximately $20.0 to $30.0 million to complete our ongoing POC Phase 1b/2a clinical trial and initiate our subsequent Phase 2b clinical trial of BIO89-100 in patients with NASH;
- approximately $5.0 to $10.0 million to fund our Phase 2 trial of BIO89-100 in patients with SHTG, as well as evaluate potential new indications for BIO89-100;
- approximately $5.0 to $10.0 million for BIO89-100 manufacturing and scale up; and
- the remainder for working capital and other general corporate purposes.

Our expected use of proceeds from this offering represents our current intentions based on our present plans and business condition. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the proceeds to be received upon the completion of this offering or the amounts that we will actually spend on the uses set forth above. We may also use a portion of the proceeds to license, acquire or invest in complementary businesses, technology, products or assets, however we have no current commitments to do so. As a result, our management will have broad discretion over the use of the proceeds from this offering.

Based on our current business plans, we believe that the net proceeds from this offering, together with our existing cash and cash equivalents and the funds available from the first tranche of the potential term loan discussed under the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources," will be sufficient to fund our planned operations into the second half of 2021. The expected net proceeds from this offering will not be sufficient for us to fund BIO89-100 or any future product candidate through regulatory approval, and we will need to raise substantial additional capital to complete the development and commercialization of BIO89-100 and any future product candidates. The amount and timing of our actual expenditures will depend on numerous factors, including the pace and results of our research and development efforts, the timing and success of clinical trials, the timing and costs associated with the manufacture and supply of product candidates, the timing of regulatory submissions and any unforeseen cash needs. For additional information regarding our potential capital requirements, including factors that could cause actual costs to vary from the estimates set forth above, see "Risk Factors."

Pending the use of the proceeds from this offering, we may invest the proceeds in interest-bearing, investment-grade securities, certificates of deposit or government securities.

DIVIDEND POLICY

We have never declared or paid cash dividends on our capital stock and have no present intention to pay cash dividends on our common stock for the foreseeable future. Any determination to pay dividends to holders of our common stock will be at the discretion of our board of directors and will depend on many factors, including our financial condition, results of operations, liquidity, earnings, projected capital and other cash requirements, legal requirements, restrictions in the agreements governing any indebtedness we may enter into, business prospects and other factors that our board of directors deems relevant.

CAPITALIZATION

The following table sets forth our cash and cash equivalents and our capitalization as of June 30, 2019:

- on an actual basis after giving effect to the Reorganization;
- on a pro forma basis to give effect to (i) the Reorganization, (ii) the issuance in July 2019 of 1,173,611 shares of our convertible preferred stock and (iii) the automatic conversion of all outstanding shares of our convertible preferred stock into 7,077,366 shares of our common stock; and
- on a pro forma as adjusted basis giving effect to (i) the Reorganization; (ii) the other pro forma items described immediately above and (iii) the issuance and sale of 4,375,000 shares of our common stock in this offering, at the assumed initial public offering price of $16.00 per share, the midpoint of the price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The pro forma as adjusted information below is illustrative only and our capitalization following the completion of this offering will be based on the actual initial public offering price and other terms of this offering. You should read the following table in conjunction with "Use of Proceeds," "Selected Consolidated Financial Data," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and related notes included elsewhere in this prospectus.

	As of June 30, 2019		
	Actual	Pro Forma	Pro Forma As Adjusted(1)
		(in thousands, except share and per share amounts)	
Cash and cash equivalents	$ 21,919	$ 23,093	$ 85,793
Convertible preferred shares, $0.001 par value; 60,000,000 shares authorized as of June 30, 2019; 42,826,389 shares issued and outstanding as of June 30, 2019 actual; no shares authorized, issued and outstanding, pro forma and pro forma as adjusted	$ 48,168	$ —	$ —
Shareholders' (deficit) equity:			
Preferred shares, $0.001 par value, no shares authorized, issued or outstanding, actual; 10,000,000 shares authorized and no shares issued or outstanding, pro forma and pro forma as adjusted	—	—	—
Common stock, $0.001 par value, 72,882,353 shares authorized, 611,226 shares issued and outstanding, actual; 100,000,000 shares authorized, 7,688,592 shares issued and outstanding, pro forma; and 100,000,000 shares authorized, 12,063,592 shares issued and outstanding, pro forma as adjusted	1	8	12
Additional paid-in capital	229	49,564	112,260
Accumulated deficit	(35,588)	(35,588)	(35,588)
Total shareholders' (deficit) equity	(35,358)	13,984	76,684
Total capitalization	$ 12,810	$ 13,984	$ 76,684

(1) Each $1.00 increase (decrease) in the assumed initial public offering price of $16.00 per share, the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) each of our pro forma as adjusted cash and cash equivalents, additional paid-in capital, total shareholders' (deficit) equity and total capitalization by approximately $4.1 million, assuming the number of shares of common stock offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of 1,000,000 shares in the number of shares of common stock offered by us would increase (decrease) each of our pro forma as adjusted cash and cash

equivalents, additional paid-in capital, total shareholders' (deficit) equity and total capitalization by approximately $14.9 million, assuming the assumed initial public offering price remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The number of shares of common stock to be outstanding following this offering (i) is based on 611,226 shares of our common stock and 42,826,389 shares of our convertible preferred stock outstanding as of June 30, 2019, (ii) includes 1,173,611 shares of our convertible preferred stock issued in July 2019, (iii) gives effect to the Reorganization and the automatic conversion immediately prior to the completion of this offering of all outstanding shares of our convertible preferred stock into 7,077,366 shares of our common stock, and (iv) excludes the following:

- 721,079 shares of our common stock issuable upon the exercise of stock options outstanding as of June 30, 2019 under our 2019 Plan at a weighted-average exercise price of $1.93 per share;
- 583,080 options to purchase shares of our common stock granted subsequent to June 30, 2019 at a weighted-average exercise price of $4.26 per share;
- 343,083 shares of our common stock reserved for future issuance under our 2019 Plan as of June 30, 2019 and 396,727 and 1,383,302 additional shares of common stock reserved for future issuance on July 28, 2019 and October 24, 2019, respectively, as well as any automatic increase in the number of shares of common stock reserved for future issuance thereunder; and
- 225,188 shares of our common stock to be reserved for future issuance under our 2019 Employee Stock Purchase Plan, which we expect to enter into and which will become effective immediately prior to the completion of this offering, as well as any automatic increase in the number of shares of common stock reserved for future issuance thereunder.

DILUTION

If you invest in the shares of our common stock in this offering, your ownership interest will be immediately diluted. Dilution represents the difference between the amount per share paid by investors in this offering and the pro forma as adjusted net tangible book value per share of our common stock immediately after the completion of this offering. The data in this section are derived from our consolidated balance sheet as of June 30, 2019. Our historical net tangible book value per share is equal to our total tangible assets less the amount of our total liabilities and convertible preferred stock, divided by the sum of the number of shares of our common stock outstanding on June 30, 2019. Our historical net tangible book value (deficit) as of June 30, 2019 was $(35.6) million, or $(58.30) per share of common stock. Pro forma net tangible book value, before the issuance and sale of shares in this offering, gives effect to the conversion of all outstanding shares of our convertible preferred stock as of June 30, 2019 and all shares of our convertible preferred stock issued in July 2019 into an aggregate of 7,077,366 shares of common stock. Our pro forma net tangible book value as of June 30, 2019 was $13.7 million, or $1.78 per share.

After giving effect to our receipt of the estimated net proceeds from the issuance and sale of our common stock in this offering at an assumed initial public offering price of $16.00 per share, the midpoint of the price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of June 30, 2019 would have been $76.6 million, or $6.35 per share of our common stock. This represents an immediate increase in net tangible book value to our existing stockholders of $4.57 per share and an immediate dilution to new investors in this offering of $9.65 per share. The following table illustrates this per share dilution:

Assumed initial public offering price per share		$16.00
Historical net tangible book value (deficit) per share as of June 30, 2019	$(58.30)	
Increase per share attributable to the pro forma adjustments described above	60.08	
Pro forma net tangible book value per share as of June 30, 2019	1.78	
Increase in net tangible book value per share attributable to new investors participating in this offering	4.57	
Pro forma as adjusted net tangible book value per share after this offering		6.35
Dilution in pro forma net tangible book value per share to new investors participating in this offering		$ 9.65

The pro forma as adjusted dilution information discussed above is illustrative only and will change based on the actual initial public offering price and other terms of this offering. Each $1.00 increase or decrease in the assumed initial public offering price of $16.00 per share, the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) our pro forma as adjusted net tangible book value by $0.34 per share and increase (decrease) the dilution to new investors by $0.66 per share, in each case assuming the number of shares of common stock offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of 1,000,000 shares in the number of shares offered by us would increase (decrease) our pro forma as adjusted net tangible book value by $0.65 per share ($0.77 per share) and increase (decrease) the dilution to new investors by $0.65 per share ($0.77 per share), in each case assuming the assumed initial public offering price remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

If the underwriters exercise their option to purchase additional shares of our common stock in full, our pro forma as adjusted net tangible book value after this offering would be $6.79 per share, and there would be an immediate dilution of approximately $9.21 per share to new investors.

The following table presents on a pro forma as adjusted basis, as described above, the differences between the existing stockholders and the purchasers of shares in this offering with respect to the number of shares purchased from us, the total consideration paid, and the average price paid per share at an assumed initial public offering price of $16.00 per share, the midpoint of the price range set forth on the cover page of this prospectus:

	Shares Purchased		Total Consideration		Weighted-Average Price Per Share
	Number	Percent	Amount (in thousands)	Percent	
Existing stockholders before this offering	7,688,592	63.7%	$ 42,287	38.0%	$ 5.57
New investors participating in this offering	4,375,000	36.3%	70,000	62.0%	$ 16.00
Total	12,063,592	100.0%	$ 112,827	100.0%	

If the underwriters were to fully exercise their option to purchase 656,250 additional shares of our common stock from us, the percentage of shares of our common stock held by existing investors would be 60.4%, and the percentage of shares of our common stock held by new investors would be 39.6%.

Our existing stockholders affiliated with our directors have indicated an interest in purchasing an aggregate of up to approximately $40 million of shares of our common stock in this offering at the initial public offering price per share and on the same terms as the other purchasers in this offering. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, fewer or no shares of common stock to any of these potential purchasers, and any of these potential purchasers could determine to purchase more, fewer or no shares of common stock in this offering. The table above does not reflect the purchase of any shares in this offering by these existing stockholders.

The number of shares of common stock to be outstanding following this offering (i) is based on 611,226 shares of our common stock and 42,826,389 shares of our convertible preferred stock outstanding as of June 30, 2019, (ii) includes 1,173,611 shares of our convertible preferred stock issued in July 2019, (iii) gives effect to the Reorganization and the automatic conversion immediately prior to the completion of this offering of all outstanding shares of our convertible preferred stock into 7,077,366 shares of our common stock, and (iv) excludes the following:

- 721,079 shares of our common stock issuable upon the exercise of stock options outstanding as of June 30, 2019 under our 2019 Plan at a weighted-average exercise price of $1.93 per share;
- 583,080 options to purchase shares of our common stock granted subsequent to June 30, 2019 at a weighted-average exercise price of $4.26 per share;
- 343,083 shares of our common stock reserved for future issuance under our 2019 Plan as of June 30, 2019 and 396,727 and 1,383,302 additional shares of common stock reserved for future issuance on July 28, 2019 and October 24, 2019, respectively, as well as any automatic increase in the number of shares of common stock reserved for future issuance thereunder; and
- 225,188 shares of our common stock to be reserved for future issuance under our 2019 Employee Stock Purchase Plan, which we expect to enter into and which will become effective immediately prior to the completion of this offering, as well as any automatic increase in the number of shares of common stock reserved for future issuance thereunder.

To the extent that outstanding options are exercised, new options or other securities are issued under our equity incentive plans, or we issue additional shares of common stock in the future, there will be further dilution to investors participating in this offering. In addition, we may choose to raise additional capital because of market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. If we raise additional capital through the sale of equity or convertible debt securities, including warrants issued pursuant to the potential term loan, the issuance of these securities could result in further dilution to our stockholders.

SELECTED CONSOLIDATED FINANCIAL DATA

The following tables set forth selected historical consolidated financial data as of and for the periods indicated. The historical consolidated statement of operations data for the period from January 18, 2018 (inception) to December 31, 2018 and the consolidated balance sheet data as of December 31, 2018 are derived from our audited consolidated financial statements included elsewhere in this prospectus. The historical consolidated statement of operations data for the period from January 18, 2018 (inception) to June 30, 2018 and the six months ended June 30, 2019 and the consolidated balance sheet data as of June 30, 2019 are derived from our unaudited interim condensed consolidated financial statements included elsewhere in this prospectus. Our unaudited interim condensed consolidated financial statements were prepared on the same basis as our audited consolidated financial statements and, in our opinion, reflect all adjustments, consisting only of normal recurring adjustments, that are necessary for the fair statement of our unaudited interim condensed consolidated financial statements.

Our historical results presented below are not necessarily indicative of the results to be expected for any future period, and our interim results are not necessarily indicative of the results to be expected for the full year or any future period. This information should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and the related notes included elsewhere in this prospectus.

	Period from January 18, 2018 (inception) to December 31, 2018	Period from January 18, 2018 (inception) to June 30, 2018	Six Months Ended June 30, 2019
	(in thousands, except share and per share data)		
Consolidated Statement of Operations Data:			
Operating expenses:			
Research and development	$ 13,681	$ 6,700	$ 7,474
General and administrative	1,481	268	1,357
Total operating expenses	15,162	6,968	8,831
Loss from operations	15,162	6,968	8,831
Other (income) expenses, net	986	405	10,552
Net loss before tax	16,148	7,373	19,383
Income tax expense	28	—	29
Net loss and comprehensive loss	$ 16,176	$ 7,373	$ 19,412
Net loss per share, basic and diluted(1)	$ 36.45	$ 26.95	$ 31.76
Weighted-average shares used to compute net loss per share, basic and diluted(1)	443,767	273,532	611,226
Pro forma net loss per share, basic and diluted (unaudited)(1)	$ 7.60		$ 4.24
Weighted-average shares used to compute pro forma net loss per share, basic and diluted (unaudited)(1)	2,127,190		4,583,692

(1) See Notes 2 and 11 to our audited consolidated financial statements and Notes 2 and 10 to our unaudited interim condensed consolidated financial statements included elsewhere in this prospectus for an explanation of the calculations of our historical and pro forma net loss per share, basic and diluted, and weighted-average number of shares used in the computation of the per share amounts.

	As of December 31, 2018	As of June 30, 2019
	(in thousands)	
Consolidated Balance Sheet Data:		
Cash and cash equivalents	$ 11,234	$ 21,919
Total assets	11,369	22,347
Total current liabilities	4,353	9,537
Convertible preferred shares	23,073	48,168
Accumulated deficit	(16,176)	(35,588)
Total shareholders' deficit	(16,057)	(35,358)

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and related notes and other financial information included elsewhere in this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those described in or implied by these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified below and those discussed in the section titled "Risk Factors" included elsewhere in this prospectus. Unless the context requires otherwise, references to "we," "us," "our," "89bio" or the "company" refer to (i) 89Bio Ltd. for the periods prior to the Reorganization and (ii) 89bio, Inc. for the periods after completion of the Reorganization, in each case together with its consolidated subsidiaries.

Overview

We are a clinical-stage biopharmaceutical company focused on the development and commercialization of innovative therapies for the treatment of liver and cardio-metabolic diseases. Our lead product candidate, BIO89-100, a specifically engineered glycoPEGylated analog of FGF21, is currently being developed for the treatment of NASH. NASH is a severe form of NAFLD, characterized by inflammation and fibrosis in the liver that can progress to cirrhosis, liver failure, HCC and death. There are currently no approved products for the treatment of NASH. FGF21 is a clinically-validated mechanism that has been shown in humans to reduce steatosis and address cardio-metabolic dysregulation. We believe BIO89-100 may be a differentiated FGF21 therapy based on its robust and durable biological effects and a favorable tolerability profile, as well as its potential for a longer dosing interval. Combining these characteristics with the ability to address the key liver pathologies in NASH, as well as the underlying metabolic dysregulation in NASH patients, BIO89-100 has the potential to become a mainstay of NASH therapy. We successfully completed a Phase 1a, first-in-human, SAD clinical trial with 58 healthy volunteers. The magnitude and significance of BIO89-100's biological effects after a single dose on lipid parameters were robust and durable. In July 2019, we initiated our POC Phase 1b/2a clinical trial in patients with NASH or patients with NAFLD and a high risk of NASH and we expect to report topline data in the second half of 2020. We also intend to develop BIO89-100 for the treatment of SHTG, a condition identified by severely elevated levels of triglycerides (greater than or equal to 500 mg/dL), which is associated with an increased risk of NASH, cardiovascular events and acute pancreatitis. We expect to initiate our Phase 2 trial in SHTG patients in the first half of 2020 in order to evaluate the ability of BIO89-100 to reduce fasting plasma triglyceride levels compared to baseline levels and to report topline data in the first half of 2021. Based on FDA guidance for the development of SHTG treatments, as well as the regulatory path followed by other companies that have successfully developed SHTG therapies, we believe that a combination of smaller clinical trials and shorter development timelines could mean that SHTG potentially represents a quicker path to market for BIO89-100. We believe BIO89-100 has the potential to address multiple drivers underlying metabolic dysregulation, which would make it an ideal candidate for selected liver and cardio-metabolic diseases.

We commenced operations in 2018 and have devoted substantially all of our resources to organizing and staffing our company, business planning, raising capital, acquiring our initial product candidate, BIO89-100, and licensing certain related technology, conducting research and development activities, including preclinical studies and early clinical trials, and providing general and administrative support for these operations. We have funded our operations since our inception to June 30, 2019 through the issuance and sale of capital stock, from which we have raised aggregate net proceeds of $42.5 million. Additionally, in July 2019, we issued and sold capital stock from which we raised aggregate net proceeds of $1.2 million. As of June 30, 2019, our cash and cash equivalents totaled $21.9 million. Based on our current operating plan, we believe that our cash and cash equivalents and the funds available from the first tranche of the potential term loan discussed below, together with the estimated net proceeds from this offering, will be sufficient to meet our anticipated cash requirements into the second half of 2021.

We do not have any products approved for sale and have incurred net losses since our inception. Our net losses for the period from January 18, 2018 (inception) to December 31, 2018 were $16.2 million. Our net loss for the six months ended June 30, 2019 was $19.4 million. As of June 30, 2019, we had an accumulated deficit of $35.6 million. We expect to continue to incur significant expenses and increasing operating losses as we advance BIO89-100 and any future product candidates through clinical trials, seek regulatory approval for BIO89-100 and any future product candidates, expand our clinical, regulatory, quality, manufacturing and commercialization capabilities, protect our intellectual property, prepare for and, if approved, proceed to commercialization of BIO89-100 and any future product candidates, expand our general and administrative support functions, including hiring additional personnel, and incur additional costs associated with operating as a public company. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical trials and our expenditures on other research and development activities.

We have never generated revenue and do not expect to generate revenue from product sales unless and until we successfully complete development and obtain regulatory approval for BIO89-100, which we expect will not be for at least several years, if ever. Accordingly, until such time as we can generate significant revenue from sales of BIO89-100, if ever, we expect to finance our cash needs through a combination of public or private equity offerings, debt financings or other capital sources, including potential collaborations, licenses and other similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements when needed would have a negative impact on our financial condition and could force us to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Reorganization

We were incorporated in January 2018 in Israel under the name 89Bio Ltd. 89bio, Inc., the registrant whose name appears on the cover page of this prospectus, was incorporated in June 2019 for the purpose of an internal reorganization transaction. In September 2019, all of the equity holders of 89Bio Ltd. exchanged 100% of the equity of 89Bio Ltd. for 100% of the equity of 89bio, Inc. Following the Reorganization, 89Bio Ltd. became a wholly owned subsidiary of 89bio, Inc. and 89bio, Inc. owns the business described and for which historical financial information is included elsewhere in this prospectus. Shares of the common stock of 89bio, Inc. are being offered by this prospectus.

Agreements with Teva

In April 2018, we entered into the FGF21 Agreement with Teva, under which we acquired certain patents, intellectual property and other assets relating to Teva's glycoPEGylated FGF21 program, including BIO89-100. Under the FGF21 Agreement, Teva also granted us a perpetual, non-exclusive (but exclusive as to BIO89-100), non-transferable, worldwide license to patents and know-how related to glycoPEGylation technology for use in the research, development, manufacture and commercialization of BIO89-100 and products containing BIO89-100. We also entered into an Asset Transfer and License Agreement with Teva under which we acquired from Teva certain patents, intellectual property and other assets relating to Teva's development program of small molecule inhibitors of FASN (the "FASN Agreement" and collectively with the FGF21 Agreement, the "Teva Agreements").

Pursuant to the Teva Agreements, we paid Teva a nonrefundable upfront payment of $6.0 million. See "Business—Agreements with Teva." In addition, we are required to make certain payments to Teva under each of the Teva Agreements of up to $2.5 million for the achievement of certain development milestones, and additional payments of up to $65.0 million upon achievement of certain commercial milestones, for a total under both Teva Agreements of up to $135.0 million. We are also obligated to pay Teva tiered royalties at percentages in the low-to-mid single-digits on worldwide net sales of products containing BIO89-100 or FASN.

The assets acquired from Teva did not meet the definition of a business and therefore, this acquisition was treated as an asset acquisition for accounting purposes. In addition, we recorded the total consideration transferred to Teva in connection with this acquisition as research and development expense because the acquired technology represented in-process research and development and had no alternative future use.

Components of Results of Operations

Research and Development

Research and development expenses consist primarily of costs incurred for the development of our lead product candidate, BIO89-100. Our research and development expenses consist primarily of external costs related to preclinical and clinical development, including costs related to acquiring patents and intellectual property, expenses incurred under license agreements and agreements with contract research organizations and consultants, costs related to acquiring and manufacturing clinical trial materials, including under agreements with contract manufacturing organizations and other vendors, costs related to the preparation of regulatory submissions and expenses related to laboratory supplies and services, as well as personnel costs. Personnel costs consist of salaries, employee benefits and share-based compensation for individuals involved in research and development efforts.

We expense all research and development expenses in the periods in which they are incurred. We accrue for costs incurred as the services are being provided by monitoring the status of specific activities and the invoices received from our external service providers. We adjust our accrual as actual costs become known. Payments associated with licensing agreements to acquire licenses to develop, use, manufacture and commercialize products that have not reached technological feasibility and do not have alternate commercial use are expensed as incurred. Where contingent milestone payments are due to third parties under research and development arrangements or license agreements, the milestone payment obligations are expensed when the milestone results are probable and estimable, which is generally upon achievement of milestones.

We expect our research and development expenses to increase substantially for the foreseeable future as we continue the development of BIO89-100 and continue to invest in research and development activities. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time consuming, and the successful development of BIO89-100 and any future product candidates is highly uncertain. To the extent that BIO89-100 continues to advance into larger and later stage clinical trials, our expenses will increase substantially and may become more variable. The actual probability of success for BIO89-100 or any future product candidate may be affected by a variety of factors, including the safety and efficacy of our product candidates, investment in our clinical programs, manufacturing capability and competition with other products. As a result, we are unable to determine the timing of initiation, duration and completion costs of our research and development efforts or when and to what extent we will generate revenue from the commercialization and sale of BIO89-100 or any future product candidate.

Our future clinical development costs may vary significantly based on factors such as:

- the cost and timing of manufacturing BIO89-100 and any future product candidates;
- per-patient trial costs;
- the number of trials required for approval;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;

- the number of patients that participate in the trials;
- the number of doses evaluated in the trials;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of patient participation in the trials and follow-up;
- the phase of development of BIO89-100 and any future product candidates; and
- the efficacy and safety profile of BIO89-100 and any future product candidates.

General and Administrative

Our general and administrative expenses consist primarily of personnel costs, expenses for outside professional services, including legal, human resource, audit and accounting services, consulting costs and allocated facilities costs. Personnel and related costs consist of salaries, benefits and share-based compensation for personnel in executive, finance and other administrative functions. Facilities costs consist of rent and maintenance of facilities. We expect our general and administrative expenses to increase for the foreseeable future as we increase the size of our administrative function to support the growth of our business and support our continued research and development activities. We also anticipate increased expenses as a result of operating as a public company, including increased expenses related to audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance premiums and investor relations costs.

Other (Income) Expenses, Net

Other (income) expenses, net primarily consists of the revaluation of our convertible preferred share liability.

Results of Operations

Period from January 18, 2018 (inception) to June 30, 2018 and the Six Months Ended June 30, 2019

The following table summarizes our results of operations for the periods presented (in thousands):

	Period from January 18, 2018 (inception) to June 30, 2018	Six Months Ended June 30, 2019	Increase/ (Decrease)
Operating expenses:			
Research and development	$ 6,700	$ 7,474	$ 774
General and administrative	268	1,357	1,089
Total operating expenses	6,968	8,831	1,863
Loss from operations	6,968	8,831	1,863
Other (income) expenses, net	405	10,552	10,147
Income tax expense	—	29	29
Net loss and comprehensive loss	$ 7,373	$ 19,412	$ 12,039

Research and Development Expenses

The following table summarizes the period-over-period changes in research and development expenses for the periods indicated:

	Period from January 18, 2018 (inception) to June 30, 2018	Six Months Ended June 30, 2019	Increase/ (Decrease)
Up-front license payment to Teva	$ 6,000	$ —	$ (6,000)
Clinical development	120	2,451	2,331
Contract manufacturing	284	2,679	2,395
Pre-clinical costs	7	418	411
Personnel-related expenses	248	1,540	1,292
Other expenses	41	386	345
Total research and development expenses	$ 6,700	$ 7,474	$ 774

Research and development expenses increased by $0.8 million, or 12%, from $6.7 million during the period from January 18, 2018 (inception) to June 30, 2018 to $7.5 million during the six months ended June 30, 2019. The increase was primarily due to an increase of $2.4 million in contract manufacturing costs, an increase of $2.3 million in clinical development costs, and an increase of $0.4 million in pre-clinical costs, related to advancing our current clinical programs with our lead product candidate, BIO89-100. In addition, personnel-related costs, including share-based compensation, increased by $1.3 million and other expenses increased by $0.3 million due to increased headcount and other costs as we ramped up our operations. These increases were partially offset by a $6.0 million decrease due to a one time up-front license payment to Teva in the period from January 18, 2018 (inception) to June 30, 2018.

General and Administrative Expenses

General and administrative expenses increased by $1.1 million, or 406%, from $0.3 million during the period January 18, 2018 (inception) to June 30, 2018 to $1.4 million during the six months ended June 30, 2019. The increase was primarily due to an increase of $0.7 million in personnel-related costs, including share-based compensation, driven by an increase in headcount and an increase of $0.4 million in professional and accounting consulting service fees, incurred in connection with our preparation to become a public company.

Other (Income) Expenses, Net

Other (income) expenses, net increased by $10.1 million, from $0.4 million during the period from January 18, 2018 (inception) to June 30, 2018 to $10.6 million during the six months ended June 30, 2019. The increase was primarily due to the revaluation of our convertible preferred share liability.

Period from January 18, 2018 (inception) to December 31, 2018

The following table summarizes our results of operations for the period presented (in thousands):

	Period from January 18, 2018 (inception) to December 31, 2018
Operating expenses:	
Research and development	$ 13,681
General and administrative	1,481
Total operating expenses	15,162
Loss from operations	15,162
Other (income) expenses, net	986
Income tax expense	28
Net loss and comprehensive loss	$ 16,176

Research and Development Expenses

Research and development expenses were $13.7 million for the period presented (in thousands):

	Period from January 18, 2018 (inception) to December 31, 2018
Up-front license payment to Teva	$ 6,000
Clinical development	1,826
Contract manufacturing	3,379
Pre-clinical costs	1,207
Personnel-related expenses	1,013
Other expenses	256
Total research and development expenses	$ 13,681

General and Administrative Expenses

General and administrative expenses were $1.5 million for the period from January 18, 2018 (inception) to December 31, 2018. General and administrative expenses consisted primarily of $0.9 million in payroll and related expenses and $0.5 million in legal fees and professional consulting service fees, each related to the establishment of our company.

Other (Income) Expenses, Net

Other (income) expenses, net was $1.0 million for the period from January 18, 2018 (inception) to December 31, 2018, which was primarily due to the revaluation of our convertible preferred share liability.

Liquidity and Capital Resources

As of September 30, 2019, we estimate that our cash and cash equivalents were approximately $16.2 million. Our independent registered public accounting firm, Brightman Almagor Zohar & Co., a Firm in the Deloitte Global Network, has not reviewed, and does not express an opinion with respect to, these estimates. Our actual cash and cash equivalents as of September 30, 2019 may differ from these estimates due to the completion of our financial closing procedures, final adjustments and other developments that may arise between now and the time the financial results for our third fiscal quarter are finalized. Our financial statements for the quarter ended September 30, 2019 will not be available until after this offering is completed, and consequently will not be available to you prior to investing in this offering.

Since our inception to June 30, 2019, we have funded our operations from the issuance and sale of capital stock, from which we have raised aggregate net proceeds of $42.5 million. As of June 30, 2019, we had available cash and cash equivalents of $21.9 million and an accumulated deficit of $35.6 million. Additionally, in July 2019, we received aggregate net proceeds of $1.2 million in connection with the issuance of Series A convertible preferred shares.

We have received a non-binding indicative term sheet from one or more financial institutions for a term loan consisting of a first tranche of $10.0 million with the potential for an additional tranche of $5.0 million subject to satisfaction of certain terms and conditions. If we enter into the term loan, we expect that we would issue to the financial institutions warrants to purchase shares of our common stock. We also expect that obligations under the term loan would be secured by a first priority lien on all assets with a negative pledge on our intellectual property. The term loan and the anticipated terms thereof are subject to the lenders' due diligence, internal approval processes and negotiation and execution of definitive agreements, and could ultimately never materialize.

Our primary use of cash is to fund operating expenses, which consist primarily of research and development expenditures related to our lead product candidate, BIO89-100. We plan to increase our research and development expenses substantially for the foreseeable future as we continue the clinical development of our current and future product candidates. At this time, due to the inherently unpredictable nature of clinical development, we cannot reasonably estimate the costs we will incur and the timelines that will be required to complete development, obtain marketing approval, and commercialize our current product candidate or any future product candidates. For the same reasons, we are also unable to predict when, if ever, we will generate revenue from product sales or our current or any future license agreements which we may enter into or whether, or when, if ever, we may achieve profitability. Clinical and preclinical development timelines, the probability of success, and development costs can differ materially from expectations. In addition, we cannot forecast the timing and amounts of milestone, royalty and other revenue from licensing activities, which future product candidates may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

Based on our current operating plans, we expect that the net proceeds from this offering, together with our existing cash and cash equivalents and the funds available from the first tranche of the potential term loan discussed above, will be sufficient to fund our operations into the second half of 2021. However, our operating plans and other demands on our cash resources may change as a result of many factors, and we may seek additional funds sooner than planned. There can be no assurance that we will be successful in acquiring additional funding at levels sufficient to fund our operations or on terms favorable to us.

Our future funding requirements will depend on many factors, including the following:

- the progress, timing, scope, results and costs of our clinical trials of BIO89-100 and preclinical studies or clinical trials of other potential product candidates we may choose to pursue in the future, including the ability to enroll patients in a timely manner for our clinical trials;
- the costs and timing of obtaining clinical and commercial supplies and validating the commercial manufacturing process for BIO89-100 and any other product candidates we may identify and develop;
- the cost, timing and outcomes of regulatory approvals;
- the timing and amount of any milestone, royalty or other payments we are required to make pursuant to current or any future collaboration or license agreements;
- costs of acquiring or in-licensing other product candidates and technologies;
- the terms and timing of establishing and maintaining collaborations, licenses and other similar arrangements;

- the costs associated with attracting, hiring and retaining additional qualified personnel as our business grows;
- our efforts to enhance operational systems and hire additional personnel to satisfy our obligations as a public company, including enhanced internal controls over financial reporting; and
- the cost of preparing, filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

We expect to continue to generate substantial operating losses for the foreseeable future as we expand our research and development activities. We will continue to fund our operations primarily through utilization of our current financial resources and through additional raises of capital. These conditions, and our cash and cash equivalents balances, raise substantial doubts about our ability to continue as a going concern for at least a year after the filing date of the interim condensed consolidated financial statements, included elsewhere in this prospectus. We plan to address these conditions by raising funds from our current investors as well as outside potential investors. However, there is no assurance that such funding will be available to us or that it will be obtained on terms favorable to us or will provide us with sufficient funds to meet our objectives. The interim condensed consolidated financial statements do not include any adjustments relating to the recoverability and classification of assets, carrying amounts or the amount or classification of liabilities that may be required should we be unable to continue as a going concern.

To the extent that we raise additional capital through partnerships or licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates, future revenue streams or research programs or to grant licenses on terms that may not be favorable to us. If we raise additional capital through public or private equity offerings, the ownership interest of our then-existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of or suspend one or more of our clinical trials or preclinical studies, research and development programs or commercialization efforts or grant rights to develop and market our product candidates even if we would otherwise prefer to develop and market such product candidates ourselves.

Pursuant to a share purchase agreement (the "Series A SPA") entered into with investors in April 2018, subject to the satisfaction, as determined in good faith by our board of directors, of certain milestones set forth in the Series A SPA, we may sell additional shares of Series A convertible preferred stock to our investors for aggregate gross proceeds of up to $16.0 million. We do not expect to fully satisfy these milestones prior to this offering and do not anticipate selling any additional shares of Series A convertible preferred stock prior to this offering. The Series A SPA will terminate upon consummation of this offering and no shares of Series A convertible preferred stock will be issued under the Series A SPA after this offering. See Note 7 to our interim condensed consolidated financial statements appearing elsewhere in this prospectus for more information about the Series A SPA.

Cash Flows

The following table summarizes our cash flows for the periods presented (in thousands):

	Period from January 18, 2018 (inception) to December 31, 2018	Period from January 18, 2018 (inception) to June 30, 2018	Six Months Ended June 30, 2019
Net cash used in operating activities	$ (12,469)	$ (6,644)	$ (8,131)
Net cash used in investing activities	(39)	(31)	(20)
Net cash provided by financing activities	23,765	14,772	18,837
Net increase in cash and cash equivalents, and restricted cash	$ 11,257	$ 8,097	$ 10,686

Net Cash Used in Operating Activities

During the six months ended June 30, 2019, net cash used in operating activities was $8.1 million, which consisted of a net loss of $19.4 million, partially offset by non-cash charges of $10.6 million and a net change of $0.7 million in our net operating assets and liabilities. The non-cash charges are primarily comprised of the revaluation of our convertible preferred share liability of $10.5 million and $0.1 million in share-based compensation. The change in our operating assets and liabilities was primarily due to a $1.3 million increase in accrued expenses as we grew our operations, offset in part by a $0.5 million decrease in accounts payable due to the timing of payments.

During the period from January 18, 2018 (inception) to June 30, 2018, net cash used in operating activities was $6.6 million, which consisted of a net loss of $7.4 million, partially offset by non-charges of $0.4 million and a net change of $0.4 million in our net operating assets and liabilities. The non-cash charges are primarily comprised of the revaluation of our convertible preferred share liability of $0.4 million. The change in our operating assets and liabilities was primarily due to a $0.4 million increase in accounts payable and accrued expenses as we grew our operations.

During the period from January 18, 2018 (inception) to December 31, 2018, net cash used in operating activities was $12.5 million, which consisted of a net loss of $16.2 million, partially offset by non-cash charges of $1.1 million and a net change of $2.6 million in our net operating assets and liabilities. The non-cash charges are primarily comprised of the revaluation of our convertible preferred share liability of $1.0 million and $0.1 million in share-based compensation. The change in our net operating assets and liabilities was primarily due to a $2.7 million increase in accounts payable and accrued expenses as we grew our operations.

Net Cash Used in Investing Activities

During the six months ended June 30, 2019, the period from January 18, 2018 (inception) to June 30, 2018, and the period from January 18, 2018 (inception) to December 31, 2018, net cash used in investing activities primarily consisted of purchases of fixed assets.

Net Cash Provided by Financing Activities

During the six months ended June 30, 2019 net cash provided by financing activities was $18.8 million, which consisted of net proceeds of $18.8 million from the issuance and sale of our convertible preferred shares.

During the period from January 18 (inception) to June 30, 2018 net cash provided by financing activities was $14.8 million, which primarily consisted of net proceeds of $14.7 million from the issuance and sale of our convertible preferred shares.

During the period from January 18, 2018 (inception) to December 31, 2018, net cash provided by financing activities was $23.8 million, which primarily consisted of net proceeds of $23.7 million from the issuance and sale of our convertible preferred shares.

Contractual Obligations and Other Commitments

The following table summarizes our contractual obligations as of December 31, 2018 (in thousands):

	Payments Due by Period				
	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years	Total
Operating lease obligations	$ 18	$ —	$ —	$ —	$ 18
Total contractual obligations	$ 18	$ —	$ —	$ —	$ 18

In addition, under the Teva Agreements, we have milestone and royalty payment obligations if and when we achieve certain milestones and commercialize products developed under the agreements. Because these obligations are uncertain, and their timing and amount are not known, they are not included in the table above. See "Business—Agreements with Teva."

The amounts in the table above do not include: (a) a non-cancellable purchase commitment entered into in July 2019 related to the supply of reagents in the amount of €1.2 million, or $1.4 million (using the exchange rate as of June 30, 2019), pursuant to a purchase order issued to Teva; or (b) non-cancellable purchases commitments entered into in June, July and August 2019 amounting in total to €4.1 million, or $4.7 million (using the exchange rate as of June 30, 2019), that we will be responsible to pay in connection with multiple statements of work with a contract manufacturer related to scale-up activities of BIO89-100 and the production of material for preclinical and clinical studies, and for the technology transfer related to the manufacturing of certain enzymes.

We also enter into agreements in the normal course of business with contract research organizations for clinical trials, preclinical studies, manufacturing and other services and products, which are generally cancelable upon written notice. These obligations and commitments are also not included in the table above.

Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements, as defined in the rules and regulations of the SEC, and do not have any holdings in variable interest entities.

Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities. We held cash and cash equivalents of $11.2 million and $21.9 million as of December 31, 2018 and June 30, 2019, respectively, which consist of bank deposits. Historical fluctuations in interest rates have not had a significant impact on our financial condition or results of operations, and a hypothetical future 10% relative increase or decrease in interest rates would not have a material impact on the value of our cash and cash equivalents or on our future financial condition or results of operations.

Foreign Currency Risk

Our expenses are generally denominated in the currencies in which our operations are located, which is primarily in the United States and Israel. We make payments to vendors for research and development services with payments denominated in foreign currencies, including the Israeli New Shekel and Euro. We are subject to foreign currency transaction gains or losses on our payments denominated in foreign currencies. To date, foreign currency transaction gains and losses have not been material and we have not had a formal hedging program with respect to foreign currency. A 10% increase or decrease in currency exchange rates would not have a material effect on our financial results.

Critical Accounting Polices and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with United States generally accepted accounting principles. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities as of the date of the consolidated financial statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on

various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

Accrued Research and Development Expenditures

We record accrued expenses for estimated preclinical and clinical trial and research expenses related to the services performed but not yet invoiced pursuant to contracts with research institutions, contract research organizations and clinical manufacturing organizations that conduct and manage preclinical studies, and clinical trials, and research services on our behalf. Payments for these services are based on the terms of individual agreements and payment timing may differ significantly from the period in which the services were performed. Our estimates are based on factors such as the work completed, including the level of patient enrollment. We monitor patient enrollment levels and related activity to the extent reasonably possible and make judgments and estimates in determining the accrued balance in each reporting period. Our estimates of accrued expenses are based on the facts and circumstances known at the time. If we underestimate or overestimate the level of services performed or the costs of these services, our actual expenses could differ from our estimates. As actual costs become known, we adjust our accrued expenses. To date, we have not experienced significant changes in our estimates of preclinical studies and clinical trial accruals.

Convertible Preferred Share Liability

The freestanding instruments related to the commitments by the Series A convertible preferred shareholders to purchase and by us to sell our Series A convertible preferred shares in subsequent closings, contingent upon the achievement of certain developmental milestones and approval by the board of directors, at a fixed price per share, are considered a liability (or an asset) measured at fair value as the shares underlying the rights contain liquidation preferences upon certain "deemed liquidation events" that are not solely within the Company's control and which are considered in-substance contingent redemption features. The instruments are subject to revaluation at each balance sheet date until settlement, with revaluations recognized as a component of other (income) expenses, net in the consolidated statement of operations and comprehensive loss.

Share-Based Compensation

We recognize compensation expense related to share-based awards granted to employees, directors, and non-employee service providers, including stock options, based on the estimated fair value of the awards on the date of grant. We estimate the grant date fair value, and the resulting share-based compensation, using the Black-Scholes option-pricing model. The grant date fair value of the share-based awards, which have graded vesting, is recognized using the straight-line method over the requisite service period of each award, which is generally the vesting period of the respective awards. We recognize forfeitures as they occur.

We use the Black-Scholes option-pricing model to estimate the fair value of stock option awards that requires the use of subjective assumptions to determine the fair value of share-based awards. These assumptions include:

- *Expected volatility*—Since we are privately held and do not have any trading history for our shares of common stock, the expected volatility is based on the historical volatilities of the shares of common stock of similar publicly traded companies in the biotechnology sector. The historical volatility data was computed using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of the share-based awards.

- *Risk-free interest rate*—The risk-free interest rate is based on the U.S. Treasury zero coupon bonds in effect at the time of grant for periods corresponding with the expected term of the option.

- *Expected term*—The expected term of options granted to employees and directors is determined using the "simplified" method. Under this approach, the expected term is presumed to be the mid-point between the weighted-average vesting term and the contractual term of the option. The simplified method makes the assumption that the employee will exercise share options evenly over the period when the share options are vested and ending on the date when the share options would expire. The expected option term for options granted to non-employees is based on the contractual term.

- *Expected dividend*—We have never paid dividends on our shares of common stock and have no plans to pay dividends on our shares of common stock. Therefore, we used an expected dividend of zero.

We will continue to use judgment in evaluating the expected volatility and expected term utilized for our share-based compensation calculations on a prospective basis.

Given the absence of a public trading market for our shares of common stock, our board of directors exercised their judgment and considered a number of objective and subjective factors to determine the best estimate of the fair value of our shares of common stock, including timely valuations of our shares of common stock prepared by an unrelated third-party valuation firm, important developments in our operations, sales of convertible preferred shares, actual operating results and financial performance, the conditions in the biotechnology industry and the economy in general, the stock price performance and volatility of comparable public companies, and the lack of liquidity of our shares of common stock, among other factors. After the closing of this offering, our board of directors will determine the fair value of each share of common stock based on the closing price of our shares of common stock as reported on the date of grant. Our board of directors intended all options granted to be exercisable at a price per share not less than the estimated per share fair value of shares of common stock underlying those options on the date of grant.

For the six months ended June 30, 2019 and during the period from January 18, 2018 (inception) to December 31, 2018, share-based compensation was $111,000 and $108,000, respectively. As of June 30, 2019, there was $682,000 of unrecognized share-based compensation related to stock options granted, which is expected to be recognized over a weighted average period of 3.0 years.

Based on the assumed initial offering price of $16.00 per share, the midpoint of the price range set forth on the cover page of this prospectus, the aggregate intrinsic value of outstanding stock options as of June 30, 2019 was $10.1 million, of which $0.9 million related to vested options and $9.2 million related to unvested options.

Recent Accounting Pronouncements

See Note 2 to our consolidated financial statements included elsewhere in this prospectus for more information about recent accounting pronouncements, the timing of their adoption, and our assessment, to the extent we have made one yet, of their potential impact on our financial condition of results of operations.

JOBS Act Accounting Election

We are an "emerging growth company," as defined in the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies.

We have elected to use this extended transition period to enable us to comply with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our consolidated financial statements and our interim condensed consolidated financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

BUSINESS

Overview

We are a clinical-stage biopharmaceutical company focused on the development and commercialization of innovative therapies for the treatment of liver and cardio-metabolic diseases. Our lead product candidate, BIO89-100, a specifically engineered glycoPEGylated analog of FGF21, is currently being developed for the treatment of NASH. NASH is a severe form of NAFLD, characterized by inflammation and fibrosis in the liver that can progress to cirrhosis, liver failure, HCC and death. There are currently no approved products for the treatment of NASH. FGF21 is a clinically-validated mechanism that has been shown in humans to reduce steatosis and address cardio-metabolic dysregulation. We believe BIO89-100 may be a differentiated FGF21 therapy based on its robust and durable biological effects and a favorable tolerability profile, as well its potential for a longer dosing interval. Combining these characteristics with the ability to address the key liver pathologies in NASH, as well as the underlying metabolic dysregulation in NASH patients, BIO89-100 has the potential to become a mainstay of NASH therapy. We successfully completed a Phase 1a, first-in-human, SAD clinical trial with 58 healthy volunteers. The magnitude and significance of BIO89-100's biological effects after a single dose on lipid parameters were robust and durable. In July 2019, we initiated our POC Phase 1b/2a clinical trial in patients with NASH or patients with NAFLD and a high risk of NASH and we expect to report topline data in the second half of 2020. We also intend to develop BIO89-100 for the treatment of SHTG, a condition identified by severely elevated levels of triglycerides (greater than or equal to 500 mg/dL), which is associated with an increased risk of NASH, cardiovascular events and acute pancreatitis. We expect to initiate our Phase 2 trial in SHTG patients in the first half of 2020 in order to evaluate the ability of BIO89-100 to reduce fasting plasma triglyceride levels compared to baseline levels and to report topline data in the first half of 2021. Based on FDA guidance for the development of SHTG treatments, as well as the regulatory path followed by other companies that have successfully developed SHTG therapies, we believe that a combination of smaller clinical trials and shorter development timelines could mean that SHTG potentially represents a quicker path to market for BIO89-100. We believe BIO89-100 has the potential to address multiple drivers underlying metabolic dysregulation, which would make it an ideal candidate for selected liver and cardio-metabolic diseases.

The prevalence of NAFLD, which affects approximately 25% of the global population, and NASH, which develops in approximately 20% to 25% of NAFLD patients, is growing and is driven primarily by the worldwide obesity epidemic. NAFLD and NASH patients have an excessive accumulation of fat in the liver resulting primarily from a caloric intake above and beyond energy needs. In NAFLD patients, this abnormal liver fat contributes to the progression to NASH, a liver necro-inflammatory state, that can lead to scarring, also known as fibrosis, and, for some, can progress to cirrhosis and liver failure. The critical pathophysiologic mechanisms underlying the development and progression of NASH include reduced ability to handle lipids, increased insulin resistance, injury to hepatocytes and liver fibrosis in response to hepatocyte injury. Patients with NASH frequently have other significant metabolic co-morbidities such as obesity, hyperglycemia, dyslipidemia and systemic hypertension (a constellation of which is commonly referred to as metabolic syndrome) and these further contribute to the risk of cardiovascular disease. The number of NASH cases in the United States is projected to expand from 16.5 million in 2015 to 27 million in 2030, with similar prevalence growth expected in Europe. Diet and exercise are currently the standard of care for NAFLD and NASH, but adherence to this treatment regimen is poor and there remains a high unmet need in the treatment of NASH.

BIO89-100 is a specifically engineered FGF21 analog that we believe has the potential to address the critical pathophysiologic mechanisms underlying NASH. FGF21 is a metabolic hormone that regulates energy expenditure and glucose and lipid metabolism. FGF21 has been clinically shown to reduce steatosis in the liver. It is also thought to exert effects on liver fibrosis by improving metabolic regulation, which reduces ongoing liver injury thus giving the liver time to heal. FGF21 also generates an on-target effect to increase adiponectin, a hormone released from adipose tissue that, among other functions, can suppress development and progression of hepatic fibrosis. However, FGF21 in its native form suffers from a short half-life and a tendency to aggregate in solution, both of which impact its suitability as a viable drug. To address these challenges, we have specifically engineered

BIO89-100 to maintain the clinical benefits of FGF21, while extending half-life in vivo, protecting against proteolysis, reducing renal clearance, minimizing susceptibility to aggregate in solution and optimizing potency.

BIO89-100 has been evaluated in seven animal studies of NASH, diabetes and obesity, including studies in mice and non-human primates. Each study was customized to assess endpoints relevant to liver and metabolic diseases and conducted according to standard practices at experienced CROs. In these preclinical studies, consistent beneficial effects across a range of endpoints were observed, including improvements in hepatic steatosis, injury and fibrosis in a diet-induced NASH study of 50 mice (see "BIO89-100—Results of DIN Mouse Studies" Figure 11 which illustrates that statistically significant mean changes with respect to hepatic steatosis and fibrosis were each observed and Figure 12 which illustrates that statistically significant mean changes with respect to injury were observed) and improved glycemic resistance and lipid handling in a study of 24 spontaneously diabetic obese cynomolgus monkeys with elevated triglycerides (see "BIO89-100—Results of Spontaneously Diabetic Obese Cynomolgus Monkey Studies" Figures 20 and 21, respectively, which illustrate that statistically significant mean changes with respect to glycemic control and lipid handling were each observed). We believe this demonstrates BIO89-100's potential to simultaneously address the multiple drivers of NASH pathogenesis. The histological endpoints assessed in these preclinical studies, NAFLD activity score ("NAS") and fibrosis score, mirror the endpoints we expect to assess in our clinical development. In addition, treatment with BIO89-100 in animal models demonstrated consistent reductions in body weight.

In May 2019, we announced positive topline data from our Phase 1a, first-in-human, SAD clinical trial of BIO89-100 in 58 healthy volunteers. In this SAD study, BIO89-100 demonstrated a favorable tolerability profile in the 43 volunteers who received BIO89-100 with a half-life of 55 to 100 hours. At single doses of 9.1 mg and higher, BIO89-100 demonstrated significant improvements in key lipid parameters measured at Day 8 and Day 15 after dosing on Day 1. The mean changes versus baseline include reductions in triglycerides (up to 51%) and LDL-C (up to 37%) and increase in HDL-C (up to 36%) despite the baseline values being in the normal range. As compared to placebo treatment, these mean changes were all statistically significant ($p < 0.001$). BIO89-100 demonstrated rapid (beginning from Day 2), sustained and durable improvements in lipid parameters for two weeks or more after single dose administration. Based on these findings and results from our animal studies, we believe such a lengthy duration of effect may confer longer dosing intervals to BIO89-100. We are currently enrolling our POC Phase 1b/2a trial with 83 total patients randomized to receive once weekly or once every two weeks subcutaneous dosing of either BIO89-100 or placebo, in each case, for up to 12 weeks. This trial is designed to assess the safety, tolerability and PK properties of BIO89-100, as well as changes in liver steatosis and key biomarker assessments.

We also intend to develop BIO89-100 for the treatment of SHTG, a condition identified by severely elevated levels of triglycerides (greater than or equal to 500 mg/dL) and which is associated with an increased risk of NASH, cardiovascular events and acute pancreatitis. SHTG accounts for up to 10% of all acute pancreatitis episodes. It is estimated that there are 2.5 million to 4 million patients in the United States with TG ^{3} 500 mg/dL and up to 50% of SHTG patients treated with certain approved drugs are refractory to current standard of care. In a study of 24 diabetic obese cynomolgus monkeys with elevated triglycerides, BIO89-100 showed significant effects on triglycerides at doses as low as 0.1 mg/kg/week, with a 78% reduction from baseline (range of 52% reduction to 94% reduction) observed at the highest dose level of 1.0 mg/kg/week on Day 56. In our Phase 1a SAD study, BIO89-100 showed a significant reduction in triglycerides of up to 51% after a single dose in healthy volunteers. While currently approved SHTG therapies decrease TG levels, they generally do not have broader metabolic benefits. To the extent that we are able to show in subsequent human clinical trials that BIO89-100 significantly decreases both TG and LDL-C levels and improve other metabolic parameters, we believe that BIO89-100 could be a differentiated therapy in this indication. We expect to initiate our Phase 2 trial in SHTG patients in the first half of 2020 in order to evaluate the ability of BIO89-100 to reduce fasting plasma triglyceride levels compared to baseline levels and to report topline data in the first half of 2021.

We retain exclusive worldwide rights to BIO89-100. BIO89-100 is protected by a family of issued patents with claims directed to composition of matter and methods of use. The first of our patents for BIO89-100

are projected to expire in the United States in 2028, with the final composition-of-matter patent projected to expire in the United States in 2038, in each case, without patent term extensions. Because BIO89-100 is a biologic drug, marketing approval is also expected to provide 12 years of market exclusivity in the United States from the approval date of a BLA. We license the patents and know-how related to the glycoPEGylation technology for use in the research, development, manufacture and commercialization of BIO89-100 from Teva and ratiopharm.

Our management team has extensive drug development, manufacturing and commercialization experience, having brought many successful drugs to market, including biologic agents. We are also supported by a group of directors and leading investors whose collective experience will assist us in realizing our corporate strategy. Our existing investors include OrbiMed, Longitude Capital, RA Capital and Pontifax.

Strategy

Our goal is to become a leading biopharmaceutical company focused on the development and commercialization of innovative therapies for the treatment of liver and cardio-metabolic diseases. The key components of our strategy are to:

- **Rapidly advance BIO89-100 through clinical development for the treatment of NASH.** We believe BIO89-100 may be a differentiated FGF21 therapy based on its robust and durable biological effects and a favorable tolerability profile, as its potential for a longer dosing interval, and is well positioned to address the complex pathophysiology of NASH. We are currently enrolling patients in our POC Phase 1b/2a clinical trial to evaluate the safety and efficacy of BIO89-100. We believe that our trial design and the use of well-established surrogate clinical endpoints can contribute meaningfully to the rapid advancement of BIO89-100 through its clinical development. With potential for BIO89-100 to be established as a mainstay monotherapy for NASH, we continue to explore opportunities to combine BIO89-100 with products targeting other pathways within NASH for possible development as a combination therapy.

- **Expand the breadth of indications for BIO89-100 with an initial focus on SHTG.** While we are focused on becoming a leader in the treatment of NASH, the mechanism of action of our FGF21 analog supports evaluation across a spectrum of liver and cardio-metabolic diseases. We believe BIO89-100's mechanism and potentially robust and durable biological effects and favorable tolerability profile, as well as its potential for a longer dosing interval make it an ideal candidate for selected liver and cardio-metabolic diseases. We intend to develop BIO89-100 for the treatment of SHTG. Based on FDA guidance for the development of SHTG treatments, as well as the regulatory path followed by other companies that have successfully developed SHTG therapies, we believe that a combination of smaller clinical trials and shorter development timelines could mean that SHTG potentially represents a quicker path to market for BIO89-100.

- **Scale-up and optimize the manufacturing of BIO89-100.** We currently use an external contract manufacturing organization ("CMO") to manufacture BIO89-100 for our ongoing and planned clinical trials. While these trials are ongoing, we plan to work with our CMO to optimize and scale-up the manufacturing process for BIO89-100 to support the increased production that will be needed for later-stage clinical trials and commercialization, if BIO89-100 is approved.

- **Establish a commercial infrastructure in key geographies.** We have worldwide rights to BIO89-100 and intend to develop the sales infrastructure required for commercialization in the United States. We also plan to evaluate options, including strategic collaborations, for commercializing BIO89-100, if approved, in other key markets, such as Europe and China.

- **Construct a diversified multi-asset pipeline of novel therapies.** We intend to employ a value-driven strategy to identify, acquire, develop and commercialize product candidates for liver and

cardio-metabolic diseases. We intend to focus on product candidates that we believe have attractive profiles in early clinical testing, address a clear unmet medical need and can advance quickly and efficiently into late-stage development.

Our Focus on Liver and Cardio-Metabolic Disease

We are focused on developing and commercializing therapeutic interventions that have a clinically meaningful impact on patients with liver and cardio-metabolic diseases. These diseases, including NASH and SHTG, represent leading global causes of morbidity and mortality. Despite a wave of public health campaigns to promote better diet and exercise habits and a range of treatment options available for many of these diseases, there is a significant unmet medical need for more effective therapies to improve patient outcomes and reduce the burden on global healthcare systems.

We are currently developing our lead product candidate, BIO89-100, a specifically engineered glycoPEGylated analog of FGF21, for the treatment of NASH. We believe BIO89-100 is an ideal candidate for the treatment of NASH based on:

- its ability to address the key liver pathologies in NASH;
- its ability to address the underlying metabolic dysregulation in NASH patients;
- its balance of its robust and durable biological effects and favorable tolerability profile; and
- its potential for a longer dosing interval.

Given the potential of BIO89-100 to meaningfully reduce triglycerides, we also intend to develop BIO89-100 for the treatment of SHTG. There is regulatory precedence for the approval of a therapy for the treatment of patients with SHTG in the United States and the reduction in triglycerides from baseline is recognized by the FDA as the primary endpoint for full approval. Based on FDA guidance for the development of SHTG treatments, as well as the regulatory path followed by other companies that have successfully developed SHTG therapies, we believe that a combination of smaller clinical trials and shorter development timelines could mean that SHTG potentially represents a quicker path to market for BIO89-100.

NASH Overview

NAFLD is emerging as the most common chronic liver disorder, driven primarily by the global obesity epidemic. NAFLD affects approximately 25% of the population globally and is often referred to as the hepatic manifestation of metabolic syndrome. Patients with NAFLD have an excessive accumulation of fat in the liver resulting from a caloric intake above and beyond energy needs. This abnormal fat in the liver contributes to the progression of NAFLD to NASH, a necro-inflammatory state in the liver that ultimately leads to scarring, also known as fibrosis; and for certain patients, progression to cirrhosis and liver failure.

Patients with NASH exhibit suboptimal lipid handling, increased insulin resistance, caloric overload and inadequate fat burning, all of which contribute to the increased risk of cardiovascular disease. Due to an increase in obesity and Type 2 diabetes, which predispose individuals to more significant liver disease, the number of NASH cases in the United States is projected to expand from 16.5 million in 2015 to 27 million in 2030. Currently, there are no approved products for the treatment of NASH and diet and exercise is established as the standard of care.

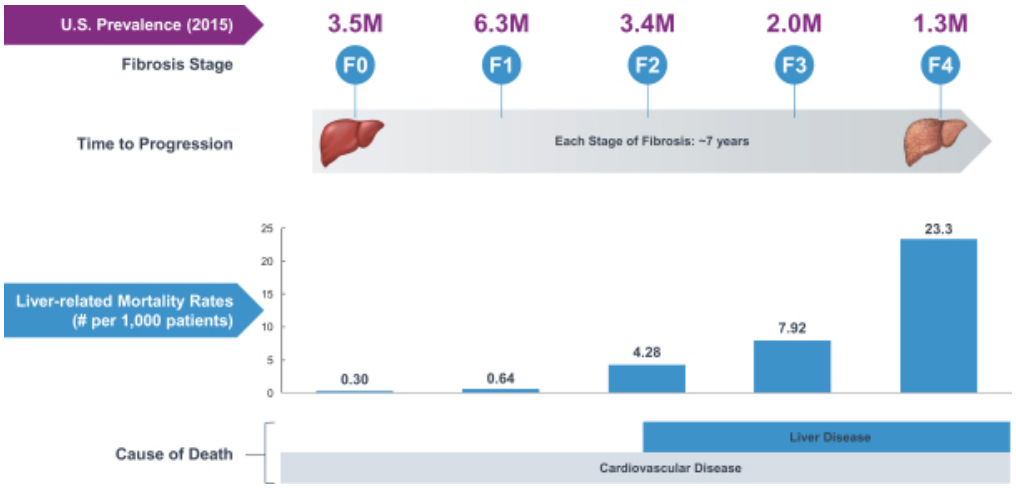
Disease Overview

NAFLD is a condition of excess fat accumulation, or steatosis, of more than 5% in liver cells, also known as hepatocytes. NASH, a severe form of NAFLD, is characterized histologically by the additional presence of inflammation and hepatocellular injury such as visible ballooning and has a significantly worse

prognosis, with the potential to progress to liver fibrosis, cirrhosis or HCC. Steatohepatitis is a key catalyst in fibrosis development, and there is a substantial collinearity between the presence of NASH and fibrosis severity. While NAFLD has historically been viewed as benign in terms of liver-related outcomes, recent studies have challenged this notion since patients with NAFLD may develop NASH and fibrosis over time.

Figure 1 below shows the increase in prevalence liver-related mortality rates by fibrosis stage.

Figure 1: Prevalence and Liver-Related Mortality Rate by Fibrosis Stage



It is estimated that 20% to 25% of NAFLD patients progress to NASH. Of those with NASH, cirrhosis develops in approximately 20% and 45% of patients and in some cases, cirrhosis progresses to decompensated cirrhosis, which results in permanent liver damage that can lead to liver failure. In addition, it is estimated that 8% of patients with advanced fibrosis will develop HCC.

There is a high unmet need in the treatment of NASH, and there are currently no approved therapies. In the United States, the number of NASH cases is projected to expand from 16.5 million in 2015 (5.1% of the population) to 27 million in 2030. The expected lifetime economic burden of all patients with NASH in the United States in 2017 is estimated at $223 billion. NASH is currently the second leading cause of liver transplants behind hepatitis C, and is expected to become the leading cause of liver transplants by 2020. Additionally, multiple epidemiological studies have linked NAFLD to increased cardiovascular disease, concluding that the majority of deaths among NAFLD patients are attributable to cardiovascular disease. As a result, we believe it is important that new therapeutics options for NASH also address the underlying cardiovascular and metabolic dysregulations in these patients.

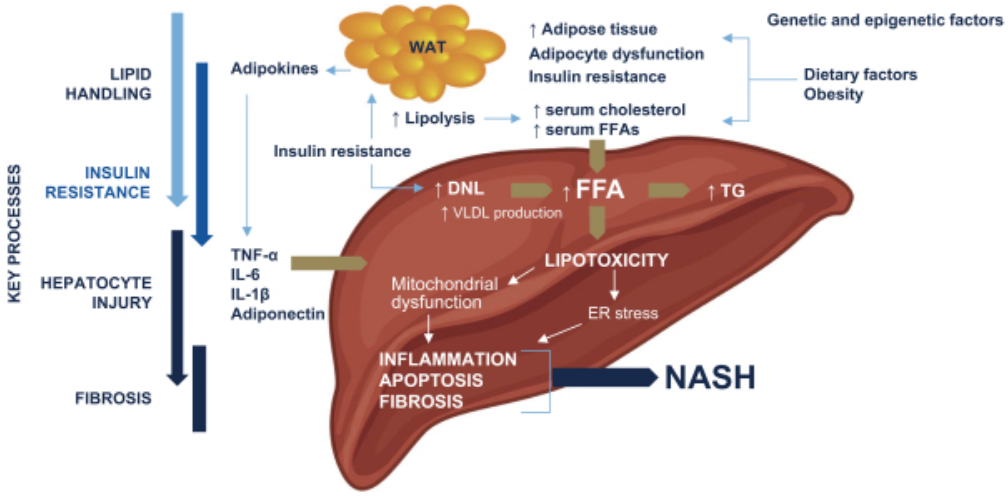
Etiology

Understanding of the pathophysiologic mechanisms that lead to NASH has evolved in recent years. Excessive caloric overload, metabolic dysregulation, cardio-metabolic co-morbidities and genetic risk factors increase the likelihood of developing NASH, with a multitude of potential mechanistic contributors to pathophysiology. In NASH, the liver's capacity to handle the primary metabolic energy substrates, carbohydrates and fatty acids, is overwhelmed. This occurs when there is an excess of free fatty acids deposited in the liver or their disposal from the liver is impaired. The accumulation of surplus free fatty acids leads to the formation of toxic lipid species. These toxic lipids then induce endoplasmic reticulum stress, oxidative stress and an

inflammatory response, which can result in hepatocellular injury and death. This may lead to fibrosis and genomic instability, which may worsen over time to cirrhosis and HCC, respectively.

As shown in Figure 2 below, the critical pathophysiologic mechanisms underlying development and progression of NASH include (1) reduced ability to handle lipids, (2) increased insulin resistance, (3) injury to hepatocytes and (4) development and progression of liver fibrosis in response to hepatocyte injury.

Figure 2: Mechanisms Underlying Development and Progression of NASH



Reduced Ability to Handle Lipids

Excess consumption of calories, poor diet and a sedentary lifestyle, each often associated with obesity, can burden the body with a surplus of carbohydrates and lipids. This burden can be progressively more difficult for the liver to handle thereby resulting in steatosis in the liver. The problem is compounded further as insulin resistance develops.

Free fatty acids ("FFA") accumulate in the liver primarily from three sources, namely, through (1) the transfer from peripheral adipose tissues where triglycerides are mobilized, (2) de-novo lipogenesis ("DNL"), and (3) direct dietary intake. The FFA that lead to NASH are believed to arise primarily from the peripheral tissue pool and secondarily through DNL. The increase in the influx of FFA to the liver from the peripheral tissues is driven by excessive caloric intake greater than the body's demand and increased insulin resistance resulting in deposition of fat to the liver for processing. DNL is a distinct process in the liver by which hepatocytes convert excess carbohydrates, especially fructose, to fatty acids.

The three main fates of fatty acids in the liver are (1) mitochondrial beta-oxidation (to release ATP, or energy), (2) re-esterification to form triglyceride, which can then be exported into the blood as very low density lipoproteins, or (3) stored in lipid droplets, resulting in liver steatosis and ultimately NASH. Adiponectin, a hormone derived from adipose tissue, appears to have a pivotal role in improving fatty acid oxidation and decreasing fatty acid synthesis, components of lipid handling.

An increase in cholesterol accumulation in the liver can also contribute to NASH, though its role is not as clearly defined as in the case of triglycerides. The dysregulation of the cholesterol pathway can result in an

increase in the cholesterol levels in the liver. The increased cholesterol can accumulate in the liver cell membranes and activate Kupffer cells (activated stellate macrophages), thereby triggering inflammatory pathways and resulting in the progression of NASH.

Increased Insulin Resistance

Insulin resistance, which typically develops in obese individuals, is considered to be a fundamental underlying mechanism in the majority of NASH patients. Fatty acids are primarily delivered to the liver from blood following lipolysis of triglycerides in adipose tissue, a process that is regulated by the actions of insulin on adipocytes. Insulin resistance in adipose tissue manifests as dysregulated lipolysis resulting in excessive delivery of FFA to the liver. The liver tries to cope with the large influx of FFA; however, the build-up of metabolic intermediates interferes with signaling, resulting in hepatic insulin resistance and the inability of the liver to process this excess FFA influx. The state of hepatic insulin resistance further exacerbates the problem by triggering DNL and the build-up of excess fat in the liver.

Injury to Hepatocytes

When the disposal of fatty acids through beta-oxidation or the formation of triglycerides is chronically overwhelmed, fatty acids can form lipotoxic species that lead to stress on the endoplasmic reticulum, oxidative stress and inflammation, all of which are pivotal processes in the development of NASH. Liver inflammation may be an important link between the initial metabolic stress and subsequent hepatocyte death and stimulation of fibrogenesis in NASH by promotion of the expression of pro-inflammatory cytokines and of apoptosis (cell death). These processes are core to the steatohepatitis that gives NASH its name. For example, hepatocyte apoptosis results in the ballooning of cells, a classic pathological feature of NASH. While hepatocytes are the primary and major target of toxic lipids, other cells such as Kupffer cells and hepatic stellate cells are also affected by lipotoxicity and contribute to the development of NASH pathology.

Additional factors, including dysregulation of cytokines and adipokines, energy depletion, anti-oxidant deficiencies, products of the gut microbiome and iron load may modulate hepatocyte vulnerability to the development of lipotoxic stress, injury and inflammation.

Development and Progression of Liver Fibrosis in Response to Hepatocyte Injury

Signaling from stressed or injured hepatocytes and Kupffer cells leads to activation of quiescent hepatic stellate cells. Upon activation, hepatic stellate cells release collagen and other factors. When the production of collagen and matrix proteins is faster than their degradation, accumulation of these proteins in the extracellular matrix can lead to progressive fibrosis. As the lipotoxicity and inflammation continue to damage the liver, the hepatic stellate cells continue to be activated resulting in greater collagen deposition that ultimately leads to fibrosis and cirrhosis.

Co-morbidities Associated with NASH

Patients with NASH frequently have other significant co-morbidities—hypertriglyceridemia, obesity, hyperlipidemia/dyslipidemia, hyperglycemia (including Type 2 diabetes) and systemic hypertension, a constellation of which is commonly referred to as metabolic syndrome—which also increase the risk of developing cardiovascular disease. Figure 3 below shows certain co-morbidities associated with NASH.

Figure 3: NASH Co-morbidities

Selected Co-morbidities	Prevalence in NASH Population
Hypertriglyceridemia	83%
Obesity	82%
Hyperlipidemia / Dyslipidemia	72%
Metabolic syndrome	71%
Type 2 diabetes	44%

The association between NASH and features of metabolic syndrome appears to be bidirectional. Metabolic syndrome increases the risk of NASH and NASH may also exacerbate several features and co-morbidities of metabolic syndrome. Type 2 diabetes, hypertriglyceridemia, obesity and other features of metabolic syndrome have all been shown to be associated with an increased risk for NASH and advanced liver fibrosis. In addition, it is estimated that approximately 30% of obese patients and approximately 30% of patients with Type 2 diabetes have NASH.

In addition, NASH was found to independently increase the risk of non-liver-related adverse outcomes, including cardiovascular risk and malignancy. Multiple epidemiological studies have linked NASH to increased cardiovascular morbidity, concluding that the majority of deaths among NASH patients are attributable to cardiovascular disease (cardiovascular death is four times higher than death related to liver disease).

In considering therapeutic options to treat NASH, we believe it is important to address the underlying metabolic co-morbidities in addition to the liver pathology.

Diagnosis

Most people with NASH are asymptomatic and their disease is often discovered incidentally following a liver imaging procedure, such as an ultrasound, prescribed for other reasons or as part of an investigation for elevated liver enzymes. Once suspected clinically, a liver biopsy is required to definitively diagnose NASH, which necessitates the joint presence of steatosis, ballooning and lobular inflammation. Once pathologically confirmed, the severity of NAFLD and NASH is determined using the histologically validated NAS, which grades disease activity on a scale of 0 to 8. The NAS is the sum of the individual scores for steatosis (0 to 3), lobular inflammation (0 to 3), and hepatocellular ballooning (0 to 2) but does not include a score for fibrosis. Fibrosis staging (F0-F4) relies on the Kleiner classification (F0 = no fibrosis; F1 = perisinusoidal or periportal fibrosis (not both); F2 = both perisinusoidal and periportal fibrosis; F3 = bridging fibrosis; F4 = cirrhosis).

Histological diagnosis remains the gold standard for assessment of NASH and fibrosis. However, given that liver biopsy is associated with risks of pain, bleeding and other morbidity, as well as significant cost, the procedure is not practical for general patient screening. Several non-invasive tools such as clinical risk scores and imaging techniques are increasingly used to assess NASH patients. Clinical risk scores such as the NAFLD fibrosis score, Fibrosis-4 index, the Enhanced Liver Fibrosis score and vibration-controlled transient elastography (“VCTE”), have been validated and are increasingly used. These tools have an excellent negative

predictive value and an acceptable positive predictive value for detection of advanced (³ F3) fibrosis, and are increasingly used in clinical settings. Additionally, evidence is emerging that shows a correlation between reduction in steatosis as measured by magnetic resonance imaging proton density fat fraction ("MRI-PDFF") and improvement histological changes in the liver. Extensive efforts are also under way to develop non-invasive means to identify patients with NAS ³4 or fibrosis ³ F2 patients without a need for a liver biopsy. In a recent draft guidance, the FDA encouraged sponsors to identify biochemical or noninvasive imaging biomarkers that, once characterized and agreed by the FDA, could replace liver biopsies for patient selection and efficacy assessment in clinical trials.

We expect that the validation and subsequent adoption of these new tools will result in an increase in the diagnosis and treatment rates for NASH in the future.

Prevalence

The prevalence of NASH has increased significantly in recent decades, paralleling similar trends in the prevalence of obesity, insulin resistance and Type 2 diabetes. Alarmingly, the prevalence of these conditions is expected to increase further in view of the unhealthy nutrition habits, such as consumption of a diet high in fructose, sucrose and saturated fats, and sedentary behavior that characterize modern lifestyle. In the United States, the number of NASH cases is projected to expand from 16.5 million in 2015 (5.1% of the population) to 27 million in 2030. Approximately 20% of the 16.5 million NASH cases in 2015 had F3/F4 fibrosis, a number that is expected to increase to 7.9 million by 2030, which will be approximately 30% of the total NASH population. Similar growth trends for NASH cases are expected in Europe (12.6 million in 2016 to 18.3 million in 2030 within France, Germany, Italy, Spain and the United Kingdom) as well as China (32.6 million in 2016 to 48.3 million in 2030).

Since no approved drugs exist currently, NASH is emerging as a major economic issue. Lifetime costs of all NASH patients in the United States in 2017 was estimated at $223 billion, and the cost of the advanced NASH population was estimated at $95 billion with estimated increase in NASH cases (as mentioned above) further expected to drive costs upwards. Progression of patients along the NASH continuum further adds to costs as mean health care costs (per month) were 32% and 247% higher for patients with compensated cirrhosis ($1,870) and end-stage liver disease ($4,931), respectively, compared to those without cirrhosis ($1,420) and these results were independent of age. The economic burden of NASH is expected to continue to increase, as NASH is anticipated to become the leading cause of liver transplants by 2020 in conjunction with the significant increase in liver transplant costs ($577,000 in 2013 to $812,500 in 2017).

Overview of NASH Treatment Options

There are currently no approved therapies for the treatment of NASH. We believe four key attributes are essential for successful NASH therapies: (1) robust efficacy with respect to liver pathologies; (2) ability to address underlying co-morbidities associated with the disease; (3) limited tolerability issues at effective doses; and (4) patient convenience. Figure 4 below summarizes the primary interventional and therapeutic approaches to NASH that are in existence or under development and their key advantages and limitations.

Figure 4: Primary Interventional and Therapeutic Approaches to NASH

Approach	Advantages	Limitations
Diet and exercise	■ Reduction in continuing injury to the liver allowing liver to regenerate ■ Inexpensive and widely available	■ Poor adherence
Farnesoid X receptor (FXR) agonism	■ Statistically significant but modest reduction in liver fibrosis ■ Liver fat reduction with some agents	■ Increase in LDL-C and pruritus with some agents ■ Limited impact on NASH resolution by histology
Peroxisome proliferator-activated receptor (PPAR) agonism	■ Improvement in glycemic control with some agents ■ Anti-inflammatory ■ Reduction in triglycerides and liver fat with some agents	■ Weight gain with certain agents ■ Safety issues with certain agents (cancer, heart failure, edema) and renal adverse events ■ No effect on liver fat with certain agents
Thyroid receptor-ß (THR-ß) agonism	■ Reduction in LDL-C and triglycerides ■ Reduction in liver fat	■ Potential for drug-drug interactions ■ Potential risk of hypothyroidism ■ Questionable effect on fibrosis
Acetyl-CoA (ACC) inhibition	■ Reduction in DNL from inhibition	■ Increase in triglycerides, risk of thrombocytopenia
Fibroblast growth factors (FGFs)	■ Reduction in liver fat and fibrosis ■ Improvements in lipid parameters with certain agents	■ FGF19 is associated with increases in LDL-C; impact on HDL and glucose unclear ■ Daily injections with some agents likely to be poorly received by patients ■ Native FGF21 is rapidly broken down by the body and is difficult to formulate in solution
GLP1	■ Reduction in body weight ■ Well-established glycemic control agent	■ No impact on lipid parameters ■ Injectable formulation in testing for NASH has burdensome dosing regime ■ Questionable impact on fibrosis and liver fat reduction

We believe that the market for NASH treatments will evolve to be similar to the multi-billion dollar markets for diabetes and dyslipidemia treatments and has the potential to support multiple successful commercial products across different therapeutic classes as well as within the same class. Further, we believe potent injectable therapies have the potential to be a preferred treatment option for some patient populations.

Our Solution

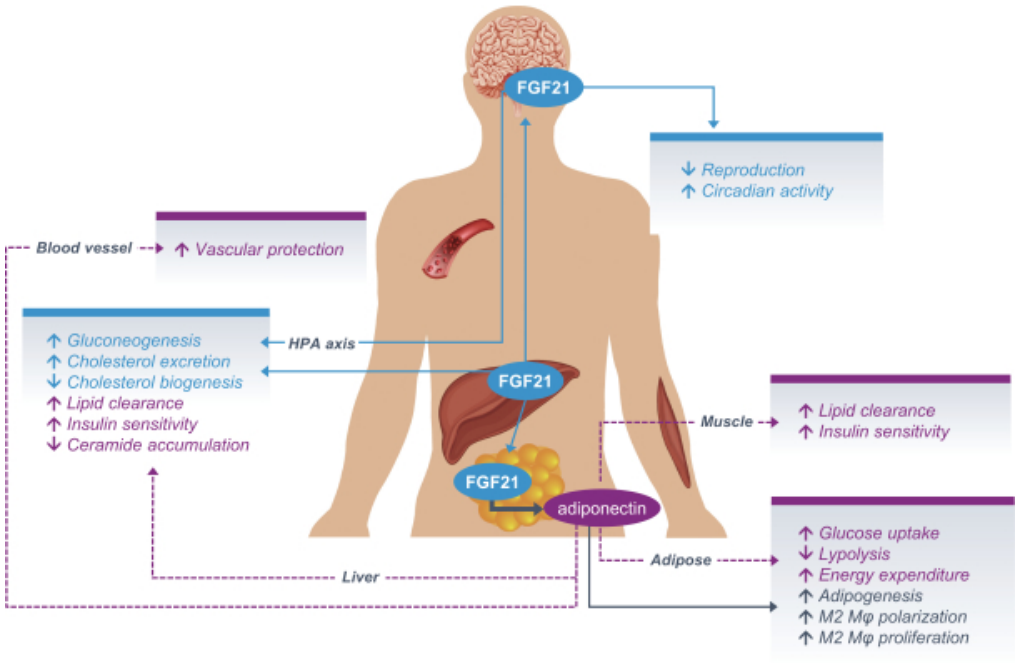
Summary

We are developing BIO89-100, a specifically engineered glycoPEGylated analog of FGF21, for the treatment of NASH and other liver and cardio-metabolic indications. FGF21 is an endogenous metabolic hormone that is naturally found as a monomeric, non-glycosylated protein and is known to play a key role in regulating energy expenditure, and glucose and lipid metabolism. FGF21 has been clinically shown to reduce steatosis in the liver. It is also thought to exert effects on liver fibrosis by improving metabolic regulation, which reduces ongoing liver injury thus giving the liver time to heal. FGF21 also generates an on-target effect to increase adiponectin, a hormone released from adipose tissue that, among other functions, can suppress development and progression of hepatic fibrosis. Given the relevant and broad-based effects of FGF21, we believe it is a compelling pharmaceutical target for treating NASH, which may offer benefits and/or address the limitations relative to the therapeutic approaches described in Figure 4 above. We believe FGF21 analogs such as ours have the potential to be the mainstay of therapies for NASH because they can address liver pathologies and the underlying metabolic dysregulation which result in NASH progression. However, FGF21 in its native form is not suitable as a pharmacological product given it is rapidly broken down by the body and it is unstable in soluble formulation. BIO89-100 is specifically engineered to overcome these challenges while maintaining the efficacious properties of the endogenous molecule. We believe BIO89-100 may be a differentiated FGF21 therapy based on its robust and durable biological effects and a favorable tolerability profile, as well its potential for a longer dosing interval. We are currently evaluating BIO89-100 in a POC Phase 1b/2a clinical trial in patients with NASH or patients with NAFLD and high risk of NASH.

FGF21 Overview

Fibroblast growth factors ("FGFs"), including FGF21 and FGF19, are a large family of cell-signaling proteins involved in the regulation of many processes within the body. FGF21 is an endogenous metabolic hormone that regulates energy homeostasis, glucose-lipid-protein metabolism and insulin sensitivity, and modulates the pathways that mitigate against intracellular stress. FGF21 is secreted primarily by the liver but is also secreted by the white adipose tissue ("WAT"), skeletal muscle and the pancreas. FGF21 exerts its biological benefits through the activation of three fibroblast growth factor receptors ("FGFRs"), FGFR1c, FGFR2c and FGFR3c, and requires co-activation of the transmembrane protein cofactor beta Klotho ("ß-Klotho"). FGF21 is not believed to activate FGFR4, which has been associated with adverse effects. FGF21 can act directly or indirectly on target organs by mediating downstream regulators, such as adiponectin, and upstream regulators that induce FGF21, such as nutritional stress or transcription factors. Figure 5 below shows effects of FGF21 on the body.

Figure 5: Biological Effects of FGF21



Reducing Liver Steatosis by Improving Lipid Handling and Insulin Sensitivity

FGF21 has been clinically shown to reduce liver steatosis. FGF21 reduces liver steatosis by (1) increasing fatty acid oxidation in the liver, (2) reducing the deposition of free fatty acids from peripheral tissue to the liver and (3) reducing DNL in the liver. FGF21 exerts its systemic effects by reducing the serum levels of lipids (e.g., triglycerides, LDL cholesterol) and increasing insulin sensitivity. Increasing insulin sensitivity reduces lipolysis and can also reduce serum levels of lipids. In particular, FGF21 has been demonstrated to reduce liver fat in patients with NASH and has also shown beneficial effects in obese diabetic patients on both serum levels of lipids and insulin resistance.

Improving Liver Inflammation and Fibrosis

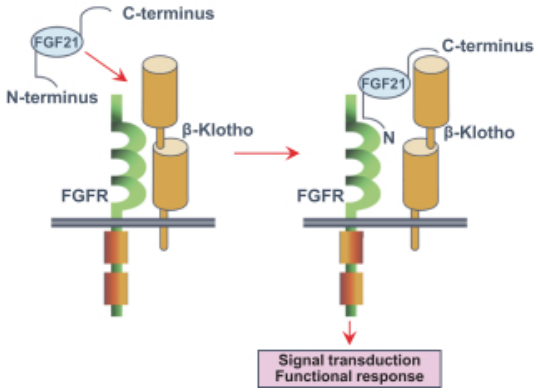
FGF21 is believed to reduce liver fibrosis, the pathological change mostly clearly linked to liver-related morbidity in NASH patients via two potential pathways. One pathway is through the metabolic benefits of FGF21 described above. Long-term improvements in metabolic regulation reduce the ongoing liver injury that drives fibrosis and thus allows the liver time to heal. The other pathway is a direct anti-fibrotic effect mediated via adiponectin, an adipokine that is upregulated by FGF21. Increased adiponectin downregulates the hepatic stellate cells that are activated upon hepatic injury and responsible for collagen deposition and subsequent fibrosis.

FGF21 Signaling

As noted above, FGF21 exerts its biological benefits through the co-activation of FGFRs and ß-Klotho. FGFRs are expressed widely throughout the body whereas ß-Klotho is primarily expressed in metabolic tissues such as adipose tissue, liver, and pancreas, thereby providing organ specificity to FGF21.

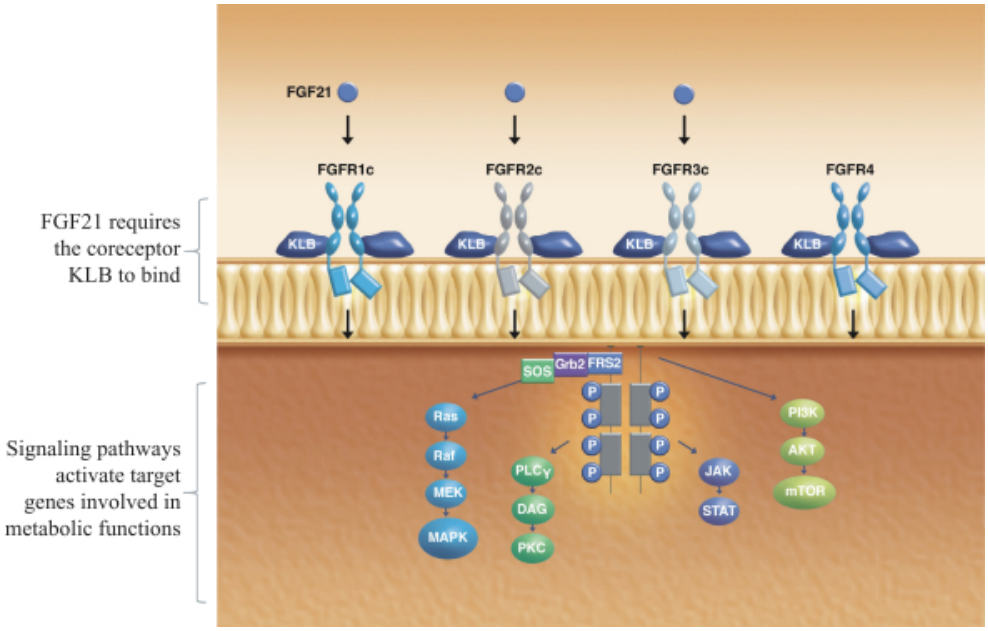
As illustrated in Figure 6 below, the binding of FGF21 is a two-step process. The C-terminus of FGF21 initially binds to ß-Klotho enabling the N-terminus to form an expanded complex with one of the FGFRs. Once the co-receptor complex has formed with ß-Klotho and one of the FGFRs, a series of intracellular signaling cascades is initiated. These signaling cascades enable FGF21 to exert its biological functions.

Figure 6: FGF21's two-step receptor binding with ß-Klotho and FGFRs



FGF21 activates three specific FGFRs (FGFR1c, FGFR2c and FGFR3c), which based on nonclinical studies and clinical trials, appear to be responsible for mediating the desired therapeutic actions of FGF21 in NASH. FGF19 activates these receptors and acts upon another FGFR known as FGFR4. Activation of FGFR4 results in an increase in LDL cholesterol and has been implicated in the etiology or progression of HCC. The activation and downstream signaling pathways of FGF21 are shown in Figure 7 below.

Figure 7: FGF21 Receptor Activation



Overcoming the Challenges of Developing FGF21 as a Pharmaceutical Product

While the observed pharmacological effects of recombinant human FGF21 in preclinical disease models clearly highlight its therapeutic potential, FGF21 in its native form is not suitable for commercialization for two key reasons:

- **Native FGF21 is rapidly broken down in the bloodstream and cleared through the kidneys.** The native form of FGF21 is a 19.4 kDa protein with a half-life estimated to be less than two hours. Reducing renal clearance and protecting both ends of the protein from proteolysis remains key to extending half-life and thereby extending the duration of its effect. If the N-terminus is not intact, signaling activity of FGF21 is significantly reduced. However, if the C-terminus is not intact, FGF21's ability to bind with ß-Klotho is impaired, thereby rendering it inactive.

- **Native FGF21 is unstable and has a tendency to aggregate in solution.** Hence, it is operationally challenging to develop a stable liquid formulation at high concentration with low viscosity, which is required to achieve good bioavailability via subcutaneous injection.

Clinical Validation of FGF21

We believe FGF21 has the potential to be the mainstay monotherapy for NASH because it addresses multiple facets of the disease. Specifically, it has the potential to reduce steatosis, improve fibrosis and importantly, impact the metabolic dysregulation which continues to promote disease progression. The potential for FGF21 analogs in the treatment for NASH has been demonstrated by clinical trial data with pegbelfermin, a pegylated form of FGF21. In a third-party Phase 1b study, pegbelfermin was observed to result in reductions in triglycerides, LDL-C and HDL. In addition, a third-party Phase 2a study conducted in patients with biopsy-proven NASH, pegbelfermin showed a significant reduction in absolute hepatic fat fraction measured by MRI-PDFF, a significant increase in adiponectin concentration, a decrease in mean liver stiffness and a significant decrease in concentration of PRO-C3, a biomarker of fibrosis. Clinical outcomes were better when dosed as a daily injection versus a weekly injection. The compound was deemed generally well tolerated, although a higher frequency of gastrointestinal adverse events was reported in treated patients versus placebo.

A second compound, selectively activating the FGFR1c and its co-receptor ß-Klotho, reported reductions in liver fat content and improvements in metabolic parameters in a study in NAFLD patients.

BIO89-100

Overview

We are developing BIO89-100, a specifically engineered glycoPEGylated analog of FGF21, for the treatment of NASH with fibrosis and other cardio-metabolic indications. BIO89-100 has successfully completed a Phase 1a study, and we are currently evaluating BIO89-100 in a POC Phase 1b/2a clinical trial in patients with NASH or NAFLD with a high risk of NASH. BIO89-100 has been specifically engineered to: (1) protect against proteolysis and reduce renal clearance, (2) have an extended half-life, (3) minimize susceptibility to aggregate in solution and (4) optimize its potency, enabling the potential use of lower dosage/doses. Additionally, we believe that BIO89-100 may enhance binding affinity for ß-Klotho, by altering the conformation of the C-terminus which could have a positive impact on efficacy.

Primary Structure and Protein Engineering of BIO89-100

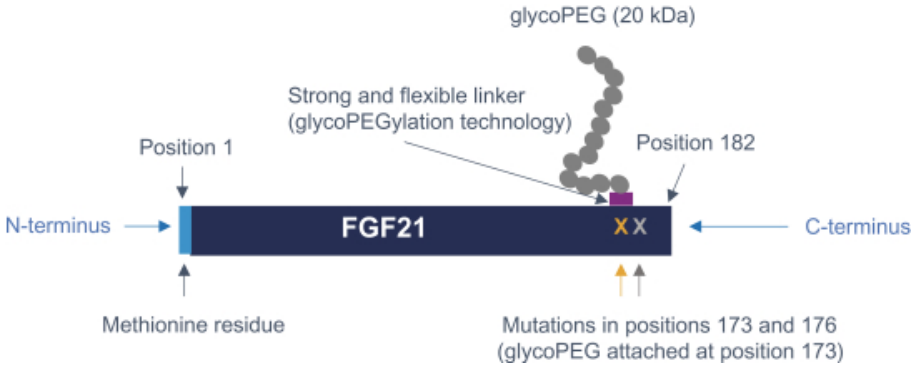
BIO89-100 has been optimally constructed with two mutations via substitutions with natural amino acids at site-specific positions (173 and 176) toward the C-terminus end of the hormone. The mutations were incorporated into the FGF21 sequence after existing proline to create a consensus sequence for glycosylation. Subsequently, the glycosyl linker and a single 20 kDa glycoPEG moiety were enzymatically introduced at the O-linked glycosylation consensus site (position 173) via the proprietary glycoPEGylation technology. Our glycoPEG moiety is an activated form of the PEG molecule with the use of Sialic Acid, CMP-SA-PEG. The proximity of the mutations ensures consistent and efficient attachment of the glycoPEG moiety.

BIO89-100 has two modified natural amino acid residues:

- S173T: Serine modified to Threonine at position 173; and
- R176A: Arginine modified to Alanine at position 176.

In addition, a Methionine residue was introduced at the N-terminus which acts as the translation initiation signal. A single 20 kDa linear glycoPEG moiety is attached to the Threonine in position 173 via the proprietary glycoPEGylation technology. Figure 8 below shows the structure of BIO89-100.

Figure 8: Structure of BIO89-100



The increase in the size of the molecule from 19.4 kDa to 40 kDa together with the site-specific mutations adjacent to the primary cleavage site of FGF21 (by the FAP enzyme between positions 171 and 172 on the native amino acid chain, which would be represented by positions 172 and 173 in our molecule starting with Methionine in position 1) are designed to prolong the half-life of the molecule. Additionally, we believe that the use of glycoPEGylation technology produces a comparatively stronger and more flexible structure, which aids in the development of a stable formulation. PEGylation technology has been used successfully in many pharmaceutical products including products that have been marketed for more than 10 years.

BIO89-100 uses a proprietary glycoPEGylation technology that has been previously validated by a third party, as this technology is incorporated in another pharmaceutical product (Lonquex® by Teva) that has received regulatory approval and is currently commercialized in the European Union.

The Development and Selection of BIO89-100

The discovery program that led to the selection of BIO89-100 was directed towards achieving an optimal PK and efficacy profile. It has been shown that the in vivo half-life of FGF21 can be extended by covalently linking a single glycoPEG moiety to the molecule. We performed extensive screening of FGF21 analogs with mutations at different positions including close to the N-terminus, as well as different glycoPEGylations to select an optimized molecule based on its potency, PK and in-vivo efficacy.

Stage I—Optimizing Selection of Mutation Sites—In Vitro Potency Testing

Mutations were inserted at different sites for both non-PEGylated FGF21 analogs and corresponding glycoPEGylated analogs and screened in a cell-based potency assay to select analogs that did not lose potency relative to the native hormone. Amongst the multiple glycoPEGylated analogs tested, only mutations at sites towards either N-terminus or C-terminus showed potency comparable to that of native FGF21 hormone and were selected for further development.

Stage II—Optimizing for glycoPEG (20 kDa vs 30 kDa)—In Vitro Potency Testing

Analogs selected in Stage I were prepared with either a 20 kDa or a 30 kDa glycoPEG moiety and tested for potency in mouse adipocytes (3T3-L1) and human embryonic kidney (HEK-293) cell lines. Minimal

differences in potencies were observed between the 20 kDa and 30 kDa glycoPEGylated analogs. However, only the glycoPEGylated analogs that had mutations and a glycoPEG attachment at the C-terminus, as distinct from those with mutations at the N-terminus, maintained their potency in both mouse and human cell lines. These analogs were selected for future development.

Stage III—Optimizing for PK Properties and Efficacy—In Vivo Testing

Selected analogs from Stage II with either a 20 kDa or a 30 kDa glycoPEG moiety, were chosen for in vivo testing in a diabetic mouse model. In addition to PK, changes from baseline in glucose, triglycerides and insulin were measured. The data showed that the circulating half-life of the glycoPEGylated analogs for both glycoPEG sizes was extended (range 15 to 30 hours) as compared to native FGF21 (2 hours). As expected, all analogs were observed to cause a reduction in blood glucose levels. However, the 20 kDa glycoPEGylated analogs were observed to outperform the 30 kDa analogs by improving triglycerides at lower doses and across broader dose ranges. BIO89-100 resulted in the greatest reduction of insulin and was selected as the candidate for clinical development.

In summary, the mutations made to the native FGF21 molecule and the addition of the 20 kDA glycoPEG moiety via the use of the glycoPEGylation technology were observed to significantly improve the PK properties of the molecule while retaining the therapeutic benefits. We believe that BIO89-100 is a well-balanced molecule with a unique profile, which has the potential to have therapeutic benefits in NASH and cardio-metabolic diseases. Figure 9 below sets forth what we believe are the key features and potential benefits of BIO89-100:

Figure 9: Summary of BIO89-100 Attributes and Benefits

Features	Description	Potential Benefit
Use of PEG (via glycoPEGylation)	■ Increases protein size and hydrodynamic volume that reduces renal filtration ■ Prevents degradation by endocytosis and proteolytic enzymes	■ Prolongs half-life
	■ Protects antigenic sites present on the protein surface (i.e. antigenic epitopes)	■ Reduces immunogenicity
	■ Steric repulsion between the PEGylated surfaces increases water solubility and reduces aggregates	■ Results in more stable formulation
Site-Specific Mutations	■ Mutation at position 173 is immediately adjacent to the primary cleavage (FAP enzyme) site of FGF21	■ Prolongs half-life
GlycoPEGylation Technology	■ Allows site specific linkage (glycoPEG moiety to position 173) ■ Proximity of the glycoPEG moiety to the C-terminus induces conformational changes to the molecule	■ Retains potency against receptor to improve efficacy
	■ Provides a strong and flexible glycosyl bond that helps the glycoPEG moiety remain intact, further reducing degradation	■ Further enhances half-life

Therapeutic Potential of BIO89-100 Supported by Preclinical Animal Models of NASH, Diabetes and Obesity

BIO89-100 was evaluated in multiple distinct animal models of NASH, diabetes and obesity, including non-human primate studies. In each of these studies, consistent and significant beneficial effects were observed

across a range of endpoints, specifically, robust improvements in lipid handling, glycemic control and insulin resistance as well as significant improvements in hepatic steatosis, injury and fibrosis. We believe these results demonstrate the potential of BIO89-100 to simultaneously address the multiple drivers of NASH pathogenesis. The histological endpoints, NAS and fibrosis score, mirror the endpoints we expect to assess in our clinical development. In addition, treatment with BIO89-100 in animal models was observed to result in consistent reductions in body weight.

BIO89-100 has been evaluated in three animal models of direct relevance to NASH. These included: (1) Stelic Animal Model ("STAM"), (2) Diet-induced NASH ("DIN") model and (3) spontaneous diabetic obese cynomolgus monkey model. Additional studies done in diabetes mouse model and diet induced obesity mouse model showed benefits in key markers of relevance in NASH.

A wide range of doses were tested in these studies as well as weekly and once every two week dosing regimen was tested in a cynomolgus monkey study. The key outcomes of these studies are summarized in Figure 10 below.

Figure 10: Summary of NASH Pharmacology Studies

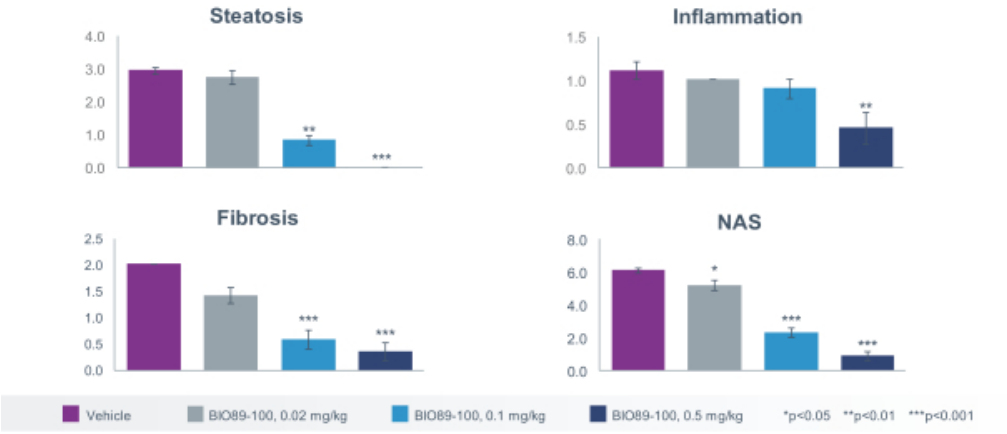
Preclinical pharmacology study with BIO89-100	Improved Insulin Sensitivity	Improved Lipid Handling	Reduced Hepatocyte Injury	Reduced Fibrosis
STAM mouse model	✓	✓	✓	*
DIN mouse model I (10 weeks)	✓	✓	✓	✓
DIN mouse model II (19 weeks)	✓	✓	✓	✓
Diabetic obese cynomolgus monkey study 1 (8 weeks; weekly dosing)	✓	✓	✓	Not evaluated
Diabetic obese cynomolgus monkey study 2 (4 weeks; QW or Q2W dosing)	✓	✓	✓	Not evaluated

Legend:
✓ Statistically significant benefit observed
* Improvement observed, but did not achieve statistical significance.

Results of DIN Mouse Studies

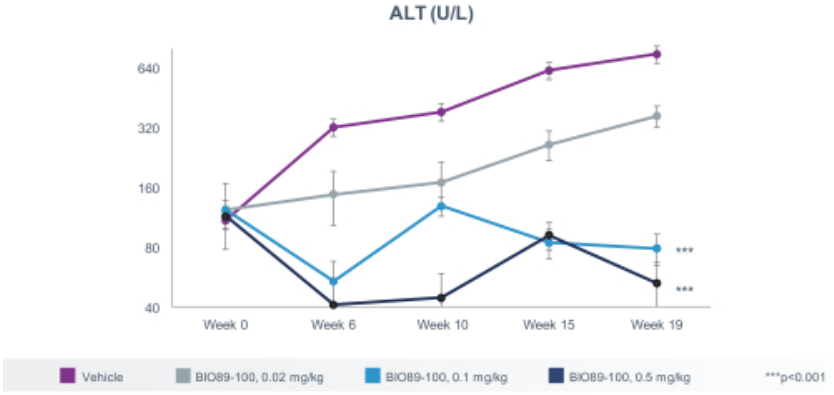
Two pharmacology studies were conducted in a DIN mouse model. In the first study of 40 mice (10 per treatment group), the animals received BIO89-100 via a subcutaneous injection at 0.5 and 2 mg/kg every 3 days for 10 weeks, and a detailed assessment of liver parameters was performed to evaluate the effectiveness of the dosing regimen. Both doses of BIO89-100 were observed to reduce the total NAS significantly based on histological evaluation and improved measures with respect to both lipid handling and insulin sensitivity. In addition, expression of hepatic genes involved in inflammation and fibrosis were significantly reduced following administration of BIO89-100. In the second DIN mouse study of 50 mice (10 per treatment group), lower dose levels of BIO89-100 were tested (0.02, 0.1 and 0.5 mg/kg every 3 days) but the treatment duration was longer at 19 weeks. In this study too, BIO89-100 was observed to result in significant reductions in the liver damage induced by the diet in a dose-dependent manner. Specifically, treatment with BIO89-100 was observed to result in a significant mean reduction of the histological markers of NASH (Figure 11), as well as a reduction in the marker of hepatic injury (alanine amino transaminase ("ALT")) (Figure 12), in liver lipids (Figure 13), and in inflammatory and fibrotic markers (Figure 14), each in a dose dependent manner compared to vehicle treatment. In addition to the beneficial effects on the liver, treatment with BIO89-100 demonstrated significant improvements in glycemic control and weight loss. As NAS and measures of fibrosis are histological endpoints for the assessment of NASH in clinical studies, we believe that the observations in the STAM and DIN mouse models suggest that BIO89-100 is a compelling candidate for the treatment of NASH.

Figure 11: Improvement in Histology with BIO89-100 in a DIN Mouse Model



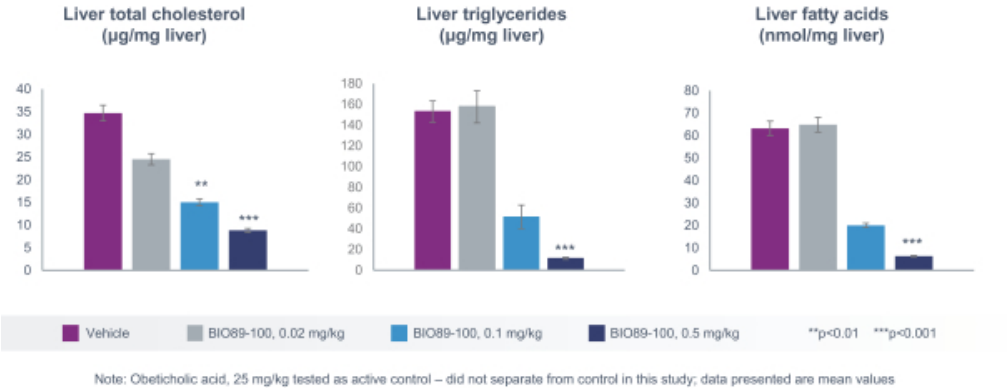
Note : Obeticholic acid, 25 mg/kg tested as active control – did not separate from control in this study
Scoring system: Steatosis (0-3), Inflammation (0-3), Fibrosis (0-4), NAS (0-13) - all were assessed at week 19; mean scores

Figure 12: Changes in ALT with BIO89-100 in a DIN Mouse Model



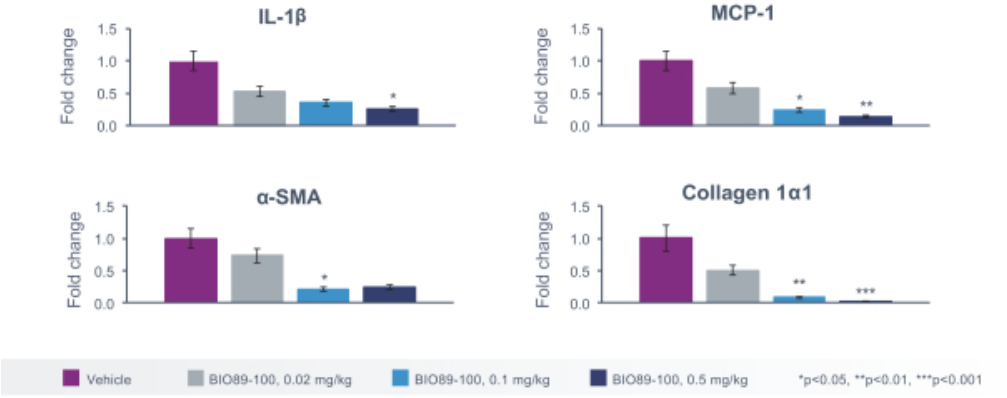
Note: Obeticholic acid, 25 mg/kg tested as active control – did not separate from control in this study; data presented are mean values

Figure 13: Reduction in Liver Lipids with BIO89-100 in a DIN Mouse Model



Note: Obeticholic acid, 25 mg/kg tested as active control – did not separate from control in this study; data presented are mean values

Figure 14: Changes in Inflammatory and Fibrotic Markers with BIO89-100 in a DIN Mouse Model



Note: Obeticholic acid, 25 mg/kg tested as active control – did not separate from control in this study; data presented are mean values

Results of Spontaneously Diabetic Obese Cynomolgus Monkey Studies

BIO89-100 efficacy was evaluated in 24 spontaneously diabetic obese cynomolgus monkeys (six per treatment group) after multiple subcutaneous doses. In the first study, BIO89-100 was administered at doses of 0.1, 0.3 and 1 mg/kg once per week for 8 weeks followed by a 6-week washout phase. Administration of BIO89-100 showed significant effects on triglycerides at all doses tested, with a highly robust 78% reduction observed at the highest dose level of 1 mg/kg/week (Figure 15). Statistically significant mean reductions were observed in total cholesterol (Figure 16), glucose (Figure 17), insulin, glycated hemoglobin (HbA1c) and ALT (Figure 18), along with improvement in oral glucose test results.

Figure 15: Changes in Triglycerides with BIO89-100 in Diabetic Monkey Study 1

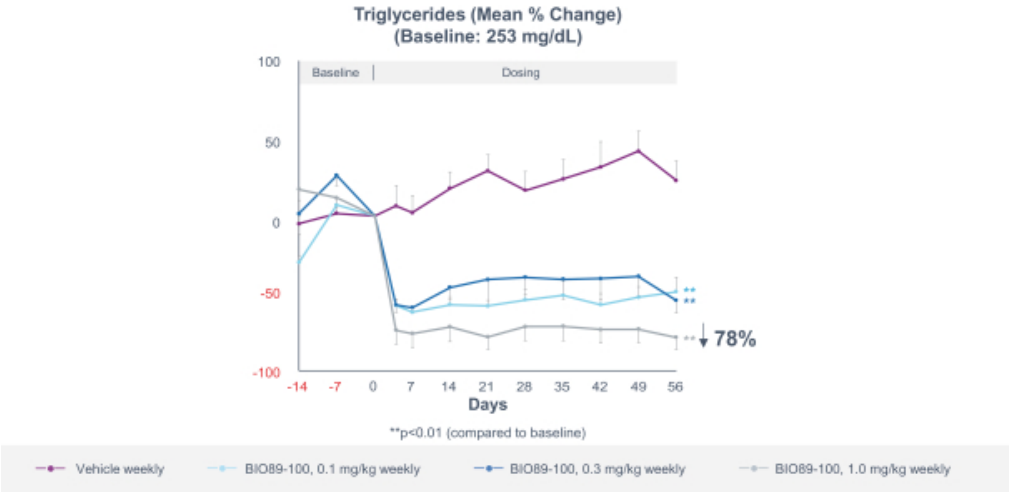


Figure 16: Changes in Total Cholesterol with BIO89-100 in Diabetic Monkey Study 1

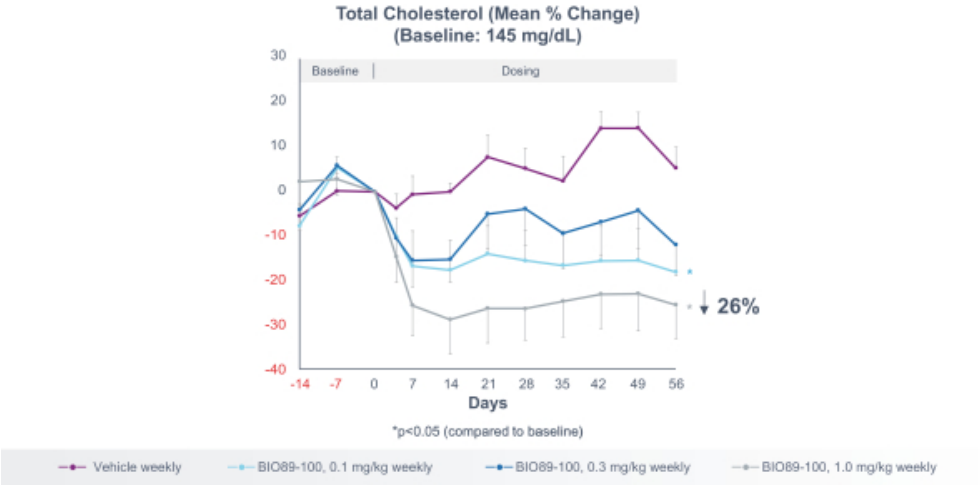


Figure 17: Changes in Blood Glucose with BIO89-100 in Diabetic Monkey Study 1

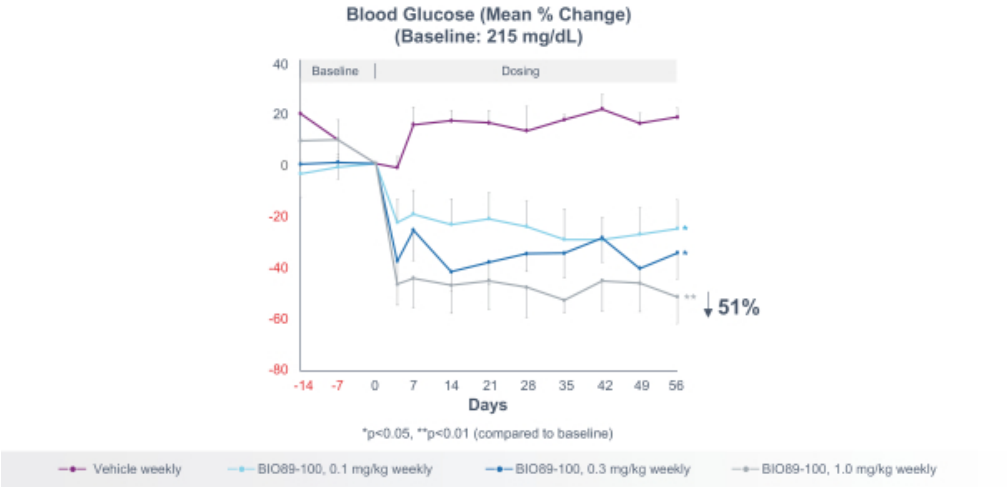
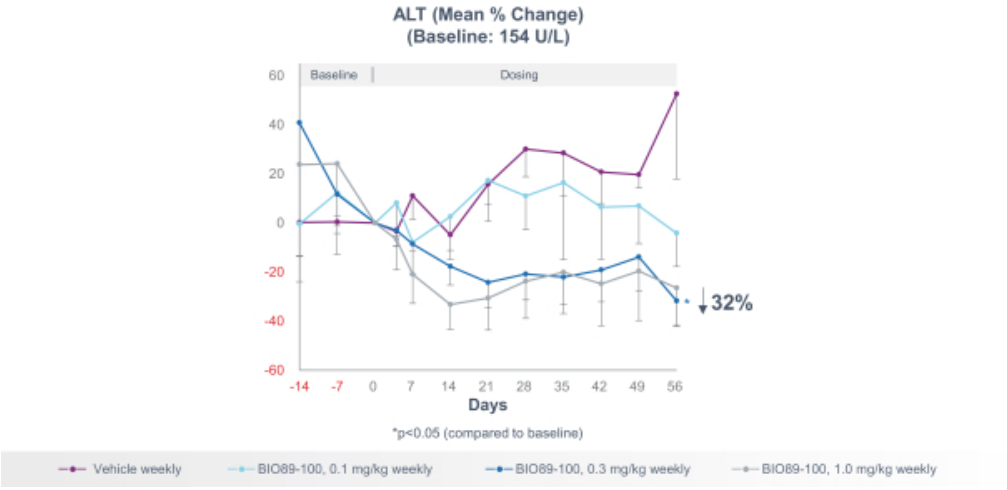


Figure 18: Changes in ALT with BIO89-100 in Diabetic Monkey Study 1



In a second multiple-dose study in 24 spontaneously diabetic obese cynomolgus monkeys (six per treatment group), BIO89-100 was administered for 4 weeks at 1 mg/kg once weekly or 1 or 2 mg/kg given once every 2 weeks. A rapid and dramatic reduction in triglycerides (Figure 21), up to 76%, was observed with BIO89-100. Statistically significant mean reductions were also observed in body weight (Figure 19), HbA1c (Figure 20), glucose, and insulin, along with increased adiponectin levels (Figure 22) and improvement in oral glucose test results in all BIO89-100-treated groups (both once weekly and every 2 weeks) in comparison to the vehicle group. The robust effect on body weight and HbA1c over the 4-week treatment period were particularly unexpected. The PD effects were relatively similar across all three dosing groups suggesting that once every two weeks could be a viable clinical dosing strategy. BIO89-100 was also assessed in a study of sweetness preference in six obese cynomolgus monkeys. Using a two-bottle sweetness preference test, monkeys given BIO89-100 at 1 mg/kg by subcutaneous injection every week for three weeks demonstrated a substantial reduction in sweetness preference and improvements in certain lipid parameters compared to monkeys given vehicle treatment.

Figure 19: Changes in Body Weight with BIO89-100 in Diabetic Monkey Study 2

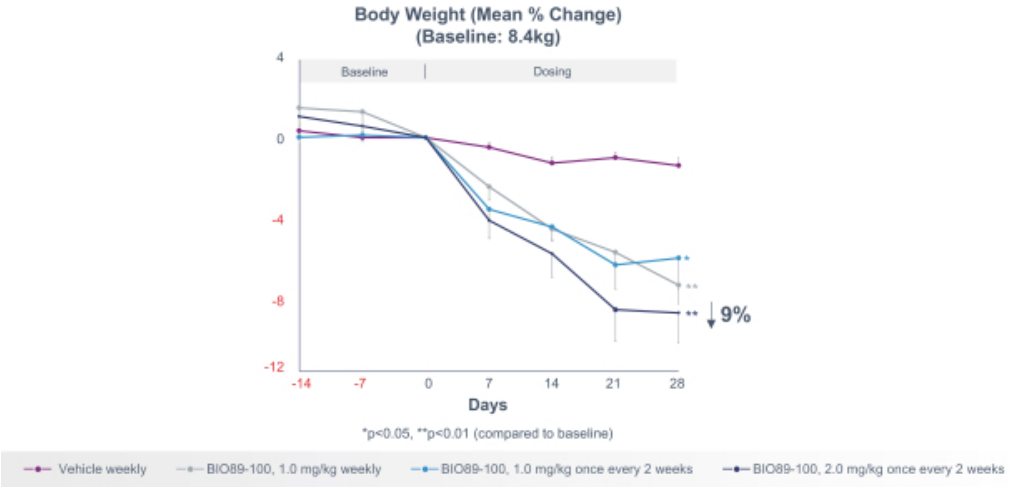


Figure 20: Changes in HbA1c with BIO89-100 in Diabetic Monkey Study 2

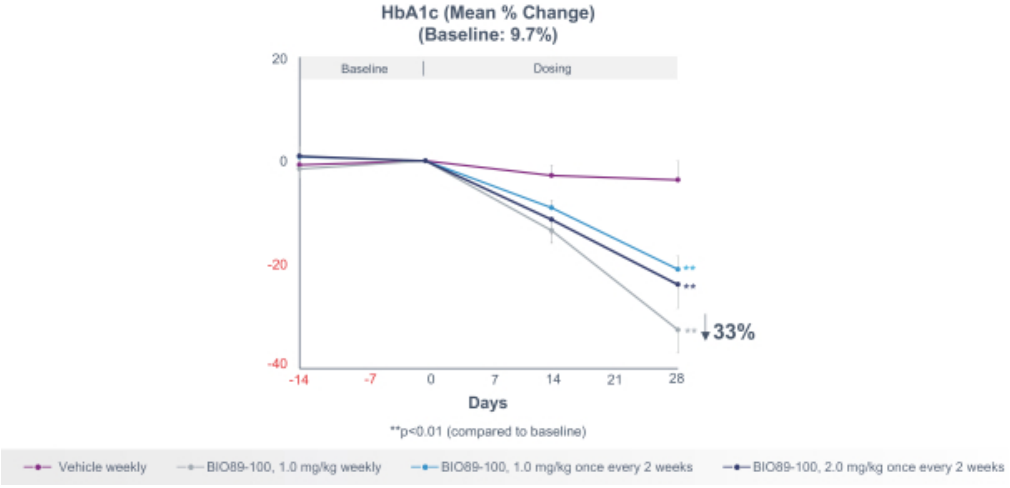


Figure 21: Changes in Triglycerides with BIO89-100 in Diabetic Monkey Study 2

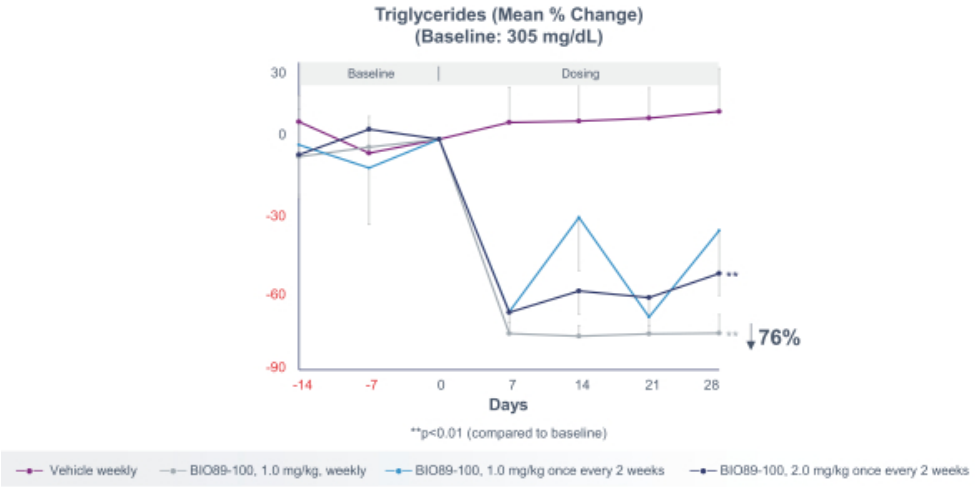
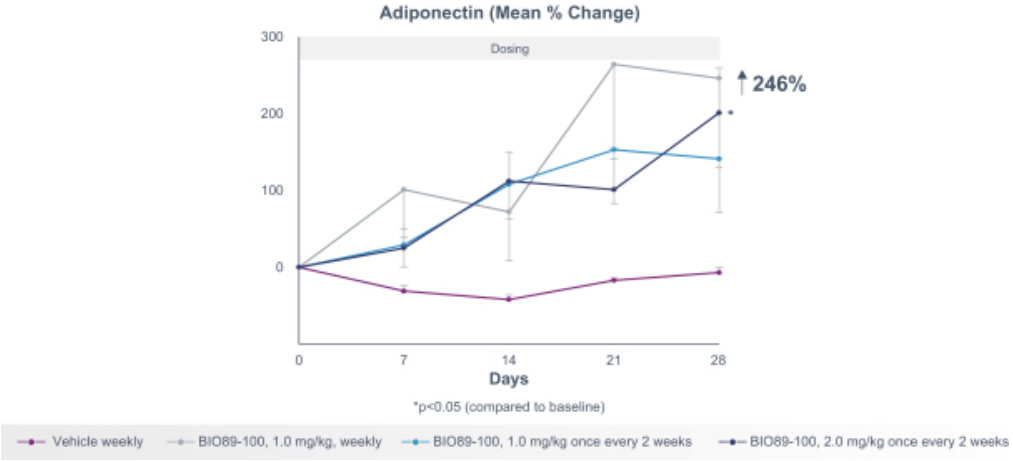


Figure 22: Changes in Adiponectin with BIO89-100 in Diabetic Monkey Study 2



We believe the PD effects observed in the animal studies suggest that BIO89-100 is a potent molecule that may address the key pathways in NASH by (1) improving lipid handling and resultant steatosis, (2) improving insulin resistance, (3) reducing hepatocyte injury and inflammation and (4) improving fibrosis. Additionally, the data from the cynomolgus monkey studies suggest that the molecule may be amenable to an extended dosing interval.

BIO89-100 Clinical Development

We are developing BIO89-100 for the indication of NASH with fibrosis. In our randomized, double-blind, placebo-controlled, Phase 1a, first-in-human, SAD clinical trial of BIO89-100 of 58 healthy volunteers, 43 healthy volunteers received BIO89-100 with a half-life of 55 to 100 hours and 15 received placebo treatment. In this SAD study, BIO89-100 was well tolerated, with all treatment related adverse events reported as mild; there were no serious adverse events reported. At single doses of 9.1 mg and higher, we observed significant improvements in key lipid parameters measured at Day 8 and Day 15 after dosing on Day 1. The mean changes versus baseline include reductions in triglycerides (up to 51%) and LDL-C (up to 37%) and increase in HDL-C (up to 36%) despite the baseline values being in the normal range. As compared to placebo treatment, these mean changes were all statistically significant ($p < 0.001$). BIO89-100 demonstrated rapid (starting from Day 2), sustained and durable improvements on lipid parameters for two weeks or more after single dose administration. We believe this duration of effect further supports the possibility of an extended dosing interval, as observed in our preclinical studies.

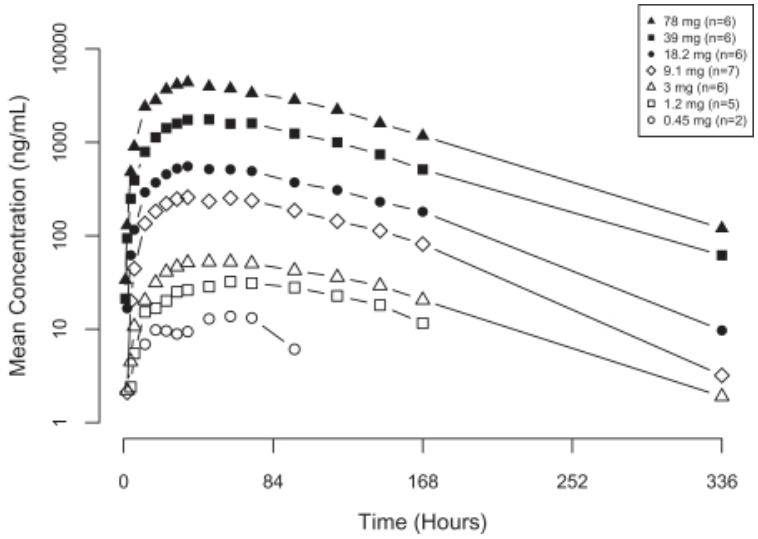
Phase 1a Clinical Trial of Single Dose of BIO89-100 in Healthy Volunteers

We conducted a Phase 1a clinical trial to evaluate the safety, tolerability and PK of BIO89-100 in healthy volunteers. We enrolled a total of 58 healthy volunteers into one of seven cohorts and randomized to receive a single dose of BIO89-100 or a placebo. Forty-three healthy subjects received BIO89-100 at the following doses: 0.45 mg, 1.2 mg, 3 mg, 9.1 mg, 18.2 mg, 39 mg and 78 mg.

BIO89-100 Exhibited Generally Linear, Dose-proportional PK

The PK profile of BIO89-100 was generally dose-proportional or slightly more than dose-proportional with T1/2 range from approximately 55 to 100 hours. As shown in Figure 23 below, the observed median time of maximum serum concentration ranged from 36 to 60 hours.

Figure 23: Single-dose PK of BIO89-100



Our Phase 1a clinical trial enrolled healthy volunteers with a mean (SD) age and BMI of 39.3 (9.7) years and 26.7 (3.1) kg/m2 respectively, with laboratory parameters in the normal range at baseline (mean values: TG 94.0 mg/dL; LDL 124.1 mg/dL; HDL 47.7 mg/dL). Even in this healthy study population, after a single dose administration of BIO89-100 at doses 9.1 mg and higher, robust and durable PD effects were observed across key lipid parameters, including triglycerides (Figures 24 and 25), LDL (Figure 26) and HDL (Figure 27), over two weeks. The changes in lipids parameters started from Day 2 with maximal effects typically observed at Day 8 or Day 15. The effect on lipid parameters was generally dose-dependent, with single doses of BIO89-100 at 9.1 mg and higher, demonstrating significant improvements versus baseline in key lipid parameters measured at Day 8 and Day 15 following dosing. The BIO89-100 effects appeared to plateau at 39 mg with minimal additional effect observed in 78 mg. BIO89-100 also led to increases in mean adiponectin levels (up to 146% relative to baseline) when measured at Day 8 and Day 29.

Figure 24: Changes in Triglycerides after Single Dose of BIO89-100

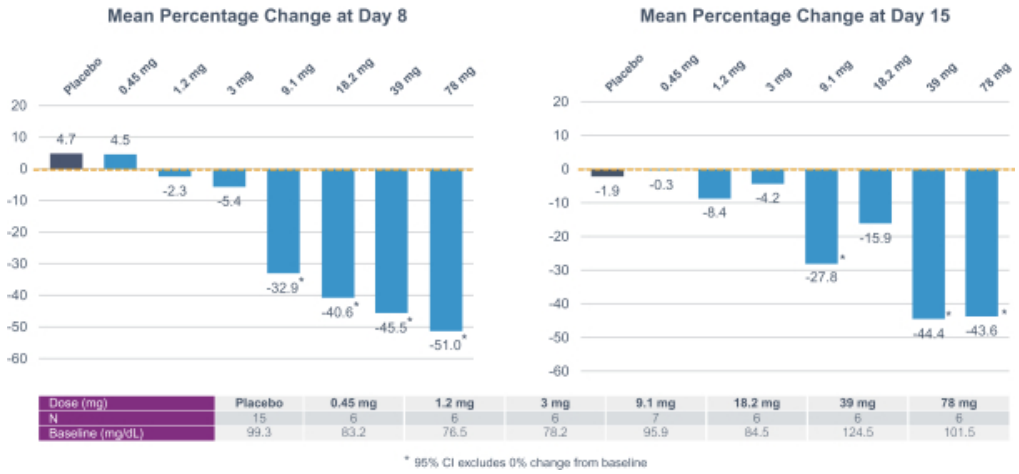


Figure 25: Changes in Triglycerides after Single Dose of BIO89-100

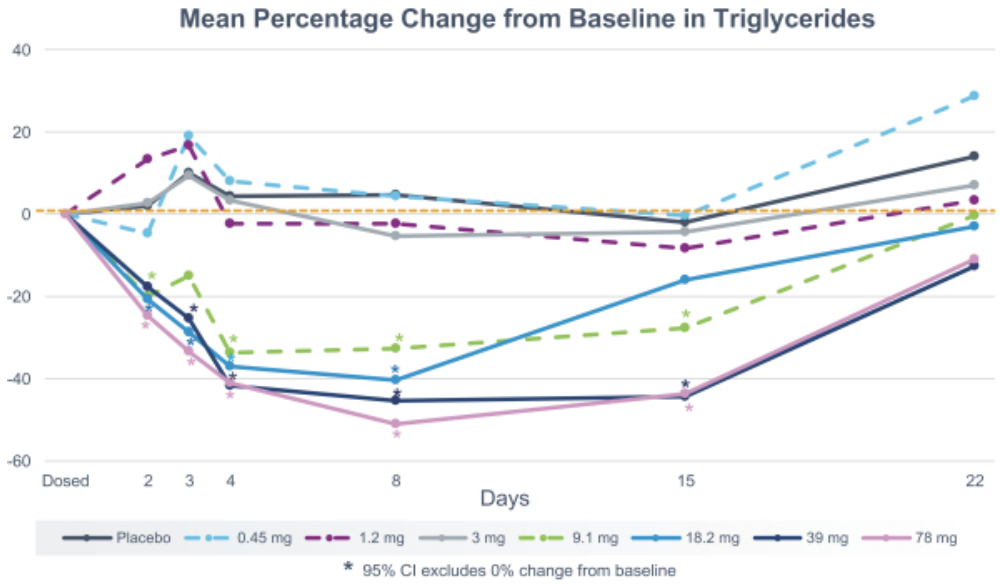


Figure 26: Changes in LDL Cholesterol after Single Dose of BIO89-100

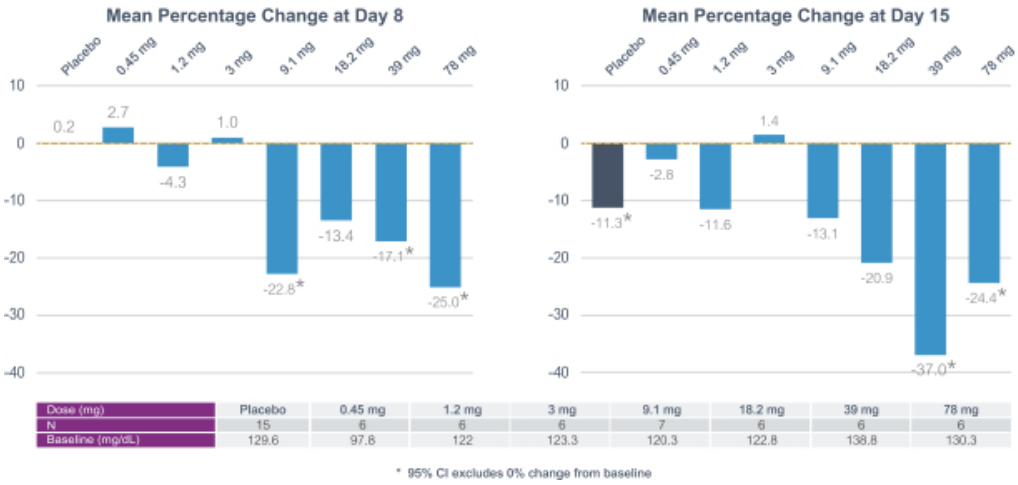
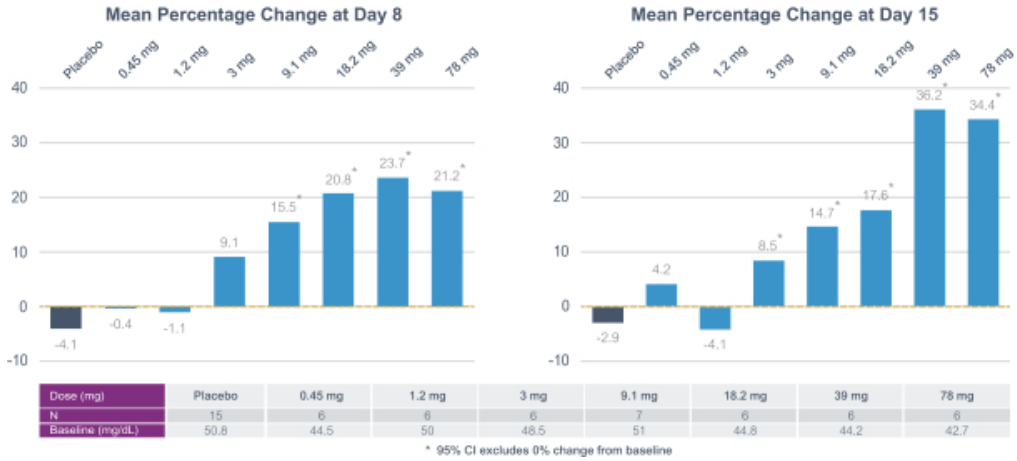


Figure 27: Changes in HDL Cholesterol after Single Dose of BIO89-100



BIO89-100 was well tolerated across the dose range in our Phase 1a clinical trial. There were no deaths, serious adverse events or discontinuations due to adverse events. The most commonly observed treatment-related adverse events, occurring in at least two subjects in the pooled BIO89-100 group, were injection site reactions and headache, all of which were reported as mild. Injection site reactions were more frequent in the 39 mg cohort, likely due to a larger injection volume administered at one time in that cohort. No clinically meaningful trends were observed in gastrointestinal events, laboratories or vital signs including blood pressure or heart rate changes. No tremors were reported. Five of 43 BIO89-100 treated subjects tested positive for anti-drug antibodies ("ADA"); however, all titers were low (£ 16) and did not appear to affect the PK or safety profile. Treatment-related treatment emergent adverse events ("TEAE") reported in two subjects or more in pooled BIO89-100 treatment group are shown in Figure 28 below.

Figure 28: Treatment-Related TEAE Reported in ³ 2 Subjects in Pooled BIO89-100 Treatment Group

	Placebo	BIO89-100						Pooled
	(N=15)	0.45 mg	1.2 mg	3 mg	9.1 mg	18.2 mg	39 mg	78 mg	BIO89-100
n (%)		(N=6)	(N=6)	(N=6)	(N=7)	(N=6)	(N=6)	(N=6)	(N=43)
Any Treatment Related TEAE	3 (20.0)	0	0	0	1	3	6	3	13 (30.2)
Injection site induration	1 (6.7)	0	0	0	1	0	5	1	7 (16.3)
Injection site erythema	1 (6.7)	0	0	0	0	0	3	2	5 (11.6)
Injection site pain	0	0	0	0	0	0	2	0	2 (4.7)
Headache	1 (6.7)	0	0	0	0	2	0	0	2 (4.7)

Note: All adverse events reported in table were Grade 1.

These data supported the advancement of BIO89-100 into a study in patients with NASH or patients with NAFLD and a high risk of NASH to evaluate BIO89-100's potential as a treatment of NASH. Based on PK/PD modeling and drug exposure analysis, we have identified BIO89-100 doses in the range of 9 mg to 36 mg weekly ("QW") or every other week ("Q2W") as the target dose range for evaluation in future clinical trials in patients with NASH or patients with NAFLD and a high risk of NASH.

We believe that the totality of the data from our Phase 1a study, the preclinical data with BIO89-100 and the clinical data from third parties collectively support the hypothesis that BIO89-100 has the potential to address the complex nature of NASH, especially given the frequency of metabolic co-morbidities in NASH patients. The magnitude and significance of BIO89-100's biological effects after a single dose on lipid parameters in healthy volunteers were observed to be robust and durable, and the magnitude of these reductions appear to be comparable or better than data reported to date in Phase 1 clinical trials of other FGF analogs, although no head-to-head studies have been conducted.

Phase 1b/2a POC Clinical Trial

We are currently enrolling patients in our Phase 1b/2a POC clinical trial. Our clinical trial is a multicenter, randomized, double-blind, placebo-controlled, multiple ascending dose-ranging trial in patients with NASH or patients with NAFLD and a high risk of NASH, with 83 total patients randomized to receive QW or Q2W subcutaneous dosing of BIO89-100 or placebo for up to 12 weeks. In October 2019, we completed enrollment of the first cohort in this trial. This clinical trial is designed to assess the safety, tolerability and PK properties of BIO89-100 as well as change in liver fat measured by MRI-PDFF and key biomarker assessments. These data are aimed at providing proof-of-concept for BIO89-100 in NASH and help inform dose selection for larger, longer-term paired-biopsy trials. At our meeting with the FDA in June 2019, the FDA concurred with our overall trial design, including study population, dose selection and study treatment duration.

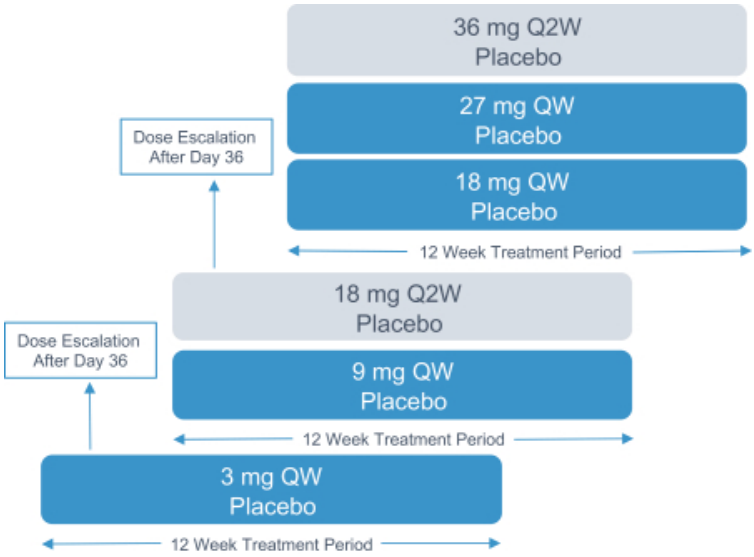
Our POC study is enrolling patients with NASH or patients with NAFLD and a high risk of NASH, defined as patients with steatosis greater than 10% who have central obesity and Type 2 diabetes or central obesity and evidence of liver injury. NAFLD patients, especially the subset of NAFLD patients we will enroll, have similar disease characteristics as patients with biopsy-proven NASH, and we expect that the data from these NAFLD patients will be informative regarding the potential of BIO89-100 as treatment for NASH. The trial will include a set number of patients with biopsy confirmed NASH with fibrosis (F1-F3) to help inform the design of subsequent clinical trials.

The key objectives of the trial are to:

- evaluate the safety and tolerability of multiple ascending doses of BIO89-100;
- assess change from baseline in liver fat (measured via MRI-PDFF);
- assess changes from baseline in lipids, glycemic control parameters, fibrosis and inflammation markers;
- characterize the PK properties of BIO89-100; and
- evaluate the immunogenicity of BIO89-100 as measured by presence of ADA.

The design of the trial is presented in Figure 29 below:

Figure 29: POC Clinical Trial Design



Our planned active treatment groups are: 3 mg, 9 mg 18 mg and 27 mg QW, and 18 mg and 36 mg Q2W. As this is a multiple ascending dose study, we expect to have two dose escalation decision points during the study. The first decision point will be to move from the 3 mg QW dose cohort to both the 9 mg QW and 18 mg Q2W dose cohorts. The second decision point will be to move from those two dose cohorts to the final three dose cohorts. We expect dose escalation decisions after Day 36 assessment in the relevant cohorts. We have designed the trial to detect differences on MRI-PDFF between BIO89-100 at different dose levels and the pooled placebo group. We expect to report topline data in the second half of 2020. In addition, we anticipate initiating a Phase 2b trial in the first half of 2021.

BIO89-100 Differentiation

We believe BIO89-100 could have a differentiated profile relative to other therapies targeting FGF21 and FGFR1c that are in development.

A PEGylated form of FGF21 is currently in two third-party Phase 2b studies in NASH. The compound has a reported half-life of 19 to 24 hours and includes mutations with non-native amino acid substitutions. In this third party's Phase 2a study, the molecule showed a significant reduction in absolute liver fat measured by MRI-PDFF and a significant decrease in concentration of PRO-C3 (a biomarker of fibrosis), but no significant changes on lipid markers. Study outcomes were better when dosed as a daily injection versus a weekly injection. The compound was deemed generally well tolerated, although a higher frequency of gastrointestinal adverse events was reported in treated patients. Sixty-three percent to 92% of treated patients in the Phase 2a study tested positive for anti-drug and anti-FGF21 antibodies.

A second compound, a long-acting Fc-FGF21 fusion protein with extended half-life of approximately three to four days, has completed third-party Phase 1 studies in which patients with Type 2 diabetes demonstrated decreases in triglycerides and increases in HDL-C, with improvements in insulin sensitivity, but modest to no

changes in LDL in doses approximating those advancing to further development. The highest doses tested in the single and multiple-ascending dose study were not well-tolerated with adverse events of significance being gastrointestinal disorders and tremors. The compound is currently in a Phase 2a study in NASH with weekly dosing.

A third compound, an agonistic antibody selectively activating FGFR1c and its co-receptor ß-Klotho, has completed a third-party Phase 1 study as a once-monthly injectable insulin sensitizer for the treatment of NASH. Reductions in liver fat content and improvements in metabolic parameters were reported in a clinical trial evaluating a high single dose in obese, insulin-resistant, non-diabetic subjects with NAFLD. The most common adverse events reported were injection site reaction and increased appetite. Subjects gained an average of 1.6 kg body weight 36 days after dosing compared to baseline. The compound agonizes only the FGFR1c receptor and is not believed to have any activity on the FGFR2c and FGFR3c receptors.

We believe BIO89-100 may be a differentiated FGF21 therapy based on its robust and durable biological effects and a favorable tolerability profile. In addition, BIO89-100 has the potential for a once every two-weeks dosing interval that could provide significant value to asymptomatic patients who will be taking the product chronically. In market research that we conducted amongst obese diabetic subjects (n=150), respondents were asked for their preference when selecting an injectable product with different dosing regimens for the treatment of a chronic liver condition. In this study, 63% of respondents expressed a preference or strong preference for a product injected once every two weeks versus a product injected every week, and 68% of respondents expressed similar preferences for a product injected once every two weeks versus a product injected daily. Further, we believe that BIO89-100 may have a differentiated tolerability profile and that tolerability issues may influence physician and patient preference in NASH, a chronic and generally asymptomatic disease. We believe the risk of CNS effects, significant gastrointestinal tolerability issues and weight gain could significantly impact adoption by physicians and patients. Finally, based on the non-human primate study results and the human SAD study results across different lipid markers (triglyceride reduction up to 51% and LDL reduction up to 37%), we believe BIO89-100 may offer robust and durable biological effects. We believe that activation of the FGFR1c, 2c and 3c receptors may confer benefits versus activation of a single receptor (FGFR1c) given the expression of the receptors in the key organs of interest (FGFR1c in adipose tissue and FGFR2c and FGFR3c in the liver) and provide a more balanced approach.

Severe Hypertriglyceridemia

We also intend to develop BIO89-100 for the treatment of SHTG. Hypertriglyceridemia (“HTG”) is characterized by elevated fasting plasma triglyceride levels higher than 200 mg/dL and SHTG is typically defined as triglyceride levels of greater than or equal to 500 mg/dL. SHTG is associated with an increased risk of NAFLD, NASH and cardiovascular diseases, as well as acute pancreatitis, accounting for up to 10% of all acute pancreatitis episodes. A recent third-party study utilizing an omega-3 fatty acid (“omega-3 FA”) demonstrated the linkage between a reduction in triglycerides and favorable cardiovascular clinical outcomes.

It is estimated that there are 2.5 million to 4 million patients in the United States with triglyceride levels of greater than or equal to 500 mg/dL. Of these patients, it is estimated that 42% have dyslipidemia and 27% have diabetes. This patient population is expected to increase due to the triple epidemic of obesity, metabolic syndrome and Type 2 diabetes. In addition, the addressable market has the potential to expand as a result of increasing awareness of the importance of treating elevated TG levels, similar to the focus today of physicians on managing LDL levels, as well as due to third party commercial efforts expected to promote TG reduction.

The treatment regimen for SHTG includes dietary restrictions and lipid-lowering drug treatment such as fibrates, omega-3 fish oils and niacin. Some statins are indicated in HTG but do not have an indication for use in SHTG. In third-party studies, up to 50% of treated SHTG patients were unable to reduce their triglyceride levels to < 500 mg/dL despite using approved drugs and are considered refractory patients. These refractory patients have substantial unmet medical need and represent a significant market opportunity as there are no approved therapies for the treatment of refractory SHTG.

Despite multiple agents approved for the treatment of SHTG, these agents have limitations that may not make them ideal for all patients. For example, fibrates have demonstrated reductions in triglycerides of up to approximately 55% at 12 weeks of treatment. However, they have also shown increases in LDL-C (up to 45%), a detrimental effect in this patient population, risk of drug-drug interactions and increases in transaminases, as well as tolerability issues including myopathy. Omega 3 fish oils have shown more modest benefits in reduction of triglycerides from baseline of approximately 25% to 45%. However, fish oils with a higher percentage reduction in triglycerides have also showed major increases in LDL-C (up to 45%). Fish oils also have a significant pill burden given the high daily doses required. In addition, these agents fail to meaningfully address the related co-morbidities of SHTG, including glycemic control, which, when left untreated, may further exacerbate the condition. Yet, despite these limitations, the existing drugs have achieved commercial success with two third parties each generating peak sales of approximately $1 billion or greater. While we believe BIO89-100 has the potential to address the co-morbidities of SHTG, there is no guarantee that it would earn comparable peak sales if it is approved by the FDA.

Given the continuing unmet need in SHTG and limitations of current treatments, there are several agents in development for the treatment of SHTG, including a fish oil product, a fibrate, and novel drugs primarily targeting rare, genetically defined subsets of SHTG, including ANGPTL3 and ApoC III inhibitors. Dyslipidemia apart from SHTG also continues to be a very active area for pharmaceutical development. We believe BIO89-100 may be a differentiated SHTG therapy due to its pleiotropic metabolic benefits and its potential to target a broader patient population versus those therapies primarily targeting rare, genetically defined subsets of SHTG.

BIO89-100 has demonstrated significant reduction in triglyceride levels in both its non-human primate studies and our Phase 1a clinical study. In diabetic obese cynomolgus monkeys with elevated triglyceride levels, BIO89-100 showed significant effects on triglycerides with a maximal reduction of 78% and 76% at doses of 1 mg/kg (see Figures 15 and 21). In monkeys treated with baseline levels of triglycerides > 500mg/dL (n=4), the three monkeys treated with BIO89-100 1 mg/kg weekly had TG reductions > 90% at study end. In our Phase 1a clinical study, in patients with baseline triglyceride values in the normal range (mean baseline 94 mg/dL), BIO89-100 demonstrated reductions of triglycerides from baseline up to 51% at Day 8 after a single dose in healthy volunteers. While currently approved SHTG therapies decrease TG levels, they generally do not have broader metabolic benefits. In our Phase 1a study, BIO89-100 demonstrated a reduction in LDL of up to 37% (see Figure 26) and to the extent that we are able to show in subsequent human clinical trials that BIO89-100 significantly decreases both TG and LDL-C levels and improves other metabolic parameters, such as glycemic control, we believe that BIO89-100 could be a differentiated therapy in this indication. Based on a mechanism of action that is distinct from the currently approved therapies, we believe that BIO89-100 has the potential to be used as a monotherapy agent or in combination with other agents. Another FGF21 analog developed by a third party has also demonstrated a statistically significant reduction in triglycerides in obese, Type 2 diabetes patients. We intend to initiate a Phase 2 trial in SHTG patients in the first half of 2020 in order to evaluate the ability of BIO89-100 to reduce triglyceride levels compared to baseline levels and to report topline data in the first half of 2021. We expect this Phase 2 trial to enroll 80 to 100 patients with triglyceride levels greater than or equal to 500 mg/dL, who will be randomized to receive multiple doses of BIO89-100 or placebo for six to eight weeks.

There is regulatory precedence in the United States for the approval of therapies to treat SHTG based on such therapies demonstrating a reduction in triglycerides from baseline at 12 weeks. The FDA surrogate endpoint table for drug approval lists a reduction in triglycerides from baseline as the endpoint for full approval of a therapy in SHTG. A clinical outcome study was not required for certain third-party approvals in SHTG or as a post-marketing commitment. The SHTG Phase 3 trial for some of these products consisted of a single study of a 12-week duration with 75 to 100 patients per treatment group. Based on current plans, we anticipate initiating Phase 3 trials in SHTG patients by the end of 2021, which we expect will follow existing SHTG regulatory precedence.

Based on FDA guidance for the development of SHTG treatments, as well as the regulatory path followed by other companies that have successfully developed SHTG therapies, we believe that a combination of

smaller clinical trials and shorter development timelines could mean that SHTG potentially represents a quicker path to market for BIO89-100.

Agreements with Teva

Agreements Relating to FGF21 Program

On April 16, 2018, we entered into the FGF21 Agreement with Teva, under which we acquired certain patents, intellectual property and other assets relating to Teva's glycoPEGylated FGF21 program. Under this agreement, Teva also granted a perpetual, non-exclusive (but exclusive as to BIO89-100), non-transferable, worldwide license to patents and know-how related to glycoPEGylation technology for use in the research, development, manufacture and commercialization of the compound BIO89-100 and products containing BIO89-100. In addition, we entered into the ratiopharm Sublicense, under which we were granted a perpetual, exclusive, worldwide sublicense to patents and know-how related to glycoPEGylation technology used in the development, manufacture and commercialization of BIO89-100 and products containing BIO89-100.

Under the FGF21 Agreement, we are obligated to use commercially reasonable efforts to develop and commercialize BIO89-100 in each of the United States and five major European countries. We have the right to sublicense all rights licensed to us by Teva under the FGF21 Agreement.

Pursuant to the FGF21 Agreement and the FASN Agreement (as described below), we paid Teva a nonrefundable upfront payment of $6.0 million. In addition, under the FGF21 Agreement, we are required to make certain payments to Teva totaling $2.5 million for the achievement of certain clinical development milestones, and additional payments totaling up to $65.0 million upon achievement of certain commercial milestones. We are also obligated to pay Teva tiered royalties at percentages in the low-to-mid single-digits on worldwide net sales of products containing BIO89-100. Our royalty obligations will terminate, on a product-by-product and country-by-country basis, at the later of: (1) the date of expiration of the last to expire valid claim in the assigned patents that covers BIO89-100 in such country, (2) the expiration of data or regulatory exclusivity for BIO89-100 in such country and (3) 10 years from the first commercial sale of BIO89-100 in such country. We are not required to make any payments to ratiopharm pursuant to the ratiopharm Sublicense.

The term of the FGF21 Agreement will continue, on a product-by-product and country-by-country basis, until the royalty term with respect to BIO89-100 in such country expires. The ratiopharm Sublicense will continue until terminated in accordance with its terms. We may terminate the FGF21 Agreement and the ratiopharm Sublicense for any reason. Either party may terminate the FGF21 Agreement for cause for the other party's uncured material breach. ratiopharm may terminate the ratiopharm Sublicense for certain material breaches by us. Either party may terminate the FGF21 Agreement or the ratiopharm Sublicense in the event of bankruptcy of the other party. Teva may terminate the FGF21 Agreement if we challenge the validity of any patent licensed to us under the FGF21 Agreement. Termination of the FGF21 Agreement or the ratiopharm Sublicense will impact our rights under the intellectual property licensed to us by Teva and ratiopharm, respectively, but will not affect our rights under the assets assigned to us.

On April 16, 2018, we also entered into a Reagent Supply and Technology Transfer Agreement, under which Teva will supply us with certain reagents required for the glycoPEGylation process that are necessary for our development and commercialization of BIO89-100, and transfer to us certain know-how required for the production of such reagents. The term of this agreement was recently extended by mutual agreement until December 31, 2022.

FASN Agreements

On April 16, 2018, we entered into the FASN Agreement with Teva under which we acquired from Teva patents, intellectual property and other assets relating to Teva's development program of small molecule inhibitors of FASN.

Under the FASN Agreement, we are obligated to use commercially reasonable efforts to develop and commercialize FASN in the United States and five major European countries. We have the right to sublicense all rights licensed to us by Teva under the FASN Agreement.

Pursuant to the FASN Agreement and the FGF21 Agreement (as described above), we paid Teva a nonrefundable upfront payment of $6.0 million. In addition, under the FASN Agreement, we are required to make certain payments to Teva totaling $2.5 million for the achievement of certain clinical development milestones, and additional payments totaling up to $65.0 million upon achievement of certain commercial milestones. We are also obligated to pay Teva tiered royalties at percentages in the low-to-mid single-digits on worldwide net sales of products arising from the FASN program. Our royalty obligations will terminate, on a product-by-product and country-by-country basis, at the later of: (1) the date of expiration of the last to expire valid claim in the assigned patents that covers FASN in such country, (2) the expiration of data or regulatory exclusivity for such product arising from the FASN program in such country and (3) 10 years from the first commercial sale of a product arising from the FASN program in such country.

The term of the FASN Agreement will continue, on a product-by-product and country-by-country basis, until the royalty term with respect to the product arising from the FASN program in such country expires. We may terminate the FASN Agreement for any reason. Either party may terminate the agreement for cause for the other party's uncured material breach, or in the event of bankruptcy of the other party.

Government Regulation and Product Approval

The FDA and other regulatory authorities at federal, state and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring and post-approval reporting of biologics, such as those we are developing. We, along with third-party contractors, will be required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our product candidates.

The process required by the FDA before biologic product candidates may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests and animal studies performed in accordance with the FDA's current Good Laboratory Practice regulation;
- submission to the FDA of an IND, which must become effective before clinical trials may begin and must be updated annually or when significant changes are made;
- approval by an independent Institutional Review Board ("IRB") or ethics committee at each clinical site before the trial is commenced;
- performance of adequate and well-controlled human clinical trials to establish the safety, purity and potency of the proposed biologic product candidate for its intended purpose;
- preparation of and submission to the FDA of a BLA after completion of all pivotal clinical trials;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with cGMP and to assure that the

facilities, methods and controls are adequate to preserve the biological product's continued safety, purity and potency, and of selected clinical investigation sites to assess compliance with current Good Clinical Practices ("cGCP"); and

- FDA review and approval of the BLA to permit commercial marketing of the product for particular indications for use in the United States.

Preclinical and Clinical Development

Prior to beginning the first clinical trial with a product candidate, we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is the general investigational plan and the protocol(s) for clinical studies. The IND also includes results of animal and in vitro studies assessing the toxicology, PK, pharmacology and PD characteristics of the product; chemistry, manufacturing and controls information; and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with cGCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site, and must monitor the study until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

For purposes of BLA approval, human clinical trials are typically conducted in three sequential phases that may overlap.

- ***Phase 1***—The investigational product is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.

- ***Phase 2***—The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.

- ***Phase 3***—The investigational product is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so called Phase 4 studies may be made a condition to approval of the BLA. Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the biological characteristics of the product candidate, and must finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product, or for biologics, the safety, purity and potency. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

BLA Submission and Review

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. The BLA must include all relevant data available from pertinent preclinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. The submission of a BLA requires payment of a substantial application user fee to FDA, unless a waiver or exemption applies.

Once a BLA has been submitted, the FDA's goal is to review standard applications within ten months after it accepts the application for filing, or, if the application qualifies for priority review, six months after the FDA accepts the application for filing. In both standard and priority reviews, the review process is often significantly extended by FDA requests for additional information or clarification. The FDA reviews a BLA to determine, among other things, whether a product is safe, pure and potent and the facility in which it is manufactured, processed, packed, or held meets standards designed to assure the product's continued safety, purity and potency. The FDA may convene an advisory committee to provide clinical insight on application review questions. Before approving a BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with cGCP. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response letter will describe all of the deficiencies that the FDA has identified in the BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the Complete Response letter without first conducting required inspections, testing submitted product lots, and/or reviewing proposed labeling. In issuing the Complete Response letter, the FDA may recommend actions that the applicant might take to place the BLA in

condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the BLA with a Risk Evaluation and Mitigation Strategy ("REMS") to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more Phase 4 postmarket studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies.

Expedited Programs for Serious Conditions

The FDA maintains several programs intended to facilitate and expedite development and review of new drugs and biologics to address unmet medical needs in the treatment of serious or life- threatening diseases or conditions. These programs include Fast Track designation, Breakthrough Therapy designation, Priority Review and Accelerated Approval. These programs can significantly reduce the time it takes for the FDA to review a BLA, but they do not guarantee that a product will receive FDA approval. Even if a product qualifies initially, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review will not be shortened. In May 2018, the Right to Try Act also established a program to increase access to unapproved, investigational treatments for patients diagnosed with life-threatening diseases or conditions who have exhausted approved treatment options and who are unable to participate in a clinical trial.

A new drug or biologic is eligible for Fast Track designation if it is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address unmet medical needs for such disease or condition. Fast Track designation provides increased opportunities for sponsor interactions with the FDA during preclinical and clinical development, in addition to the potential for rolling review once a marketing application is filed, meaning that the agency may review portions of the marketing application before the sponsor submits the complete application, as well as Priority Review, discussed below. In addition, a new drug or biologic may be eligible for Breakthrough Therapy designation if it is intended to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Breakthrough Therapy designation provides all the features of Fast Track designation in addition to intensive guidance on an efficient drug development program beginning as early as Phase 1, and FDA organizational commitment to expedited development, including involvement of senior managers and experienced review staff in a cross-disciplinary review, where appropriate.

Any product submitted to the FDA for approval, including a product with Fast Track or Breakthrough Therapy designation, may also be eligible for additional FDA programs intended to expedite the review and approval process, including Priority Review designation and accelerated approval. A product is eligible for Priority Review if it has the potential to provide a significant improvement in safety or effectiveness in the treatment, diagnosis or prevention of a serious disease or condition. Under priority review, FDA will review an application in six months compared to ten months for a standard review. Products are eligible for accelerated

approval if they can be shown to have an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or an effect on a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality which is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatment. Accelerated approval is usually contingent on a sponsor's agreement to conduct additional post-approval studies to verify and describe the product's clinical benefit. In addition, unless otherwise informed by the FDA, the FDA currently requires, as a condition for accelerated approval, that all advertising and promotional materials that are intended for dissemination or publication be submitted to FDA for review before the initial dissemination or publication.

Post-Approval Requirements

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing user fee requirements, under which FDA assesses an annual program fee for each product identified in an approved BLA. Biologic manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of a product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals;
- product seizure or detention, or refusal of the FDA to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of biologics. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result

in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

Biosimilars and Reference Product Exclusivity

The Patient Protection and Affordable Care Act, as amended by the Affordable Care Act, signed into law in 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-approved reference biological product. To date, a number of biosimilars have been licensed under the BPCIA, and numerous biosimilars have been approved in Europe. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars.

Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. Complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that applicant's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

The BPCIA is complex and continues to be interpreted and implemented by the FDA. In addition, recent government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate impact, implementation, and impact of the BPCIA is subject to significant uncertainty.

Other U.S. Healthcare Laws and Compliance Requirements

In the United States, our current and future operations are subject to regulation by various federal, state and local authorities in addition to the FDA, including but not limited to, the CMS, other divisions of the U.S. Department of Health and Human Services ("HHS") (such as the Office of Inspector General, Office for Civil Rights and the Health Resources and Service Administration), the U.S. Department of Justice ("DOJ"), and state and local governments. For example, our clinical research, sales, marketing and scientific/educational grant programs may have to comply with the anti-fraud and abuse provisions of the Social Security Act, the false claims laws, the privacy and security provisions of HIPAA, and similar state laws, each as amended, as applicable.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between therapeutic product manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Our practices may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor. The statutory exceptions and regulatory safe harbors are also subject to change.

Additionally, the intent standard under the Anti-Kickback Statute was amended by the Affordable Care Act, to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the Affordable Care Act also codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal FCA (discussed below).

The federal false claims and civil monetary penalty laws, including the FCA, which imposes significant penalties and can be enforced by private citizens through civil qui tam actions, prohibit any person or entity from, among other things, knowingly presenting, or causing to be presented, a false or fraudulent claim for payment to, or approval by, the federal government, including federal healthcare programs, such as Medicare and Medicaid; knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government; or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government. A claim includes “any request or demand” for money or property presented to the U.S. government. Although we would not submit claims directly to payors, manufacturers can be held liable under these laws if they are deemed to “cause” the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. In addition, our future activities relating to the reporting of wholesaler or estimated retail prices for our products, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state, and third-party reimbursement for our products, and the sale and marketing of our products, are subject to scrutiny under this law. For example, pharmaceutical companies have been prosecuted under the FCA in connection with their alleged off-label promotion of drugs, purportedly concealing price concessions in the pricing information submitted to the government for government price reporting purposes, and allegedly providing free product to customers with the expectation that the customers would bill federal health care programs for the product.

HIPAA created additional federal criminal statutes that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Like the Anti-Kickback Statute, the Affordable Care Act amended the intent standard for certain healthcare fraud statutes under HIPAA such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

Also, many states have similar, and typically more prohibitive, fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

In addition, we may be subject to data privacy, data security and data breach notification laws, regulations, standards, and codes of conduct by both the U.S. federal government and the states. These laws, regulations, standards, and codes of conduct may govern the collection, use, disclosure and protection of health-related and other personal information. HIPAA, as amended by the HITECH, imposes requirements relating to the privacy, security and transmission of individually identifiable health information. HIPAA requires covered entities to limit the use and disclosure of protected health information to specifically authorized situations, and requires covered entities to implement security measures to protect health information that they maintain in electronic form. The federal government may impose civil, criminal, and administrative fines and penalties and/or additional reporting or oversight obligations for a violation of HIPAA's requirements. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to business associates that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition to HIPAA and HITECH, many state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways, are often not pre-empted by federal law, and may have a more prohibitive effect than federal law, thus complicating compliance efforts.

We may develop products that, once approved, may be administered by a physician. Under currently applicable U.S. law, certain products not usually self-administered (including injectable drugs) may be eligible for coverage under Medicare through Medicare Part B. Medicare Part B is the part of Medicare that covers outpatient services and supplies, including certain pharmaceutical products, that are medically necessary to treat a beneficiary's health condition. As a condition of receiving Medicare Part B reimbursement for a manufacturer's eligible drugs, the manufacturer is required to participate in other government healthcare programs, including the Medicaid Drug Rebate Program and the 340B Drug Pricing Program. The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of HHS as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. Under the 340B Drug Pricing Program, the manufacturer must extend discounts to entities that participate in the program.

In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely.

Additionally, the federal Physician Payments Sunshine Act (the "Sunshine Act") within the Affordable Care Act, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) report annually to CMS information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members. This information is made publicly available on a CMS website, and failure to report accurately could result in penalties. In addition, many states also govern the reporting of payments or other transfers of value, many of which differ from each other in significant ways, are often not pre-empted, and may have a more prohibitive effect than the Sunshine Act, thus further complicating compliance efforts.

In order to distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of drug and biological products in a state, including, in

certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several state and local laws have been enacted requiring pharmaceutical and biotechnology companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical and biotechnology companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. In addition, all of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

Ensuring business arrangements with third parties comply with applicable healthcare laws and regulations is a costly endeavor. If our operations are found to be in violation of any of the federal and state healthcare laws described above or any other current or future governmental regulations that apply to us, we may be subject to significant penalties, including without limitation, civil, criminal and/or administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, private "qui tam" actions brought by individual whistleblowers in the name of the government, or refusal to allow us to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we may obtain regulatory approval. In the United States and in foreign markets, sales of any products for which we receive regulatory approval for commercial sale will depend, in part, on the extent to which third-party payors provide coverage and establish adequate reimbursement levels for such products. In the United States, third-party payors include federal and state healthcare programs, private managed care providers, private health insurers and other organizations. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid in the United States, and commercial payors are critical to new product acceptance.

Our ability to commercialize any products successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which therapeutics they will pay for and establish reimbursement levels. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a therapeutic is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

We cannot be sure that reimbursement will be available for any product that we commercialize and, if coverage and reimbursement are available, what the level of reimbursement will be. Coverage may also be more limited than the purposes for which the product is approved by the FDA or comparable foreign regulatory authorities. Reimbursement may impact the demand for, or the price of, any product for which we obtain regulatory approval.

Third-party payors are increasingly challenging the price, examining the medical necessity, and reviewing the cost-effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy. Obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with branded drugs and drugs administered under the supervision of a physician. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. Obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our product on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize any product candidate that we successfully develop.

Different pricing and reimbursement schemes exist in other countries. In the European Union, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs has become intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any product candidates for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care, the increasing influence of health maintenance organizations, and additional legislative changes in the United States has increased, and we expect will continue to increase, the pressure on healthcare pricing. The downward pressure on the rise in healthcare costs in general, particularly prescription medicines, medical devices and surgical procedures and other treatments, has become very intense. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Healthcare Reform

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect the ability to profitably sell product candidates for which marketing approval is obtained. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States,

the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

For example, the Affordable Care Act has substantially changed healthcare financing and delivery by both governmental and private insurers. The Affordable Care Act and its implementing regulations, among other things, revised the methodology for calculating rebates for covered outpatient drugs and certain biologics owed by manufacturers to the state and federal government under the Medicaid Drug Rebate Program, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program, extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, subjected manufacturers to new annual fees and taxes for certain branded prescription drugs, and expanded programs designed to test innovative payment models, service delivery models, or value-based arrangements, and fund comparative effectiveness research.

Some of the provisions of the Affordable Care Act have yet to be implemented, and there have been legal and political challenges to certain aspects of the Affordable Care Act. Since January 2017, President Trump has signed two executive orders and other directives designed to delay, circumvent or loosen certain requirements mandated by the Affordable Care Act. On December 22, 2017, President Trump signed into law the Tax Cuts and Jobs Act of 2017, or Tax Act which included a provision that repealed the tax penalty for an individual's failure to maintain Affordable Care Act-mandated health insurance, effective January 1, 2019. Further, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain Affordable Care Act-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Moreover, the Bipartisan Budget Act of 2018, or the BBA, among other things, amended the Affordable Care Act, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." Additionally, in December 2018, CMS published a final rule permitting further collections and payments to and from certain Affordable Care Act qualified health plans and health insurance issuers under the Affordable Care Act risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment.

On December 14, 2018, a United States District Court judge in Texas ruled that the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act of 2017. The decision has been appealed to the United States Court of Appeals for the Fifth Circuit. On March 25, 2019, the DOJ submitted a filing to the Fifth Circuit stating that the district court's judgment should be affirmed and, on May 1, 2019, filed a brief in the Fifth Circuit arguing that the Affordable Care Act should be struck down in its entirety. While this U.S. District Court judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals and other efforts to repeal and replace the Affordable Care Act will impact the Affordable Care Act.

We anticipate that the Affordable Care Act, if substantially maintained in its current form, will continue to result in additional downward pressure on coverage and the price that we receive for any approved product, and could seriously harm our business. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

In addition, further legislation or regulation could be passed that could harm our business, financial condition and results of operations. Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, in August 2011, President Obama signed into law the Budget

Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction of at least $1.2 trillion for fiscal years 2012 through 2021, triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect beginning on April 1, 2013 and will stay in effect through 2027 unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, the Trump administration's budget proposals for fiscal years 2019 and 2020 contain further drug price control measures that could be enacted during the budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Further, the Trump administration released a "Blueprint," or plan, to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. While some proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs.

Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. For example, after some pharmacy benefit managers and insurers adopted policies stating that the amount of a copay coupon would not be applied to the enrollee's deductible or out-of-pocket maximum (referred to as "accumulator adjustment programs"), some states passed legislation banning these policies. Based on a rule that will take effect in the 2020 plan year, CMS will allow accumulator adjustment programs only when used for a branded drug that has a generic equivalent. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates, if approved.

Additional Regulation

In addition to the foregoing, local, state and federal laws, including in the United States and Israel, regarding such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act and the Toxic Substances Control Act, affect our business. These and other laws govern our use, handling and disposal of various biological, chemical and radioactive substances used in, and wastes generated by, our operations. If our operations result in contamination of the environment or expose individuals to hazardous or biohazardous substances, we could be liable for damages, environmental remediation, and/or governmental fines. We believe that we are in material compliance with applicable environmental laws and occupational health and safety laws that continued compliance therewith will not have a material adverse effect on our business. We cannot predict, however, how changes in these laws may affect our future operations. We may incur significant costs to comply with such laws and regulations now or in the future.

Competition

The biopharmaceutical industry is intensely competitive and subject to rapid innovation and significant technological advancements. We believe the key competitive factors that will affect the development and commercial success of BIO89-100 and any future product candidates are efficacy, safety and tolerability profile, reliability, convenience of dosing, price, the level of generic competition and reimbursement. Our competitors include multinational pharmaceutical companies, specialized biotechnology companies, universities and other research institutions. A number of biotechnology and pharmaceutical companies are pursuing the development or marketing of pharmaceuticals that target the same diseases that we are targeting. Smaller or earlier-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Given the high incidence of NASH, it is likely that the number of companies seeking to develop products and therapies for the treatment of liver and cardio-metabolic diseases, such as NASH, will increase.

If BIO89-100 is approved for the treatment of NASH, future competition could also arise from products currently in development, including: cenicriviroc, an immunomodulator that blocks CCR2 and CCR5 from Allergan plc; GS-0976, an ACC inhibitor, and GS-9674, an FXR agonist, from Gilead Sciences, Inc.; PF-05221304, an ACC inhibitor, and PF-06835919, a KHK inhibitor, from Pfizer Inc.; Ocaliva, an FXR agonist from Intercept Pharmaceuticals, Inc.; MGL-3196, a beta-thyroid hormone receptor agonist from Madrigal Pharmaceuticals, Inc.; VK2809, a beta-thyroid hormone receptor agonist from Viking Therapeutics, Inc.; NGM-282, an FGF19 analog from NGM Biopharmaceuticals, Inc.; MK-3655, an FGFR1c/KLB agonist antibody from Merck & Co., Inc.; pegbelfermin, a PEGylated FGF21 analog from Bristol-Myers Squibb Company; AKR-001, a FGF21 fusion protein from Akero Therapeutics, Inc.; elobixibat, an IBAT-inhibitor from Albireo Pharma, Inc.; a Galectin-3 inhibitor from Galectin Therapeutics Inc.; a synthetic conjugate of cholic acid and arachidic acid from Galmed Pharmaceuticals Ltd.; an FXR agonist from Metacrine, Inc.; FXR agonists from Novartis AG; a mitochondrial pyruvate complex modulator from Cirius Therapeutics, Inc.; seladelpar, a PPAR delta agonist from CymaBay Therapeutics, Inc.; semaglutide, a GLP-1 receptor agonist from Novo Nordisk A/S; tirzepatide, a dual IP/GLP-1 receptor agonist from Eli Lilly and Company; and elafibranor, a PPAR alpha/delta agonist from Genfit S.A.

If BIO89-100 is approved for the treatment of SHTG, we would face competition from currently approved and marketed products, including statins, fibrates, Vascepa, Epanova and Lovaza, as well as generic products. Further competition could arise from products currently in development, including: AKCEA-APOCIII-LRx, an ApoC III inhibitor from Akcea Therapeutics, Inc.; evinacumab, an Anti-ANGPTL3 from Regeneron Pharmaceuticals, Inc.; pemafibrate, a PPAR alpha agonist from Kowa Research Institute, Inc.; gemcabene; CaPre, an omega-3 fatty acid from Acasti Pharma Inc.; and ARO-APOC3, an ApoC III inhibitor from Arrowhead Pharmaceuticals, Inc.

Many of our competitors have substantially greater financial, technical, human and other resources than we do and may be better equipped to develop, manufacture and market technologically superior products. In addition, many of these competitors have significantly longer operating histories and greater experience than we have in undertaking nonclinical studies and human clinical trials of new pharmaceutical products and in obtaining regulatory approvals of human therapeutic products. Many of our competitors have established distribution channels for the commercialization of their products, whereas we have no such channel or capabilities. In addition, many competitors have greater name recognition and more extensive collaborative relationships. As a result, our competitors may obtain regulatory approval of their products more rapidly than we do or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidate or any future product candidates. Our competitors may also develop and succeed in obtaining approval for drugs that are more effective, more convenient, more widely used and less costly or have a better safety profile than our products and these competitors may also be more successful than we are in manufacturing and marketing their products. If we are unable to compete effectively against these companies, then we may not be able to commercialize our product candidate or any future product candidates or

achieve a competitive position in the market. This would adversely affect our ability to generate revenue. Our competitors also compete with us in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical trial sites and enrolling patients for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Manufacturing and Supply

We do not own or operate manufacturing facilities for the production of BIO89-100, nor do we have plans to develop our own manufacturing operations in the foreseeable future. We currently rely, and expect to continue to rely, on third parties for the manufacturing of our product candidates for preclinical and clinical testing, as well as for commercial manufacturing if BIO89-100 or any future product candidate receives marketing approval.

BIO89-100 drug substance is manufactured by fermentation of a recombinant strain of the bacterium E. coli. Product accumulates as insoluble particles (inclusion bodies) within the cells and is recovered by cell disruption, followed by solubilization of the inclusion bodies, protein refolding and purification with two chromatographic separation columns. Purified material is glycoPEGylated in a 2-step enzymatic reaction where a 20kDa linear glycoPEG moiety is attached to the protein through GalNAc and Sialic Acid linkers. GlycoPEGylated protein is purified with two chromatographic columns to yield product with target quality attributes. Purified glycoPEGylated protein is concentrated and then formulated to a target concentration with formulation buffer as drug product.

BTPH is our sole source supplier for BIO89-100. While any reduction or halt in supply of drug product from BTPH could limit our ability to develop BIO89-100 until a replacement contract manufacturer is found and qualified, we have recently produced several batches to support toxicology and clinical studies. We currently have material available to support our ongoing Phase POC 1b/2a trial of BIO89-100 for the treatment of NASH and for the initiation of our SHTG trial.

We are working with BTPH on process optimization to support large-scale production for future trials and commercialization. In parallel, we have entered into a contract with a formulation development company to explore the potential for a new refrigerated liquid formulation and/or a freeze-dried, or lyophilized product.

BTPH Agreement

On May 7, 2018, we entered into a master services agreement with BTPH, under which BTPH agreed to provide us certain services, including the manufacturing, packaging, labeling and storing of BIO89-100, under statements of work for such services to be agreed by the parties from time to time. The master services agreement will continue for the duration of time that BTPH is providing services to us, unless earlier terminated by either party upon its terms. We may terminate the agreement at any time after a specified notice period and subject to the payment of certain agreed upon fees where such termination results in cancellation of manufacturing scheduled within a certain period. In addition, either party may terminate the agreement for cause for the other party's uncured material breach, in the event of bankruptcy of the other party, in the event of the commission of fraud by the other party or in the event of a force majeure.

Sales and Marketing

We currently have no marketing, sales or distribution capabilities. In order to commercialize any products that are approved for commercial sale, we must either develop a sales and marketing infrastructure or collaborate with third parties that have sales and marketing experience.

We may elect to establish our own sales force to market and sell a product for which we obtain regulatory approval if we expect that the geographic market for a product we develop on our own is limited or

that the prescriptions for the product will be written principally by a relatively small number of physicians. If we decide to market and sell any products ourselves, we do not expect to establish direct sales capability until shortly before the products are approved for commercial sale.

We plan to seek third-party support from established pharmaceutical and biotechnology companies for those products that would benefit from the promotional support of a large sales and marketing force. In these cases, we might seek to promote our products in collaboration with marketing partners or rely on relationships with one or more companies with large established sales forces and distribution systems.

Intellectual Property

Our success depends in part upon our ability to protect our core technology and intellectual property. To protect our intellectual property rights, we rely on patents, trademarks, copyrights and trade secret laws, confidentiality procedures, and employee disclosure and invention assignment agreements. Our intellectual property is critical to our business and we strive to protect it through a variety of approaches, including by obtaining and maintaining patent protection in the United States and internationally for our product candidates, novel biological discoveries, new targets and applications, and other inventions that are important to our business. For our product candidates, we generally intend to pursue patent protection covering compositions of matter, methods of making and methods of use. As we continue the development of our product candidates, we plan to identify additional means of obtaining patent protection that would potentially enhance commercial success, including pursuit of claims directed to new therapeutic indications.

FGF21 Patents

Our FGF21 patent portfolio includes two families: the first is entitled “Remodeling and GlycoPEGylation of Fibroblast Growth Factor (FGF)” and the second is entitled “Mutant FGF-21 Peptide Conjugate and Uses Thereof.” The first family provides granted patent protection in 39 countries around the globe, including the United States (USPN 9,200,049; expiry June 25, 2028), Canada, Europe (broadly), and Japan (latter three expire October 31, 2025) for FGF21 conjugates comprising a variety of modifying groups that can be attached at several different amino acid positions. GlycoPEGylated FGF21 is specifically claimed. The granted claims broadly protect our lead drug candidate BIO89-100 and pharmaceutical compositions thereof, as well as methods for making and using BIO89-100 to treat FGF21 deficiency in a patient in need thereof. One U.S. application is pending in this family.

The second family is specifically directed to BIO89-100. The progenitor PCT Application for this family was filed on September 4, 2018 (PCT/US18/49379; projected expiry September 4, 2038). A U.S. Prioritized Examination Continuation Patent Application (Application Serial No. 16/225,640) was filed in parallel with PCT/US18/49379 on September 4, 2018 and from which U.S. Patent Number 10,407,479 issued on September 10, 2019. The issued claims are directed to BIO89-100 and a defined genus specifically encompassing BIO89-100 and compositions thereof (including site-specific mutations at positions 173 and 176), as well as methods for making and using BIO89-100 for a variety of therapeutic indications. Such indications include methods for treating NASH or metabolic syndrome. Subjects wherein there is a need to reduce blood glucose or to reduce HbA1C include those afflicted with diabetes Type 2, NASH and metabolic syndrome. The claims encompass different therapeutic regimens for administering BIO89-100 (e.g., once a week or once every two weeks), which regimens are based on BIO89-100’s surprisingly long half-life in vivo.

National phase entry of this PCT Application in March of 2020 provides the opportunity to pursue global protection of specific mutant FGF21 peptide conjugates, and particularly BIO89-100. National phase entry is envisioned in at least Europe, China, Japan, Canada, Israel and Korea.

FASN Patents

Our FASN patent portfolio currently consists of three patent families, including patents and/or patent applications in the United States, the European Patent Convention, Canada, Mexico, Israel and Japan.

The first patent family, directed to TEV-48317, which we acquired from Teva under the FASN Agreement, and other 1,4-substituted piperidine-based FASN inhibitors, is currently protected by two granted U.S. patents that cover these compounds, pharmaceutical compositions comprising these compounds, and methods of treating FASN-mediated disorders using these compounds. The non-extended term for these patents would expire on June 17, 2036. A pending U.S. application is directed to additional methods of treatment using these compounds. The second patent family is directed to other 1,4-substituted piperidine-based FASN inhibitors, pharmaceutical compositions, and methods of treating FASN-mediated disorders. The third patent family is directed to spiropiperidine FASN inhibitors, pharmaceutical compositions containing these compounds, and methods of treating FASN-mediated disorders using these compounds.

Employees

As of June 30, 2019, we had 13 full-time employees and 14 total employees. 11 employees are engaged in research and development activities. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

Facilities

We lease office space, which consists of approximately 1,600 square feet located at 6 Hamada Street, Herzliya, 4673340, Israel. The lease expires on April 30, 2020. We also lease access to shared office space at 535 Mission Street, San Francisco, California 94105 on a month-to-month basis. We believe that our current spaces are adequate for our needs. We also believe we will be able to obtain additional space, as needed, on commercially reasonable terms.

Legal Proceedings

We are currently not a party to any material legal proceedings. From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity, reputational harm and other factors, and there can be no assurances that favorable outcomes will be obtained.

MANAGEMENT

Executive Officers and Directors

The following table sets forth certain information regarding our executive officers and directors as of October 28, 2019.

Name	Age	Position
Executive Officers		
Rohan Palekar	53	Chief Executive Officer and Director
Ram Waisbourd	52	Chief Operating Officer and Chief Business Officer
Ryan Martins	43	Chief Financial Officer
Hank Mansbach, M.D.	54	Chief Medical Officer
Quoc Le-Nguyen	51	Chief Technical Operations Officer and Head of Quality
Non-Employee Directors		
Derek DiRocco, Ph.D.(1)(3)	39	Director
Gregory Grunberg, M.D.(2)(3)	47	Director
Michael Hayden, M.B. Ch.B., Ph.D.(1)(2)	67	Director
Tomer Kariv(1)	58	Director
Anat Naschitz(2)(3)	52	Director

(1) Member of the Audit Committee
(2) Member of the Compensation Committee
(3) Member of the Nominating and Corporate Governance Committee

The following is a biographical summary of the experience of our executive officers and directors:

Executive Officers

Rohan Palekar has served as our Chief Executive Officer and a member of our board of directors since June 2018. Prior to joining our company, Mr. Palekar served as the president and Chief Executive Officer of Avanir Pharmaceuticals, Inc., a specialty pharmaceutical company, from December 2015 to July 2017, where he led the company following its acquisition by Otsuka Pharmaceutical Co., Ltd. in 2015. Mr. Palekar also served as Executive Vice President and Chief Operating Officer of Avanir in 2015 and as Senior Vice President and Chief Commercial Officer of Avanir from March 2012 to March 2015. Prior to Avanir, Mr. Palekar served as Chief Commercial Officer for Medivation, Inc., a biopharmaceutical company, from 2008 to 2011, where he was responsible for all commercial activities, chemistry, manufacturing and controls, medical affairs and public relations functions. Prior to Medivation, Mr. Palekar spent over 16 years at Johnson & Johnson, a diversified healthcare company, in various senior commercial and strategic management roles. Mr. Palekar earned his M.B.A. from the Tuck School of Business at Dartmouth College, his B.Com. in Accounting from the University of Mumbai and his L.L.B. in Law from the University of Mumbai.

We believe Mr. Palekar is qualified to serve on our board of directors because of his broad and long experience in the biopharmaceutical industry.

Ram Waisbourd has served as our Chief Operating Officer and Chief Business Officer since May 2018. Prior to joining our company, Mr. Waisbourd served as Vice President of Strategy and Transformation, Global Research and Development, at Teva Pharmaceutical Industries Ltd., a pharmaceutical company, from November 2016 to April 2018, where he was responsible for Teva research and development strategy, novel pipeline funding transactions and digital initiatives. Mr. Waisbourd also served as Vice President of Transformational Initiatives and Operations, Global Research and Development at Teva from September 2015 to October 2016 and Senior Director, Chief of the Research and Development Office from August 2012 to August 2015. Previously,

Mr. Waisbourd served as Vice President of Business Development of XTL Biopharmaceuticals Ltd., a biotechnology company, and as Vice President of Biomedical Investments, an investment fund. Mr. Waisbourd earned his M.B.A from Tel-Aviv University and his B.Sc. in Economics from The Wharton School at the University of Pennsylvania.

Ryan Martins has served as our Chief Financial Officer since July 2019 and previously served as our consultant since April 2019. Prior to joining our company, Mr. Martins was Chief Financial Officer at Revolution Medicines, Inc., from March 2018 to October 2018, where he was responsible for all aspects of the finance function including financial accounting, capital planning, audit, tax and investor relations. Before Revolution Medicines, Mr. Martins was Vice President and Head of Corporate Strategy and Investor Relations at Ultragenyx Pharmaceutical, Inc., from September 2015 to March 2018, where he was responsible for strategic planning, capital raising, investor relations and assisting business development. Prior to Ultragenyx, Mr. Martins spent nearly 10 years as a biotechnology analyst at Jefferies, Lazard, and Barclays/Lehman Brothers after holding operating roles at Chiron Corporation from 2001 to 2006. Mr. Martins earned his B.Sc. in Life Sciences from St. Xavier's College, a M.S. degree in Biology from Virginia Tech and an M.B.A. from the Haas School of Business at U.C. Berkeley.

Hank Mansbach, M.D. has served as our Chief Medical Officer since December 2018. Prior to joining our company, Dr. Mansbach was at Ultragenyx Pharmaceutical Inc., a biotechnology company where he served Head of Global Clinical Development for Metabolic and Neurologic Diseases from June 2018 to December 2018, Vice President of Global Clinical Development and Ultra Programs from March 2017 to June 2018 and Vice President of Medical Affairs from May 2015 to March 2017. During his time at Ultragenyx, Dr. Mansbach was responsible for leading clinical development programs for metabolic disorders and building and leading the Medical Affairs team. Before Ultragenyx, Dr. Mansbach served as Vice President of Medical Affairs at Medivation, Inc., a biopharmaceutical company, from August 2009 to April 2015, where he played a key role in the development and commercialization of enzalutamide for the treatment of advanced prostate cancer. Earlier in his career, Dr. Mansbach served as Senior Vice President of Global Drug Development at Valeant Pharmaceuticals and Chief Medical Officer at Cortex Pharmaceuticals, Inc., a pharmaceutical company. Dr. Mansbach began his industry career at Glaxo Wellcome after clinical practice and research in neurology. He earned his M.D. from Duke University and a B.A. in Philosophy from Yale University.

Quoc Le-Nguyen has served as our Chief Technical Operations Officer and Head of Quality since March 2019. Prior to joining our company, Mr. Le-Nguyen was Senior Vice President, Global Head of Technical Operations & Quality for Aduro BioTech, Inc., a biotechnology company, from September 2015 to July 2018, where he was responsible for clinical supply including analytical and process development, manufacturing, supply chain and quality for cell therapy, small molecule and antibody platforms. Prior to Aduro, Mr. Le-Nguyen was the Vice President of Manufacturing Operations for Bayer AG from September 2007 to September 2013, where he was responsible for the Betaferon/Betaseron franchise. Prior to Bayer, Mr. Le-Nguyen worked in biologics manufacturing for Novartis International AG, Chiron Corporation and BioMarin Pharmaceutical Inc. Mr. Le-Nguyen earned his B.S. in Biochemistry from the University of California, Davis.

Non-Employee Directors

Derek DiRocco, Ph.D. has served as a member of our board of directors since April 2018. Dr. DiRocco has been a principal at RA Capital Management, LLC, an investment advisory firm that invests in healthcare and life science companies, since December 2017 and was previously an analyst from June 2015 to December 2017 and an associate from July 2013 to June 2015. Dr. DiRocco earned his Ph.D. in Pharmacology from the University of Washington and his B.A. in Biology from College of the Holy Cross.

We believe Dr. DiRocco is qualified to serve on our board of directors because of his experience as an investor in biotechnology companies and role in early stage companies.

Gregory Grunberg, M.D. has served as a member of our board of directors since April 2018. Dr. Grunberg has been a Managing Director at Longitude Capital Management Co., LLC, a venture capital firm, since February 2012. Prior to joining Longitude, Dr. Grunberg was a Principal at Rho Ventures, a venture capital firm, where he worked from May 2007 to January 2012. Dr. Grunberg maintains a limited clinical practice in internal medicine and affiliations with University of California, San Francisco and Kaiser Permanente. Dr. Grunberg has served on the boards of Kala Pharmaceuticals Inc., a pharmaceutical company, since April 2016, and WelbeHealth LLC, a private healthcare services company, since April 2018. He has served as a board observer at Sydnexis, Inc., an private biotechnology company, since September 2017. He previously served on the board of California Cryobank (acquired by GI Partners) from August 2014 to August 2018 and led Longitude's investment in Practice Fusion (acquired by Allscripts Healthcare Solutions, Inc.). While at Rho Ventures he served on the board of AqueSys Inc. (acquired by Allergan plc) from June 2010 to December 2011 and was a board observer at both SARCode Bioscience Inc. (acquired by Shire plc) from June 2011 to February 2012 and PHT Corporation (acquired by eResearchTechnology, Inc.) from November 2010 to November 2012. Dr. Grunberg earned his M.D. and M.B.A. from Duke University and his A.B. in Economics and English from Amherst College.

We believe Dr. Grunberg is qualified to serve on our board of directors because of his extensive experience investing in and guiding early phase companies.

Michael Hayden, M.B. Ch.B., Ph.D. has served as a member of our board of directors since April 2018. Dr. Hayden is currently a Killam Professor at the University of British Columbia and the director of the Translational Laboratory in Genetic Medicine at the National University of Singapore and A*STAR. Dr. Hayden was the President of Global Research and Development and Chief Scientific Officer at Teva Pharmaceutical Industries Ltd., a pharmaceutical company, from May 2012 to December 2017, and served as an advisor to Teva from December 2017 to August 2018. During this time approximately 35 new products were approved in major markets with many for diseases of the CNS such as migraine. He led the development of the first deuterated drug to be approved by the FDA and the second drug ever to be approved for Huntington disease. He is also the Founder and a Senior Scientist of the Centre for Molecular Medicine and Therapeutics at the University of British Columbia. Dr. Hayden has served on the boards of Aurinia Pharmaceuticals Inc., a biopharmaceutical company, since February 2018, Ionis Pharmaceuticals, Inc., a biopharmaceutical company, since September 2018, and Xenon Pharmaceuticals, Inc., a pharmaceutical company, since November 1996. Dr. Hayden received his M.B. Ch.B. in Medicine, Ph.D. in Genetics and Diploma in Child Health from the University of Cape Town. He received his American Board Certification in both internal medicine and clinical genetics from Harvard Medical School and an FRCPC in internal medicine from the University of British Columbia.

We believe Dr. Hayden is qualified to serve on our board of directors because of his extensive experience as a senior executive and member of the board of other life science companies.

Tomer Kariv has served as a member of our board of directors since May 2018. Mr. Kariv has served as co-founder and managing partner of the Pontifax Group, a venture capital firm, since December 2004. He serves on the boards of Eloxx Pharmaceuticals, Inc., a pharmaceutical company, since December 2017, and Logicbio Therapeutics, Inc., a pharmaceutical company, since June 2017. He previously served on the board of VBI Vaccines Inc., a pharmaceutical company, from January 2018 to June 2019, Medical Compression Systems Ltd, a pharmaceutical company, from August 2012 to April 2015, Macrocure Ltd, a pharmaceutical company, from March 2008 to January 2017, Arno Therapeutics Inc., a pharmaceutical company, from September 2010 to August 2017, and Check-Cap Ltd, a medical diagnostics company, from March 2008 to June 2018. Mr. Kariv earned his B.A. in Economics from Harvard University and a J.D. from Harvard Law School.

We believe Mr. Kariv is qualified to serve on our board of directors of his extensive experience in investing in, guiding and leading start-up companies and experience as a director in similar stage companies.

Anat Naschitz has served as a member of our board of directors since January 2018, and played a key role in creating 89Bio, Ltd. as a spinout from a pharmaceutical company. Ms. Naschitz has served as Managing

Director at OrbiMed, a global healthcare investment firm, since January 2010. Ms. Naschitz has over 20 years of healthcare experience. Previously, Ms. Naschitz created, invested in and advised healthcare companies across stages and substance. She was an Associate Partner with McKinsey in London from 1995 to 2002, where she managed strategy, company formation through spinouts and mergers and acquisitions projects for senior management of the world's leading pharmaceutical and biotechnology companies. Subsequently Ms. Naschitz was a Principal at Apax Partners, where she invested in healthcare companies. She currently serves on the boards of biotech and digital health companies and served on the board of Medigus Ltd., a medical device company, from March 2013 to June 2017. Ms. Naschitz earned her M.B.A. at INSEAD and her L.L.B. at Tel Aviv University.

We believe Ms. Naschitz is qualified to serve on our board of directors because of her long industry experience and experience as an investor in biotechnology companies.

Family Relationships

There are no family relationships among any of our directors or executive officers.

Composition of our Board of Directors

Our board of directors currently consists of six members, each of whom are members pursuant to the board composition provisions of our current certificate of incorporation and agreements with our stockholders. Our current certificate of incorporation and agreements among our stockholders provide for two directors to be appointed by entities affiliated with OrbiMed, one director to be appointed by Longitude, one director to be appointed by RA Capital and two directors (only one of which has been appointed to date) to be appointed by the holders of at least 50% of our Series A convertible preferred shares, including either OrbiMed IL or OrbiMed US (the "Requisite Preferred"), and one director who shall be the presiding Chief Executive Officer of our company, currently Mr. Palekar. Ms. Naschitz is the designee of OrbiMed IL, Mr. Kariv is the designee of OrbiMed US, Dr. DiRocco is the designee of RA Capital, Dr. Grunberg is the designee of Longitude and Dr. Hayden is an industry director who has been appointed by the Requisite Preferred. These board composition provisions will terminate upon the completion of this offering. Upon the termination of these provisions, there will be no further contractual obligations regarding the election of our directors, although no changes to our board composition are expected at that time. Our board of directors may therefore consider a broad range of factors relating to the qualifications and background of nominees, including the identification of persons who will further the interests of our stockholders through their established record of professional accomplishment, the ability to contribute positively to the collaborative culture among board members, knowledge of our business, understanding of the competitive landscape, and professional and personal experiences and expertise relevant to our growth strategy. We have no formal policy regarding board diversity. Our Amended Certificate and Amended Bylaws, both to become effective upon the completion of this offering, provide that the number of directors shall be fixed from time to time by a resolution of the majority of our board of directors.

Director Independence

Our board of directors has determined that all members of our board of directors, except Mr. Palekar, are independent directors for purposes of applicable Nasdaq listing rules. In making such independence determination, our board of directors considered the relationships that each non-employee director has with us and all other facts and circumstances that our board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director. In considering the independence of the directors listed above, our board of directors considered the association of our directors with the holders of more than 5% of our common stock and other affiliations, including family and other relationships.

Upon the completion of this offering, we expect that the composition and functioning of our board of directors and each of our committees will comply with all applicable requirements of the Nasdaq listing rules and

the rules and regulations of the SEC. Mr. Palekar is not an independent director under these rules because he is currently employed as the chief executive officer of our company.

Term of Office, Removal and Vacancies

Our directors hold office until their successors have been elected and qualified or until the earlier of their resignation or removal. Our Amended Certificate and Amended Bylaws provide that our directors may be removed only for cause by the affirmative vote of the holders of at least 66⅔% of the votes that all our stockholders would be entitled to cast in an annual election of directors, and that any vacancy on our board of directors, including a vacancy resulting from an enlargement of our board of directors, may be filled only by vote of a majority of our directors then in office.

Election of Directors

Our Amended Certificate provides that our board of directors will be divided into three staggered classes of directors and each will be assigned to one of the three classes. At each annual meeting of the stockholders, a class of directors will be elected for a three-year term to succeed the directors of the same class whose terms are then expiring. The terms of the directors will expire upon the election and qualification of successor directors at the annual meeting of stockholders to be held during the years 2020 for Class I directors, 2021 for Class II directors and 2022 for Class III directors.

- Our Class I directors will be Mr. Palekar and Dr. Grunberg;
- Our Class II directors will be Dr. Hayden and Mr. Kariv; and
- Our Class III directors will be Dr. DiRocco and Ms. Naschitz.

The division of our board of directors into three classes with staggered three-year terms may delay or prevent stockholder efforts to effect a change of our management or a change in control.

Board Leadership Structure and the Role of our Board in Risk Oversight

Board Leadership Structure

Our board of directors has designated Ms. Naschitz and Dr. Grunberg to serve as co-lead independent directors as our board of directors currently does not have a chairman. Separating the role of lead independent director from the chief executive officer position allows our chief executive officer to focus on our day-to-day business, while allowing the co-lead independent directors to lead our board of directors in its fundamental role of providing advice to and oversight of management. Our board of directors is actively seeking to identify additional candidates for our board of directors, including a candidate to serve as chairman of our board of directors.

Although our Amended Bylaws do not require that we separate the chief executive officer and board leadership positions, our board of directors believes that having separate positions is the appropriate leadership structure for us at this time. Our board of directors recognizes that, depending on the circumstances, other leadership models, such as combining the role of executive chairman of the board with the role of chief executive officer, might be appropriate. Accordingly, our board of directors may periodically review its leadership structure. Our board of directors believes its administration of its risk oversight function has not affected its leadership structure.

Our independent directors will meet alone in executive session regularly throughout each year. The purpose of these executive sessions is to promote open and candid discussion among independent directors.

Role of our Board in Risk Oversight

We face a number of risks, including those described under the section titled “Risk Factors” included elsewhere in this prospectus. Our board of directors believes that risk management is an important part of

establishing, updating and executing on the company's business strategy. Our board of directors, as a whole and at the committee level, has oversight responsibility relating to risks that could affect the corporate strategy, business objectives, compliance, operations and the financial condition and performance of the company. Our board of directors focuses its oversight on the most significant risks facing the company and on its processes to identify, prioritize, assess, manage and mitigate those risks. Our board of directors and its committees receive regular reports from members of the company's senior management on areas of material risk to the company, including strategic, operational, financial, legal and regulatory risks. While our board of directors has an oversight role, management is principally tasked with direct responsibility for management and assessment of risks and the implementation of processes and controls to mitigate their effects on the company.

Committees of our Board of Directors

Our board of directors has established an audit committee, a compensation committee, and a nominating and corporate governance committee, each of which will operate pursuant to a charter that will be effective upon the completion of this offering. The composition and functioning of all of our committees will comply with all applicable requirements of the Sarbanes-Oxley Act of 2002, The Nasdaq Global Market and SEC rules and regulations. A current copy of the charters of the committees of our board of directors will be posted on our website, which is located at *www.89bio.com*.

Audit Committee

Dr. DiRocco and Dr. Hayden serve on the audit committee, which is chaired by Mr. Kariv. Our board of directors has determined that each member of the audit committee is "independent" for audit committee purposes as that term is defined in the rules of the SEC and the applicable Nasdaq listing rules, and has sufficient knowledge in financial and auditing matters to serve on the audit committee. Our board of directors has designated Mr. Kariv as an "audit committee financial expert," as defined under the applicable rules of the SEC as a result of his more than 25 years of experience in identifying and managing investments in, and evaluating financial statements of, both private and public companies, including 15 years serving as founder and chief executive officer of a healthcare-focused venture capital firm, as well as his service on other public company audit committees. In order to be considered independent for purposes of Rule 10A-3 under the Exchange Act, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors or any other board committee: (1) accept, directly or indirectly, any consulting, advisory or other compensatory fee from the listed company or any of its subsidiaries; or (2) be an affiliated person of the listed company or any of its subsidiaries. In determining that Mr. Kariv is independent, our board of directors considered his role as managing partner of the Pontifax Group, which currently holds slightly greater than 10% of our outstanding voting stock, and the fact that Rule 10A-3 under the Exchange Act provides that an audit committee member may still be considered independent if he or she does not fall within the less-than-10% stock ownership safe harbor provision of this rule.

The primary responsibilities of the audit committee are to oversee the accounting and financial reporting processes and the internal and external audit processes. The audit committee also assists our board of directors in fulfilling its oversight responsibilities by reviewing the financial information provided to stockholders and others and the system of internal controls established by management and our board of directors. The audit committee oversees the independent auditors, including their independence and objectivity. However, committee members will not act as professional accountants or auditors, and their functions are not intended to duplicate or substitute for the activities of management and the independent auditors. The audit committee is empowered to retain independent legal counsel and other advisors as it deems necessary or appropriate to assist it in fulfilling its responsibilities, and to approve the fees and other retention terms of the advisors.

Compensation Committee

Dr. Grunberg and Dr. Hayden serve on the compensation committee, which is chaired by Ms. Naschitz. Our board of directors has determined that each member of the compensation committee is "independent" as

defined in the applicable Nasdaq listing rules, including the additional independence requirements set forth in Nasdaq Rule 5605(d)(2). In order to be considered independent for purposes of Nasdaq Rule 5605(d)(2), a member of a compensation committee of a listed company may not, other than in his or her capacity as a member of the compensation committee, our board of directors or any other board committee, accept, directly or indirectly, any consulting, advisory or other compensatory fee from the listed company or any of its subsidiaries.

The primary responsibilities of the compensation committee are to periodically review and approve the compensation and other benefits for our employees, officers and independent directors. This includes reviewing and approving corporate goals and objectives relevant to the compensation of our executive officers in light of those goals and objectives, and setting compensation for these officers based on those evaluations.

Nominating and Corporate Governance Committee

Ms. Naschitz and Dr. DiRocco serve on the nominating and corporate governance committee, which is chaired by Dr. Grunberg. Our board of directors has determined that each member of the nominating and corporate governance committee is "independent" as defined in the applicable Nasdaq listing rules. The primary responsibilities of the nominating and corporate governance committee are to develop and recommend to our board of directors criteria for identifying and evaluating qualified candidates for directorships and recommend candidates for election or reelection to our board of directors at each annual stockholders' meeting. The nominating and corporate governance committee also is responsible for making recommendations to our board of directors concerning the structure, composition and function of our board of directors and its committees.

Our board of directors may from time to time establish other committees.

Other Governance Matters

Compensation Committee Interlocks and Insider Participation

None of the members of our compensation committee has at any time during the prior three years been one of our officers or employees. None of our executive officers currently serves, or in the past fiscal year has served, as a member of our board of directors or compensation committee of any entity that has one or more executive officers serving on our board of directors or compensation committee.

Code of Business Conduct and Ethics

Our board of directors has adopted a written code of business conduct and ethics, effective upon the completion of this offering, that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. A current copy of the code will be posted on the investor relations section of our website, which is located at *www.89bio.com*. If we make any substantive amendments to, or grant any waivers from, the code of business conduct and ethics for any officer or director, we will disclose the nature of such amendment or waiver on our website or in a current report on Form 8-K.

Director Compensation

The following table sets forth the total cash and equity compensation paid to our non-employee directors for service on our board of directors during 2018:

Name	Fees Earned or Paid in Cash ($)	Option Awards ($)(1)	Total ($)
Michael Hayden	26,700(2)	112,860	129,560
Derek DiRocco	—	—	—
Gregory Grunberg	—	—	—
Tomer Kariv	—	—	—
Anat Naschitz	—	—	—

(1) Amounts shown in this column represent the aggregate grant date fair value (calculated in accordance with FASB Accounting Standards Codification Topic 718) of stock options granted during the year. A description of the methodologies and assumptions we use to value equity awards and the manner in which we recognize the related expense are described in Note 8 to our consolidated financial statements included elsewhere in this prospectus, Share-Based Compensation. These amounts may not correspond to the actual value eventually realized by the director because the value depends on the market value of our common stock at the time the award is exercised. As of December 31, 2018, Dr. Hayden held 97,847 outstanding stock options.

(2) Dr. Hayden is party to a letter agreement with the Company pursuant to which the Company pays him a monthly fee of $3,334 for service on the Board. Includes $10,000 paid in 2019 for services rendered in 2018.

Other than as set forth in the Director Compensation Table above, we did not compensate our non-employee directors for 2018. We have also reimbursed directors for their reasonable out-of-pocket expenses, including travel, food and lodging, incurred in attending meetings of our board of directors and/or its committees. We did not compensate Mr. Palekar for his service on our board of directors during 2018 and we do not expect to compensate our employee directors for their service on our board of directors in the future.

Non-Employee Director Compensation Policy

Our board of directors has adopted a non-employee director compensation policy, effective upon the completion of this offering. Under the policy, each director who is not an employee will be paid cash compensation as set forth below:

Annual retainer for board of directors membership	$40,000
Additional annual retainer for service as a committee chair*	$10,000
Additional annual retainer for service as chairman of the board of directors	$60,000

* Applies with respect to each of the audit, compensation, and nominating and corporate governance committees

We will pay all such amounts in quarterly installments. In addition, the compensation committee of our board of directors may in its discretion grant equity awards to any or all non-employee directors under the 2019 Plan. Such awards may include: (i) an initial, one-time equity award granted to a new non-employee director upon his or her election to our board of directors; (ii) equity awards granted to non-employee directors on an annual basis for their service on our board of directors; and/or (iii) equity awards granted to non-employee directors on an annual basis for their service in a leadership role or on a committee of our board of directors.

We will reimburse all necessary and reasonable out-of-pocket expenses incurred by non-employee directors in connection with their service on our board of directors, subject to any applicable Company policies that may be in effect from time to time.

A non-employee director may decline all or any portion of his or her compensation by giving notice to us prior to, as the case may be, the date cash is to be paid or equity awards are to be granted.

Our board of directors periodically reviews our director compensation program and may revise the compensation arrangements for our directors from time to time.

Indemnification Agreements

We have entered into indemnification agreements with our officers and directors. The indemnification agreements and our Amended Bylaws, to be effective upon the completion of this offering, require us to indemnify these individuals to the fullest extent permitted by Delaware law.

EXECUTIVE COMPENSATION

Our named executive officers ("NEOs") for 2018, which consist of our principal executive officer and the next most highly-compensated executive whose total compensation did not exceed $100,000 in 2018, are:

- Rohan Palekar, our Chief Executive Officer; and
- Ram Waisbourd, our Chief Operating Officer and Chief Business Officer.

2018 Summary Compensation Table

The following table summarizes the compensation awarded to, earned by or paid to our NEOs for 2018.

Name and Principal Position(1)	Year	Salary ($)	Bonus ($)(2)	Option Awards ($)(3)	All Other Compensation ($)	Total ($)
Rohan Palekar, *Chief Executive Officer*	2018	194,792	97,396	414,908	1,065(4)	708,161
Ram Waisbourd, *Chief Operating Officer and Chief Business Officer(5)*	2018	115,522	36,288	130,383	35,809(6)	318,002

(1) Messrs. Palekar and Waisbourd commenced employment as of July 16, 2018 and May 1, 2018, respectively.
(2) Following the end of the fiscal year, we awarded Messrs. Palekar and Waisbourd bonuses in respect of our performance in fiscal year 2018.
(3) Amounts shown in this column represent the aggregate grant date fair value (calculated in accordance with FASB Accounting Standards Codification Topic 718) of stock options granted during the year. A description of the methodologies and assumptions we use to value equity awards and the manner in which we recognize the related expense are described in Note 9 to our consolidated financial statements included elsewhere in this prospectus, Share-Based Compensation. These amounts may not correspond to the actual value eventually realized by each NEO because the value depends on the market value of our common stock at the time the award is exercised.
(4) Represents 401(k) employer matching contribution.
(5) We paid the amounts reported for Mr. Waisbourd in New Israeli Shekels. We have translated amounts paid in New Israeli Shekels into U.S. dollars based on the foreign exchange rate as of December 31, 2018.
(6) Includes a $9,623 contribution by us to Mr. Waisbourd's severance fund, a $6,444 contribution by us for Israeli social insurance and $11,185 in aggregate contributions to pension and Israeli educational funds and a car allowance of $8,557.

Outstanding Equity Awards at 2018 Fiscal-Year End

The following table sets forth information regarding outstanding equity awards at the end of 2018 for each of our NEOs.

	Option Awards (1)			
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date
Rohan Palekar	—	325,231	1.93	11/09/2028
Ram Waisbourd	—	102,203	1.93	11/09/2028

(1) Each option award expires on the tenth anniversary of the date of grant. Twenty-five percent of each outstanding stock option award vests on the one-year anniversary of the employee's start date (July 16, 2018, in the case of Mr. Palekar and May 1, 2018, in the case of Mr. Waisbourd) and the remainder vests in equal quarterly installments thereafter, subject to continued service through each such vesting date.

Employment Agreements

During 2018, we were party to an offer letter agreement with Mr. Palekar, effective as of July 16, 2018, pursuant to which he serves as our Chief Executive Officer. The agreement provides for a base salary, eligibility

to receive an annual performance bonus and eligibility to participate in employee benefit or group insurance plans maintained from time to time by the Company. The agreement also provided for the grant of a stock option award as described in the 2018 Summary Compensation Table. The agreement provides for employment on an at-will basis and thus either party may terminate at any time for any or no reason, subject to the severance provisions described below in the section titled "Post-Employment Compensation and Change in Control Payments and Benefits."

During 2018, we were party to an employment agreement with Ram Waisbourd, effective as of May 1, 2018, pursuant to which he serves as our Chief Operating Officer and Chief Business Officer. The employment agreement provides for employment on an at-will basis and thus either party may terminate the agreement by providing 90 days prior written notice; provided, however, that we may terminate earlier and without prior notice, or with shorter notice, provided that we make payment in lieu of such notice and further provided that we may terminate the agreement immediately upon written notice in the event of "cause" (as defined therein). The agreement provides for a base salary, global overtime remuneration (collectively, the "Salary"), eligibility to receive an annual performance bonus, vacation, sick leave, car allowance and convalescence pay. Pursuant to the agreement, we have effected a manager's insurance policy for Mr. Waisbourd pursuant to which we make contributions on his behalf as well as the required statutory deductions from Salary and any other amounts payable under the agreement on his behalf to the relevant authorities in accordance with Israeli law. We contribute an amount equal to 8.5% of his Salary toward the policy for the severance pay component and 6.5% of his Salary toward the policy for pension and disability insurance. We also make the required statutory deductions on behalf of Mr. Waisbourd equal to 6% of his Salary and contribute an amount equal to 7.5% of his Salary to an education fund. The agreement also provided for the grant of a stock option award as described in the 2018 Summary Compensation Table.

For 2018, Mr. Palekar's annualized base salary was $425,000 and Mr. Waisbourd's annualized Salary was $173,283.

Incentive Compensation

For fiscal year 2018, Mr. Palekar and Mr. Waisbourd had target bonus opportunities equal to 45% of base salary and 20% of Salary, respectively, pro-rated for the length of time employed during the year.

Following the end of the fiscal year, our board of directors evaluated the performance of Messrs. Palekar and Waisbourd and based on Company performance in 2018, determined to award bonuses equal to $97,396 and $36,288, respectively.

Post-Employment Compensation and Change in Control Payments and Benefits

Severance

Mr. Palekar

Pursuant to the terms of the employment agreement with Mr. Palekar, upon a termination without cause (as defined in the agreement) not in connection with a change in control (as defined in the agreement), Mr. Palekar will receive, subject to execution and non-revocation of a release of claims in favor of the Company (the "release condition"), severance equal to six months of the base salary as then in effect, a pro-rata amount of the target bonus opportunity based on the number of months employed during the year of termination and payment or reimbursement of COBRA premiums for up to six months, or, if sooner, until eligible for similar coverage through another employer.

If Mr. Palekar is terminated without cause or for good reason (as defined in the agreement) within 90 days prior to, or 12 months following, the consummation of a change in control, then, subject to the release condition, the benefits described above will be provided for 12 months and all outstanding equity awards will vest in full.

Mr. Waisbourd

Pursuant to the terms of his employment agreement, as well as in accordance with Israeli law, upon a termination of Mr. Waisbourd's employment, Mr. Waisbourd is entitled to the payments we have made on his behalf to the Manager's Insurance Policy. If Mr. Waisbourd is terminated without cause within 12 months following a change of control transaction, all outstanding equity awards will vest in full. Further, upon the completion of 12 months of employment with the Company or any successor following a change of control transaction, all unvested options granted pursuant to his employment agreement will vest in full.

Employee Benefit Plans

Amended and Restated 2019 Equity Incentive Plan

In 2018, our board of directors adopted and our shareholders approved the 89Bio Ltd. 2018 Equity Incentive Plan (the "2018 Plan"). In connection with the Reorganization, in September 2019, our board of directors adopted and our stockholders approved the 2019 Plan, the successor to the 2018 Plan. From and after the effective date of the 2019 Plan, no additional stock awards can be made under the 2018 Plan. In addition, all stock awards granted under the 2018 Plan prior to the effective time of the 2019 Plan that were outstanding as of the effectiveness of the 2019 Plan were canceled and replaced with equivalent awards under the 2019 Plan. In October 2019, our board of directors adopted and our stockholders approved an amendment and restatement of the 2019 Plan to, among other things, increase the aggregate maximum number of shares of our common stock that may be issued pursuant to stock awards under the 2019 Plan (the "Share Reserve").

Purpose. The 2019 Plan is intended to help us secure and retain the services of eligible award recipients, provide incentives for such persons to exert maximum efforts for our success and the success of our affiliates and provide a means by which the eligible recipients may benefit from increases in the value of our common stock.

Eligibility. Awards may be granted to our and our affiliates' employees, including officers, non-employee directors and consultants. Only our employees and those of our affiliates are eligible to receive incentive stock options.

Types of Awards. The 2019 Plan provides for the grant of incentive stock options within the meaning of Section 422 of the Code, nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance stock awards and performance cash awards.

Authorized Shares. Subject to adjustment for certain dilutive or related events, the Share Reserve is 2,844,193 shares of common stock. On January 1, 2020, and each January 1 thereafter until January 1, 2029, the Share Reserve will automatically increase by 4% of the number of shares of our capital stock issued and outstanding on the immediately preceding December 31, or a lesser number of shares determined by our board of directors.

The Share Reserve will not be reduced if an award or any portion thereof (i) expires, is cancelled or forfeited or otherwise terminates without all of the shares covered by such award having been issued or (ii) is settled in cash. If any shares of common stock issued under an award are forfeited back to or repurchased by us, such shares will revert to and again be made available for issuance under the 2019 Plan. Any shares retained or not issued by us in satisfaction of tax withholding obligations or as consideration for the exercise or purchase price of an award will also again become available for issuance under the 2019 Plan.

The aggregate maximum number of shares of common stock that may be issued on the exercise of incentive stock options is 2,844,193.

Shares issued under the 2019 Plan may consist of our authorized but unissued or reacquired common stock, including shares repurchased by us on the open market or otherwise or shares classified as treasury shares.

Plan Administration. Our board of directors has the authority to administer the 2019 Plan, including the powers to: (i) determine who will be granted awards and what type of award, when and how each award will be granted, the provisions of each award (which need not be identical), the number of shares or cash value subject to

an award and the fair market value applicable to an award; (ii) construe and interpret the 2019 Plan and awards granted thereunder and establish, amend and revoke rules and regulations for administration of the 2019 Plan and awards, including the ability to correct any defect, omission or inconsistency in the 2019 Plan or any award document; (iii) settle all controversies regarding the 2019 Plan and awards granted thereunder; (iv) accelerate or extend, in whole or in part, the time during which an award may be exercised or vested or at which cash or shares may be issued; (v) suspend or terminate the 2019 Plan; (vi) amend the 2019 Plan; (vii) submit any amendment to the 2019 Plan for stockholder approval; (viii) approve forms of award documents for use under the 2019 Plan and to amend the terms of any one or more outstanding awards; (ix) generally exercise such powers and perform such acts as our board of directors may deem necessary or expedient to promote our best interests and that are not in conflict with the provisions of the 2019 Plan or any award documents; and (x) adopt procedures and sub-plans as are necessary or appropriate.

Subject to the provisions of the 2019 Plan, our board of directors may delegate all or some of the administration of the 2019 Plan to a committee of one or more directors and may delegate to one or more officers the authority to designate employees who are not officers to be recipients of options and stock appreciation rights (and, to the extent permitted by applicable law, other stock awards) and, to the extent permitted by applicable law, to determine the terms of such awards and the number of shares of common stock to be subject to such stock awards granted to such employees. Unless otherwise provided by our board of directors, delegation of authority by our board of directors to a committee or an officer will not limit the authority of our board of directors. All determinations, interpretations and constructions made by our board of directors (or another authorized committee or officer exercising powers delegated by our board of directors) in good faith will be final, binding and conclusive on all persons.

Stock Options. A stock option may be granted as an incentive stock option or a nonqualified stock option. The option exercise price may not be less than the fair market value of the stock subject to the option on the date the option is granted (or, with respect to incentive stock options, less than 110% of the fair market value if the recipient owns stock possessing more than 10% of the total combined voting power of all classes of our stock or the stock of any affiliate (a "Ten Percent Stockholder") unless the option was granted pursuant to an assumption or substitution for another option in a manner satisfying the provisions of Section 409A and, if applicable, Section 424(a) of the Code, including, for avoidance of doubt, the options granted in substitution for awards outstanding under the 2018 Plan). Options will not be exercisable after the expiration of ten years from the date of grant (or five years, in the case of an incentive stock option issued to a Ten Percent Stockholder). Each award agreement will set forth the number of shares subject to each option. The purchase price of any shares acquired pursuant to an option may be payable in cash, check, bank draft, money order, net exercise or as otherwise determined by our board of directors and set forth in the award agreement, including through an irrevocable commitment by a broker to pay over such amount from a sale of the shares issuable under the option and the delivery of previously owned shares. The vesting schedule applicable to any option, including any performance conditions, will be as set forth in the award agreement.

Stock Appreciation Rights. A stock appreciation right ("SAR") is a right that entitles the participant to receive, in cash or shares of stock or a combination thereof, as determined by our board of directors, value equal to or otherwise based on the excess of (i) the fair market value of a specified number of shares at the time of exercise over (ii) the exercise price of the right, as established by our board of directors on the date of grant. Upon exercising a SAR, the participant is entitled to receive the amount by which the fair market value of the stock at the time of exercise exceeds the exercise price of the SAR. The exercise price of each SAR may not be less than the fair market value of the stock subject to the award on the date the SAR is granted, unless the SAR was granted pursuant to an assumption of or substitution for another option in a manner satisfying the provisions of Section 409A of the Code. SARs will not be exercisable after the expiration of ten years from the date of grant. Each award agreement will set forth the number of shares subject to the SAR. The vesting schedule applicable to any SAR, including any performance conditions, will be as set forth in the award agreement.

Provisions Applicable to Both Options and SARs.

Transferability. Our board of directors may, in its sole discretion, impose limitations on the transferability of options and SARs. Unless our board of directors provides otherwise, an option or SAR will not be transferable except by will or the laws of descent and distribution and will be exercisable during the lifetime of a participant only by such participant. Our board of directors may permit transfer of an option or SAR in a manner not prohibited by applicable law. Subject to approval by our board of directors, an option or SAR may be transferred pursuant to the terms of a domestic relations order or similar instrument or pursuant to a beneficiary designation.

Termination of Service. Except as otherwise provided in an applicable award document or other agreement between us or any affiliate and a participant, upon a termination for any reason other than for cause or due to death or disability, a participant may exercise his or her option or SAR (to the extent such award was exercisable as of the date of termination) for a period of three months following the termination date or, if earlier, until the expiration of the term of such award. Upon a termination due to a participant's disability, unless otherwise provided in an applicable award or other agreement, the participant may exercise his or her option or SAR (to the extent that such award was exercisable as of the date of termination) for a period of twelve months following the termination date or, if earlier, until the expiration of the term of such award. Upon a termination due to a participant's death, unless otherwise provided in an applicable award or other agreement, the participant's estate may exercise the option or SAR (to the extent such award was exercisable as of the termination date) for a period of eighteen months following the termination date or, if earlier, until the expiration of the term of such award. Unless provided otherwise in an award or other agreement, an option or SAR will terminate on the date that a participant is terminated for cause and the participant will not be permitted to exercise such award.

Awards Other Than Options and SARs.

Restricted Stock and Restricted Stock Units. Restricted shares are awards of shares, the grant, issuance, retention, vesting and/or transferability of which is subject during specified periods of time to such conditions (including continued employment) and terms as our board of directors deems appropriate. Restricted stock units ("RSUs") are an award denominated in units under which the issuance of shares (or cash payment in lieu thereof) is subject to such conditions (including continued employment) and terms as our board of directors deems appropriate. Each award document evidencing a grant of restricted stock or RSUs will set forth the terms and conditions of each award, including vesting and forfeiture provisions, transferability and, if applicable, right to receive dividends or dividend equivalents.

Performance Awards. A performance award is a stock or cash award that is payable contingent upon the attainment during a performance period of certain performance goals. A performance award may, but need not, require the completion of a specified period of service. The length of any performance period, the applicable performance goals and the measurement of whether and to what degree such performance goals have been attained will be as determined by the compensation committee, our board of directors or an authorized officer. We retain the discretion to reduce or eliminate the compensation or economic benefit upon the attainment of any performance goals and to define the manner of calculating the performance criteria it selects to use for a performance period.

Certain Adjustments. In the event of any change in our capitalization, our board of directors will appropriately and proportionately adjust: (i) the class(es) and maximum number of securities subject to the 2019 Plan; (ii) the class(es) and maximum number of securities that may be issued pursuant to the exercise of incentive stock options; and (iii) the class(es) and number of securities or other property and value (including price per share of stock) subject to outstanding stock awards. Our board of directors will make such adjustments, and its determination will be final, binding and conclusive. Unless provided otherwise in an award or other agreement, in the event of our dissolution or liquidation, all outstanding stock awards (other than stock awards consisting of

vested and outstanding shares of our common stock not subject to a forfeiture condition or the our right of repurchase) will terminate immediately prior to the completion of such dissolution or liquidation, and the shares of common stock subject to the our repurchase rights or subject to forfeiture may be repurchased or reacquired by us notwithstanding the fact that the holder of such stock award is providing continuous service; provided, however, that our board of directors may, in its sole discretion, provide that some or all stock awards will become fully vested, exercisable and/or no longer subject to repurchase or forfeiture (to the extent not already expired or terminated) before the dissolution or liquidation is completed but contingent upon its completion.

Change in Control. Unless provided otherwise in an award agreement or other agreement between us or an affiliate and the participant, in the event of Change in Control (as defined in the 2019 Plan), our board of directors will take one or more of the following actions with respect to each outstanding award, contingent upon the closing or completion of the Change in Control:

(i) arrange for the surviving corporation or acquiring corporation (or the surviving or acquiring corporation's parent company) to assume or continue the award or to substitute a similar stock award for the award (including, but not limited to, an award to acquire the same consideration per share paid to the stockholders of the company pursuant to the Change in Control);

(ii) arrange for the assignment of any reacquisition or repurchase rights held by us in respect of common stock issued pursuant to the award to the surviving corporation or acquiring corporation (or the surviving or acquiring corporation's parent company);

(iii) accelerate the vesting, in whole or in part, of the award (and, if applicable, the time at which the award may be exercised) to a date prior to the effective time of such Change in Control as determined by our board of directors, with such award terminating if not exercised (if applicable) at or prior to the effective time of the Change in Control, and with such exercise reversed if the Change in Control does not become effective;

(iv) arrange for the lapse, in whole or in part, of any reacquisition or repurchase rights held by us with respect to the award;

(v) cancel or arrange for the cancellation of the award, to the extent not vested or not exercised prior to the effective time of the Change in Control, in exchange for such cash consideration, if any, as our board of directors, in its reasonable determination, may consider appropriate as an approximation of the value of the canceled award; and

(vi) cancel or arrange for the cancellation of the award, to the extent not vested or not exercised prior to the effective time of the Change in Control, in exchange for a payment equal to the excess, if any, of (A) the value in the Change in Control of the property the participant would have received upon the exercise of the award immediately prior to the effective time of the Change in Control, over (B) any exercise price payable by such holder in connection with such exercise.

Our board of directors need not take the same action or actions with respect to all awards or portions thereof or with respect to all participants and may take different actions with respect to the vested and unvested portions of an award.

In the absence of any affirmative determination by our board of directors at the time of a Change in Control, each outstanding award will be assumed or an equivalent award will be substituted by such successor corporation or a parent or subsidiary of such successor corporation, referred to as a Successor Corporation, unless the Successor Corporation does not agree to assume the award or to substitute an equivalent award, in which case the vesting of such award will accelerate in its entirety (along with, if applicable, the time at which the award may be exercised) to a date prior to the effective time of such Change in Control as our board of directors will determine (or, if our board of directors does not determine such a date, to the date that is five days prior to the

effective date of the Change in Control), with such award terminating if not exercised (if applicable) at or prior to the effective time of the Change in Control, and with such exercise reversed if the Change in Control does not become effective.

Acceleration of Awards upon a Change in Control. An award may be subject to additional acceleration of vesting and exercisability upon or after a Change in Control as may be provided in the award agreement for such award or as may be provided in any other written agreement between us or an affiliate and the participant, but in the absence of such provision, no such acceleration will occur.

Termination and Amendment. Our board of directors or the compensation committee may suspend or terminate the 2019 Plan at any time. No incentive stock options may be granted under the 2019 Plan after the tenth anniversary of the date our board of directors adopted the 2019 Plan. No awards may be granted under the 2019 Plan while the 2019 Plan is suspended or after it is terminated.

2019 Employee Stock Purchase Plan

In October 2019, our board of directors adopted and our stockholders approved our 2019 Employee Stock Purchase Plan in order to enable eligible employees to purchase shares of our common stock at a discount following the date of this offering. Purchases will be accomplished through participation in discrete offering periods. Our 2019 Employee Stock Purchase Plan, excluding any sub-plans thereunder, is intended to qualify as an employee stock purchase plan under Section 423 of the Code. We have initially reserved a number of shares of our common stock for issuance under our 2019 Employee Stock Purchase Plan equal to 225,188 shares. The number of shares of common stock reserved for issuance under our 2019 Employee Stock Purchase Plan will increase automatically on January 1 of each year, for ten years, by 1% of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year. However, our board of directors may reduce the amount of the increase in any particular year at their discretion, including a reduction to zero. The maximum number of shares that may be issued to any employee in a given offering period will be 1,666 shares of common stock; provided, however, that the administrator of the 2019 Employee Stock Purchase Plan may change this limitation at any time on a prospective basis to apply to future offering periods.

Our compensation committee will administer our 2019 Employee Stock Purchase Plan. All of our employees who work 20 or more hours per week or for five more months per year that are employed at the beginning of an enrollment period are generally eligible to participate in our 2019 Employee Stock Purchase Plan. Employees who are 5% stockholders, or would become 5% stockholders as a result of their participation in our 2019 Employee Stock Purchase Plan, cannot participate in our 2019 Employee Stock Purchase Plan. Under our 2019 Employee Stock Purchase Plan, eligible employees will be able to acquire shares of our common stock by accumulating funds through payroll deductions. Our eligible employees will be able to select a rate of payroll deduction between 1% and 15% of their eligible compensation. We will also have the right to amend or terminate our 2019 Employee Stock Purchase Plan at any time. Our 2019 Employee Stock Purchase Plan will continue until terminated in accordance with the provisions therein.

For each offering period, new participants will be required to enroll in a timely manner. Once an employee is enrolled, participation will be automatic in subsequent purchase periods. No offering period can run for more than 27 months. An employee's participation automatically ends upon termination of employment for any reason, unless provided otherwise by the compensation committee in the event of a termination occurring within 30 days prior to the end of an offering period.

In addition to the share limit for each offering period, no participant will have the right to purchase shares of our common stock in an amount, when aggregated with purchase rights under all our employee stock purchase plans that are also in effect in the same calendar year, that has a fair market value of more than $25,000, determined as of the first day of the applicable purchase period, for each calendar year in which that right is

outstanding. The purchase price for shares of our common stock purchased under our 2019 Employee Stock Purchase Plan will be not less than 85% of the lesser of the fair market value of our common stock on (i) the first trading day of the applicable offering period and (ii) the last trading day of each purchase period in the applicable offering period.

If we experience any change in our capitalization without receipt of consideration by the Company, the type and number of securities covered by each outstanding purchase right and the number of authorized shares under the 2019 Employee Stock Purchase Plan will be appropriately and proportionately adjusted by our board of directors.

If we experience a proposed liquidation or dissolution, any offering period will terminate immediately prior to the consummation of such transaction and all outstanding purchase rights will automatically terminate and the amounts of all payroll deductions will be refunded without interest to the participants. In the event of a proposed sale of all or substantially all of our assets, or our merger or consolidation or similar combination of the Company with or into another entity, then in the sole discretion of our board of directors, (1) each purchase right will be assumed or an equivalent right substituted by the successor corporation or parent or subsidiary of such successor entity, (2) on a date established by our board of directors on or before the date of consummation of such merger, consolidation, combination or sale, such date will be treated as a purchase date, and all outstanding purchase rights will be exercised on such date, (3) all outstanding purchase rights will terminate and the accumulated payroll deductions will be refunded without interest to the participants, or (4) outstanding purchase rights will continue unchanged.

The compensation committee may adopt rules or procedures relating to the operation and administration of our 2019 Employee Stock Purchase Plan to accommodate specific requirements of local laws and jurisdictions and, if necessary, can establish sub-plans for particular foreign jurisdictions.

Our board of directors or compensation committee may terminate or suspend our 2019 Employee Stock Purchase Plan at any time and may revise or amend the plan in any respect, subject to required stockholder approval.

401(k) Plan

The Company offers eligible employees, including its NEO based in the United States, the opportunity to participate in its tax-qualified 401(k) plan. Employees can contribute 1%-100% of their eligible earnings up to the Internal Revenue Service's annual limits on a before-tax basis. For every dollar an employee contributes up to 6% of their compensation, the Company may contribute 25 cents per dollar, provided that there are no matching contributions in excess of 1.5% of eligible IRS compensation. The Company match provided to our Chief Executive Officer in 2018 is reflected in the "All Other Compensation" column of the 2018 Summary Compensation Table above. The Company funds are 100% vested after the completion of one year of service.

Other Retirement Benefits

We do not maintain any defined benefit pension plans or any nonqualified deferred compensation plans.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following is a summary of each transaction or series of similar transactions since January 18, 2018, our inception, or any currently proposed transaction, to which we were or are a party in which:

- the amount involved exceeded or exceeds $120,000 or one percent of our total assets at December 31, 2018; and
- any of our directors or executive officers or any beneficial owners of 5% of any class of our voting capital stock or and affiliate or immediate family member thereof, had or will have a direct or indirect material interest, other than compensation and other arrangements that are described under the section titled “Executive Compensation” or that were approved by our compensation committee.

Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to such securities.

Related Party Transactions

Sales of Securities

In April 2018, with subsequent closings in December 2018 and June and July 2019, we issued an aggregate of 44,000,000 shares of our Series A convertible preferred shares at a purchase price of $1.00 per share pursuant to a share purchase agreement entered into with investors, for an aggregate purchase price of approximately $44.0 million. Each share of our Series A convertible preferred shares will automatically convert into 0.161 shares of our common stock immediately prior to the completion of this offering. Additionally, in April 2018, we issued 610,865 shares of our ordinary shares to OrbiMed Israel Partners II, L.P. and OrbiMed Private Investments VI, L.P., for total proceeds of $10,994. All purchasers of our convertible preferred shares are entitled to specified registration rights. See “Description of Capital Stock—Registration Rights” for more information regarding these registration rights. The following table summarizes purchases of our Series A convertible preferred shares by related persons:

Participant	Shares of Series A Convertible Preferred Shares	Total Purchase Price
Entities affiliated with OrbiMed(1)	15,888,888	$ 15,888,888
Entities affiliated with Pontifax(2)	5,500,001	$ 5,500,001
Entities affiliated with RA Capital(3)	10,327,777	$ 10,327,777
Longitude Venture Partners III, L.P.(4)	11,916,667	$ 11,916,667
Genworks 2 Consulting Inc.(5)	366,667	$ 366,667

(1) OrbiMed Israel Partners II, L.P. (“OrbiMed Israel”) together with its affiliate fund OrbiMed Private Investments VI, L.P. is a holder of 5% or more of our capital stock. Anat Naschitz is a managing director at OrbiMed Israel and a member of our board of directors.
(2) Pontifax (Israel) V L.P., together with its affiliate funds Pontifax (Cayman) V L.P. and Pontifax (China) V L.P., is a holder of 5% or more of our capital stock. Tomer Kariv is co-founder and managing partner of the Pontifax Group and a member of our board of directors.
(3) RA Capital Healthcare Fund, L.P. together with its affiliate funds Blackwell Partners LLC - Series A and RA Capital Nexus Fund, L.P. is a holder of 5% or more of our capital stock. Derek DiRocco is a principal at RA Capital Management, LLC and a member of our board of directors.
(4) Longitude Venture Partners III, L.P. is a holder of 5% or more of our capital stock. Gregory Grunberg, M.D. is a Managing Director at Longitude Capital Management Co., LLC and a member of our board of directors.
(5) Dr. Michael Hayden, a member of our board of directors, is affiliated with Genworks 2 Consulting Inc.

Investors' Rights Agreement

We are a party to an investors' rights agreement, effective as of September 17, 2019 (the "IRA"), with the holders of our Series A convertible preferred shares, including our 5% stockholders and entities affiliated with our directors. The IRA provides these holders the right, following the completion of this offering, to demand that we file a registration statement or request that their shares be covered by a registration statement that we are otherwise filing. See "Description of Capital Stock—Registration Rights" for additional information regarding these registration rights. The IRA also provides such holders a right of first offer to purchase future securities sold by us, which such right shall terminate immediately prior to the consummation of this offering and do not apply to the shares of common stock issued pursuant to this registration statement. See "Description of Capital Stock—Registration Rights" for additional information regarding these registration rights.

Voting Agreement

We are party to a voting agreement, effective as of September 17, 2019 (the "Voting Agreement"), with the holders of our Series A convertible preferred shares, including our 5% stockholders and entities affiliated with our directors. Each of our 5% stockholders have appointed representatives to our board of directors. The voting agreement will terminate upon the completion of this offering, and members previously elected to our board of directors pursuant to this agreement will continue to serve as directors until they resign, are removed or their successors are duly elected by the holders of our common stock. The composition of our board of directors after this offering is described in more detail under "Management—Composition of Our Board of Directors."

Right of First Refusal and Co-Sale Agreement

We are a party to a right of first refusal and co-sale agreement, effective as of September 17, 2019 (the "ROFR Agreement"), with the holders of our Series A convertible preferred shares, including our 5% stockholders and entities affiliated with our directors. The ROFR Agreement will terminate upon completion of this offering.

Employment Agreements

We have entered into employment agreements with our named executive officers. For more information regarding the agreements with our named executive officers, see "Executive Compensation—Employment Agreements."

Director Compensation

See "Director Compensation" for information regarding compensation of our directors.

Indemnification Agreements

In connection with this offering, we entered into agreements to indemnify our directors and executive officers. These agreements will, among other things, require us to indemnify these individuals for certain expenses (including attorneys' fees), judgments, fines and settlement amounts reasonably incurred by such person in any action or proceeding, including any action by or in our right, on account of any services undertaken by such person on behalf of our company or that person's status as a member of our board of directors to the maximum extent allowed under Delaware law.

Stock Option Grants to Executive Officers and Directors

We have granted stock options to our executive officers and certain of our directors as more fully described in the sections entitled "Executive Compensation" and "Management—Director Compensation."

Indications of Interest to Participate in this Offering

Our existing stockholders affiliated with our directors have indicated an interest in purchasing an aggregate of up to approximately $40 million of shares of our common stock in this offering at the initial public offering price per share and on the same terms as the other purchasers in this offering. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, fewer or no shares of common stock to any of these potential purchasers, and any of these potential purchasers could determine to purchase more, fewer or no shares of common stock in this offering.

PRINCIPAL STOCKHOLDERS

The following table presents information regarding beneficial ownership of our equity interests as of October 28, 2019 by:

- each stockholder or group of stockholders known by us to be the beneficial owner of more than 5% of our outstanding equity interests (our "5% and Greater Stockholders");
- each of our directors;
- our NEOs; and
- all of our directors and executive officers as a group.

Beneficial ownership is determined in accordance with the rules of the SEC, and thus represents voting or investment power with respect to our securities as of October 28, 2019. Under such rules, beneficial ownership includes any shares over which the individual has sole or shared voting power or investment power as well as any shares that the individual has the right to acquire within 60 days after October 28 knowledge and subject to applicable community property rules, the persons and entities named in the table have sole voting and sole investment power with respect to all equity interests beneficially owned. Unless otherwise indicated, the address of each individual listed in this table is 535 Mission Street, 14th Floor, San Francisco, CA 94105.

The percentage ownership information shown in the column titled "Shares Beneficially Owned Prior to the Offering" in the table below is based on 7,688,592 shares of our common stock outstanding as of October 28, 2019, which includes 7,077,366 shares of our common stock resulting from the conversion of all outstanding shares of our convertible preferred stock into our common stock immediately prior to the completion of this offering, as if this conversion had occurred as of October 28, 2019. The percentage ownership information shown in the column titled "Shares Beneficially Owned After the Offering" in the table below is based on 12,063,592 shares of our common stock outstanding after this offering, assuming 4,375,000 shares of common stock being sold in this offering. Shares of our common stock that a person has the right to acquire within 60 days after September 30, 2019 are deemed outstanding for purposes of computing the percentage ownership of the person holding such rights, but are not deemed outstanding for purposes of computing the percentage ownership of any other person, except with respect to the percentage ownership of all directors and executive officers as a group.

Our existing stockholders affiliated with our directors have indicated an interest in purchasing an aggregate of up to approximately $40.0 million of shares of our common stock in this offering at the initial public offering price per share and on the same terms as the other purchasers in this offering. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, fewer or no shares of common stock to any of these potential purchasers, and any of these potential

purchasers could determine to purchase more, fewer or no shares of common stock in this offering. The following table does not reflect the purchase of any shares in this offering by these existing stockholders.

Name and Address of Beneficial Owner	Shares Beneficially Owned	Percentage of Shares Beneficially Owned	
		Before the Offering	After the Offering
5% and Greater Stockholders			
Entities affiliated with OrbiMed(1)	3,166,942	41.2%	26.3%
Longitude Venture Partners III, L.P.(2)	1,916,787	24.9%	15.9%
Entitles affiliated with RA Capital(3)	1,661,214	21.6%	13.8%
Entities affiliated with Pontifax(4)	884,671	11.5%	7.3%
Named Executive Officers and Directors			
Rohan Palekar(5)	101,634	1.3%	*
Ram Waisbourd(6)	45,865	*	*
Derek DiRocco	—	*	*
Gregory Grunberg(2)	1,916,787	24.9%	15.9%
Michael Hayden(7)	95,670	1.2%	*
Tomer Kariv(4)	884,671	11.5%	7.3%
Anat Naschitz	—	*	*
All Executive Officers and Directors as a group (10 persons)	3,069,178	39.9%	25.4%

* Represents beneficial ownership of less than one percent.

(1) Consists of (a) 305,613 shares of common stock owned by OrbiMed Israel Partners II, L.P., (b) 305,613 shares of common stock owned by OrbiMed Private Investments VI, L.P., (c) 1,277,858 shares of common stock issuable upon the conversion of shares of convertible preferred stock owned by OrbiMed Israel Partners II, L.P., and (d) 1,277,858 shares of common stock issuable upon the conversion of shares of convertible preferred stock owned by OrbiMed Private Investments VI, L.P. The business address of OrbiMed Israel Partners II, L.P. ("OIP II") is 89 Medinat Hayehudim St., building E, Herzliya 4614001 Israel. OrbiMed Israel GP II, L.P. ("Israel GP II") is the general partner of OIP II, and OrbiMed Advisors Israel II Limited ("Advisors Israel II") is the general partner of Israel GP II. Advisors Israel II and Israel GP II may be deemed to have shared voting and investment power over all of the shares of common and convertible preferred stock held by OIP II, and both Advisors Israel II and Israel GP II may be deemed to directly or indirectly, including by reason of their mutual affiliation, to be the beneficial owners of the shares held by OIP II. Advisors Israel II exercises this investment power through an investment committee comprised of Carl L. Gordon, Jonathan T. Silverstein, Nissim Darvish, Anat Naschitz, and Erez Chimovits, each of whom disclaims beneficial ownership of the shares held by OIP II.

(2) Consists of 1,916,787 shares of common stock issuable upon the conversion of shares of convertible preferred stock. Longitude Capital Partners III, LLC ("LCP III") is the general partner of Longitude Venture Partners III, L.P. ("LVP III") and may be deemed to have shared voting, investment and dispositive power over the shares held by LVP III. Patrick G. Enright and Juliet Tammenoms Bakker are managing members of LCP III and in their capacity as such, may be deemed to exercise shared voting and investment power over the shares held by LCP III and LVP III. Gregory Grunberg is a member of LCP III. Each of these individuals disclaims beneficial ownership of such shares except to the extent of his or her pecuniary interest therein. Gregory Grunberg shares in the control of the Company securities held directly or indirectly by LVP III/LCP III due to (a) his beneficial ownership in the Company's shares and (b) his position as a director of the Company. The mailing address of Longitude Venture Partners III, L.P. is 2740 Sand Hill Road, 2nd Floor, Menlo Park, CA 94025.

(3) Consists of (a) 1,185,315 shares of common stock issuable upon the conversion of shares of convertible preferred stock owned by RA Capital Healthcare Fund, L.P., or RA Capital Fund, (b) 287,125 shares of common stock issuable upon the conversion of shares of convertible preferred stock owned by a separately managed account (the "Account"), and (c) 188,774 shares of common stock issuable upon the conversion of shares of convertible preferred stock owned by RA Capital Nexus Fund, L.P. (the "RA Capital Nexus Fund"). Dr. Peter Kolchinsky is the managing member of RA Capital Management, LLC ("RA Capital"), the general partner and investment advisor of RA Capital Fund and the investment advisor of the Account and RA Capital Nexus Fund. Dr. Kolchinsky and RA Capital may be deemed to beneficially own the shares held by RA Capital Fund, the Account and RA Capital Nexus Fund. Dr. Kolchinsky and RA Capital disclaim beneficial ownership of all applicable shares except to the extent of their actual pecuniary interest therein. The mailing address for the entities listed above is 200 Berkeley Street, 18th Floor, Boston, MA 02116.

(4) Consists of (a) 534,342 shares of common stock issuable upon the conversion of shares of convertible preferred stock owned by Pontifax (Israel) V, L.P., (b) 142,726 shares of common stock issuable upon the conversion of shares of convertible preferred stock owned by Pontifax (Cayman) V, L.P., and (c) 207,603 shares of common stock issuable upon the conversion of shares of convertible preferred stock owned by Pontifax (China) V, L.P. (together, the "Pontifax Entities") Pontifax 5 G.P. L.P., or Pontifax 5 G.P., is the general partner of each of the Pontifax Entities, and Pontifax Management 4 G.P. (2015) Ltd., or Pontifax Management, is the general partner of Pontifax 5 G.P. Mr. Tomer Kariv, a member of our board of directors, and Mr. Ran Nussbaum, are the Managing Partners of Pontifax

Management and, as a result, may be deemed to share voting and investment power with respect to the shares held by each of the Pontifax Entities. In that context, Mr. Kariv disclaims beneficial ownership of such shares, except to the extent of his pecuniary interest therein, and the inclusion of the shares in this report shall not be deemed to be an admission of beneficial ownership of the reported shares for purposes of Section 16 of the Securities Exchange Act of 1934, as amended, or otherwise. The address of each of the Pontifax Entities is c/o The Pontifax Group, 14 Shenkar Street, Herzelia, Israel.

(5) Consists of 101,634 shares of common stock underlying options that are exercisable as of October 28, 2019 or will become exercisable within 60 days after such date.

(6) Consists of 45,865 shares of common stock underlying options that are exercisable as of October 28, 2019 or will become exercisable within 60 days after such date.

(7) Consists of (a) 58,978 shares of common stock issuable upon the conversion of shares of convertible preferred stock owned by Genworks 2 Consulting Inc., over which Dr. Hayden's wife has sole voting and investment power, and (b) 36,692 shares of common stock underlying options that are exercisable as of October 28, 2019 or will become exercisable within 60 days after such date. The address of Genworks 2 Consulting Inc. is 4484 West 7th Avenue, Vancouver, BC, Canada V6R1W9.

DESCRIPTION OF CAPITAL STOCK

General

The following is a summary of the material terms of our capital stock, as well as other material terms of our Amended Certificate and Amended Bylaws, as each will be in effect prior to the closing of this offering, and certain provisions of Delaware law. This summary does not purport to be complete and is qualified in its entirety by the provisions of our Amended Certificate and Amended Bylaws, copies of which will be filed with the SEC as exhibits to the registration statement, of which this prospectus forms a part.

Upon the completion of this offering, our authorized capital stock will consist of 100,000,000 shares of common stock, $0.001 par value per share, and 10,000,000 shares of preferred stock, $0.001 par value per share.

As of October 28, 2019, 611,226 shares of our common stock and 44,000,000 shares of convertible preferred stock were outstanding and held by 10 stockholders of record. This amount does not take into account the conversion of all outstanding shares of our convertible preferred stock into common stock upon the completion of this offering.

Common Stock

Our Amended Certificate will authorize the issuance of up to 100,000,000 shares of our common stock. All outstanding shares of our common stock are validly issued, fully paid and nonassessable, and the shares of our common stock to be issued in connection with this offering will be validly issued, fully paid and nonassessable.

The holders of our common stock will be entitled to one vote per share on all matters submitted to a vote of stockholders, and our Amended Certificate will not provide for cumulative voting in the election of directors. The holders of our common stock will receive ratably any dividends declared by our board of directors out of funds legally available therefor. In the event of our liquidation, dissolution or winding-up, the holders of our common stock will be entitled to share ratably in all assets remaining after payment of or provision for any liabilities.

Preferred Stock

As of October 28, 2019, there were 44,000,000 shares of our preferred stock outstanding, which will convert into 7,077,366 shares of our common stock upon the closing of this offering such that we will have no shares of preferred stock outstanding. Under the terms of our Amended Certificate, upon the consummation of this offering, our board of directors will have the authority, without further action by our stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the dividend, voting and other rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon, and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding.

Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of our common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in our control and may adversely affect the market price of our common stock and the voting and other rights of the holders of our common stock. We have no current plans to issue any shares of preferred stock.

Registration Rights

Upon the completion of this offering, the holders of 7,077,366 shares of our common stock, including those issuable upon the conversion of convertible preferred stock will be entitled to rights with respect to the registration of these securities under the Securities Act. These rights are provided under the terms of the IRA. The IRA includes demand registration rights, short-form registration rights and piggyback registration rights. All fees, costs and expenses of underwritten registrations under this agreement will be borne by us and all selling expenses, including underwriting discounts and selling commissions, will be borne by the holders of the shares being registered.

Demand Registration Rights

Beginning 180 days after the effective date of this registration statement, the holders of 7,077,366 shares of our common stock, including those issuable upon the conversion of convertible preferred stock upon completion of this offering, are entitled to demand registration rights. Under the terms of the IRA, we will be required, upon the written request of at least 50% of the holders of the registrable securities, including either OrbiMed Israel Partners II, L.P. or OrbiMed Private Investments VI, LP, provided that the anticipated aggregate offering price is at least $10 million, to file a registration statement on Form S-1 and use commercially reasonable efforts to effect the registration of these shares for public resale. The right to have such shares registered on Form S-1 is further subject to other specified conditions and limitations.

Piggyback Registration Rights

Pursuant to the IRA, if we register any of our common stock either for our own account or for the account of other security holders, the holders of Registrable Shares party to the IRA are entitled to include their shares in the registration, subject to certain marketing and other limitations. We may terminate or withdraw any registration initiated before the effective date of such registration in our sole discretion.

Form S-3 Registration Rights

Pursuant to the IRA, if we are eligible to file a registration statement on Form S-3, upon the written request of at least 10% of the holders of registrable securities to sell registrable securities at an aggregate price of at least $5 million, we will be required to use commercially reasonable efforts to effect a registration of such shares. The right to have such shares registered on Form S-3 is further subject to other specified conditions and limitations.

Anti-Takeover Effects of Our Amended Certificate, Amended Bylaws and Delaware Law

Our Amended Certificate and our Amended Bylaws, both to become effective upon the completion of this offering, include a number of provisions that may have the effect of delaying, deferring or preventing another party from acquiring control of us and encouraging persons considering unsolicited tender offers or other unilateral takeover proposals to negotiate with our board of directors rather than pursue non-negotiated takeover attempts.

- ***Issuance of undesignated preferred stock:*** Under our Amended Certificate, our board of directors has the authority, without further action by the stockholders, to issue up to 10,000,000 shares of undesignated preferred stock with rights and preferences, including voting rights, designated from time to time by our board of directors. The existence of authorized but unissued shares of preferred stock enables our board of directors to make it more difficult to attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise.

- ***Classified board*****:** Our Amended Certificate establishes a classified board of directors consisting of three classes of directors, with staggered three-year terms. Only one class of directors will be

elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms. This provision may have the effect of delaying a change in control of our board of directors.

- ***Election and removal of directors and board vacancies*:** Our Amended Bylaws provide that directors will be elected by a plurality vote. Our Amended Certificate and Amended Bylaws also provide that our board of directors has the right to increase or decrease the size of the board and to fill vacancies on the board. Directors may be removed only for cause by the affirmative vote of the holders of at least 66⅔% of the votes that all our stockholders would be entitled to cast in an annual election of directors. Only our board of directors is authorized to fill vacant directorships. In addition the number of directors constituting our board of directors may be set only by resolution adopted by a majority vote of the directors then in office. These provisions prevent stockholders from increasing the size of our board of directors and gaining control of our board of directors by filling the resulting vacancies with its own nominees.

- ***Requirements for advance notification of stockholder nominations and proposals*:** Our Amended Bylaws establish advance notice procedures with respect to stockholder proposals and the nomination of candidates for election as directors that specify certain requirements as to the timing, form and content of a stockholder's notice. Business that may be conducted at an annual meeting of stockholders will be limited to those matters properly brought before the meeting. These provisions may make it more difficult for our stockholders to bring matters before our annual meeting of stockholders or to nominate directors at annual meetings of stockholders.

- ***No written consent of stockholders*:** Our Amended Certificate provides that all stockholder actions be taken by a vote of the stockholders at an annual or special meeting, and that stockholders may not take any action by written consent in lieu of a meeting. This limit may lengthen the amount of time required to take stockholder actions and would prevent the amendment of our Amended Bylaws or removal of directors by our stockholders without holding a meeting of stockholders.

- ***No stockholder ability to call special meetings*:** Our Amended Certificate and Amended Bylaws provide that only a majority of the members of our board of directors then in office may be able to call special meetings of stockholders and only those matters set forth in the notice of the special meeting may be considered or acted upon at a special meeting of stockholders.

- ***Amendments to certificate of incorporation and bylaws:*** Any amendment to our Amended Certificate will be required to be approved by a majority of our board of directors as well as, if required by law or the Amended Certificate, a majority of the outstanding shares entitled to vote on the amendment and a majority of the outstanding shares of each class entitled to vote thereon as a class, except that the amendment of provisions to board classification, stockholder action, certificate amendments, and liability of directors must be approved by not less than 66⅔% of the outstanding shares entitled to vote on the amendment, voting together as a single class. Any amendment to our Amended Bylaws must be approved by either a majority of our board of directors or not less than 66⅔% of the outstanding shares entitled to vote on the amendment, voting together as a single class.

These provisions are designed to enhance the likelihood of continued stability in the composition of our board of directors and its policies, to discourage certain types of transactions that may involve an actual or threatened acquisition of us and to reduce our vulnerability to an unsolicited acquisition proposal. We also designed these provisions to discourage certain tactics that may be used in proxy fights. However, these provisions could have the effect of discouraging others from making tender offers for our shares and, as a consequence, they may also reduce fluctuations in the market price of our shares that could result from actual or rumored takeover attempts.

Section 203 of the Delaware General Corporation Law

Upon completion of this offering, we will be subject to the provisions of Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a three-year period following the time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner.

Choice of Forum

Our Amended Certificate requires that the Court of Chancery of the State of Delaware be the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (1) any derivative action or proceeding brought on our behalf; (2) any action asserting a breach of fiduciary duty owed by any director, officer or other employee to us or our stockholders; (3) any action asserting a claim against us or any director or officer or other employee arising pursuant to the Delaware General Corporation Law, our Amended Certificate or Amended Bylaws; or (4) any action asserting a claim against us or any director or officer or other employee that is governed by the internal affairs doctrine. This provision would not apply to claims brought to enforce a duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Our Amended Certificate provides further that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, subject to and contingent upon a final adjudication in the State of Delaware of the enforceability of such exclusive forum provision. Although we believe these provisions benefit us by providing increased consistency in the application of Delaware law for the specified types of actions and proceedings, the provisions may have the effect of discouraging lawsuits against us or our directors or officers.

Transfer Agent and Registrar

American Stock Transfer and Trust Company, LLC will serve as the transfer agent and registrar for our common stock.

Listing

We have applied to list our common stock on The Nasdaq Global Market under the symbol "ETNB."

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for shares of our common stock. Future sales of our common stock, including shares issued upon the vesting of restricted stock units or the exercise of options or warrants, in the public market after this offering, or the perception that those sales may occur, could cause the prevailing market price for our common stock to fall or impair our ability to raise equity capital in the future. As described below, only a limited number of shares of our common stock will be available for sale in the public market for a period of several months after the completion of this offering due to the contractual and legal restrictions on resale described below. Future sales of our common stock in the public market either before (to the extent permitted) or after restrictions lapse, or the perception that those sales may occur, could adversely affect the prevailing market price of our common stock at such time and our ability to raise equity capital at a time and price we deem appropriate.

Sale of Restricted Shares

Immediately following the completion of this offering, we will have an aggregate of 12,063,592 shares of common stock outstanding. Of the outstanding shares of our common stock, the 4,375,000 shares sold in this offering (or 5,031,250 shares if the underwriters exercise in full their option to purchase additional shares) will be freely tradable without restriction or further registration under the Securities Act, except that any shares held by our affiliates, as that term is defined in Rule 144 of the Securities Act, may generally be sold only in compliance with the limitations described below. All remaining shares of our common stock held by existing stockholders immediately prior to the closing of this offering will be "restricted securities" as such term is defined in Rule 144. These restricted securities were issued and sold by us, or will be issued and sold by us, in private transactions and are eligible for public sale only if registered under the Securities Act or if they qualify for an exemption from registration under the Securities Act, including the exemptions provided by Rule 144 or Rule 701, which rules are summarized below.

Lock-Up Agreements

We and all of our directors and officers, as well as the other holders of substantially all shares of our common stock outstanding immediately prior to the completion of this offering, have agreed with the underwriters that, for a period of 180 days following the date of this prospectus, subject to certain exceptions, we and they will not, directly or indirectly, offer, sell, contract to sell, pledge, grant any option to purchase, make any short sale or otherwise dispose of any of shares of our common stock, or any options or warrants to purchase any shares of our common stock, or any securities convertible into, or exchangeable for or that represent the right to receive shares of our common stock. BofA Securities, Inc., SVB Leerink LLC and RBC Capital Markets, LLC may, in their discretion, release all or any portion of the shares from these restrictions.

Rule 144

In general, under Rule 144, as currently in effect, once we have been subject to the public company reporting requirements of the Exchange Act for at least 90 days, a person (or persons whose shares are required to be aggregated) who is not deemed to have been one of our "affiliates" for purposes of Rule 144 at any time during the three months preceding a sale, and who has beneficially owned restricted securities within the meaning of Rule 144 for at least 6 months, including the holding period of any prior owner other than one of our "affiliates," is entitled to sell those shares in the public market (subject to the lock-up agreement referred to above, if applicable) without complying with the manner of sale, volume limitations or notice provisions of Rule 144, but subject to compliance with the public information requirements of Rule 144. If such a person has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any prior owner other than affiliates, then such person is entitled to sell such shares in the public market without complying with any of the requirements of Rule 144 (subject to the lock-up agreement referred to above, if applicable). In general, under Rule 144, as currently in effect, once we have been subject to the public company

reporting requirements of the Exchange Act for at least 90 days, our affiliates, as defined in Rule 144, who have beneficially owned the shares proposed to be sold for at least 6 months are entitled to sell in the public market, upon expiration of any applicable lock-up agreements and within any three-month period, a number of those shares of our common stock that does not exceed the greater of:

- one percent of the number of shares of our common stock then outstanding, which will equal approximately 120,635 shares of our common stock immediately after this offering (calculated on the basis of the assumptions described above and assuming no exercise of the underwriter's option to purchase additional shares of our common stock); or

- the average weekly trading volume of our common stock on The Nasdaq Global Market during the 4 calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Such sales under Rule 144 by our "affiliates" or persons selling shares on behalf of our "affiliates" are also subject to certain manner of sale provisions, notice requirements and to the availability of current public information about us. Notwithstanding the availability of Rule 144, the holders of substantially all of our restricted securities have entered into lock-up agreements as referenced above and their restricted securities will become eligible for sale (subject to the above limitations under Rule 144) upon the expiration of the restrictions set forth in those agreements.

Upon expiration of the 180-day lock-up period described above, 7,688,592 shares of our common stock will be eligible for sale under Rule 144 (including shares issued pursuant to Rule 701 described below). We cannot estimate the timing or the number of shares that our existing stockholders and other equity holders may elect to sell under Rule 144 or pursuant to Form S-8 registration statements. See "Description of Capital Stock—Registration Rights."

Rule 701

In general, under Rule 701 as currently in effect, any of our employees, directors, officers, consultants or advisors who acquired common stock from us in connection with a written compensatory stock or option plan or other written agreement in compliance with Rule 701 under the Securities Act before the effective date of the registration statement of which this prospectus is a part (to the extent such common stock is not subject to a lock-up agreement) is entitled to rely on Rule 701 to resell such shares beginning 90 days after we become subject to the public company reporting requirements of the Exchange Act in reliance on Rule 144, but without compliance with the holding period requirements contained in Rule 144. Accordingly, subject to any applicable lock-up agreements, beginning 90 days after we become subject to the public company reporting requirements of the Exchange Act, under Rule 701, persons who are not our affiliates, as defined in Rule 144, may resell those shares without complying with the minimum holding period or public information requirements of Rule 144, and persons who are our affiliates may resell those shares without compliance with Rule 144's minimum holding period requirements (subject to the terms of the lock-up agreements referred to above, if applicable). In addition, after the effective date of this offering, we plan to register on a Form S-8 registration statement all shares of our common stock that we may issue under our equity compensation plans. As a result, these shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates.

Upon expiration of the 180-day lock-up period described above, 7,688,592 shares of our common stock will be eligible for sale under Rule 144 (including shares issued pursuant to Rule 701). We cannot estimate the timing or the number of shares that our existing stockholders and other equity holders may elect to sell under Rule 144 or pursuant to registration statements. For a description of certain registration rights granted, see "Description of Capital Stock—Registration Rights."

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS

The following discussion is a summary of material U.S. federal income tax consequences to Non-U.S. Holders (as defined below) of the purchase, ownership and disposition of our common stock issued pursuant to this offering. The discussion does not purport to be a complete analysis of all potential tax consequences. The consequences of other U.S. federal tax laws, such as estate and gift tax laws, and any applicable state, local or non-U.S. tax laws, are not discussed. This discussion is based on the U.S. Internal Revenue Code of 1986, as amended (the "Code"), Treasury Regulations promulgated under the Code, judicial decisions and published rulings and administrative pronouncements of the U.S. Internal Revenue Service (the "IRS"), in each case in effect as of the date hereof. These authorities may change or be subject to differing interpretations. Any such change or differing interpretation may be applied retroactively in a manner that could adversely affect a Non-U.S. Holder of our common stock. We have not sought and will not seek any rulings from the IRS regarding the matters discussed below. There can be no assurance the IRS or a court will not take a contrary position to that discussed below regarding the tax consequences of the purchase, ownership and disposition of our common stock.

This discussion is limited to Non-U.S. Holders that purchase our common stock pursuant to this offering and hold our common stock as a "capital asset" within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all U.S. federal income tax consequences relevant to a Non-U.S. Holder's particular circumstances, including without limitation the impact of the Medicare contribution tax on net investment income. In addition, it does not address consequences relevant to Non-U.S. Holders subject to special rules, including, without limitation:

- U.S. expatriates and former citizens or long-term residents of the United States;
- persons subject to the alternative minimum tax;
- persons holding our common stock as part of a hedge, straddle or other risk-reduction strategy or as part of a conversion transaction or other integrated investment;
- banks, investment funds, insurance companies and other financial institutions;
- brokers, dealers or traders in securities;
- "controlled foreign corporations," "passive foreign investment companies" and corporations that accumulate earnings to avoid U.S. federal income tax;
- partnerships or other entities or arrangements classified as partnerships for U.S. federal income tax purposes (and investors therein);
- tax-exempt organizations or governmental organizations;
- persons deemed to sell our common stock under the constructive sale provisions of the Code;
- persons required to accelerate the recognition of any item of gross income with respect to our common stock as a result of such income being recognized on an applicable financial statement;
- persons that own, or have owned, actually or constructively, more than 5% of our common stock;
- persons who hold or receive our common stock pursuant to the exercise of any employee stock option or otherwise as compensation; and
- tax-qualified retirement plans.

This discussion is for informational purposes only and is not tax advice. Investors should consult their tax advisors with respect to the application of the U.S. federal income tax laws to their particular situations as well as any tax consequences of the purchase, ownership and disposition of our common stock arising under the U.S. federal estate or gift tax laws or under the laws of any state, local or non-U.S. taxing jurisdiction or under any applicable income tax treaty.

Definition of a Non-U.S. Holder

For purposes of this discussion, a "Non-U.S. Holder" is any beneficial owner of our common stock that is not a "U.S. person." A "U.S. person" is any person that, for U.S. federal income tax purposes, is or is treated as any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation created or organized under the laws of the United States, any state thereof or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust that: (i) is subject to the primary supervision of a U.S. court and the control of one or more "United States persons" (within the meaning of Section 7701(a)(30) of the Code); or (ii) has a valid election in effect to be treated as a U.S. person for U.S. federal income tax purposes.

Distributions

If we make distributions of cash or other property on our common stock, those distributions will generally constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. If the amount of such distributions exceed our current and accumulated earnings and profits, such excess will generally constitute a tax-free return of capital and will first be applied against and reduce a Non-U.S. Holder's adjusted tax basis in its common stock, but not below zero. Any excess will be treated as capital gain and will be treated as described below under "Sale or Other Taxable Disposition."

Subject to the discussion below on effectively connected income, dividends paid to a Non-U.S. Holder of our common stock generally will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends (or such lower rate specified by an applicable income tax treaty, provided the Non-U.S. Holder furnishes the applicable withholding agent with documentation required to claim benefits under such tax treaty (generally, a valid IRS Form W-8BEN or W-8BEN-E or a suitable successor or substitute form)). This certification must be provided before the payment of dividends and must be updated periodically. A Non-U.S. Holder that does not timely furnish the required documentation, but that qualifies for a reduced treaty rate, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. Non-U.S. Holders should consult their tax advisors regarding U.S. federal withholding tax on distributions, including their eligibility for benefits under any applicable income tax treaties and the availability of a refund on any excess U.S. federal tax withheld.

If dividends paid to a Non-U.S. Holder are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (or, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment in the United States to which such dividends are attributable), the Non-U.S. Holder will generally be exempt from the U.S. federal withholding tax described above. To claim the exemption, the Non-U.S. Holder must furnish to the applicable withholding agent a valid IRS Form W-8ECI (or a suitable successor or substitute form) certifying that the dividends are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States.

However, any such effectively connected dividends will be subject to U.S. federal income tax on a net income basis at the regular graduated rates applicable to U.S. persons. A Non-U.S. Holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected dividends, as adjusted for certain items. Non-U.S. Holders should consult their tax advisors regarding any applicable tax treaties that may provide for different rules.

The foregoing discussion is subject to the discussion below under "Additional Withholding Tax on Payments Made to Foreign Accounts" and "Information Reporting and Backup Withholding."

Sale or Other Taxable Disposition

Subject to the discussion below regarding backup withholding and the Foreign Account Tax Compliance Act ("FATCA"), a Non-U.S. Holder generally will not be subject to U.S. federal income or withholding tax on any gain realized upon the sale or other taxable disposition of our common stock unless:

- the gain is effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (or, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment in the United States to which such gain is attributable);
- the Non-U.S. Holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the disposition and certain other requirements are met; or
- our common stock constitutes a U.S. real property interest ("USRPI") by reason of our status as a U.S. real property holding corporation ("USRPHC") for U.S. federal income tax purposes.

Gain described in the first bullet point above generally will be subject to U.S. federal income tax on a net income basis at the regular graduated rates applicable to U.S. persons. A Non-U.S. Holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected gain, as adjusted for certain items.

Gain described in the second bullet point above will be subject to U.S. federal income tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty), which may be offset by U.S. source capital losses of the Non-U.S. Holder (even though the individual is not considered a resident of the United States), provided the Non-U.S. Holder has timely filed U.S. federal income tax returns with respect to such losses.

With respect to the third bullet point above, we believe we currently are not, and we do not anticipate becoming, a USRPHC. However, because the determination of whether we are a USRPHC depends on the fair market value of our USRPIs relative to the fair market value of our non-U.S. real property interests and our other business assets, we cannot assure you that we will not become a USRPHC in the future. Even if we are or were to become a USRPHC, gain arising from the sale or other taxable disposition by a Non-U.S. Holder of our common stock will not be subject to U.S. federal income tax if our common stock is "regularly traded" on an "established securities market" (as such terms are defined by applicable Treasury Regulations), and such Non-U.S. Holder owned, actually and constructively, 5% or less of our common stock throughout the shorter of the 5-year period ending on the date of the sale or other taxable disposition or the Non-U.S. Holder's holding period. If we are determined to be a USRPHC and the foregoing exception does not apply, the Non-U.S. Holder generally will be taxed on its net gain derived from the disposition at the graduated U.S. federal income tax rates applicable to U.S. persons and, in addition, a purchaser of our common stock may be required to withhold tax with respect to that obligation. No assurance can be provided that our common stock will be regularly traded on an established securities market for purposes of the rules described above.

Non-U.S. Holders should consult their tax advisors regarding potentially applicable income tax treaties that may provide for different rules.

Information Reporting and Backup Withholding

Payments of dividends on our common stock generally will not be subject to backup withholding provided the applicable withholding agent does not have actual knowledge or reason to know the Non-U.S. Holder is a U.S. person and the Non-U.S. Holder certifies its non-U.S. status by furnishing a valid IRS Form W-8BEN, W-8BEN-E, W-8ECI, W-8EXP, or other applicable IRS form, or otherwise establishes an exemption. Information returns are required to be filed with the IRS in connection with any dividends on our common stock paid to the Non-U.S. Holder, regardless of whether any tax was actually withheld. Copies of these information returns may also be made available under the provisions of an applicable treaty or agreement to the tax authorities of the country in which the Non-U.S. Holder resides or is established.

Information reporting and, depending on the circumstances, backup withholding generally will apply to the proceeds of the sale or other taxable disposition of our common stock within the United States or conducted through certain U.S.-related brokers, unless the applicable withholding agent receives the certification described above and does not have actual knowledge or reason to know that the Non-U.S. Holder is a U.S. person, or the holder otherwise establishes an exemption. Proceeds of a disposition of our common stock conducted through a non-U.S. office of a non-U.S. broker that does not have certain enumerated relationships with the United States generally will not be subject to backup withholding or information reporting.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a Non-U.S. Holder's U.S. federal income tax liability, provided the required information is timely furnished to the IRS.

Additional Withholding Tax on Payments Made to Foreign Accounts

Withholding taxes may be imposed under Sections 1471 to 1474 of the Code (such Sections commonly referred to as FATCA) on certain types of payments made to non-U.S. financial institutions and certain other non-U.S. entities. Specifically, a 30% withholding tax may be imposed on dividends on, and subject to the discussion of certain proposed U.S. Treasury regulations below, the gross proceeds from the sale or other disposition of, our common stock paid to a "foreign financial institution" or a "non-financial foreign entity" (each as defined in the Code), unless: (i) the foreign financial institution undertakes certain diligence, reporting and withholding obligations; (ii) the non-financial foreign entity either certifies it does not have any "substantial U.S. owners" (as defined in the Code) or furnishes identifying information regarding each substantial U.S. owner; or (iii) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. If the payee is a foreign financial institution and is subject to the diligence, reporting and withholding requirements in (i) above, it must enter into an agreement with the U.S. Department of the Treasury requiring, among other things, that it undertake to identify accounts held by certain "specified U.S. persons" or "United States owned foreign entities" (each as defined in the Code), annually report certain information about such accounts, and withhold 30% on certain payments to noncompliant foreign financial institutions and certain other account holders. Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the United States governing FATCA may be subject to different rules.

The U.S. Treasury recently released proposed regulations which, if finalized in their present form, would eliminate the federal withholding tax of 30% applicable to the gross proceeds of a sale or other disposition of our common stock. In its preamble to such proposed regulations, the U.S. Treasury stated that taxpayers may generally rely on the proposed regulations until final regulations are issued. There can be no assurance that final regulations would provide an exemption from the FATCA withholding tax for gross proceeds. The FATCA withholding tax generally applies to all withholdable payments without regard to whether the beneficial owner of the payment would otherwise be entitled to an exemption from imposition of withholding tax pursuant to an applicable tax treaty with the United States or U.S. domestic law.

Prospective investors should consult their tax advisors regarding the potential application of withholding under FATCA to their investment in our common stock.

UNDERWRITING

BofA Securities, Inc., SVB Leerink LLC and RBC Capital Markets, LLC are acting as representatives of each of the underwriters named below. Subject to the terms and conditions set forth in an underwriting agreement among us and the underwriters, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the number of shares of common stock set forth opposite its name below.

Underwriter	Number of Shares
BofA Securities, Inc.	
SVB Leerink LLC	
RBC Capital Markets, LLC	
Oppenheimer & Co. Inc.	
Total	4,375,000

Subject to the terms and conditions set forth in the underwriting agreement, the underwriters have agreed, severally and not jointly, to purchase all of the shares sold under the underwriting agreement if any of these shares are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the non-defaulting underwriters may be increased or the underwriting agreement may be terminated.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, or to contribute to payments the underwriters may be required to make in respect of those liabilities.

The underwriters are offering the shares, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel, including the validity of the shares, and other conditions contained in the underwriting agreement, such as the receipt by the underwriters of officer's certificates and legal opinions. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

Our existing stockholders affiliated with our directors have indicated an interest in purchasing an aggregate of up to approximately $40 million of shares of our common stock in this offering at the initial public offering price per share and on the same terms as the other purchasers in this offering. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, fewer or no shares of common stock to any of these potential purchasers, and any of these potential purchasers could determine to purchase more, fewer or no shares of common stock in this offering. The underwriters will receive the same underwriting discount and commissions on these shares of common stock as they will on any other shares of common stock sold to the public in this offering.

Commissions and Discounts

The representatives have advised us that the underwriters propose initially to offer the shares to the public at the public offering price set forth on the cover page of this prospectus and to dealers at that price less a concession not in excess of $ per share. After the initial offering, the public offering price, concession or any other term of the offering may be changed.

The following table shows the public offering price, underwriting discount and proceeds before expenses to us. The information assumes either no exercise or full exercise by the underwriters of their option to purchase additional shares.

	Per Share	Without Option	With Option
Public offering price	$	$	$
Underwriting discount	$	$	$
Proceeds, before expenses, to us	$	$	$

The expenses of the offering, not including the underwriting discount, are estimated at $2.4 million and are payable by us. We have also agreed to reimburse the underwriters for certain of their expenses incurred in connection with, among others, the review and clearance by the Financial Industry Regulatory Authority, Inc. in an amount of up to $40,000.

Option to Purchase Additional Shares

We have granted an option to the underwriters, exercisable for 30 days after the date of this prospectus, to purchase up to 656,250 additional shares at the public offering price, less the underwriting discount. If the underwriters exercise this option, each will be obligated, subject to conditions contained in the underwriting agreement, to purchase a number of additional shares proportionate to that underwriter's initial amount reflected in the above table.

No Sales of Similar Securities

We, our executive officers and directors and our other existing security holders have agreed not to sell or transfer any common stock or securities convertible into, exchangeable for, exercisable for, or repayable with common stock, for 180 days after the date of this prospectus without first obtaining the written consent of BofA Securities, Inc., SVB Leerink LLC and RBC Capital Markets, LLC. Specifically, we and these other persons have agreed, with certain limited exceptions, not to directly or indirectly:

- offer, pledge, sell or contract to sell any common stock,
- sell any option or contract to purchase any common stock,
- purchase any option or contract to sell any common stock,
- grant any option, right or warrant for the sale of any common stock,
- lend or otherwise dispose of or transfer any common stock,
- request or demand that we file or make a confidential submission of a registration statement related to the common stock, or
- enter into any swap or other agreement that transfers or is designed to, intended to, or which could reasonably be expected to lead to or result in the transfer, in whole or in part, the economic consequence of ownership of any common stock whether any such swap or transaction is to be settled by delivery of shares or other securities, in cash or otherwise.

This lock-up provision applies to common stock and to securities convertible into or exchangeable or exercisable for or repayable with common stock. It also applies to common stock owned now or acquired later by the person executing the agreement or for which the person executing the agreement later acquires the power of disposition.

The Nasdaq Global Market Listing

We expect the shares to be approved for listing on The Nasdaq Global Market, subject to notice of issuance, under the symbol "ETNB."

Before this offering, there has been no public market for our common stock. The initial public offering price will be determined through negotiations between us and the representatives. In addition to prevailing market conditions, the factors to be considered in determining the initial public offering price are:

- the valuation multiples of publicly traded companies that the representatives believe to be comparable to us,
- our financial information,
- the history of, and the prospects for, our company and the industry in which we compete,
- an assessment of our management, its past and present operations, and the prospects for, and timing of, our future revenues,
- the present state of our development, and
- the above factors in relation to market values and various valuation measures of other companies engaged in activities similar to ours.

An active trading market for the shares may not develop. It is also possible that after the offering the shares will not trade in the public market at or above the initial public offering price.

The underwriters do not expect to sell more than 5% of the shares in the aggregate to accounts over which they exercise discretionary authority.

Price Stabilization, Short Positions and Penalty Bids

Until the distribution of the shares is completed, SEC rules may limit underwriters and selling group members from bidding for and purchasing our common stock. However, the representatives may engage in transactions that stabilize the price of the common stock, such as bids or purchases to peg, fix or maintain that price.

In connection with the offering, the underwriters may purchase and sell our common stock in the open market. These transactions may include short sales, purchases on the open market to cover positions created by short sales and stabilizing transactions. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering. "Covered" short sales are sales made in an amount not greater than the underwriters' option to purchase additional shares described above. The underwriters may close out any covered short position by either exercising their option to purchase additional shares or purchasing shares in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the option granted to them. "Naked" short sales are sales in excess of such option. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of our common stock in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of shares of common stock made by the underwriters in the open market prior to the completion of the offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Similar to other purchase transactions, the underwriters' purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. The underwriters may conduct these transactions on The Nasdaq Global Market, in the over-the-counter market or otherwise.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. In addition, neither we nor any of the underwriters make any representation that the representatives will engage in these transactions or that these transactions, once commenced, will not be discontinued without notice.

Electronic Distribution

In connection with the offering, certain of the underwriters or securities dealers may distribute prospectuses by electronic means, such as e-mail.

Other Relationships

Some of the underwriters and their affiliates have engaged in, and may in the future engage in, investment banking and other commercial dealings in the ordinary course of business with us or our affiliates. They have received, or may in the future receive, customary fees and commissions for these transactions.

In addition, in the ordinary course of their business activities, the underwriters and their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers. Such investments and securities activities may involve securities and/or instruments of ours or our affiliates. The underwriters and their affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or financial instruments and may hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

Notice to Prospective Investors in the European Economic Area

In relation to each Member State of the European Economic Area (each a "Member State"), no shares have been offered or will be offered pursuant to the to the public in that Member State prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that Member State or, where appropriate, approved in another Member State and notified to the competent authority in that Member State, all in accordance with the Prospectus Regulation), except that offers of shares may be made to the public in that Member State at any time under the following exemptions under the Prospectus Regulation:

a. to any legal entity which is a qualified investor as defined under the Prospectus Regulation;

b. to fewer than 150 natural or legal persons (other than qualified investors as defined under the Prospectus Regulation), subject to obtaining the prior consent of representatives for any such offer; or

c. in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of shares shall require us or any representative to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

Each person in a Member State who initially acquires any shares or to whom any offer is made will be deemed to have represented, acknowledged and agreed to and with us and the representatives that it is a qualified investor within the meaning of the Prospectus Regulation.

In the case of any shares being offered to a financial intermediary as that term is used in Article 5(1) of the Prospectus Regulation, each such financial intermediary will be deemed to have represented, acknowledged and agreed that the shares acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer to the public other than their offer or resale in a Relevant Member State to qualified investors, in circumstances in which the prior consent of the representatives has been obtained to each such proposed offer or resale.

We, the representatives and their affiliates will rely upon the truth and accuracy of the foregoing representations, acknowledgements and agreements.

For the purposes of this provision, the expression an "offer to the public" in relation to any shares in any Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares, and the expression "Prospectus Regulation" means Regulation (EU) 2017/1129.

Notice to Prospective Investors in the United Kingdom

In addition, in the United Kingdom, this document is being distributed only to, and is directed only at, and any offer subsequently made may only be directed at persons who are "qualified investors" (as defined in the Prospectus Directive) (i) who have professional experience in matters relating to investments falling within Article 19 (5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the "Order") and/or (ii) who are high net worth companies (or persons to whom it may otherwise be lawfully communicated) falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as "relevant persons"). This document must not be acted on or relied on in the United Kingdom by persons who are not relevant persons. In the United Kingdom, any investment or investment activity to which this document relates is only available to, and will be engaged in with, relevant persons.

Notice to Prospective Investors in Switzerland

The shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange ("SIX") or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the shares or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, our company or the shares have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of shares will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA (FINMA), and the offer of shares has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes ("CISA"). The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of shares.

Notice to Prospective Investors in the Dubai International Financial Centre

This prospectus relates to an Exempt Offer in accordance with the Offered Securities Rules of the Dubai Financial Services Authority ("DFSA"). This prospectus is intended for distribution only to persons of a type

specified in the Offered Securities Rules of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus nor taken steps to verify the information set forth herein and has no responsibility for the prospectus. The shares to which this prospectus relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the shares offered should conduct their own due diligence on the shares. If you do not understand the contents of this prospectus you should consult an authorized financial advisor.

Notice to Prospective Investors in Australia

No placement document, prospectus, product disclosure statement or other disclosure document has been lodged with the Australian Securities and Investments Commission, in relation to the offering. This prospectus does not constitute a prospectus, product disclosure statement or other disclosure document under the Corporations Act 2001 (the "Corporations Act"), and does not purport to include the information required for a prospectus, product disclosure statement or other disclosure document under the Corporations Act.

Any offer in Australia of the shares may only be made to persons (the "Exempt Investors") who are "sophisticated investors" (within the meaning of section 708(8) of the Corporations Act), "professional investors" (within the meaning of section 708(11) of the Corporations Act) or otherwise pursuant to one or more exemptions contained in section 708 of the Corporations Act so that it is lawful to offer the shares without disclosure to investors under Chapter 6D of the Corporations Act.

The shares applied for by Exempt Investors in Australia must not be offered for sale in Australia in the period of 12 months after the date of allotment under the offering, except in circumstances where disclosure to investors under Chapter 6D of the Corporations Act would not be required pursuant to an exemption under section 708 of the Corporations Act or otherwise or where the offer is pursuant to a disclosure document which complies with Chapter 6D of the Corporations Act. Any person acquiring shares must observe such Australian on-sale restrictions.

This prospectus contains general information only and does not take account of the investment objectives, financial situation or particular needs of any particular person. It does not contain any securities recommendations or financial product advice. Before making an investment decision, investors need to consider whether the information in this prospectus is appropriate to their needs, objectives and circumstances, and, if necessary, seek expert advice on those matters.

Notice to Prospective Investors in Hong Kong

The shares have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than (a) to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance; or (b) in other circumstances which do not result in the document being a "prospectus" as defined in the Companies Ordinance (Cap. 32) of Hong Kong or which do not constitute an offer to the public within the meaning of that Ordinance. No advertisement, invitation or document relating to the shares has been or may be issued or has been or may be in the possession of any person for the purposes of issue, whether in Hong Kong or elsewhere, which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to securities which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" as defined in the Securities and Futures Ordinance and any rules made under that Ordinance.

Notice to Prospective Investors in Japan

The shares have not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948, as amended) and, accordingly, will not be offered or sold, directly or indirectly, in

Japan, or for the benefit of any Japanese Person or to others for re-offering or resale, directly or indirectly, in Japan or to any Japanese Person, except in compliance with all applicable laws, regulations and ministerial guidelines promulgated by relevant Japanese governmental or regulatory authorities in effect at the relevant time. For the purposes of this paragraph, "Japanese Person" shall mean any person resident in Japan, including any corporation or other entity organized under the laws of Japan.

Notice to Prospective Investors in Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, the shares were not offered or sold or caused to be made the subject of an invitation for subscription or purchase and will not be offered or sold or caused to be made the subject of an invitation for subscription or purchase, and this prospectus or any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares, has not been circulated or distributed, nor will it be circulated or distributed, whether directly or indirectly, to any person in Singapore other than (i) to an institutional investor (as defined in Section 4A of the Securities and Futures Act (Chapter 289) of Singapore, as modified or amended from time to time (the "SFA")) pursuant to Section 274 of the SFA, (ii) to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions specified in Section 275 of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

(a) a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or

(b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

securities or securities-based derivatives contracts (each term as defined in Section 2(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares pursuant to an offer made under Section 275 of the SFA except:

(a) to an institutional investor or to a relevant person, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;

(b) where no consideration is or will be given for the transfer;

(c) where the transfer is by operation of law; or

(d) as specified in Section 276(7) of the SFA.

Notice to Prospective Investors in Canada

The shares may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 *Prospectus Exemptions* or subsection 73.3(1) of the *Securities Act* (Ontario), and are permitted clients, as defined in National Instrument 31-103 *Registration Requirements, Exemptions and Ongoing Registrant Obligations*. Any resale of the shares must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 (or, in the case of securities issued or guaranteed by the government of a non-Canadian jurisdiction, section 3A.4) of National Instrument 33-105 *Underwriting Conflicts* (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

LEGAL MATTERS

The validity of the shares of our common stock offered by this prospectus will be passed upon for us by Gibson, Dunn & Crutcher LLP. Certain legal matters in connection with this offering will be passed upon for the underwriters by Cooley LLP.

EXPERTS

The consolidated financial statements included in this prospectus have been audited by Brightman Almagor Zohar & Co., a Firm in the Deloitte Global Network, an independent registered public accounting firm, as stated in their report appearing herein which report expresses an unqualified opinion on the consolidated financial statements and includes an explanatory paragraph referring to going concern. Such consolidated financial statements have been so included in reliance upon the report of such Firm given upon their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of our common stock offered hereby. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement, some items of which are contained in exhibits to the registration statement as permitted by the rules and regulations of the SEC. For further information with respect to us and our common stock, we refer you to the registration statement and its exhibits. Statements contained in this prospectus concerning the contents of any contract or any other document are not necessarily complete. If a contract or document has been filed as an exhibit to the registration statement, please see the copy of the contract or document that has been filed. Each statement in this prospectus relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit. The exhibits to the registration statement should be reviewed for the complete contents of these contracts and documents. A copy of the registration statement and its exhibits may be obtained from the SEC upon the payment of fees prescribed by it. The SEC maintains a website at *www.sec.gov* that contains reports, proxy and information statements and other information regarding companies that file electronically with it.

Upon completion of this offering, we will become subject to the information and periodic and current reporting requirements of the Exchange Act, and in accordance therewith, will file periodic and current reports, proxy statements and other information with the SEC. The registration statement, such periodic and current reports and other information can be obtained electronically by means of the SEC's website at *www.sec.gov.* We maintain a website at *www.89bio.com*, at which, following the completion of this offering, you may access these material free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. Information contained on or accessible through our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is an inactive textual reference only.

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Report of Independent Registered Public Accounting Firm

To the Board of Directors of 89bio, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheet of 89bio, Inc. (the "Company") as of June 28, 2019 (inception), and the related notes (collectively referred to as the "financial statement"). In our opinion, the financial statement presents fairly, in all material respects, the financial position of the Company as of June 28, 2019, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

This financial statement is the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statement based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statement is free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the financial statement, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statement. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statement. We believe that our audit provides a reasonable basis for our opinion.

/s/ Brightman Almagor Zohar & Co.
Certified Public Accountants
A Firm in the Deloitte Global Network

Tel Aviv, Israel
September 19, 2019,
except for the retroactive effect of the 1-for-6.217 reverse stock split and the Reorganization, as described in Note 2 and Note 4, respectively, as to which the date is October 28, 2019

We have served as the Company's auditor since 2019.

89bio, Inc.
Balance Sheet

	June 28, 2019 (inception)
Assets	
Total assets	$ —
Liabilities and stockholders' equity	
Total liabilities	$ —
Commitments and contingencies	
Stockholders' equity:	
Common stock, $0.001 par value, 1,000 shares authorized, none issued and outstanding	$ —
Total liabilities and stockholders' equity	$ —

The accompanying notes are an integral part of this balance sheet.

89bio, Inc.
Notes to Balance Sheet

1. Organization and Background

89bio, Inc. (the "Corporation") was formed as a Delaware corporation on June 28, 2019. The Corporation was formed for the purpose of completing an initial public offering and related transactions in order to carry on the business of 89Bio Ltd. As the manager of 89Bio Ltd., the Corporation will operate and control all of the businesses and affairs of 89Bio Ltd., and its subsidiaries.

2. Summary of Significant Accounting Policies

Basis of Presentation

The balance sheet is presented in accordance with generally accepted accounting principles in the United States of America ("GAAP"). Statements of operations, stockholders' equity and cash flows have not been presented because there have been no activities in this entity.

Reverse Stock Split

On October 24, 2019, the Corporation's board of directors approved an amendment to the Corporation's amended and restated certificate of incorporation to effect a 1-for-6.217 reverse split ("Reverse Split") of shares of the Corporation's common stock and a proportional adjustment to the conversion ratio of its convertible preferred stock, which was effected on October 25, 2019. The par value and authorized shares of common stock and the par value, authorized and outstanding shares of convertible preferred stock were not adjusted as a result of the Reverse Split. All of the share and per share information included in the accompanying financial statement has been adjusted to reflect the Reverse Split.

Underwriting Commissions and Offering Costs

Underwriting commissions and offering costs to be incurred in connection with the Corporation's common share offerings will be reflected as a reduction of additional paid-in capital. Underwriting commissions and offering costs are not recorded in the Corporation's balance sheet because such costs are not the Corporation's liability until the Corporation completes a successful initial public offering.

Organizational Costs

Organizational costs are not recorded in the Corporation's balance sheet because such costs are not the Corporation's liability until the Corporation completes a successful initial public offering. Thereafter, costs incurred to organize the Corporation will be expensed as incurred.

3. Stockholders' Equity

The Corporation is authorized to issue 1,000 shares of common stock, par value $0.001 per share, none of which have been issued or are outstanding as of June 28, 2019.

4. Subsequent Events

In September 2019, the Corporation increased its authorized shares from 1,000 to 72,882,353 shares of common stock, 611,226 of which have been issued and are outstanding as of September 19, 2019. Additionally, the Corporation authorized 60,000,000 shares of preferred stock, 44,000,000 of which have been issued and are outstanding as of September 19, 2019.

89bio, Inc.
Notes to Balance Sheet

In September 2019, an internal reorganization transaction was completed pursuant to which 89Bio, Ltd. became a wholly owned subsidiary.

On October 24, 2019, the Corporation's board of directors approved the Reverse Split, which was effected on October 25, 2019 (see Note 2). Additionally, the Corporation increased its authorized shares from 72,882,353 to 100,000,000 shares of common stock, which is to become effective immediately prior to the completion of the Corporation's initial public offering. As of October 28, 2019, 611,226 shares of common stock have been issued and are outstanding.

Subsequent events through September 19, 2019, the date on which the balance sheet was available to be issued, and October 28, 2019, the date the balance sheet was reissued, were evaluated by the Corporation to determine the need, if any, for recognition or disclosure in this balance sheet. The Corporation concluded that no other subsequent events have occurred that would require recognition or disclosure to the balance sheet.

Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of
89Bio Ltd.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of 89Bio Ltd. and subsidiaries (the "Company") as of December 31, 2018 and the related consolidated statements of operations and comprehensive loss, change in convertible preferred shares and shareholders' deficit and cash flows for the period from January 18, 2018 (inception) to December 31, 2018, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018, and the results of its operations and its cash flow for the period from January 18, 2018 (inception) to December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company's lack of revenues and substantial operating losses raise substantial doubt about its ability to continue as a going concern. Management's plans concerning these matters are also described in Note 1 to the financial statements. The financial statements do not include any adjustments that might result from the outcome of these uncertainties.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ Brightman Almagor Zohar & Co.
Certified Public Accountants
A Firm in the Deloitte Global Network

Tel Aviv, Israel
August 15, 2019,
except for the retroactive effect of the 1-for-6.217 reverse stock split and the Reorganization as described in Note 2 and Note 13, respectively, as to which the date is October 28, 2019

We have served as the Company's auditor since 2018.

89Bio Ltd.
Consolidated Balance Sheet
(In thousands, except share and per share amounts)

	December 31, 2018
Assets	
Current assets:	
Cash and cash equivalents	$ 11,234
Restricted cash	23
Other current assets	59
Total current assets	11,316
Property and equipment, net	33
Deferred tax assets	20
Total assets	$ 11,369
Liabilities and shareholders' equity	
Current liabilities:	
Accounts payable	$ 1,509
Accrued expenses	1,173
Convertible preferred share liability	1,671
Total current liabilities	4,353
Commitments and contingencies (Note 5)	
Convertible preferred shares, NIS 0.01 nominal value; 60,000,000 shares authorized as of December 31, 2018; 24,000,000 shares issued and outstanding as of December 31, 2018; aggregate liquidation preference of $24,000 as of December 31, 2018	23,073
Shareholders' deficit:	
Ordinary shares, NIS 0.01 nominal value, 10,415,900 shares authorized at December 31, 2018; 611,226 shares issued and outstanding as of December 31, 2018	1
Additional paid-in capital	118
Accumulated deficit	(16,176)
Total shareholders' deficit	(16,057)
Total liabilities, convertible preferred shares and shareholders' deficit	$ 11,369

The accompanying notes are an integral part of these consolidated financial statements.

89Bio Ltd.
Consolidated Statement of Operations and Comprehensive Loss
(In thousands, except share and per share amounts)

	Period from January 18, 2018 (inception) to December 31, 2018
Operating expenses:	
Research and development	$ 13,681
General and administrative	1,481
Total operating expenses	15,162
Loss from operations	15,162
Other (income) expenses, net	986
Net loss before tax	16,148
Income tax expense	28
Net loss and comprehensive loss	$ 16,176
Net loss per share, basic and diluted	$ 36.45
Weighted-average shares used to compute net loss per share, basic and diluted	443,767
Pro forma net loss per share, basic and diluted (unaudited)	$ 7.60
Weighted-average shares used to compute pro forma net loss per share, basic and diluted (unaudited)	2,127,190

The accompanying notes are an integral part of these consolidated financial statements.

89Bio Ltd.
Consolidated Statement of Convertible Preferred Shares and Shareholders' Deficit (in thousands, except share amounts)

	Convertible Preferred Shares		Ordinary Shares		Additional Paid-in Capital	Accumulated Deficit	Total Shareholders' Deficit
	Shares	Amounts	Shares	Amounts			
Balance as of January 18, 2018 (inception)	—	$ —	—	$ —	$ —	$ —	$ —
Issuance of ordinary shares	—	—	611,226	1	10	—	11
Issuance of convertible preferred shares, net of issuance costs of $235 and the recognition of the convertible preferred share liability of $692	23,900,000	22,973	—	—	—	—	—
Conversion of convertible note into preferred shares	100,000	100	—	—	—	—	—
Share-based compensation	—	—	—	—	108	—	108
Net loss and comprehensive loss	—	—	—	—	—	(16,176)	(16,176)
Balance as of December 31, 2018	24,000,000	$23,073	611,226	$ 1	$ 118	$ (16,176)	$ (16,057)

The accompanying notes are an integral part of these consolidated financial statements.

89Bio Ltd.
Consolidated Statement of Cash Flows (in thousands)

	Period from January 18, 2018 (inception) to December 31, 2018
Cash flows from operating activities:	
Net loss	$ (16,176)
Adjustments to reconcile net loss to net cash used in operating activities:	
Depreciation	6
Share-based compensation	108
Deferred tax assets	(20)
Revaluation of convertible preferred share liability	979
Changes in operating assets and liabilities:	
Other current assets	(48)
Accrued expenses	1,173
Accounts payable	1,509
Net cash used in operating activities	(12,469)
Cash flows from investing activities:	
Purchase of property and equipment	(39)
Net cash used in investing activities	(39)
Cash flows from financing activities:	
Proceeds from issuance of convertible preferred shares and convertible preferred share liability, net of issuance costs	23,665
Proceeds from issuance of convertible note	100
Net cash provided by financing activities	23,765
Net increase in cash and cash equivalents, and restricted cash	11,257
Cash and cash equivalents, and restricted cash at beginning of period	—
Cash and cash equivalents, and restricted cash at end of period	$ 11,257
Components of cash and cash equivalents, and restricted cash:	
Cash and cash equivalents	$ 11,234
Restricted cash	23
Total cash and cash equivalents, and restricted cash	$ 11,257
Supplemental disclosures of non-cash investing and financing information:	
Conversion of convertible note into preferred shares	$ 100

The accompanying notes are an integral part of these consolidated financial statements.

89Bio Ltd.
Notes to the Consolidated Financial Statements

1. Organization and Basis of Presentation

Description of Business

89Bio Ltd. ("89Bio" or the "Company") is a clinical-stage biopharmaceutical company focused on the development and commercialization of innovative therapies for the treatment of liver and cardio-metabolic diseases. The Company's lead product candidate, BIO89-100, a specifically engineered glycoPEGylated analog of fibroblast growth factor 21, is currently being developed for the treatment of nonalcoholic steatohepatitis. 89Bio Ltd. was incorporated in Israel in January 2018. The Company has two wholly owned subsidiaries: 89bio Management, Inc., located in San Francisco, California and UAB 89bio Lithuania, located in Vilnius, Lithuania.

89bio, Inc., a Delaware corporation, does not currently have any operations and was incorporated in June 2019 for the purpose of an internal reorganization transaction. In September 2019, all of the equity holders of 89Bio Ltd. exchanged 100% of the equity of 89Bio Ltd. for 100% of the equity of 89bio, Inc. Following this exchange, 89Bio Ltd. became a wholly-owned subsidiary of 89bio, Inc. and 89bio, Inc. indirectly owns the business described herein. Upon the completion of a qualified public offering on specified terms, the Company's outstanding convertible preferred shares will automatically convert into shares of common stock (see Note 7).

Going Concern

The accompanying consolidated financial statements are prepared assuming the Company will continue as a going concern, which contemplates the realization of assets and liquidation of liabilities in the normal course of business. To date, the Company has not generated revenues from its activities and has incurred substantial operating losses. Management expects the Company to continue to generate substantial operating losses for the foreseeable future until it completes development of its products and seeks regulatory approvals to market such products. Management will continue to fund its operations primarily through utilization of its current financial resources and through additional raises of capital.

Such conditions raise substantial doubts about the Company's ability to continue as a going concern for at least a year after the issuance date of the accompanying consolidated financial statements. Management plans to address these conditions by raising funds from its current investors as well as outside potential investors. However, there is no assurance that such funding will be available to the Company or that it will be obtained on terms favorable to the Company or will provide the Company with sufficient funds to meet its objectives. The accompanying consolidated financial statements do not include any adjustments relating to the recoverability and classification of assets, carrying amounts or the amount or classification of liabilities that may be required should the Company be unable to continue as a going concern.

2. Summary of Significant Accounting Policies

Basis of Presentation:

The consolidated financial statements have been prepared in conformity with accounting principles generally accepted in United Sates of America ("U.S. GAAP").

Reverse Stock Split

In September 2019, the Company completed an internal reorganization transaction pursuant to which 89Bio Ltd. became a wholly owned subsidiary of 89bio, Inc. (see Note 1). On October 24, 2019, 89bio, Inc.'s

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board of directors approved an amendment to the amended and restated certificate of incorporation of 89bio, Inc. to effect a 1-for-6.217 reverse split ("Reverse Split") of shares of the common stock of 89bio, Inc. and a proportional adjustment to the conversion ratio of the convertible preferred stock, which was effected on October 25, 2019. The par value and authorized shares of common stock and the par value, authorized and outstanding shares of convertible preferred stock were not adjusted as a result of the Reverse Split. All of the share and per share information for 89Bio Ltd. included in the accompanying financial statements has been adjusted to reflect the Reverse Split.

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the consolidated financial statements and the reported amounts of expenses during the reporting period. Significant estimates and assumptions made in the accompanying consolidated financial statements include but are not limited to the fair value of stock options, the convertible preferred share liability and certain accruals. The Company evaluates its estimates and assumptions on an ongoing basis using historical experience and other factors and adjusts those estimates and assumptions when facts and circumstances dictate. Actual results could differ from those estimates.

Consolidated Financial Statements in U.S. Dollars

The Company's functional currency is the U.S. dollar ("dollar" or "$") since the dollar is the currency of the primary economic environment in which the Company has operated and expects to continue to operate in the foreseeable future. Transactions and balances denominated in dollars are presented at their original amounts. Transactions and balances denominated in foreign currencies have been re-measured to dollars. All transaction gains and losses from re-measurement of monetary balance sheet items denominated in non-dollar currencies are reflected in the consolidated statement of operations and comprehensive loss as other (income) expenses, net. Net foreign currency transaction losses were not material for the period from January 18, 2018 (inception) to December 31, 2018.

Cash and Cash Equivalents and Restricted Cash

The Company considers all highly liquid investments purchased with original maturities of three months or less from the purchase date to be cash equivalents. Cash equivalents consist primarily of amounts invested in money market accounts and are stated at fair value. Restricted cash consists of a money market account that serves as collateral for a credit card agreement at one of the Company's financial institutions.

Fair Value Measurements

Financial assets and liabilities are recorded at fair value on a recurring basis in the consolidated balance sheet. The carrying values of Company's financial assets and liabilities, including cash and cash equivalents, restricted cash, other current assets, accounts payable, and accrued expenses approximate to their fair value due to the short-term maturity of these instruments. Fair value is defined as the price that would be received to sell an

asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. Assets and liabilities recorded at fair value in the consolidated financial statements are categorized based upon the level of judgment associated with the inputs used to measure their fair value. Hierarchical levels are directly related to the amount of subjectivity with the inputs to the valuation of these assets or liabilities as follows:

Level 1—Observable inputs such as unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date;

Level 2—Inputs (other than quoted prices included in Level 1) are either directly or indirectly observable inputs for similar assets or liabilities. These include quoted prices for identical or similar assets or liabilities in active markets and quoted prices for identical or similar assets of liabilities in markets that are not active;

Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Convertible Preferred Share Liability

The freestanding instruments related to the commitment by the Series A convertible preferred shareholders to purchase and by the Company to sell its Series A convertible preferred shares in subsequent closings, contingent upon the achievement of certain developmental milestones and approval by the board of directors, at a fixed price per share, are considered a liability (or an asset), measured at fair value as the shares underlying the rights contain liquidation preferences upon certain “deemed liquidation events” that are not solely within the Company’s control and which are considered in-substance contingent redemption features (refer to Note 7 for further discussion on the redemption rights of the convertible preferred shares). The instruments are subject to revaluation at each balance sheet date until settlement, with revaluations recognized as a component of other (income) expenses, net in the consolidated statement of operations and comprehensive loss.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to a concentration of credit risk consist primarily of cash and cash equivalents. Bank deposits are held by accredited financial institutions and these deposits may at times be in excess of insured limits. The Company limits its credit risk associated with cash and cash equivalents by placing them with financial institutions that it believes are of high quality. The Company has not experienced any losses on its deposits of cash or cash equivalents.

Property and Equipment, Net

Property and equipment are stated at cost, less accumulated depreciation. Depreciation is calculated on a straight-line basis over the estimated useful lives of the related assets, generally ranging from three to seven years. Leasehold improvements are amortized on a straight-line basis over the shorter of the assets’ estimated useful life or the remaining term of the lease. Maintenance and repair costs are expensed as incurred.

Impairment of Long-Lived Assets

The Company periodically evaluates its long-lived assets, including property and equipment, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets or group of assets may not be fully recoverable. If indicators of impairment exist and the undiscounted future

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cash flows that the assets are expected to generate are less than the carrying value of the assets, the Company reduces the carrying amount of the assets through an impairment charge, to their estimated fair values based on a discounted cash flow approach or, when available and appropriate, to comparable market values. There were no such indicators for the period presented.

Accrued Post-Employment Benefit

Under Israeli employment laws, employees of the Company are included under Section 14 of the Severance Compensation Act, 1963 ("Section 14") for a portion of their salaries. According to Section 14, these employees are entitled to monthly payments made by the Company on their behalf with insurance companies.

Payments in accordance with Section 14 release the Company from any future severance payments with respect of those employees. The obligation to make the monthly deposits is expensed as incurred. In addition, the aforementioned deposits are not recorded as an asset in the consolidated balance sheet, and there is no liability recorded as the Company does not have a future obligation to make any additional payments.

Leases

The Company leases its office facility under a non-cancelable operating lease agreement and recognizes related rent expense on a straight-line basis over the term of the lease.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for the development of the Company's lead product candidate, BIO89-100. Research and development expenses consist primarily of external costs related to acquiring and licensing patents and intellectual properties, preclinical and clinical development and related supplies, and personnel costs. Personnel costs consist of salaries, employee benefits and share-based compensation for individuals involved in research and development efforts. The Company estimates preclinical and clinical study and research expenses based on the services performed, pursuant to contracts with research institutions that conduct and manage preclinical and clinical studies and research services on its behalf. The Company records the costs of research and development activities based upon the estimated amount of services provided but not yet invoiced and includes these costs in accrued liabilities in the consolidated balance sheet. These costs are a component of the Company's research and development expenses. The Company accrues for these costs based on factors such as estimates of the work completed and in accordance with agreements established with its third-party service providers under the service agreements. The Company makes significant judgments and estimates in determining the accrued liabilities balance. As actual costs become known, the Company adjusts its accrued expenses. The Company has not experienced any material differences between accrued costs and actual costs incurred. However, the status and timing of actual services performed may vary from the Company's estimates, resulting in adjustments to expense in future periods. Changes in these estimates that result in material changes to the Company's accruals could materially affect the Company's results of operations. Payments associated with licensing agreements to acquire licenses to develop, use, manufacture and commercialize products that have not reached technological feasibility and do not have alternate commercial use are expensed as incurred. Contingent milestone payments, if any, are expensed when the milestone results are probable and estimable, which is generally upon achievement of the milestone.

Share-Based Compensation

The Company measures its share-based payment awards made to employees, directors, and non-employee service providers based on estimated fair values and recognizes compensation over the requisite service period.

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The Company estimates the fair value of share-based payment awards on the date of grant using a Black-Scholes option pricing model. The value of the portion of the share-based payment award that is ultimately expected to vest is recognized as an expense over the requisite service period in the consolidated statement of operations and comprehensive loss.

The Company recognizes compensation for the value of share-based payment awards, which have graded vesting, using the straight-line method over the requisite service period of each award. The Company accounts for forfeitures as they occur.

The Black-Scholes option pricing model requires a number of assumptions, of which the most significant are share price, expected volatility, expected option term (the time from the grant date until the options are exercised or expire), risk-free rate, and expected divided rate. Expected volatility is estimated based on volatility of similar public companies in the biotechnology sector. The Company has historically not paid dividends and has no foreseeable plans to pay dividends, therefore the Company uses an expected dividend yield of 0%. The risk-free interest rate is based on the yield from U.S. Treasury zero-coupon bonds with an equivalent expected term. The expected option term is calculated for options granted to employees and directors using the "simplified" method. Under this approach, the expected term is presumed to be the midpoint between the weighted average vesting term and the contractual term of the option. The simplified method makes the assumption that the employee will exercise share options evenly over the period when the share options are vested and ending on the date when the share options expire. The expected option term for options granted to non-employees is based on the contractual term. Changes in the determination of each of the inputs can affect the fair value of the share options granted and the results of operations of the Company.

Income Taxes

Income taxes are accounted for under the asset and liability method. Under this method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the consolidated financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates applied to taxable income in the years in which those temporary differences are expected to be realized. The effect on deferred tax assets and liabilities of a change in tax rates is recognized as income or loss in the period that includes the enactment date. A valuation allowance is established when necessary to reduce deferred tax assets to the amount expected to be realized. Interest and penalties related to unrecognized tax benefits are included within the provision of income tax. To date, there have been no unrecognized tax benefits balances.

Basic and Diluted Net Loss per Share

Basic loss per share is computed by dividing the net loss by the weighted average number of ordinary shares outstanding during the period. Diluted loss per share is computed by dividing the net loss by the weighted average number of ordinary shares outstanding together with the number of additional ordinary shares that would have been outstanding if all potentially dilutive ordinary shares had been issued. Since the Company was in a loss position for the period presented, basic net loss per share is the same as diluted net loss per share since the effects of potentially dilutive securities are antidilutive.

Unaudited Pro Forma Net Loss per Share

Immediately prior to the completion of the Company's anticipated initial public offering (the "IPO"), all outstanding shares of convertible preferred shares will convert into ordinary shares. The unaudited pro forma net loss per share for the period from January 18, 2018 (inception) to December 31, 2018 was computed using the

weighted-average number of shares of ordinary shares outstanding, including the pro forma effect of the conversion of all outstanding shares of convertible preferred shares into shares of ordinary shares as if such conversion had occurred at the beginning of the period, or their issuance dates if later. Pro forma net loss per share does not include the shares expected to be sold in the IPO.

Comprehensive Loss

The Company has no components of comprehensive loss other than net loss. Thus, comprehensive loss is the same as net loss for the period presented.

Segment Reporting

The Company has one operating segment. The Company's chief operating decision maker, its Chief Executive Officer, manages the Company's operations on a consolidated basis for the purposes of allocating resources and evaluating financial performance.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("ASU") 2014-09—*Revenue from contracts with customers*, to achieve a consistent application of revenue recognition, resulting in a single revenue model to be applied by reporting companies under U.S. GAAP. Under the new model, recognition of revenue occurs when a customer obtains control of the promised goods or services in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. In addition, the standard requires that reporting companies disclose the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. The standard is effective for public entities for fiscal years beginning after December 15, 2017 and is effective for nonpublic entities for fiscal years beginning after December 15, 2018. The standard is required to be applied retrospectively to each prior reporting period presented or retrospectively with the cumulative effect of initially applying it recognized at the date of initial application. The Company adopted this standard on January 1, 2019, and as the Company has not incurred revenues to date, the adoption of the standard will not have a significant impact on its consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02—*Leases*, requiring the recognition of lease assets and liabilities on the balance sheet. The standard: (a) clarifies the definition of a lease; (b) requires a dual approach to lease classification similar to current lease classifications; and (c) causes lessees to recognize leases on the balance sheet as a lease liability with a corresponding right-of-use asset for leases with a lease-term of more than twelve months. The standard is effective for public entities for fiscal years beginning after December 15, 2018 and for nonpublic entities for fiscal years beginning after December 15, 2019. The Company is currently evaluating the impact of this standard and expects the adoption will result in an insignificant increase in the assets and liabilities on its consolidated balance sheet for operating leases.

In June 2018, the FASB issued ASU No. 2018-07 *Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*, which is intended to reduce the cost and complexity and to improve financial reporting for nonemployee share based payment. The standard expands the scope of Topic 718, (which currently only includes share-based payments to employees) to include share-based payments issued to nonemployees for goods or services. Consequently, the accounting for share-based payments to nonemployees and employees will be substantially aligned. The standard is effective for public entities for fiscal years beginning after December 15, 2019 and nonpublic entities for fiscal years beginning after December 15, 2020. Early adoption is permitted but no earlier than a company's adoption date of Topic 606. The Company early adopted this standard on January 1, 2019, and the impact of its adoption on the Company's consolidated financial statements is not material.

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3. Fair Value Measurements

The fair value of the Company's financial liabilities measured at fair value on a recurring basis by level within the fair value hierarchy are as follows (in thousands):

	December 31, 2018			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Convertible preferred share liability	$ —	$ —	$1,671	$1,671
Total financial liabilities	$ —	$ —	$1,671	$1,671

The changes in the fair value of the Company's Level 3 financial liabilities, which are measured on a recurring basis are as follows (in thousands):

	December 31, 2018
Beginning balance	$ —
Recognition of convertible preferred share liability upon issuance of convertible preferred shares	638
Revaluation of convertible preferred share liability recorded in other (income) expense, net	979
Partial settlement of convertible preferred share liability upon second closing	54
Ending balance	$ 1,671

The fair value of the Company's convertible preferred share liability is based on significant inputs not observed in the market, and thus represent a Level 3 measurement. Refer to Note 7 for further discussion on the convertible preferred share liability.

4. Consolidated Balance Sheet Components

Property and Equipment, Net

Property and equipment, net consists of the following (in thousands):

	December 31, 2018
Computer software and electronic equipment	$ 33
Furniture and office equipment	6
Total property and equipment	39
Less: accumulated depreciation	(6)
Total property and equipment, net	$ 33

Depreciation expense for property and equipment was $6,000 for the period from January 18, 2018 (inception) to December 31, 2018.

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Accrued Expenses

Accrued expenses consist of the following (in thousands):

	December 31, 2018
Accrued research and development expense	$ 890
Accrued employee and related expenses	283
Total accrued expenses	$ 1,173

5. Commitments and Contingencies

Lease

In May 2018, the Company entered into an operating lease agreement for its facility in Israel. The lease term was for 12 months and was amended in April 2019 to extend the lease term to April 2020. Under the lease agreement, monthly lease payments are approximately $4,000.

Future minimum lease payments under the Company's non-cancellable operating lease obligations as of December 31, 2018, are as follows (in thousands):

2019	$18
Total future minimum annual payments	$18

Rent expense was $39,000 during the period from January 18, 2018 (inception) to December 31, 2018. The Company has a security deposit balance of $23,000, which is included in other current assets in the consolidated balance sheet as of December 31, 2018.

Asset Transfer and License Agreement with Teva Pharmaceutical Industries Ltd

In April 2018, the Company concurrently entered into two Asset Transfer and License Agreements (the "Teva Agreements") with Teva Pharmaceutical Industries Ltd ("Teva") under which it acquired certain patents and intellectual property relating to two programs: (1) Teva's glycoPEGylated FGF21 program, including the compound TEV-47948 (BIO89-100), a glycoPEGylated long-acting FGF21 and (2) Teva's development program of small molecule inhibitors of Fatty Acid Synthase. Pursuant to the Teva Agreements, the Company paid Teva an initial nonrefundable upfront payment of $6.0 million and the Company could be obligated to pay Teva up to $67.5 million under each program, for a total of $135.0 million, upon the achievement of certain clinical development and commercial milestones. In addition, the Company is obligated to pay Teva tiered royalties at percentages in the low-to-mid single-digits on worldwide net sales on all products containing the Teva compounds.

The Teva Agreements can be terminated (i) by the Company without cause, after the first anniversary of the effective date, upon 120 days' written notice to Teva, (ii) by either party, if the other party materially breaches any of its obligations under the Agreements and fails to cure such breach within 60 days after receiving notice thereof, or (iii) by either party, if a bankruptcy petition is filed against the other party and is not dismissed within 60 days. In addition, Teva can also terminate the agreement related to the Company's glycoPEGylated FGF21 program in the event the Company, or any of its affiliates or sublicensees, challenges any of the Teva patents licensed to the Company, and the challenge is not withdrawn within 30 days of written notice from Teva.

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The Company accounted for the acquisition of technology as an asset acquisition because it did not meet the definition of a business. The Company recorded the total consideration transferred to Teva as research and development expense in the consolidated statement of operations and comprehensive loss because the acquired technology represented in-process research and development and had no alternative future use.

6. Convertible Note

In March 2018, the Company entered into a Convertible Loan Agreement (the "Convertible Note") with a principal amount of $100,000 and a fixed interest rate of 8% per annum. The Convertible Note was automatically convertible into the Company's next equity financing, or upon an earlier event of default. In April 2018, the entire amount outstanding converted into 100,000 shares of Series A convertible preferred shares upon the closing of the Series A financing.

7. Convertible Preferred Shares

In April 2018, the Company entered into the Series A Share Purchase Agreement (the "SPA"), pursuant to which the investors committed to invest an aggregate amount of up to $60.0 million for the issuance of Series A convertible preferred shares at a price of $1.00 per share.

The initial closing occurred on April 16, 2018, and the Company issued 14,900,000 Series A convertible preferred shares at a price per share of $1.00 for net cash proceeds of $14.7 million. The investors also committed to purchase 15,000,000 and 30,000,000 shares of Series A convertible preferred shares at a price of $1.00 per share in second and third closings, respectively, contingent upon the achievement by the Company of certain development milestones and approval by the board of directors.

The investors' commitment to purchase and the Company's commitment to sell Series A convertible preferred shares represent a freestanding instrument accounted for at fair value and re-measured at each reporting date. The Company estimates the fair value of this commitment using the Black Scholes option pricing model. On the date of the initial closing, the Company recorded the commitments associated with the second and third closings of the Series A convertible preferred shares at a net value of $638,000. For the period from January 18, 2018 (inception) to December 31, 2018, the Company recorded an expense of $979,000 for the revaluation of the convertible preferred share liability, within other (income) expense, net in the consolidated statement of operations and comprehensive loss.

In December 2018, the Series A convertible preferred shareholders partially accelerated the second closing and the Company issued 9,000,000 Series A convertible preferred shares at a price of $1.00 per share and received net proceeds of $9.0 million.

As of December 31, 2018, 36,000,000 Series A convertible preferred shares were subject to issuance upon completion of remaining milestones or as the preferred shareholders elected to waive such milestones.

In June 2019, the Company and the Series A convertible preferred shares investors agreed to issue the remaining 6,000,000 Series A convertible preferred shares at a price of $1.00 per share related to the second closing, and to partially accelerate 14,000,000 Series A convertible preferred shares at a price of $1.00 per share related to the third closing. The shares were issued and the aggregate net proceeds of $20.0 million were received in June and July 2019.

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Convertible Preferred Shares

Convertible preferred shares consist of the following:

	December 31, 2018			
Convertible Preferred Shares	Shares Authorized	Shares Issued and Outstanding	Carrying Value	Liquidation Preference
Series A	60,000,000	24,000,000	$ 23,073,000	$ 24,000,000
Total	60,000,000	24,000,000	$ 23,073,000	$ 24,000,000

The holders of the Company's convertible preferred shares have various rights, preferences, and privileges as follows:

Dividends

The holders of each share of Series A convertible preferred share shall be entitled to receive, when and if declared by the board of directors, a noncumulative dividend at the rate of $0.08 per share per annum on each outstanding convertible preferred share. Such dividends are payable in preference to the payment of any dividends on ordinary shares declared by the board of directors. No dividends have been declared to date.

Automatic Conversion Rights

Each share of Series A convertible preferred share is convertible, at the option of the holder at any time, into the number of ordinary shares as is determined by dividing the original issue price for such series of preferred share by the conversion price for such series of preferred share that is in effect at the time of conversion. The initial conversion price for the series of preferred share is the original issue price for such series of preferred share multiplied by 6.217. The original issue price was $1.00 per share for the Series A convertible preferred shares. The applicable conversion price of each is subject to adjustment upon any future stock splits or combinations, recapitalizations, or upon the issuance of any new securities as a price per share lower than the applicable conversion price of the Series A convertible preferred shares in effect immediately prior to such issuance.

Each share of Series A convertible preferred share will automatically be converted into ordinary shares upon the earlier of: (i) the closing of an underwritten public offering of ordinary shares of the Company at a price per share not less than $5.00 with aggregate gross proceeds to the Company of at least $50.0 million (a "qualified public offering"); or (ii) the written consent of the holders of at least 50% of the Series A convertible preferred shares, including OrbiMed Israel Partners II, L.P., or OrbiMed Private Investments VI, L.P.

Mandatory Conversion

In the event a holder of Series A convertible preferred shares does not fund its full pro rata portion of the applicable milestone closing, then unless otherwise waived in writing by the requisite preferred, such holder's Series A convertible preferred shares and/or ordinary shares issued upon conversion of Series A convertible preferred shares will be converted to ordinary shares, at a conversion ratio of 10 Series A convertible preferred shares to 1 ordinary share. Such holder will lose any rights as a holder of Series A convertible preferred shares, including the right to invest in any subsequent equity or debt financing, the right to received Series A convertible preferred share preference, and the right, if any, to designate a board seat.

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Voting Rights

Each holder of the Series A convertible preferred share is entitled to one vote for each ordinary share into which such Series A convertible preferred share could be converted.

Liquidation Preference

In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company, or deemed liquidation event (a consolidation, merger or reorganization or a sale of all or substantially all of the Company's assets, or substantially all of the Company's issued and outstanding share capital of the Company), the holders of the series A convertible preferred shares will be entitled to receive on a pro rata basis, prior and in preference to the holders of ordinary shares, an amount equal to the original issuance price (as adjusted for any share split, share combination, share dividend, recapitalization or like events), less the amount of any distributions received in any prior liquidation event, and all declared by unpaid dividends.

Redemption

The Company's articles of association do not provide redemption rights to the holders of the Series A convertible preferred shares. In the event of a liquidation event, all the funds and assets of the Company available for distribution among all the shareholders shall be distributed in the following order of preference: (a) the holders of the Series A convertible preferred shares shall be entitled to receive an amount per share equal to $1.00 per each Series A convertible preferred share (less the amount of distributions actually received in any prior liquidation event, plus all declared but unpaid dividends) and (b) the remaining assets of the Company available for distribution to shareholders shall be distributed among the holders of ordinary shares and to the holders of the Series A convertible preferred shares on an as-converted and pro rata basis.

Although the convertible preferred shares are not redeemable, in the event of certain "deemed liquidation events" that are not solely within the Company's control (including merger, acquisition, or sale of all or substantially all of the Company's assets), the holders of the convertible preferred shares would be entitled to preference amounts paid before distribution to other shareholders (as explained in the previous paragraph) and hence effectively redeeming the preference amount. The convertible preferred shares are classified outside of shareholders' deficit as a result of these in-substance contingent redemption rights.

As of December 31, 2018, the Company did not adjust the carrying values of the convertible preferred shares to the deemed liquidation values of such shares since a liquidation event was not probable of occurring.

8. Ordinary Shares

Pursuant to the Company's amended articles of association filed on May 30, 2018, the Company is authorized to issue a total of 10,415,900 ordinary shares, of which 611,226 ordinary shares were issued and outstanding as of December 31, 2018. The proceeds from the issuance of the Company's ordinary shares were received in April 2019.

The holders of ordinary shares are entitled to one vote per ordinary share on all matters to be voted on by the shareholders of the Company and are entitled to dividends, if and when declared by the board of directors, subject to the prior rights of the preferred shareholders. No dividends have been declared as of December 31, 2018.

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Total ordinary shares reserved for issuance are summarized as follows (in thousands):

	December 31, 2018
Series A convertible preferred shares outstanding, as converted	3,860,383
Options issued and outstanding	591,448
Shares available for future option grants	472,714
Total ordinary shares reserved for issuance	4,924,545

9. Share-Based Compensation

In November 2018, the board of directors of the Company (the "Board") authorized the 2018 Equity Incentive Share Option Plan (the "2018 Plan"). The 2018 Plan provides for the grant of 1,064,162 share-based awards, including incentive stock options to employees, directors, and non-employee service providers of the Company. The aggregate number of ordinary shares reserved and available for grant under the 2018 Plan was 472,714 as of December 31, 2018.

The Board determines the period over which options become exercisable and options generally vest over a four-year period, with 25% of options vesting on the first anniversary of employment, and thereafter, the remaining options vesting quarterly, over the following 36-month period. The options will expire within ten years from the date of grant. The exercise price of awards granted will not be less than the estimated fair value of the shares on the date of grant.

The Company recorded share-based compensation for the period indicated as follows (in thousands):

	Period from January 18, 2018 (inception) to December 31, 2018
Research and development	$ 13
General and administrative	95
Total share-based compensation	$ 108

The fair value of option awards granted was estimated at the date of grant using a Black-Scholes option-pricing model with the following assumptions:

	Period from January 18, 2018 (inception) to December 31, 2018
Expected term (years)	5.92
Expected volatility	73.16%
Risk-free interest rate	3.1%
Expected dividend	—

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The following table summarizes stock option activity under the 2018 Plan:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (In Years)
Balance as of January 18, 2018 (inception)	—	$ —	
Granted	591,448	1.93	
Exercised	—	—	
Cancelled	—	—	
Balance outstanding as of December 31, 2018	591,448	$ 1.93	9.87
Exercisable as of December 31, 2018	—	$ —	—

Options granted for the period from January 18, 2018 (inception) to December 31, 2018 were subject to cliff vesting as of December 31, 2018, and accordingly, there were no vested options during the period. The weighted-average grant date fair value of options granted for the period from January 18, 2018 (inception) to December 31, 2018 was $1.31 per share. As of December 31, 2018, there was $668,000 of unrecognized share-based compensation cost related to stock options granted under the 2018 Plan, which is expected to be recognized over a weighted-average period of 3.5 years.

Included in the option activity table were 13,001 stock options granted to non-employee service providers during the period from January 18, 2018 (inception) to December 31, 2018. These options were granted in exchange for consulting services to be rendered and vest over the term specified in the grant. The Company recorded non-employee share-based compensation of $2,000 during the period from January 18, 2018 (inception) to December 31, 2018.

10. Income Taxes

Tax Rates Applicable to the Income of the Company and its Subsidiaries

The Company is taxed according to Israeli tax laws. The tax rates applicable to the income of the Company and its subsidiaries are as follows:

	Period from January 18, 2018 (inception) to December 31, 2018
89Bio Ltd.	23%
89bio Management, Inc.	21%
UAB 89bio Lithuania	15%

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The expense for income taxes is comprised of (in thousands):

	Period from January 18, 2018 (inception) to December 31, 2018
Current:	
Foreign	$ 48
	48
Deferred:	
Foreign	(20)
	(20)
Income tax expense	$ 28

Deferred Income Taxes

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets are as follows (in thousands):

	December 31, 2018
Net operating loss carryforward	$ 1,536
Research and development expenses	1,966
Other	20
Total deferred tax assets	3,522
Less: valuation allowance	(3,502)
Net deferred tax asset	$ 20

As of December 31, 2018, the Company has provided a valuation allowance of $3.5 million in respect of deferred tax assets resulting from tax loss carryforwards and other temporary differences. Realization of deferred tax assets is dependent upon future earnings, if any, the time and amount of which are uncertain. As the Company is still in its development stage and has not yet generated revenues, it is more likely than not that sufficient taxable income will not be available for the tax losses to be utilized in the future. Therefore, a valuation allowance was recorded to reduce the deferred tax assets to their recoverable amounts.

Available Carryforward Tax Losses

As of December 31, 2018, the Company has an accumulated tax loss carryforward of approximately $6.7 million. Carryforward tax losses in Israel have no expiration date.

89Bio Ltd.
Notes to the Consolidated Financial Statements

Loss from Continuing Operations, Before Taxes on Income

The Company recorded loss from continuing operations, before taxes on income for the period indicated as follows (in thousands):

	Period from January 18, 2018 (inception) to December 31, 2018
United States	$ 50
Lithuania	50
Israel	(16,248)
Net loss before tax	$ (16,148)

The reconciliation of income tax expense based on the statutory tax rate to the effective tax rate is as follows (in thousands):

	Period from January 18, 2018 (inception) to December 31, 2018
Income tax expense computed at statutory rates	$ (3,714)
Change in valuation allowance	3,502
Revaluation of convertible preferred share liability	226
Other	14
Income tax expense	$ 28

11. Net Loss and Unaudited Pro Forma Net Loss Per Share

The following outstanding potentially dilutive ordinary share equivalents have been excluded from the calculation of diluted net loss per share for the period presented due to their anti-dilutive effect:

	Period from January 18, 2018 (inception) to December 31, 2018
Convertible preferred shares	3,860,383
Stock options to purchase ordinary shares	591,448
Total	4,451,831

Unaudited Pro Forma Net Loss Per Share

Pro forma basic and diluted net loss per share has been computed to give effect to the assumed conversion of all outstanding convertible preferred shares into ordinary shares.

89Bio Ltd.
Notes to the Consolidated Financial Statements

The following table sets forth the computation of the unaudited pro forma net loss per share for the period presented (in thousands except share and per share amounts):

	Period from January 18, 2018 (inception) to December 31, 2018
Numerator:	
Net loss	$ 16,176
Denominator:	
Weighted-average number of shares used to compute net loss per share, basic and diluted	443,767
Pro forma adjustment to reflect assumed conversion of convertible preferred shares	1,683,423
Weighted-average number of shares used to compute pro forma loss per share, basic and diluted (unaudited)	2,127,190
Pro forma net loss per share, basic and diluted (unaudited)	$ 7.60

12. Related Party Transactions

The Company incurred $147,000 in professional services expense related to certain members of the board of directors for the period from January 18, 2018 (inception) to December 31, 2018. The related party liability balance was $23,000 as of December 31, 2018.

13. Subsequent Events

In January and July 2019, the board of directors granted 143,121 and 511,024 stock options, respectively, to its employees and non-employee service providers. 25% of the options will vest on the first anniversary of employment or the first anniversary of the day of grant, and the remaining options will thereafter vest quarterly over the following 36-month period.

In June 2019, the Company agreed to issue 20,000,000 Series A convertible preferred shares at $1.00 per share. The shares were issued and the aggregate net proceeds of $20.0 million were received in June and July 2019 (see Note 7).

In June 2019, the Company formed 89bio, Inc. for the purpose of an internal reorganization transaction. In September 2019, all of the equity holders of 89Bio Ltd. exchanged 100% of the equity of 89Bio Ltd. for 100% of the equity of 89bio, Inc. Following this exchange, 89Bio Ltd. became a wholly owned subsidiary of 89bio, Inc. (as mentioned in Note 1).

On October 24, 2019, 89bio, Inc.’s board of directors approved the Reverse Split, which was effected on October 25, 2019 (see Note 2).

In accordance with ASC 855 “*Subsequent Events*” the Company evaluated subsequent events through August 15, 2019, the date these consolidated financial statements were available to be issued and October 28, 2019, the date these consolidated financial statements were reissued. The Company concluded that no other subsequent events have occurred that would require recognition or disclosure in the consolidated financial statements.

89Bio Ltd.
Condensed Consolidated Balance Sheets
(In thousands, except share and per share amounts)

	December 31, 2018	June 30, 2019 (unaudited)	Pro Forma June 30, 2019 (unaudited)
Assets			
Current assets:			
Cash and cash equivalents	$ 11,234	$ 21,919	
Restricted cash	23	24	
Other current assets	59	84	
Total current assets	11,316	22,027	
Property and equipment, net	33	46	
Deferred offering costs	—	204	
Deferred tax assets	20	70	
Total assets	$ 11,369	$ 22,347	
Liabilities and shareholders' (deficit) equity			
Current liabilities:			
Accounts payable	$ 1,509	$ 968	
Accrued expenses	1,173	2,656	
Convertible preferred share liability	1,671	5,913	
Total current liabilities	4,353	9,537	
Commitments and contingencies (Note 5)			
Convertible preferred shares, NIS 0.01 nominal value; 60,000,000 shares authorized as of December 31, 2018 and June 30, 2019 (unaudited); 24,000,000 and 42,826,389 shares issued and outstanding as of December 31, 2018 and June 30, 2019 (unaudited), actual; aggregate liquidation preference of $24,000 and $42,826 as of December 31, 2018 and June 30, 2019 (unaudited), actual; no shares issued and outstanding as of June 30, 2019 pro forma (unaudited)	23,073	48,168	$ —
Shareholders' (deficit) equity:			
Ordinary shares, NIS 0.01 nominal value, 10,415,900 shares authorized at December 31, 2018 and June 30, 2019 (unaudited); 611,226 shares issued and outstanding as of December 31, 2018 and June 30, 2019 (unaudited), actual; 7,499,818 issued and outstanding as of June 30, 2019 pro forma (unaudited)	1	1	8
Additional paid-in capital	118	229	48,390
Accumulated deficit	(16,176)	(35,588)	(35,588)
Total shareholders' (deficit) equity	(16,057)	(35,358)	$ 12,810
Total liabilities, convertible preferred shares and shareholders' (deficit) equity	$ 11,369	$ 22,347	

The accompanying notes are an integral part of these condensed consolidated financial statements.

89Bio Ltd.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)
(In thousands, except share and per share amounts)

	Period from January 18, 2018 (inception) to June 30, 2018	Six Months Ended June 30, 2019
Operating expenses:		
Research and development	$ 6,700	$ 7,474
General and administrative	268	1,357
Total operating expenses	6,968	8,831
Loss from operations	6,968	8,831
Other (income) expenses, net	405	10,552
Net loss before tax	7,373	19,383
Income tax expense	—	29
Net loss and comprehensive loss	$ 7,373	$ 19,412
Net loss per share, basic and diluted	$ 26.95	$ 31.76
Weighted-average shares used to compute net loss per share, basic and diluted	273,532	611,226
Pro forma net loss per share, basic and diluted		$ 4.24
Weighted-average shares used to compute pro forma net loss per share, basic and diluted		4,583,692

The accompanying notes are an integral part of these condensed consolidated financial statements.

89Bio Ltd.
Condensed Consolidated Statements of Convertible Preferred Shares and Shareholders' Deficit
(Unaudited)
(In thousands, except share and per share amounts)

	Convertible Preferred Shares		Ordinary Shares		Additional Paid-in Capital	Accumulated Deficit	Total Shareholders' Deficit
	Shares	Amounts	Shares	Amounts			
Balance as of January 18, 2018 (inception)	—	$ —	—	$ —	$ —	$ —	$ —
Issuance of ordinary shares	—	—	611,226	1	10	—	11
Issuance of convertible preferred shares, net of issuance costs of $228 and the recognition of the convertible preferred share liability of $638	14,900,000	14,034	—	—	—	—	—
Conversion of convertible note into preferred shares	100,000	100	—	—	—	—	—
Net loss and comprehensive loss	—	—	—	—	—	(7,373)	(7,373)
Balance as of June 30, 2018	15,000,000	$14,134	611,226	$ 1	$ 10	$ (7,373)	$ (7,362)

	Convertible Preferred Shares		Ordinary Shares		Additional Paid-in Capital	Accumulated Deficit	Total Shareholders' Deficit
	Shares	Amounts	Shares	Amounts			
Balance as of December 31, 2018	24,000,000	$23,073	611,226	$ 1	$ 118	$ (16,176)	$ (16,057)
Issuance of convertible preferred shares, net of issuance costs of $0 and the partial settlement of the convertible preferred share liability of $6,269	18,826,389	25,095	—	—	—	—	—
Share-based compensation	—	—	—	—	111	—	111
Net loss and comprehensive loss	—	—	—	—	—	(19,412)	(19,412)
Balance as of June 30, 2019	42,826,389	$48,168	611,226	$ 1	$ 229	$ (35,588)	$ (35,358)

The accompanying notes are an integral part of these condensed consolidated financial statements.

89Bio Ltd.
Condensed Consolidated Statements of Cash Flows
(Unaudited)
(In thousands)

	Period from January 18, 2018 (inception) to June 30, 2018	Six Months Ended June 30, 2019
Cash flows from operating activities:		
Net loss	$ (7,373)	$ (19,412)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	—	7
Share-based compensation	—	111
Deferred tax assets	—	(50)
Revaluation of convertible preferred share liability	357	10,511
Changes in operating assets and liabilities:		
Other current assets	(33)	(36)
Accrued expenses	197	1,279
Accounts payable	208	(541)
Net cash used in operating activities	(6,644)	(8,131)
Cash flows from investing activities:		
Purchase of property and equipment	(31)	(20)
Net cash used in investing activities	(31)	(20)
Cash flows from financing activities:		
Proceeds from issuance of convertible preferred shares and convertible preferred share liability, net of issuance costs	14,672	18,826
Proceeds from issuance of convertible note	100	—
Proceeds from issuance of ordinary shares	—	11
Net cash provided by financing activities	14,772	18,837
Net increase in cash and cash equivalents, and restricted cash	8,097	10,686
Cash and cash equivalents, and restricted cash at beginning of period	—	11,257
Cash and cash equivalents, and restricted cash at end of period	$ 8,097	$ 21,943
Components of cash and cash equivalents, and restricted cash:		
Cash and cash equivalents	$ 8,073	$ 21,919
Restricted cash	24	24
Total cash and cash equivalents, and restricted cash	$ 8,097	$ 21,943
Supplemental disclosures of noncash investing and financing information:		
Conversion of convertible note into preferred shares	$ 100	$ —
Deferred offering costs included in accrued expenses	$ —	$ 204

The accompanying notes are an integral part of these condensed consolidated financial statements.

89Bio Ltd.
Notes to Unaudited Interim Condensed Consolidated Financial Statements

1. Organization and Basis of Presentation

Description of Business

89Bio Ltd. ("89Bio" or the "Company") is a clinical-stage biopharmaceutical company focused on the development and commercialization of innovative therapies for the treatment of liver and cardio-metabolic diseases. The Company's lead product candidate, BIO89-100, a specifically engineered glycoPEGylated analog of fibroblast growth factor 21, is currently being developed for the treatment of nonalcoholic steatohepatitis. 89Bio Ltd. was incorporated in Israel in January 2018. The Company has two wholly owned subsidiaries: 89bio Management, Inc., located in San Francisco, California and UAB 89bio Lithuania, located in Vilnius, Lithuania.

Going Concern

The accompanying condensed consolidated financial statements are prepared assuming the Company will continue as a going concern, which contemplates the realization of assets and liquidation of liabilities in the normal course of business. To date, the Company has not generated revenues from its activities and has incurred substantial operating losses. Management expects the Company to continue to generate substantial operating losses for the foreseeable future until it completes development of its products and seeks regulatory approvals to market such products. Management will continue to fund its operations primarily through utilization of its current financial resources and through additional raises of capital.

Such conditions raise substantial doubts about the Company's ability to continue as a going concern for at least a year after the filing date of the accompanying condensed consolidated financial statements. Management plans to address these conditions by raising funds from its current investors as well as outside potential investors. However, there is no assurance that such funding will be available to the Company or that it will be obtained on terms favorable to the Company or will provide the Company with sufficient funds to meet its objectives. The accompanying condensed consolidated financial statements do not include any adjustments relating to the recoverability and classification of assets, carrying amounts or the amount or classification of liabilities that may be required should the Company be unable to continue as a going concern.

2. Summary of Significant Accounting Policies

Reverse Stock Split

In September 2019, the Company completed an internal reorganization transaction pursuant to which 89Bio Ltd. became a wholly owned subsidiary of 89bio, Inc. (see Note 12). On October 24, 2019, 89bio, Inc.'s board of directors approved an amendment to the amended and restated certificate of incorporation of 89bio, Inc. to effect a 1-for-6.217 reverse split ("Reverse Split") of shares of the common stock of 89bio, Inc. and a proportional adjustment to the conversion ratio of the convertible preferred stock, which was effected on October 25, 2019. The par value and authorized shares of common stock and the par value, authorized and outstanding shares of convertible preferred stock were not adjusted as a result of the Reverse Split. All of the share and per share information for 89Bio Ltd. included in the accompanying unaudited interim condensed consolidated financial statements has been adjusted to reflect the Reverse Split.

Unaudited Interim Condensed Consolidated Financial Statements

The unaudited interim condensed consolidated financial statements have been prepared on the same basis as the audited financial statements as of December 31, 2018 and for the period from January 18, 2018 (inception) to December 31, 2018 and, in the opinion of management, reflect all adjustments, which include only

normal recurring adjustments, necessary to present fairly the Company's financial position as of June 30, 2019, and its results of operations and comprehensive loss, cash flows and shareholders' deficit for the period from January 18, 2018 (inception) to June 30, 2018 and the six months ended June 30, 2019. The financial data and the other financial information contained in these notes to the condensed consolidated financial statements related to the period from January 18, 2018 (inception) to June 30, 2018 and the six months ended June 30, 2019 are unaudited. The results of operations for the six months ended June 30, 2019 are not necessarily indicative of the results to be expected for the year ending December 31, 2019 or for any other future annual or interim period. These condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements.

Unaudited Pro Forma Financial Information

The Company completed an internal reorganization transaction in September 2019, pursuant to which 89Bio Ltd. became a wholly owned subsidiary of 89bio, Inc., a newly formed Delaware corporation. As part of the transaction, all of the equity holders of 89Bio Ltd. exchanged 100% of the equity of 89Bio Ltd. for 100% of the equity of 89bio, Inc.

The unaudited pro forma balance sheet information as of June 30, 2019 has been prepared to give effect to the exchange of all outstanding convertible preferred shares of 89Bio Ltd. into shares of common stock of 89bio, Inc. as if the exchange had occurred on June 30, 2019. The shares of common stock issuable and the proceeds expected to be received in the Company's anticipated IPO are excluded from such pro forma financial information.

The unaudited pro forma net loss per share, basic and diluted for the six months ended June 30, 2019 was computed using the weighted-average number of shares of ordinary shares outstanding, including to give effect to the exchange of all outstanding shares of convertible preferred shares of 89Bio Ltd. into equivalent shares of common stock of 89bio, Inc. as if such exchange had occurred at the beginning of the period, or their issuance dates if later.

Use of Estimates

The preparation of condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the condensed consolidated financial statements and the reported amounts of expenses during the reporting period. Significant estimates and assumptions made in the accompanying condensed consolidated financial statements include but are not limited to the fair value of stock options, the convertible preferred share liability and certain accruals. The Company evaluates its estimates and assumptions on an ongoing basis using historical experience and other factors and adjusts those estimates and assumptions when facts and circumstances dictate. Actual results could differ from those estimates.

Fair Value Measurements

Financial assets and liabilities are recorded at fair value on a recurring basis in the balance sheets. The carrying values of Company's financial assets and liabilities, including cash and cash equivalents, restricted cash, other current assets, accounts payable, and accrued expenses approximate to their fair value due to the short-term maturity of these instruments. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. Assets and liabilities recorded at fair value are categorized based upon the level of judgment associated with the

inputs used to measure their fair value. Hierarchical levels are directly related to the amount of subjectivity with the inputs to the valuation of these assets or liabilities as follows:

Level 1—Observable inputs such as unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date;

Level 2—Inputs (other than quoted prices included in Level 1) are either directly or indirectly observable inputs for similar assets or liabilities. These include quoted prices for identical or similar assets or liabilities in active markets and quoted prices for identical or similar assets of liabilities in markets that are not active;

Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Convertible Preferred Share Liability

The freestanding instruments related to the commitment by the Series A convertible preferred shareholders to purchase and by the Company to sell its Series A convertible preferred shares in subsequent closings, contingent upon the achievement of certain developmental milestones and approval by the board of directors, at a fixed price per share, are considered a liability (or an asset), measured at fair value as the shares underlying the rights contain liquidation preferences upon certain "deemed liquidation events" that are not solely within the Company's control and which are considered in-substance contingent redemption features (refer to Note 7 for further discussion on the redemption rights of the convertible preferred shares). The instruments are subject to revaluation at each balance sheet date until settlement, with revaluations recognized as a component of other (income) expenses, net in the consolidated statements of operations and comprehensive loss.

Deferred Offering Costs

The Company has deferred offering costs consisting of legal, accounting and other fees and costs directly attributable to the Company's anticipated IPO. The deferred offering costs will be offset against the proceeds received upon the completion of the anticipated IPO. In the event the anticipated IPO is terminated, all of the deferred offering costs will be expensed. As of December 31, 2018, the Company did not record any deferred offering costs. As of June 30, 2019, the Company had $204,000 of deferred offering costs on the consolidated balance sheet.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("ASU") 2014-09—*Revenue from contracts with customers*, to achieve a consistent application of revenue recognition, resulting in a single revenue model to be applied by reporting companies under U.S. GAAP. Under the new model, recognition of revenue occurs when a customer obtains control of the promised goods or services in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. In addition, the standard requires that reporting companies disclose the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. The standard is effective for public entities for fiscal years beginning after December 15, 2017 and is effective for nonpublic entities for fiscal years beginning after December 15, 2018. The standard is required to be applied retrospectively to each prior reporting period presented or retrospectively with the cumulative effect of initially applying it recognized at the date of initial application. The Company adopted this standard on January 1, 2019, and as the Company has not incurred revenues to date, the adoption of the standard did not have a significant impact on its consolidated financial statements.

89Bio Ltd.
Notes to Unaudited Interim Condensed Consolidated Financial Statements

In February 2016, the FASB issued ASU 2016-02—*Leases*, requiring the recognition of lease assets and liabilities on the balance sheet. The standard: (a) clarifies the definition of a lease; (b) requires a dual approach to lease classification similar to current lease classifications; and (c) causes lessees to recognize leases on the balance sheet as a lease liability with a corresponding right-of-use asset for leases with a lease-term of more than twelve months. The standard is effective for public entities for fiscal years beginning after December 15, 2018 and for nonpublic entities for fiscal years beginning after December 15, 2019. The Company is currently evaluating the impact of this standard and expects the adoption will result in an insignificant increase in the assets and liabilities on its consolidated balance sheet for operating leases.

In June 2018, the FASB issued ASU No. 2018-07 *Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*, which is intended to reduce the cost and complexity and to improve financial reporting for nonemployee share based payment. The standard expands the scope of Topic 718, (which currently only includes share-based payments to employees) to include share-based payments issued to nonemployees for goods or services. Consequently, the accounting for share-based payments to nonemployees and employees will be substantially aligned. The standard is effective for public entities for fiscal years beginning after December 15, 2019 and nonpublic entities for fiscal years beginning after December 15, 2020. Early adoption is permitted but no earlier than a company's adoption date of Topic 606. The Company early adopted this standard on January 1, 2019, and the impact of its adoption on the Company's consolidated financial statements is not material.

3. Fair Value Measurements

The fair value of the Company's financial liabilities measured at fair value on a recurring basis by level within the fair value hierarchy are as follows (in thousands):

	December 31, 2018			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Convertible preferred share liability	$ —	$ —	$1,671	$1,671
Total financial liabilities	$ —	$ —	$1,671	$1,671

	June 30, 2019			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Convertible preferred share liability	$ —	$ —	$5,913	$5,913
Total financial liabilities	$ —	$ —	$5,913	$5,913

89Bio Ltd.
Notes to Unaudited Interim Condensed Consolidated Financial Statements

The changes in the fair value of the Company's Level 3 financial liabilities, which are measured on a recurring basis are as follows (in thousands):

	December 31, 2018	June 30, 2019
Beginning balance	$ —	$ 1,671
Recognition of convertible preferred share liability upon issuance of convertible preferred shares	638	—
Revaluation of convertible preferred share liability recorded in other (income) expense, net	979	10,511
Partial settlement of convertible preferred share liability upon second closing	54	(1,860)
Partial settlement of convertible preferred share liability upon third closing	—	(4,409)
Ending balance	$ 1,671	$ 5,913

The fair value of the Company's convertible preferred share liability is based on significant inputs not observed in the market, and thus represent a Level 3 measurement. Refer to Note 7 for further discussion on the convertible preferred share liability.

4. Consolidated Balance Sheet Components

Accrued Expenses

Accrued expenses consist of the following (in thousands):

	December 31, 2018	June 30, 2019
Accrued research and development expense	$ 890	$2,015
Accrued employee and related expenses	283	641
Total accrued expenses	$ 1,173	$2,656

5. Commitments and Contingencies

Asset Transfer and License Agreement with Teva Pharmaceutical Industries Ltd

In April 2018, the Company concurrently entered into two Asset Transfer and License Agreements (the "Teva Agreements") with Teva Pharmaceutical Industries Ltd ("Teva") under which it acquired certain patents and intellectual property relating to two programs: (1) Teva's glycoPEGylated FGF21 program, including the compound TEV-47948 (BIO89-100), a glycoPEGylated long-acting FGF21 and (2) Teva's development program of small molecule inhibitors of Fatty Acid Synthase. Pursuant to the Teva Agreements, the Company paid Teva an initial nonrefundable upfront payment of $6.0 million and the Company could be obligated to pay Teva up to $67.5 million under each program, for a total of $135.0 million, upon the achievement of certain clinical development and commercial milestones. In addition, the Company is obligated to pay Teva tiered royalties at percentages in the low-to-mid single-digits on worldwide net sales on all products containing the Teva compounds.

The Teva Agreements can be terminated (i) by the Company without cause, after the first anniversary of the effective date, upon 120 days' written notice to Teva, (ii) by either party, if the other party materially breaches any of its obligations under the Agreements and fails to cure such breach within 60 days after receiving

notice thereof, or (iii) by either party, if a bankruptcy petition is filed against the other party and is not dismissed within 60 days. In addition, Teva can also terminate the agreement related to the Company's glycoPEGylated FGF21 program in the event the Company, or any of its affiliates or sublicensees, challenges any of the Teva patents licensed to the Company, and the challenge is not withdrawn within 30 days of written notice from Teva.

The Company accounted for the acquisition of technology as an asset acquisition because it did not meet the definition of a business. The Company recorded the total consideration transferred to Teva as research and development expense in the condensed consolidated statements of operations and comprehensive loss because the acquired technology represented in-process research and development and had no alternative future use.

6. Convertible Note

In March 2018, the Company entered into a Convertible Loan Agreement (the "Convertible Note") with a principal amount of $100,000 and a fixed interest rate of 8% per annum. The Convertible Note was automatically convertible into the Company's next equity financing, or upon an earlier event of default. In April 2018, the entire amount outstanding converted into 100,000 shares of Series A convertible preferred shares upon the closing of the Series A financing.

7. Convertible Preferred Shares

In April 2018, the Company entered into the Series A Share Purchase Agreement (the "SPA"), pursuant to which the investors committed to invest an aggregate amount of up to $60.0 million for the issuance of Series A convertible preferred shares at a price of $1.00 per share.

The initial closing occurred on April 16, 2018, and the Company issued 14,900,000 Series A convertible preferred shares at a price per share of $1.00 for net cash proceeds of $14.7 million. The investors also committed to purchase 15,000,000 and 30,000,000 shares of Series A convertible preferred shares at a price of $1.00 per share in second and third closings, respectively, contingent upon the achievement by the Company of certain development milestones and approval by the board of directors.

The investors' commitment to purchase and the Company's commitment to sell Series A convertible preferred shares represent a freestanding instrument accounted for at fair value and re-measured at each reporting date. The Company estimates the fair value of this commitment using the Black Scholes option pricing model. On the date of the initial closing, the Company recorded the commitments associated with the second and third closings of the Series A convertible preferred shares at a net value of $638,000. For the period from January 18, 2018 (inception) to June 30, 2018 and for the six months ended June 30, 2019, the Company recorded an expense of $357,000 and $10.5 million, respectively, for the revaluation of the convertible preferred share liability, within other (income) expense, net in the condensed consolidated statements of operations and comprehensive loss.

In December 2018, the Series A convertible preferred shareholders partially accelerated the second closing and the Company issued 9,000,000 Series A convertible preferred shares at a price of $1.00 per share and received net proceeds of $9.0 million.

In June 2019, the Company and the Series A convertible preferred shares investors agreed to issue the remaining 6,000,000 Series A convertible preferred shares at a price of $1.00 per share related to the second closing, and to partially accelerate 14,000,000 Series A convertible preferred shares at a price of $1.00 per share related to the third closing. The shares were issued and the aggregate net proceeds of $20.0 million were received in June and July 2019.

89Bio Ltd.
Notes to Unaudited Interim Condensed Consolidated Financial Statements

Immediately subsequent to the issuance of shares as agreed by the Company and the investors in June 2019, 16,000,000 Series A convertible preferred shares were subject to issuance upon completion of remaining milestones or as the preferred shareholders elect to waive such milestones.

Convertible Preferred Shares

Convertible preferred shares consist of the following:

	December 31, 2018			
Convertible Preferred Shares	Shares Authorized	Shares Issued and Outstanding	Carrying Value	Liquidation Preference
Series A	60,000,000	24,000,000	$ 23,073,000	$ 24,000,000
Total	60,000,000	24,000,000	$ 23,073,000	$ 24,000,000

	June 30, 2019			
Convertible Preferred Shares	Shares Authorized	Shares Issued and Outstanding	Carrying Value	Liquidation Preference
Series A	60,000,000	42,826,389	$ 48,168,000	$ 42,826,000
Total	60,000,000	42,826,389	$ 48,168,000	$ 42,826,000

The Company's articles of association do not provide redemption rights to the holders of the Series A convertible preferred shares. In the event of a liquidation event, all the funds and assets of the Company available for distribution among all the shareholders shall be distributed in the following order of preference: (a) the holders of the Series A convertible preferred shares shall be entitled to receive an amount per share equal to $1.00 per each Series A convertible preferred share (less the amount of distributions actually received in any prior liquidation event, plus all declared but unpaid dividends) and (b) the remaining assets of the Company available for distribution to shareholders shall be distributed among the holders of ordinary shares and to the holders of the Series A convertible preferred shares on an as-converted and pro rata basis.

Although the convertible preferred shares are not redeemable, in the event of certain "deemed liquidation events" that are not solely within the Company's control (including merger, acquisition, or sale of all or substantially all of the Company's assets), the holders of the convertible preferred shares would be entitled to preference amounts paid before distribution to other shareholders and hence effectively redeeming the preference amount. The convertible preferred shares are classified outside of shareholders' deficit as a result of these in-substance contingent redemption rights.

As of December 31, 2018, and June 30, 2019, the Company did not adjust the carrying values of the convertible preferred shares to the deemed liquidation values of such shares since a liquidation event was not probable of occurring.

89Bio Ltd.
Notes to Unaudited Interim Condensed Consolidated Financial Statements

8. Ordinary Shares

Total ordinary shares reserved for issuance are summarized as follows (in thousands):

	December 31, 2018	June 30, 2019
Series A convertible preferred shares outstanding, as converted	3,860,383	6,888,592
Options issued and outstanding	591,448	721,079
Shares available for future option grants	472,714	343,083
Total ordinary shares reserved for issuance	4,924,545	7,952,754

9. Share-Based Compensation

As of June 30, 2019, there were 343,083 ordinary shares reserved and available for grant under the 2018 Plan.

The Company recorded share-based compensation for the periods indicated as follows (in thousands):

	Period from January 18, 2018 (inception) to June 30, 2018	Six months ended June 30, 2019
Research and development	$ —	$ 20
General and administrative	—	91
Total share-based compensation	$ —	$ 111

The fair value of option awards granted for the periods indicated was estimated at the date of grant using a Black-Scholes option-pricing model with the following assumptions:

	Period from January 18, 2018 (inception) to June 30, 2018	Six months ended June 30, 2019
Expected term (years)	—	6.11
Expected volatility	—	61.80%
Risk-free interest rate	—	2.54-2.60%
Expected dividend	—	—

89Bio Ltd.
Notes to Unaudited Interim Condensed Consolidated Financial Statements

The following table summarizes stock option activity under the 2018 Plan for the six months ended June 30, 2019:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (In years)	Aggregate Intrinsic Value (In thousands)
Balance outstanding as of December 31, 2018	591,448	$ 1.93	9.87	$ —
Granted	143,121	1.93		
Exercised	—	—		
Cancelled	(13,490)	1.93		
Balance outstanding as of June 30, 2019	721,079	$ 1.93	9.40	$ 852
Exercisable as of June 30, 2019	66,041	$ 1.93	9.40	$ 78

10. Net Loss and Unaudited Pro Forma Net Loss Per Share

The following outstanding potentially dilutive ordinary share equivalents have been excluded from the calculation of diluted net loss per share for the periods presented due to their anti-dilutive effect:

	Period from January 18, 2018 (inception) to June 30, 2018	Six Months Ended June 30, 2019
Convertible preferred shares	2,412,739	6,888,592
Stock options to purchase ordinary shares	—	721,079
Total	2,412,739	7,609,671

Unaudited Pro Forma Net Loss Per Share

Pro forma basic and diluted net loss per share has been computed to give effect to the completion of an internal reorganization transaction and assumes the exchange of all outstanding shares of convertible preferred shares of 89Bio Ltd. into shares of common stock of 89bio, Inc.

	Six Months Ended June 30, 2019
Numerator:	
Net loss	$ 19,412
Denominator:	
Weighted-average number of shares used to compute net loss per share, basic and diluted	611,226
Pro forma adjustment to reflect assumed conversion of convertible preferred shares	3,972,466
Weighted-average number of shares used to compute pro forma loss per share, basic and diluted	4,583,692
Pro forma net loss per share, basic and diluted	$ 4.24

89Bio Ltd.
Notes to Unaudited Interim Condensed Consolidated Financial Statements

11. Related Party Transactions

The Company incurred $128,000 and $80,000 in professional services expense related to certain members of the board of directors for the period from January 18, 2018 (inception) to June 30, 2018 and for the six months ended June 30, 2019, respectively. The related party liability balance was $23,000 and $4,000 as of December 31, 2018 and June 30, 2019, respectively.

12. Subsequent Events

In July 2019, the board of directors granted 511,024 stock options, to its employees and non-employee service providers. 25% of the options will vest on the first anniversary of employment or the first anniversary of the day of grant, and the remaining options will thereafter vest quarterly over the following 36-month period.

In July 2019, the Company issued 1,173,611 Series A convertible preferred shares at $1.00 per share and aggregate net proceeds of $1.2 million were also received in July 2019, related to the shares the Company agreed to issue to investors in June 2019 (see Note 7).

In September 2019, the Company completed an internal reorganization transaction pursuant to which 89Bio Ltd. became a wholly owned subsidiary of 89bio, Inc., a newly formed Delaware corporation. As part of the transaction, all of the equity holders of 89Bio Ltd. exchanged 100% of the equity of 89Bio Ltd. for 100% of the equity of 89bio, Inc.

On October 24, 2019, 89bio, Inc.'s board of directors approved the Reverse Split, which was effected on October 25, 2019 (see Note 2).

In accordance with ASC 855 "*Subsequent Events*" the Company evaluated subsequent events through September 19, 2019, the date the unaudited interim condensed consolidated financial statements were available to be filed and October 28, 2019, the date the unaudited interim condensed consolidated financial statements were reissued. The Company concluded that no other subsequent events have occurred that would require recognition or disclosure in the accompanying financial statements.

Through and including , 2019, (the 25th day after the date of this prospectus), all dealers effecting transactions in our common stock, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

Shares

Common Stock

PROSPECTUS

BofA Securities

SVB Leerink

RBC Capital Markets

Oppenheimer & Co.

, 2019

PART II

INFORMATION NOT REQUIRED IN THE PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

The following table sets forth the various expenses, other than underwriting discounts and commissions, payable by the registrant in connection with the sale of common stock being registered. All of the amounts shown are estimated except the Securities and Exchange Commission (the "SEC") registration fee, the Financial Industry Regulatory Authority, Inc. ("FINRA") filing fee and The Nasdaq Global Market listing fee.

	Amount To Be Paid
SEC registration fee	$ 11,102
FINRA filing fee	13,330
The Nasdaq Global Market listing fee	150,000
Printing and engraving expenses	45,000
Legal fees and expenses	1,400,000
Accounting fees and expenses	600,000
Blue Sky, qualification fees and expenses	10,000
Transfer agent and registrar fees	10,000
Miscellaneous fees and expenses	160,568
Total	$ 2,400,000

Item 14. Indemnification of Directors and Officers.

The company is a Delaware corporation. Section 145(a) of the Delaware General Corporation Law (the "DGCL") provides that a Delaware corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative, other than an action by or in the right of the corporation, by reason of the fact that such person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with such action, suit or proceeding if the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful.

Section 145(b) of the DGCL provides that a Delaware corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the corporation to procure a judgment in its favor by reason of the fact that such person acted in any of the capacities set forth above, against expenses (including attorneys' fees) actually and reasonably incurred by such person in connection with the defense or settlement of such action or suit if the person acted in good faith and in a manner the person reasonably believed to be in, or not opposed to, the best interests of the corporation, except that no indemnification shall be made in respect of any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation, unless and only to the extent that the Court of Chancery or the court in which such action or suit was brought shall determine, upon application, that, despite the adjudication of liability but in view of all the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the court shall deem proper.

Further subsections of DGCL Section 145 provide that:

(1) to the extent a present or former director or officer of a corporation has been successful on the merits or otherwise in the defense of any action, suit or proceeding referred to in subsections (i) and (ii) of Section 145 or in the defense of any claim, issue or matter therein, such person shall be indemnified against expenses, including attorneys' fees, actually and reasonably incurred by such person in connection therewith;

(2) the indemnification and advancement of expenses provided for pursuant to Section 145 shall not be deemed exclusive of any other rights to which those seeking indemnification or advancement of expenses may be entitled under any bylaw, agreement, vote of shareholders or disinterested directors or otherwise; and

(3) the corporation shall have the power to purchase and maintain insurance of behalf of any person who is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against any liability asserted against such person and incurred by such person in any such capacity, or arising out of such person's status as such, whether or not the corporation would have the power to indemnify such person against such liability under Section 145.

As used in this Item 14, the term "proceeding" means any threatened, pending or completed action, suit or proceeding, whether or not by or in the right of the company, and whether civil, criminal, administrative, investigative or otherwise.

Section 145 of the DGCL makes provision for the indemnification of officers and directors in terms sufficiently broad to indemnify officers and directors of the company under certain circumstances from liabilities (including reimbursement for expenses incurred) arising under the Securities Act of 1933. We expect that the Company's Second Amended and Restated Certificate of Incorporation and Second Amended and Restated Bylaws will provide, in effect, that, to the fullest extent and under the circumstances permitted by Section 145 of the DGCL, the company will indemnify any and all of its officers and directors. Before the completion of this offering, the company intends to enter into indemnification agreements with its officers and directors. The company may, in its discretion, similarly indemnify its employees and agents. We expect that the Company's Second Amended and Restated Certificate of Incorporation will also relieve the Company's directors from monetary damages to the company or its shareholders for breach of such director's fiduciary duty as a director to the fullest extent permitted by the DGCL. Under Section 102(b)(7) of the DGCL, a corporation may relieve its directors from personal liability to such corporation or its shareholders for monetary damages for any breach of their fiduciary duty as directors except (i) for a breach of the duty of loyalty, (ii) for failure to act in good faith, (iii) for intentional misconduct or knowing violation of law, (iv) for willful or negligent violations of certain provisions in the DGCL imposing certain requirements with respect to stock repurchases, redemptions and dividends or (v) for any transactions from which the director derived an improper personal benefit.

The company has purchased insurance policies that, within the limits and subject to the terms and conditions thereof, cover certain expenses and liabilities that may be incurred by directors and officers in connection with proceedings that may be brought against them as a result of an act or omission committed or suffered while acting as a director or officer of the company.

The form of Underwriting Agreement, to be entered into in connection with this offering and to be attached as Exhibit 1.1 hereto, provides for the indemnification by the underwriters of us and our officers and directors for certain liabilities, including liabilities arising under the Securities Act, and affords certain rights of contribution with respect thereto.

Item 15. Recent Sales of Unregistered Securities.

Since our inception in January 2018, we have made the following sales of unregistered securities:

Issuances of Capital Stock

In January 2018, we issued 361 shares of our common stock for gross aggregate consideration of $6 to two investors.

In March 2018, we issued to an investor a convertible promissory note (the "Convertible Note") in the aggregate principal amount of $100,000.

In April 2018, we issued 610,865 shares of our common stock for gross aggregate consideration of $10,996 to two investors.

Also in April 2018, we issued 15,000,000 shares of our Series A convertible preferred stock for gross aggregate consideration of $14,900,000 to nine investors, including the conversion of the Convertible Note.

In December 2018, we issued 9,000,000 shares of our Series A convertible preferred stock for gross aggregate consideration of $9,000,000 to nine investors.

In June and July 2019, we issued an aggregate of 20,000,000 shares of our Series A convertible preferred stock for gross aggregate consideration of $20,000,000 to ten investors.

In September 2019, pursuant to an internal reorganization, we issued 611,226 shares of our common stock and 44,000,000 shares of our convertible preferred stock to our existing stockholders in exchange for their shares of 89Bio, Ltd.

Grants of Stock Options

Since January 2018, we have granted stock options to purchase an aggregate of 1,317,649 shares of our common stock at a weighted-average exercise price of $2.96 to employees, directors and non-employee service providers.

None of the foregoing transactions involved any underwriters, underwriting discounts or commissions, or any public offering. The offers, sales and issuances of the securities listed in this Item 15 were deemed to be exempt from registration under the Securities Act under either (1) Rule 701 promulgated under the Securities Act as offers and sales of securities pursuant to certain compensatory benefit plans and contracts relating to compensation in compliance with Rule 701 or (2) Section 4(a)(2) of the Securities Act, including Regulation D promulgated thereunder, as offers and sales made to a limited number of accredited investors and qualified institutional buyers.

Item 16. Exhibits and Financial Statement Schedules.

(a) Exhibits

Exhibit Number	Description of Exhibit
1.1	Form of Underwriting Agreement.
2.1*	Contribution and Exchange Agreement, dated as of September 17, 2019, by and among 89Bio, Ltd., the registrant and its shareholders.
3.1	Certificate of Incorporation of the registrant, as amended, as currently in effect.
3.2	Form of Second Amended and Restated Certificate of Incorporation of the registrant, to be in effect upon completion of this offering.
3.3*	Bylaws of the registrant, as currently in effect.
3.4	Form of Second Amended and Restated Bylaws of the registrant, to be in effect upon completion of this offering.
4.1	Specimen common stock certificate of the registrant.
4.2*	Investors' Rights Agreement, dated as of September 17, 2019, by and among the registrant and certain of its shareholders.
5.1	Opinion of Gibson, Dunn & Crutcher LLP.
10.1*+	Form of Indemnification Agreement for directors and executive officers, to be in effect upon completion of this offering.
10.2+	Amended and Restated 2019 Equity Incentive Plan and forms of agreements thereunder.
10.3+	2019 Employee Stock Purchase Plan.
10.4*+	Executive Employment Offer Letter, dated June 25, 2018, by and between 89Bio Ltd. and Rohan Palekar.
10.5*+	Executive Employment Agreement, dated April 23, 2018, by and between 89Bio Ltd. and Ram Waisbourd.
10.6*+	Executive Employment Offer Letter, dated November 20, 2018, by and between 89Bio Ltd. and Hank Mansbach.
10.7*+	Executive Employment Offer Letter, dated February 28, 2019, by and between 89Bio Ltd. and Quoc Le-Nguyen.
10.8*+	Executive Employment Offer Letter, dated July 21, 2019, by and between 89Bio Ltd. and Ryan Martins.
10.9*+	Director Offer Letter, dated July 1, 2018, by and between 89Bio Ltd. and Michael Hayden.
10.10+	Non-Employee Director Compensation Policy.
10.11*#	Asset Transfer and License Agreement—FGF21 by and among 89Bio Ltd., ratiopharm GmbH, Teva Branded Pharmaceutical Products R&D, Inc. and Teva Pharmaceutical Industries Ltd, dated as of April 16, 2018.
10.12*#	Reagent Supply and Technology Transfer Agreement by and between 89Bio Ltd. and Teva Biotech GmbH, dated as of April 16, 2018, as amended.
10.13*#	Sublicense Agreement by and between 89Bio Ltd. and ratiopharm GmbH, dated as of April 16, 2018.
10.14*#	Master Services Agreement by and between 89Bio Ltd. and Biotechpharma UAB, dated as of May 7, 2018, as amended.
21.1*	List of subsidiaries.
23.1	Consent of Independent Registered Public Accounting Firm.
23.2	Consent of Independent Registered Public Accounting Firm.
23.3	Consent of Gibson, Dunn & Crutcher LLP (see Exhibit 5.1).
24.1*	Power of Attorney.

* Previously filed.
\+ Indicates management contract or compensatory plan.
\# Portions of the exhibit have been omitted for confidentiality purposes.

(b) No financial statement schedules are provided because the information called for is not required or is shown in the financial statements or the notes thereto.

Item 17. Undertakings.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned Registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance on Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be a part of this registration statement as of the time it was declared effective.

(2) For purposes of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of San Francisco, State of California, on October 28, 2019.

89bio, Inc.

By: /s/ Rohan Palekar
Rohan Palekar
Chief Executive Officer

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities set forth opposite their names and on the date indicated above.

Signature	Title	Date
/s/ Rohan Palekar Rohan Palekar	Chief Executive Officer (*principal executive officer*)	October 28, 2019
/s/ Ryan Martins Ryan Martins	Chief Financial Officer (*principal financial and accounting officer*)	October 28, 2019
* Derek DiRocco, Ph.D.	Director	October 28, 2019
* Gregory Grunberg, M.D.	Director	October 28, 2019
* Michael Hayden, M.B., Ch.B., Ph.D.	Director	October 28, 2019
* Tomer Kariv	Director	October 28, 2019
* Anat Naschitz	Director	October 28, 2019

*By: /s/ Rohan Palekar
Rohan Palekar
Attorney-in-fact

Exhibit 1.1

89BIO, INC.

(a Delaware corporation)

[●] Shares of Common Stock

UNDERWRITING AGREEMENT

Dated: November [●], 2019

89BIO, INC.

(a Delaware corporation)

[●] Shares of Common Stock

UNDERWRITING AGREEMENT

November [●], 2019

BofA Securities, Inc.
SVB Leerink LLC
RBC Capital Markets, LLC

as Representatives of the several Underwriters

c/o BofA Securities, Inc.
One Bryant Park
New York, New York 10036

c/o SVB Leerink LLC
255 California Street, 12th Floor
San Francisco, California 94111

c/o RBC Capital Markets, LLC
200 Vesey Street
New York, New York 10281

Ladies and Gentlemen:

89bio, Inc., a Delaware corporation (the "Company"), confirms its agreement with BofA Securities, Inc. ("BofAS"), SVB Leerink LLC ("SVB Leerink"), RBC Capital Markets, LLC ("RBC") and each of the other Underwriters named in Schedule A hereto (collectively, the "Underwriters," which term shall also include any underwriter substituted as hereinafter provided in Section 10 hereof), for whom BofAS, SVB Leerink and RBC are acting as representatives (in such capacity, the "Representatives"), with respect to (i) the sale by the Company and the purchase by the Underwriters, acting severally and not jointly, of the respective numbers of shares of Common Stock, par value $0.001 per share, of the Company (the "Common Stock") set forth in Schedule A hereto and (ii) the grant by the Company to the Underwriters, acting severally and not jointly, of the option described in Section 2(b) hereof to purchase all or any part of [●] additional shares of Common Stock. The aforesaid [●] shares of Common Stock (the "Initial Securities") to be purchased by the Underwriters and all or any part of the [●] shares of Common Stock subject to the option described in Section 2(b) hereof (the "Option Securities") are herein called, collectively, the "Securities."

The Company understands that the Underwriters propose to make a public offering of the Securities as soon as the Representatives deem(s) advisable after this Agreement has been executed and delivered.

The Company has filed with the Securities and Exchange Commission (the "Commission") a registration statement on Form S-1 (No. 333-234174), including the related preliminary prospectus or prospectuses, covering the registration of the sale of the Securities under the Securities Act of 1933, as amended (the "1933 Act"). Promptly after execution and delivery of this Agreement, the Company will prepare and file a prospectus in accordance with the provisions of Rule 430A ("Rule 430A") of the rules and regulations of the Commission under the 1933 Act (the "1933 Act Regulations") and Rule 424(b) ("Rule 424(b)") of the 1933 Act Regulations. The information included in such prospectus that was omitted from such registration statement at the time it became effective but that is deemed to be part of such registration statement at the time it became effective pursuant to Rule 430A(b) is herein called the "Rule 430A Information." Such registration statement, including the amendments thereto, the exhibits thereto and any schedules thereto, at the time it became effective, and including the Rule 430A Information, is herein called the "Registration Statement." Any registration statement filed pursuant to Rule 462(b) of the 1933 Act Regulations is herein called the "Rule 462(b) Registration Statement" and, after any such filing, the term "Registration Statement" shall include the Rule 462(b) Registration Statement. Each prospectus used prior to the effectiveness of the Registration Statement, and each prospectus that omitted the Rule 430A Information and was used after such effectiveness and prior to the execution and delivery of this Agreement, is herein called a "preliminary prospectus." The final prospectus, in the form first furnished to the Underwriters for use in connection with the offering of the Securities, is herein called the "Prospectus." For purposes of this Agreement, all references to the Registration Statement, any preliminary prospectus, the Prospectus or any amendment or supplement to any of the foregoing shall be deemed to include the copy filed with the Commission pursuant to its Electronic Data Gathering, Analysis and Retrieval system or any successor system ("EDGAR").

As used in this Agreement:

"1934 Act" means the Securities Exchange Act of 1934, as amended.

"1934 Act Regulations" means the rules and regulations of the Commission under the 1934 Act.

"Applicable Time" means [●] [p.m.][a.m.], New York City time, on November [●], 2019 or such other time as agreed by the Company and BofAS.

"General Disclosure Package" means any Issuer General Use Free Writing Prospectuses issued at or prior to the Applicable Time, the most recent preliminary prospectus that is distributed to investors prior to the Applicable Time and the information included on Schedule B-1 hereto, all considered together.

"Issuer Free Writing Prospectus" means any "issuer free writing prospectus," as defined in Rule 433 of the 1933 Act Regulations ("Rule 433"), including without limitation any "free writing prospectus" (as defined in Rule 405 of the 1933 Act Regulations ("Rule 405")) relating to the Securities that is (i) required to be filed with the Commission by the Company, (ii) a "road show that is a written communication" within the meaning of Rule 433(d)(8)(i), whether or not required to be filed with the Commission, or (iii) exempt from filing with the Commission pursuant to Rule 433(d)(5)(i) because it contains a description of the Securities or of the offering that does not reflect the final terms, in each case, in the form filed or required to be filed with the Commission or, if not required to be filed, in the form retained in the Company's records pursuant to Rule 433(g).

"Issuer General Use Free Writing Prospectus" means any Issuer Free Writing Prospectus that is intended for general distribution to prospective investors (other than a "*bona fide* electronic road show," as defined in Rule 433 (the "Bona Fide Electronic Road Show")), as evidenced by its being specified in Schedule B-2 hereto.

"Issuer Limited Use Free Writing Prospectus" means any Issuer Free Writing Prospectus that is not an Issuer General Use Free Writing Prospectus.

"Testing-the-Waters Communication" means any oral or written communication with potential investors undertaken in reliance on Section 5(d) of the 1933 Act.

"Written Testing-the-Waters Communication" means any Testing-the-Waters Communication that is a written communication within the meaning of Rule 405 under the 1933 Act.

SECTION 1. Representations and Warranties.

(a) *Representations and Warranties by the Company*. The Company represents and warrants to each Underwriter as of the date hereof, the Applicable Time, the Closing Time (as defined below) and any Date of Delivery (as defined below), and agrees with each Underwriter, as follows:

(i) Registration Statement and Prospectuses. Each of the Registration Statement and any amendment thereto has become effective under the 1933 Act. No stop order suspending the effectiveness of the Registration Statement or any post-effective amendment thereto has been issued under the 1933 Act, no order preventing or suspending the use of any preliminary prospectus or the Prospectus has been issued by the Commission and no proceedings for any of those purposes have been instituted or are pending or, to the Company's knowledge, contemplated by the Commission. The Company has complied with each request (if any) from the Commission for additional information.

Each of the Registration Statement and any post-effective amendment thereto, at the time it became effective, the Applicable Time, the Closing Time and any Date of Delivery complied and will comply in all material respects with the requirements of the 1933 Act and the 1933 Act Regulations. Each preliminary prospectus, the Prospectus and any amendment or supplement thereto, at the time each was filed with the Commission, and, in each case, at the Applicable Time, the Closing Time and any Date of Delivery complied and will comply in all material respects with the requirements of the 1933 Act and the 1933 Act Regulations. Each preliminary prospectus delivered to the Underwriters for use in connection with this offering and the Prospectus was or will be identical to the electronically transmitted copies thereof filed with the Commission pursuant to EDGAR, except to the extent permitted by Regulation S-T.

(ii) Accurate Disclosure. Neither the Registration Statement nor any amendment thereto, at its effective time, on the date hereof, at the Closing Time or at any Date of Delivery, contained, contains or will contain an untrue statement of a material fact or omitted, omits or will omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading. At the Applicable Time and any Date of Delivery, none of (A) the General Disclosure Package, (B) any individual Issuer Limited Use Free Writing Prospectus, when considered together with the General Disclosure Package and (C) any individual Written Testing-the-Waters Communication, when considered together with the General Disclosure Package, included, includes or will include an untrue statement of a material fact or omitted, omits or will omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. Neither the Prospectus nor any amendment or supplement thereto, as of its issue date, at the time of any filing with the Commission pursuant to Rule 424(b), at the Closing Time or at any Date of Delivery, included, includes or will include an untrue statement of a material fact or omitted, omits or will omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading.

The representations and warranties in this subsection shall not apply to statements in or omissions from the Registration Statement (or any amendment thereto), the General Disclosure Package or the Prospectus (or any amendment or supplement thereto) made in reliance upon and in conformity with written information furnished to the Company by any Underwriter through BofAS expressly for use therein. For purposes of this Agreement, the only information so furnished shall be the information in the first paragraph under the heading "Underwriting—Commissions and Discounts," the information in the second, third and fourth paragraphs under the heading "Underwriting—Price Stabilization, Short Positions and Penalty Bids" and the information under the heading "Underwriting—Electronic Offer, Sale and Distribution of Shares" in each case contained in the Prospectus (collectively, the "Underwriter Information").

(iii) Issuer Free Writing Prospectuses. No Issuer Free Writing Prospectus conflicts or will conflict with the information contained in the Registration Statement or the Prospectus, and any preliminary or other prospectus deemed to be a part thereof that has not been superseded or modified. The foregoing sentence does not apply to statements in or omissions from any Issuer Free Writing Prospectus made in reliance upon and in conformity with the Underwriter Information. The Company has made available a Bona Fide Electronic Road Show in compliance with Rule 433(d)(8)(ii) such that no filing of any "road show" (as defined in Rule 433(h)) is required in connection with the offering of the Securities.

(iv) Testing-the-Waters Materials. The Company (A) has not engaged in any Testing-the-Waters Communication other than Testing-the-Waters Communications with the consent of the Representatives with entities that are qualified institutional buyers within the meaning of Rule 144A under the 1933 Act or institutions that are accredited investors within the meaning of Rule 501 under the 1933 Act and (B) has not authorized anyone other than the Representatives to engage in Testing-the-Waters Communications. The Company reconfirms that the Representatives have been authorized to act on its behalf in undertaking Testing-the-Waters Communications specifically authorized by the Company. The Company has not distributed any Written Testing-the-Waters Communications other than those listed on Schedule B-3 hereto.

(v) Company Not Ineligible Issuer. At the time of filing the Registration Statement and any post-effective amendment thereto, at the earliest time thereafter that the Company or another offering participant made a *bona fide* offer (within the meaning of Rule 164(h)(2) of the 1933 Act Regulations) of the Securities and at the date hereof, the Company was not and is not an "ineligible issuer," as defined in Rule 405, without taking account of any determination by the Commission pursuant to Rule 405 that it is not necessary that the Company be considered an ineligible issuer.

(vi) Emerging Growth Company Status. From the time of the initial confidential submission of the Registration Statement to the Commission (or, if earlier, the first date on which the Company engaged directly or through any Person authorized to act on its behalf in any Testing-the-Waters Communication) through the date hereof, the Company has been and is an "emerging growth company," as defined in Section 2(a) of the 1933 Act (an "Emerging Growth Company").

(vii) Independent Accountants. The accountants who certified the financial statements included in the Registration Statement, the General Disclosure Package and the Prospectus are independent public accountants with respect to the Company as required by the 1933 Act, the 1933 Act Regulations and the Public Company Accounting Oversight Board.

(viii) Financial Statements. The financial statements included in the Registration Statement, the General Disclosure Package and the Prospectus, together with the related notes, present fairly in all material respects the financial position of the Company and its consolidated subsidiaries at the dates indicated and the statements of operations and comprehensive loss, convertible preferred shares and shareholders' deficit and cash flows of the Company and its consolidated subsidiaries for the periods specified; said financial statements have been prepared in conformity with U.S. generally accepted accounting principles ("GAAP") applied on a consistent basis throughout the periods involved except, in the case of unaudited interim financial statements, subject to normal year-end audit adjustments and the exclusion of certain footnotes as permitted by the applicable rules of the Commission. The selected financial data and the summary financial information included in the Registration Statement, the General Disclosure Package and the Prospectus present fairly in all material respects the information shown therein and have been compiled on a basis consistent with that of the audited financial statements included therein. Except as included therein, no historical or pro forma financial statements or supporting schedules are required to be included in the Registration Statement, the General Disclosure Package or the Prospectus under the 1933 Act or the 1933 Act Regulations.

(ix) No Material Adverse Change in Business. Except as otherwise stated therein, since the respective dates as of which information is given in the Registration Statement, the General Disclosure Package or the Prospectus, (A) there has been no material adverse change in the condition, financial or otherwise, or in the earnings, business affairs or business prospects of the Company and its subsidiaries considered as one enterprise, whether or not arising in the ordinary course of business (a "Material Adverse Effect"), (B) there have been no transactions entered into by the Company or any of its subsidiaries, other than those in the ordinary course of business, which are material with respect to the Company and its subsidiaries considered as one enterprise, and (C) there has been no dividend or distribution of any kind declared, paid or made by the Company on any class of its capital stock.

(x) Good Standing of the Company. The Company has been duly organized and is validly existing as a corporation in good standing under the laws of the State of Delaware and has corporate power and authority to own, lease and operate its properties and to conduct its business as described in the Registration Statement, the General Disclosure Package and the Prospectus and to enter into and perform its obligations under this Agreement; and the Company is duly qualified as a foreign corporation to transact business and is in good standing in each other jurisdiction (or such equivalent concept to the extent it exists under the laws of such jurisdiction) in which such qualification is required, whether by reason of the ownership or leasing of property or the conduct of business, except where the failure so to qualify or to be in good standing would not result in a Material Adverse Effect.

(xi) Good Standing of Subsidiaries. Each "significant subsidiary" of the Company (as such term is defined in Rule 1-02 of Regulation S-X) (each, a "Subsidiary" and, collectively, the "Subsidiaries") has been duly organized and is validly existing in good standing under the laws of the jurisdiction of its incorporation or organization (or such equivalent concept to the extent it exists under the laws of such jurisdiction), has corporate or similar power and authority to own, lease and operate its properties and to conduct its business as described in the Registration Statement, the General Disclosure Package and the Prospectus and is duly qualified to transact business and is in good standing in each jurisdiction in which such qualification is required (or such equivalent concept to the extent it exists under the laws of such jurisdiction), whether by

reason of the ownership or leasing of property or the conduct of business, except where the failure to so qualify or to be in good standing would not result in a Material Adverse Effect. Except as otherwise disclosed in the Registration Statement, the General Disclosure Package and the Prospectus, all of the issued and outstanding capital stock of each Subsidiary has been duly authorized and validly issued, is fully paid and non-assessable (or such equivalent concept to the extent it exists under the laws of such jurisdiction) and is owned by the Company, directly or through subsidiaries, free and clear of any security interest, mortgage, pledge, lien, encumbrance, claim or equity. None of the outstanding shares of capital stock of any Subsidiary were issued in violation of the preemptive or similar rights of any securityholder of such Subsidiary. The only subsidiaries of the Company are (A) the subsidiaries listed on Exhibit 21 to the Registration Statement.

(xii) Capitalization. The authorized, issued and outstanding shares of capital stock of the Company are as set forth in the Registration Statement, the General Disclosure Package and the Prospectus in the column entitled "Actual" under the caption "Capitalization" (except for subsequent issuances, if any, pursuant to this Agreement, pursuant to reservations, agreements or employee benefit or equity incentive plans referred to in the Registration Statement, the General Disclosure Package and the Prospectus, pursuant to the exercise of convertible securities or options referred to in the Registration Statement, the General Disclosure Package and the Prospectus or pursuant to the automatic conversion of preferred stock of the Company into shares of Common Stock as a result of the public offering contemplated hereby, as described in the Registration Statement, the General Disclosure Package and the Prospectus). The outstanding shares of capital stock of the Company have been duly authorized and validly issued and are fully paid and non-assessable. None of the outstanding shares of capital stock of the Company were issued in violation of the preemptive or other similar rights of any securityholder of the Company.

(xiii) Authorization of Agreement. This Agreement has been duly authorized, executed and delivered by the Company.

(xiv) Authorization and Description of Securities. The Securities to be purchased by the Underwriters from the Company have been duly authorized for issuance and sale to the Underwriters pursuant to this Agreement and, when issued and delivered by the Company pursuant to this Agreement against payment of the consideration set forth herein, will be validly issued and fully paid and non-assessable; and the issuance of the Securities is not subject to the preemptive or other similar rights of any securityholder of the Company except as have been duly and validly waived in writing as of the date of this Agreement. The Common Stock conforms in all material respects to all statements relating thereto contained in the Registration Statement, the General Disclosure Package and the Prospectus and such description conforms in all material respects to the rights set forth in the instruments defining the same. No holder of Securities will be subject to personal liability by reason of being such a holder.

(xv) Registration Rights. There are no persons with registration rights or other similar rights to have any securities registered for sale pursuant to the Registration Statement or otherwise registered for sale or sold by the Company under the 1933 Act pursuant to this Agreement, other than those rights that have been disclosed in the Registration Statement, the General Disclosure Package and the Prospectus and have been waived.

(xvi) Absence of Violations, Defaults and Conflicts. Neither the Company nor any of its subsidiaries is (A) in violation of its charter, by-laws or similar organizational document, (B) in default in the performance or observance of any obligation, agreement, covenant or condition contained in any contract, indenture, mortgage, deed of trust, loan or credit agreement, note, lease

or other agreement or instrument to which the Company or any of its subsidiaries is a party or by which it or any of them may be bound or to which any of the properties or assets of the Company or any subsidiary is subject (collectively, "Agreements and Instruments"), except for such defaults that would not reasonably be expected to, singly or in the aggregate, result in a Material Adverse Effect, or (C) in violation of any law, statute, rule, regulation, judgment, order, writ or decree of any arbitrator, court, governmental body, regulatory body, administrative agency or other authority, body or agency having jurisdiction over the Company or any of its subsidiaries or any of their respective properties, assets or operations (each, a "Governmental Entity"), except for such violations that would not reasonably be expected to, singly or in the aggregate, result in a Material Adverse Effect. The execution, delivery and performance of this Agreement and the consummation of the transactions contemplated herein and in the Registration Statement, the General Disclosure Package and the Prospectus (including the issuance and sale of the Securities and the use of the proceeds from the sale of the Securities as described therein under the caption "Use of Proceeds") and compliance by the Company with its obligations hereunder have been duly authorized by all necessary corporate action and do not and will not, whether with or without the giving of notice or passage of time or both, conflict with or constitute a breach of, or default or Repayment Event (as defined below) under, or result in the creation or imposition of any lien, charge or encumbrance upon any properties or assets of the Company or any subsidiary pursuant to, the Agreements and Instruments (except for such conflicts, breaches, defaults or Repayment Events or liens, charges or encumbrances that would not, singly or in the aggregate, result in a Material Adverse Effect), nor will such action result in any violation of (x) the provisions of the charter, by-laws or similar organizational document of the Company or any of its subsidiaries or (y) any law, statute, rule, regulation, judgment, order, writ or decree of any Governmental Entity, except with respect to clause (y), such violations as would not reasonably be expected to, singly or in the aggregate, result in a Material Adverse Effect. As used herein, a "Repayment Event" means any event or condition which gives the holder of any note, debenture or other evidence of indebtedness (or any person acting on such holder's behalf) the right to require the repurchase, redemption or repayment of all or a portion of such indebtedness by the Company or any of its subsidiaries.

(xvii) Absence of Labor Dispute. No labor dispute with the employees of the Company or any of its subsidiaries exists or, to the knowledge of the Company, is imminent, and the Company is not aware of any existing or imminent labor disturbance by the employees of any of its or any subsidiary's principal suppliers, manufacturers, partners, collaborators, customers or contractors, which, in either case, would result in a Material Adverse Effect.

(xviii) Absence of Proceedings. There is no action, suit, proceeding, inquiry or investigation before or brought by any Governmental Entity now pending or, to the knowledge of the Company, threatened, against or affecting the Company or any of its subsidiaries, which would reasonably be expected to result in a Material Adverse Effect, or which would reasonably be expected to materially and adversely affect their respective properties or assets or the consummation of the transactions contemplated in this Agreement or the performance by the Company of its obligations hereunder; and the aggregate of all pending legal or governmental proceedings to which the Company or any such subsidiary is a party or of which any of their respective properties or assets is the subject which are not described in the Registration Statement, the General Disclosure Package and the Prospectus, including ordinary routine litigation incidental to the business, would not reasonably be expected to result in a Material Adverse Effect.

(xix) Accuracy of Exhibits. There are no contracts or documents which are required under the 1933 Act or the 1933 Act Regulations to be described in the Registration Statement, the General Disclosure Package or the Prospectus or to be filed as exhibits to the Registration Statement which have not been so described and filed as required.

(xx) Absence of Further Requirements. No filing with, or authorization, approval, consent, license, order, registration, qualification or decree of, any Governmental Entity is necessary or required for the performance by the Company of its obligations hereunder, in connection with the offering, issuance or sale of the Securities hereunder or the consummation of the transactions contemplated by this Agreement, except (A) such as have been already obtained or as may be required under the 1933 Act, the 1933 Act Regulations, the rules of The Nasdaq Global Market, state securities laws or the rules of the Financial Industry Regulatory Authority, Inc. ("FINRA"); or (B) such as which the failure to obtain would not, singly or in the aggregate, impair the power or ability of the Company to perform its obligations under this Agreement or consummate the transactions contemplated hereby.

(xxi) Possession of Licenses and Permits. The Company and its subsidiaries possess such permits, licenses, approvals, consents, exemptions and other authorizations (collectively, "Governmental Licenses") issued by the appropriate Governmental Entities necessary to conduct the business now operated by them, except where the failure so to possess would not, singly or in the aggregate, reasonably be expected to result in a Material Adverse Effect. The Company and its subsidiaries are in compliance with the terms and conditions of all Governmental Licenses, except where the failure so to comply would not reasonably be expected to, singly or in the aggregate, result in a Material Adverse Effect. The Company has fulfilled and performed all of its material obligations with respect to the Governmental Licenses and no event has occurred which allows, or after notice or lapse of time would allow, revocation or termination thereof or results in any other material impairment of the rights of the Company as a holder of any permit, except where the failure to so fulfill or perform, or the occurrence of such event, would not, singly or in the aggregate, result in a Material Adverse Effect. All of the Governmental Licenses are valid and in full force and effect, except when the invalidity of such Governmental Licenses or the failure of such Governmental Licenses to be in full force and effect would not, singly or in the aggregate, reasonably be expected to, result in a Material Adverse Effect. Neither the Company nor any of its subsidiaries has received any notice of proceedings relating to the revocation or modification of, or non-compliance with, any Governmental Licenses which, singly or in the aggregate, if the subject of an unfavorable decision, ruling or finding, would reasonably be expected to result in a Material Adverse Effect.

(xxii) Title to Property. The Company and its subsidiaries have good and marketable title to all real property owned by them and good title to all other properties owned by them, in each case, free and clear of all mortgages, pledges, liens, security interests, claims, restrictions or encumbrances of any kind except such as (A) are described in the Registration Statement, the General Disclosure Package and the Prospectus or (B) do not, singly or in the aggregate, materially and adversely affect the value of such property and do not materially interfere with the use made and proposed to be made of such property by the Company or any of its subsidiaries; and all of the leases and subleases material to the business of the Company and its subsidiaries, considered as one enterprise, and under which the Company or any of its subsidiaries holds properties described in the Registration Statement, the General Disclosure Package or the Prospectus, are in full force and effect, except to the extent that any such failure to be in full force and effect would not, singly or in the aggregate, result in a Material Adverse Effect, and neither the Company nor any such subsidiary has any notice of any material claim of any sort that has been asserted by anyone adverse to the rights of the Company or any subsidiary under any of the leases or subleases mentioned above, or affecting or questioning the rights of the Company or such subsidiary to the continued possession of the leased or subleased premises under any such lease or sublease.

(xxiii) Possession of Intellectual Property. The Company and its subsidiaries own, or have obtained adequate rights and licenses under, or can acquire rights on reasonable terms to, all patents, patent rights, patent applications, inventions, copyrights, other works of authorship, know how (including trade secrets and other proprietary or confidential information, systems or procedures), trademarks, service marks, trade names, trade and service mark registrations, trade names, designs, processes, licenses, computer programs, technical data and information, and other intellectual property (collectively, "Intellectual Property") that are necessary to carry on the business of the Company as currently conducted and to commercialize the products or services as disclosed in the Registration Statement, the General Disclosure Package and the Prospectus as under development (all such Intellectual Property is collectively referred to as the " Company Intellectual Property"). Except as disclosed in the Registration Statement, the General Disclosure Package and the Prospectus: (A) to the Company's knowledge there are no third parties who have rights to any Intellectual Property, including no liens, security interest, or other encumbrances, except for customary reversionary rights of third-party licensors with respect to Intellectual Property that is disclosed in the Registration Statement, the General Disclosure Package and the Prospectus as licensed to the Company or one or more of its subsidiaries; (B) the Company has taken reasonable steps to secure its interests in the Intellectual Property owned by the Company from its employees and contractors; (C) to the Company's knowledge, there is no infringement, misappropriation or violation by third parties of any Company Intellectual Property owned by, or exclusively licensed to, the Company or its subsidiaries; (D) to the Company's knowledge, the Company is not infringing the intellectual property rights of third parties and (E) none of the Company Intellectual Property owned by the Company or, to the Company's knowledge, exclusively licensed to the Company has been adjudged invalid or unenforceable in whole or in part, in the case of clause (C) and clause (D), which infringement, misappropriation or violation, singly or in the aggregate, would reasonably be expected to result in a Material Adverse Effect. There is no pending or threatened action, suit, proceeding or claim by others of which the Company has received written notice: (A) challenging the Company's rights in or to any Company Intellectual Property, and the Company is unaware of any facts which would form a reasonable basis for any such action, suit, proceeding or claim; (B) challenging the validity, enforceability or scope of any Company Intellectual Property owned by, or exclusively licensed to, the Company or its subsidiaries, and the Company is unaware of any facts which would form a reasonable basis for any such action, suit, proceeding or claim; or (C) asserting that the Company or any of its subsidiaries infringes or otherwise violates, or would, upon the commercialization of any product or service described in the Registration Statement, the General Disclosure Package or the Prospectus as under development, infringe or violate, any Intellectual Property rights of others, and the Company and its subsidiaries are unaware of any facts which would form a reasonable basis for any such action, suit, proceeding or claim. To the Company's knowledge, no employee of the Company who has developed Company Intellectual Property is in violation of any term of any employment contract, patent disclosure agreement, invention assignment agreement, non-competition agreement, non-solicitation agreement, nondisclosure agreement or any restrictive covenant to or with a former employer where the basis of such violation relates to such employee's employment with the Company. The Company and its subsidiaries are in compliance in all material respects with the terms of each agreement pursuant to which Company Intellectual Property is licensed to the Company or any subsidiary, and all such agreements are in full force and effect in accordance with their terms. The patents included in the Company Intellectual Property owned by the Company or, to the Company's knowledge, exclusively licensed to the Company are subsisting and have not lapsed and the patent applications in the Intellectual Property owned by the Company or exclusively licensed to the Company are pending

and have not been abandoned. To the Company's knowledge, except as set forth in the Registration Statement, the General Disclosure Package and the Prospectus, the Company and its subsidiary are not obligated or under any liability whatsoever to make any material payment by way of royalties, fees or otherwise to any owner or licensee of, or other claimant to, any Intellectual Property, with respect to the use thereof or in connection with the conduct of their respective businesses or otherwise. No technology employed by the Company or its subsidiaries has been obtained or is being used by the Company or its subsidiaries in violation of any contractual or legal obligation binding on the Company, its subsidiaries, or any of their officers, directors, employees, or contractors, or in violation of any contractual rights of any persons. All patents and patent applications included in the Company Intellectual Property that are owned by or exclusively licensed to the Company have been duly and properly filed and maintained and the parties prosecuting such applications have complied in all material respects with their duty of candor and disclosure to the U.S. Patent and Trademark Office (the "USPTO") in connection with such applications. To the Company's knowledge, there is no patent or published patent application, in the U.S. or other jurisdiction, that is not included in the Company Intellectual Property and that, in the case of a patent, contains claims, or in the case of a published patent application contains patentable claims, that dominates any of the Company Intellectual Property described in the Preliminary Prospectus and Prospectus as being owned by or licensed to the Company or that interferes with the issued or pending claims of any of the Company Intellectual Property owned by or, to the Company's knowledge, exclusively licensed to the Company.

(xxiv) Clinical Data and Regulatory Compliance. The preclinical tests and clinical trials, and other studies conducted by or on behalf of the Company (collectively, "studies") that are described in, or the results of which are referred to in, the Registration Statement, the General Disclosure Package or the Prospectus were and, if still pending, are being conducted in all material respects in accordance with the protocols, procedures and controls designed and approved for such studies and with Good Clinical Practices and all applicable laws, including, without limitation, the Federal Food, Drug, and Cosmetic Act and its implementing regulations at 21 C.F.R. Parts 50, 54, 56, 58, and 312; each description of the results of such studies is accurate and complete in all material respects and fairly presents the data derived from such studies, and the Company and its subsidiaries have no knowledge of any other studies the results of which are inconsistent with, or otherwise call into question, the results described or referred to in the Registration Statement, the General Disclosure Package or the Prospectus; neither the Company nor any of its subsidiaries has received any notice of, or correspondence from, any Regulatory Agency requiring the termination, suspension or modification of any clinical trials that are described or referred to in the Registration Statement, the General Disclosure Package or the Prospectus.

(xxv) Compliance with Healthcare Laws. The Company: (i) has operated and currently operates its business in compliance in all material respects with applicable provisions of the health care laws, including Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395lll (the Medicare statute); Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396w-5 (the Medicaid statute); the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b); the civil False Claims Act, 31 U.S.C. §§ 3729 et seq.; the criminal False Claims Act 42 U.S.C. 1320a-7b(a); the criminal laws relating to health care fraud and abuse, including 18 U.S.C. §§ 286 and 287 and the health care fraud criminal provisions under the Health Insurance Portability and Accountability Act of 1996, 42 U.S.C. §§ 1320d et seq., ("HIPAA"); the Civil Monetary Penalties Law, 42 U.S.C. §§ 1320a-7a; the Physician Payments Sunshine Act, 42 U.S.C. § 1320a-7h; the exclusion law, 42 U.S.C. § 1320a-7; HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, 42 U.S.C. §§ 17921 et seq.; the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et seq.; the Public Health Service Act, 42 U.S.C. §§ 201 et seq.;

the regulations promulgated pursuant to such laws; and any similar federal, state, local and foreign laws and regulations of any governmental authority including the United States Food and Drug Administration of the U.S. Department of Health and Human Services or any committee thereof or from any other U.S. or foreign government or drug or medical device regulatory agency, or health care facility Institutional Review Board (collectively, the "Regulatory Agencies") applicable to the ownership, testing, development, manufacture, packaging, processing, use, distribution, storage, import, export or disposal of any of the Company's product candidates, (collectively the "Health Care Laws"); (ii) has not received any United States Food and Drug Administration Form 483, written notice of adverse finding, warning letter, untitled letter or other correspondence or written notice from any court or arbitrator or governmental or regulatory authority alleging or asserting non-compliance with (A) any Health Care Laws or (B) any licenses, approvals, clearances, exemptions, permits, registrations, authorizations, and supplements or amendments thereto required by any such Health Care Laws ("Regulatory Authorizations"); (iii) possesses all Regulatory Authorizations required to conduct its business as currently conducted and such Regulatory Authorizations are valid and in full force and effect and the Company is not in violation, in any material respect, of any term of any such Regulatory Authorizations; (iv) has fulfilled and performed all of its material obligations with respect to the Regulatory Authorizations and, to the Company's knowledge, no event has occurred which allows, or after notice or lapse of time would allow, revocation or termination thereof or results in any other material impairment of the rights of the holder of any such Regulatory Authorization; (v) has not received notice of any claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action ("Proceeding") from any governmental authority including any Regulatory Agency or any other third party alleging a material violation of any Health Care Laws or Regulatory Authorizations or limiting, suspending, modifying, or revoking any material Regulatory Authorizations, and has no knowledge that any governmental authority including any Regulatory Agencies or any other third party is considering any Proceeding; (vi) has filed, obtained, maintained or submitted all material reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments as required by any Health Care Laws or Regulatory Authorizations ("Reports") and that all such Reports were materially complete and correct on the date filed (or were materially corrected or supplemented by a subsequent submission); (vii) along with its employees, officers and directors, and to the Company's knowledge, independent contractors and agents, is not a party to or has any ongoing reporting obligations pursuant to any corporate integrity agreements, deferred prosecution agreements, monitoring agreements, consent decrees, settlement orders, plans of correction or similar agreements with or imposed by any governmental authority including any Regulatory Agencies; and (viii) along with its employees, officers and directors, and, to the Company's knowledge, independent contractors and agents, has not been excluded, suspended or debarred from, or otherwise ineligible for participation in any government health care program or human clinical research.

(xxvi) Environmental Laws. Except as would not, singly or in the aggregate, result in a Material Adverse Effect, (A) neither the Company nor any of its subsidiaries is in violation of any federal, state, local or foreign statute, law, rule, regulation, ordinance, code, policy or rule of common law or any judicial or administrative interpretation thereof, including any judicial or administrative order, consent, decree or judgment, relating to pollution or protection of human health, the environment (including, without limitation, ambient air, surface water, groundwater, land surface or subsurface strata) or wildlife, including, without limitation, laws and regulations relating to the release or threatened release of chemicals, pollutants, contaminants, wastes, toxic substances, hazardous substances, petroleum or petroleum products, asbestos-containing materials or mold (collectively, "Hazardous Materials") or to the manufacture, processing, distribution, use, treatment, storage, disposal, transport or handling of Hazardous Materials

(collectively, "Environmental Laws"), (B) the Company and its subsidiaries have all permits, authorizations and approvals required under any applicable Environmental Laws and are each in compliance with their requirements, (C) there are no pending or, to the Company's knowledge, threatened administrative, regulatory or judicial actions, suits, demands, demand letters, claims, liens, notices of noncompliance or violation, investigations or proceedings relating to any Environmental Law against the Company or any of its subsidiaries and (D) to the Company's knowledge, there are no events or circumstances that would reasonably be expected to form the basis of an order for clean-up or remediation, or an action, suit or proceeding by any private party or Governmental Entity, against or affecting the Company or any of its subsidiaries relating to Hazardous Materials or any Environmental Laws.

(xxvii) Accounting Controls. The Company and its subsidiaries, on a consolidated basis, maintain a system of effective internal control over financial reporting (as defined under Rules 13-a15 and 15d-15 under the 1934 Act Regulations) and a system of internal accounting controls sufficient to provide reasonable assurances that (A) transactions are executed in accordance with management's general or specific authorization; (B) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain accountability for assets; (C) access to assets is permitted only in accordance with management's general or specific authorization; and (D) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences. Except as described in the Registration Statement, the General Disclosure Package and the Prospectus, since the end of the Company's most recent audited fiscal year, there has been (1) no material weakness in the Company's internal control over financial reporting (whether or not remediated) and (2) no change in the Company's internal control over financial reporting that has materially and adversely affected, or is reasonably likely to materially and adversely affect, the Company's internal control over financial reporting.

(xxviii) Compliance with the Sarbanes-Oxley Act. The Company has taken all necessary actions to ensure that, upon the effectiveness of the Registration Statement, it will be in compliance with all provisions of the Sarbanes-Oxley Act of 2002 and all rules and regulations promulgated thereunder or implementing the provisions thereof (the "Sarbanes-Oxley Act") that are then in effect and with which the Company is required to comply as of the effectiveness of the Registration Statement, and is, or will be, taking reasonable steps to enable it to be in compliance with other provisions of the Sarbanes-Oxley Act not currently in effect, upon the effectiveness of such provisions, or which will become applicable to the Company at all times after the effectiveness of the Registration Statement.

(xxix) Payment of Taxes. All United States federal income tax returns of the Company and its subsidiaries required by law to be filed by them have been filed or a timely extension has been requested thereof and all taxes shown by such returns, which are due and payable, have been paid, except taxes against which appeals have been or will be promptly taken and as to which adequate reserves have been provided in accordance with GAAP or to the extent any failure to file or pay such taxes or assessments would not result in a Material Adverse Effect. The United States federal income tax returns of the Company through the fiscal year ended December 31, 2018 have been settled and no assessment in connection therewith has been made against the Company. The Company and its subsidiaries have filed all other tax returns that are required to have been filed by them pursuant to applicable foreign, state, local or other law except insofar as the failure to do so would not reasonably be expected to result in a Material Adverse Effect, and has paid all taxes due pursuant to such returns or pursuant to any assessment received by the Company and its subsidiaries, except for such taxes, if any, as are being contested in good faith and as to which adequate reserves have been established by the Company in accordance with

GAAP or where the failure to do so would not result in a Material Adverse Effect. No tax deficiency has been determined adversely to the Company (nor does the Company have any notice or knowledge of any tax deficiency which could reasonably be expected to be determined adversely to the Company). The charges, accruals and reserves on the books of the Company in respect of any income or corporation tax liability for any years not finally determined are adequate to meet any assessments or re-assessments for additional income tax for any years not finally determined, except to the extent of any inadequacy that would not reasonably be expected to result in a Material Adverse Effect.

(xxx) Insurance. The Company and its subsidiaries carry or are entitled to the benefits of insurance, with financially sound and reputable insurers, in such amounts and covering such risks as the Company reasonably believes is generally maintained by companies of established repute and comparable size engaged in the same or similar business, and all such insurance is in full force and effect. The Company has no reason to believe that it or any of its subsidiaries will not be able (A) to renew its existing insurance coverage as and when such policies expire or (B) to obtain comparable coverage from similar institutions as may be necessary or appropriate to conduct its business as now conducted and at a cost that would not reasonably be expected to result in a Material Adverse Effect. Neither of the Company nor any of its subsidiaries has been denied any insurance coverage which it has sought or for which it has applied.

(xxxi) Investment Company Act. The Company is not required, and upon the issuance and sale of the Securities as herein contemplated and the application of the net proceeds therefrom as described in the Registration Statement, the General Disclosure Package and the Prospectus will not be required, to register as an "investment company" under the Investment Company Act of 1940, as amended.

(xxxii) Absence of Manipulation. Neither the Company nor any affiliate of the Company has taken, nor will the Company or any affiliate take, directly or indirectly, any action which is designed, or would reasonably be expected, to cause or result in, or which constitutes, the stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of the Securities or to result in a violation of Regulation M under the 1934 Act.

(xxxiii) Foreign Corrupt Practices Act. None of the Company, any of its subsidiaries or, to the knowledge of the Company, any director, officer, agent, employee, affiliate or other person acting on behalf of the Company or any of its subsidiaries is aware of or has taken any action, directly or indirectly, that would result in a violation by such persons of the Foreign Corrupt Practices Act of 1977, as amended, and the rules and regulations thereunder (the "FCPA"), including, without limitation, making use of the mails or any means or instrumentality of interstate commerce corruptly in furtherance of an offer, payment, promise to pay or authorization of the payment of any money, or other property, gift, promise to give, or authorization of the giving of anything of value to any "foreign official" (as such term is defined in the FCPA) or any foreign political party or official thereof or any candidate for foreign political office, in contravention of the FCPA and the Company and, to the knowledge of the Company, its affiliates have conducted their businesses in compliance with the FCPA and have instituted and maintain policies and procedures designed to ensure, and which are reasonably expected to continue to ensure, continued compliance therewith.

(xxxiv) Money Laundering Laws. The operations of the Company and its subsidiaries are and have been conducted at all times in compliance with applicable financial recordkeeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as amended, the money laundering statutes of all applicable jurisdictions, the rules and regulations

thereunder and any related or similar rules, regulations or guidelines, issued, administered or enforced by any Governmental Entity (collectively, the "Money Laundering Laws"); and no action, suit or proceeding by or before any Governmental Entity involving the Company or any of its subsidiaries with respect to the Money Laundering Laws is pending or, to the knowledge of the Company, threatened.

(xxxv) OFAC. None of the Company, any of its subsidiaries or, to the knowledge of the Company, any director, officer, agent, employee, affiliate or representative of the Company or any of its subsidiaries is an individual or entity ("Person"), currently the subject or target of any sanctions administered or enforced by the United States Government, including, without limitation, the U.S. Department of the Treasury's Office of Foreign Assets Control ("OFAC"), the United Nations Security Council, the European Union, Her Majesty's Treasury, or other relevant sanctions authority (collectively, "Sanctions"), nor is the Company located, organized or resident in a country or territory that is the subject of Sanctions; and the Company will not directly or indirectly use the proceeds of the sale of the Securities, or lend, contribute or otherwise make available such proceeds to any subsidiaries, joint venture partners or other Person, to fund any activities of or business with any Person, or in any country or territory, that, at the time of such funding, is the subject of Sanctions or in any other manner that will result in a violation by any Person (including any Person participating in the transaction, whether as underwriter, advisor, investor or otherwise) of Sanctions.

(xxxvi) Lending Relationship. Except as disclosed in the Registration Statement, the General Disclosure Package and the Prospectus, the Company (i) does not have any material lending or other relationship with any banking or lending affiliate of any Underwriter and (ii) does not intend to use any of the proceeds from the sale of the Securities to repay any outstanding debt owed to any affiliate of any Underwriter.

(xxxvii) Statistical and Market-Related Data. Any statistical and market-related data included in the Registration Statement, the General Disclosure Package or the Prospectus are based on or derived from sources that the Company believes, after reasonable inquiry, to be reliable and accurate and, to the extent required, the Company has obtained the written consent to the use of such data from such sources.

(xxxviii) No Rated Debt. No securities issued or guaranteed by, or loans to, the Company are rated by any "nationally recognized statistical rating organization" (as defined by the Commission in Section 3(a)(62) of the 1934 Act).

(xxxix) Data Privacy and Security Laws. The Company and its subsidiaries are, and at all prior times since inception were, in material compliance with all applicable data privacy and data security laws and regulations, including without limitation HIPAA, the HITECH Act, and the European Union General Data Protection Regulation ("GDPR") (EU 2016/679) (and all other applicable laws and regulations with respect to Personal Data (defined below) that have been announced as of the date hereof as becoming effective within 12 months after the date hereof, and for which any non-compliance with same would be reasonably likely to create a material liability) (collectively, the "Privacy Laws"). To support compliance with the Privacy Laws, the Company and its subsidiaries have in place, and take appropriate steps reasonably designed to ensure compliance in all material respects with, policies and procedures relating to data privacy and data security and the collection, storage, use, disclosure, handling, and analysis of Personal Data (the "Policies"). At all times since inception, the Company has provided accurate notice of its Policies then in effect to its customers, employees, third party vendors and representatives. Each of the Company Policies provides accurate and sufficient notice of the Company's then-current privacy

practices relating to its subject matter and such Company Policies do not contain any material omissions of the Company's then-current privacy practices. "Personal Data" means (i) a natural person's name, street address, telephone number, e-mail address, photograph, social security number or tax identification number, driver's license number, passport number, credit card number, bank information, or customer or account number; (ii) any information which would qualify as "personally identifying information" under the Federal Trade Commission Act, as amended; (iii) Protected Health Information as defined by HIPAA; (iv) "personal data" as defined by GDPR, and (v) any other piece of information that allows the identification of such natural person, or his or her family, or permits the collection or analysis of any data related to an identified person's health or sexual orientation that is not aggregated with the data of other individuals or otherwise irreversibly anonymized such that a natural person cannot be identified. The Company and its subsidiaries since inception have at all times made all disclosures to users or customers required by applicable laws and regulatory rules or requirements, and have provided accurate notice of its Policies then in effect to its customers, employees, third party vendors and representatives. None of such disclosures made or contained in any of the Policies have been inaccurate, misleading, deceptive or in violation of any Privacy Laws or Policies in any material respect. The execution, delivery and performance of this Agreement or any other agreement referred to in this Agreement will not result in a breach of violation of any Privacy Laws or Policies. The Company further certifies that neither it nor any subsidiary: (i) has received notice of any actual or potential liability under or relating to, or actual or potential violation of, any of the Privacy Laws, and has no knowledge of any event or condition that would reasonably be expected to result in any such notice; (ii) is currently conducting or paying for, in whole or in part, any investigation, remediation, or other corrective action pursuant to any Privacy Law; or (iii) is a party to any order, decree, or agreement that imposes any obligation or liability under any Privacy Law.

(xl) Cybersecurity; Data Protection. (A) To the Company's knowledge, there has been no security breach or incident, attack, or other compromise of or relating to any of the Company or its subsidiaries information technology and computer systems, networks, hardware, software, data and databases (including the data of their respective customers, employees, suppliers, vendors and any third party data maintained, processed or stored by the Company and its subsidiaries, and any such data processed or stored by third parties on behalf of the Company and its subsidiaries), equipment or technology (collectively, "IT Systems and Data"): (B) neither the Company nor its subsidiaries have been notified of, and each of them have no knowledge of any event or condition that would reasonably be expected to result in, any material security breach or incident, attack or other compromise to their IT Systems and Data and (C) the Company and its subsidiaries have implemented appropriate controls, policies, procedures, and technological safeguards reasonably likely to maintain and protect the integrity, continuous operation, redundancy and security of their IT Systems and Data reasonably consistent with industry standards and practices, or as required by applicable regulatory standards. The Company and its subsidiaries are presently in compliance with all applicable laws or statutes and all judgments, orders, rules and regulations of any court or arbitrator or governmental or regulatory authority, internal policies and contractual obligations relating to the privacy and security of IT Systems and Data and to the protection of such IT Systems and Data from unauthorized use, access, misappropriation or modification, except as would not be reasonably expected to result in a Material Adverse Effect.

(b) *Officer's Certificates*. Any certificate signed by any officer of the Company or any of its subsidiaries delivered to the Representatives or to counsel for the Underwriters shall be deemed a representation and warranty by the Company to each Underwriter as to the matters covered thereby.

SECTION 2. Sale and Delivery to Underwriters; Closing.

(a) *Initial Securities*. On the basis of the representations and warranties herein contained and subject to the terms and conditions herein set forth, the Company agrees to sell to each Underwriter, severally and not jointly, and each Underwriter, severally and not jointly, agrees to purchase from the Company, at the price per share set forth in Schedule A, that number of Initial Securities set forth in Schedule A opposite the name of such Underwriter, plus any additional number of Initial Securities which such Underwriter may become obligated to purchase pursuant to the provisions of Section 10 hereof, subject, in each case, to such adjustments among the Underwriters as the Representatives in their sole discretion shall make to eliminate any sales or purchases of fractional shares.

(b) *Option Securities*. In addition, on the basis of the representations and warranties herein contained and subject to the terms and conditions herein set forth, the Company hereby grant(s) an option to the Underwriters, severally and not jointly, to purchase up to an additional [●] shares of Common Stock, at the price per share set forth in Schedule A, less an amount per share equal to any dividends or distributions declared by the Company and payable on the Initial Securities but not payable on the Option Securities. The option hereby granted may be exercised for 30 days after the date hereof and may be exercised in whole or in part at any time from time to time upon notice by the Representatives to the Company setting forth the number of Option Securities as to which the several Underwriters are then exercising the option and the time and date of payment and delivery for such Option Securities. Any such time and date of delivery (a "Date of Delivery") shall be determined by the Representatives, but shall not be later than seven full business days after the exercise of said option, nor in any event prior to the Closing Time. If the option is exercised as to all or any portion of the Option Securities, each of the Underwriters, acting severally and not jointly, will purchase that proportion of the total number of Option Securities then being purchased which the number of Initial Securities set forth in Schedule A opposite the name of such Underwriter bears to the total number of Initial Securities, subject, in each case, to such adjustments as the Representatives in their sole discretion shall make to eliminate any sales or purchases of fractional shares.

(c) *Payment*. Payment of the purchase price for, and delivery of certificates or security entitlements for, the Initial Securities shall be made at the offices of Cooley LLP, 101 California Street, San Francisco, CA 94111, or at such other place as shall be agreed upon by the Representatives and the Company, at 9:00 a.m. (New York City time) on the second (third, if the pricing occurs after 4:30 p.m. (New York City time) on any given day) business day after the date hereof (unless postponed in accordance with the provisions of Section 10), or such other time not later than ten business days after such date as shall be agreed upon by the Representatives and the Company (such time and date of payment and delivery being herein called "Closing Time").

In addition, in the event that any or all of the Option Securities are purchased by the Underwriters, payment of the purchase price for, and delivery of certificates or security entitlements for, such Option Securities shall be made at the above-mentioned offices, or at such other place as shall be agreed upon by the Representatives and the Company, on each Date of Delivery as specified in the notice from the Representatives to the Company.

Payment shall be made to the Company by wire transfer of immediately available funds to a bank account designated by the Company against delivery to the Representatives for the respective accounts of the Underwriters of certificates or security entitlements for the Securities to be purchased by them. It is understood that each Underwriter has authorized the Representatives, for its account, to accept delivery of, receipt for, and make payment of the purchase price for, the Initial Securities and the Option Securities, if any, which it has agreed to purchase. Each of the Representatives, individually and not as representative of the Underwriters, may (but shall not be obligated to) make payment of the purchase price for the Initial Securities or the Option Securities, if any, to be purchased by any Underwriter whose funds have not been received by the Closing Time or the relevant Date of Delivery, as the case may be, but such payment shall not relieve such Underwriter from its obligations hereunder.

SECTION 3. Covenants of the Company. The Company covenants with each Underwriter as follows:

(a) *Compliance with Securities Regulations and Commission Requests*. The Company, subject to Section 3(b), will comply with the requirements of Rule 430A, and will notify the Representatives promptly, and confirm the notice in writing, (i) when any post-effective amendment to the Registration Statement shall become effective or any amendment or supplement to the Prospectus shall have been filed, (ii) of the receipt of any comments from the Commission, (iii) of any request by the Commission for any amendment to the Registration Statement or any amendment or supplement to the Prospectus or for additional information, (iv) of the issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement or any post-effective amendment or of any order preventing or suspending the use of any preliminary prospectus or the Prospectus, or of the suspension of the qualification of the Securities for offering or sale in any jurisdiction, or of the initiation or threatening of any proceedings for any of such purposes or of any examination pursuant to Section 8(d) or 8(e) of the 1933 Act concerning the Registration Statement and (v) if the Company becomes the subject of a proceeding under Section 8A of the 1933 Act in connection with the offering of the Securities. The Company will effect all filings required under Rule 424(b), in the manner and within the time period required by Rule 424(b) (without reliance on Rule 424(b)(8)), and will take such steps as it deems necessary to ascertain promptly whether the form of prospectus transmitted for filing under Rule 424(b) was received for filing by the Commission and, in the event that it was not, it will promptly file such prospectus. The Company will make every reasonable effort to prevent the issuance of any stop order, prevention or suspension and, if any such order is issued, to obtain the lifting thereof as soon as reasonably practicable.

(b) *Continued Compliance with Securities Laws*. The Company will comply with the 1933 Act and the 1933 Act Regulations so as to permit the completion of the distribution of the Securities as contemplated in this Agreement and in the Registration Statement, the General Disclosure Package and the Prospectus. If at any time when a prospectus relating to the Securities is (or, but for the exception afforded by Rule 172 of the 1933 Act Regulations ("Rule 172"), would be) required by the 1933 Act to be delivered in connection with sales of the Securities, any event shall occur or condition shall exist as a result of which it is necessary, in the opinion of counsel for the Underwriters or for the Company, to (i) amend the Registration Statement in order that the Registration Statement will not include an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading, (ii) amend or supplement the General Disclosure Package or the Prospectus in order that the General Disclosure Package or the Prospectus, as the case may be, will not include any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein not misleading in the light of the circumstances existing at the time it is delivered to a purchaser or (iii) amend the Registration Statement or amend or supplement the General Disclosure Package or the Prospectus, as the case may be, in order to comply with the requirements of the 1933 Act or the 1933 Act Regulations, the Company will promptly (A) give the Representatives notice of such event, (B) prepare any amendment or supplement as may be necessary to correct such statement or omission or to make the Registration Statement, the General Disclosure Package or the Prospectus comply with such requirements and, a reasonable amount of time prior to any proposed filing or use, furnish the Representatives with copies of any such amendment or supplement and (C) file with the Commission any such amendment or supplement; provided, that the Company shall not file or use any such amendment or supplement to which the Representatives or counsel for the Underwriters shall reasonably object. The Company will furnish to the Underwriters such number of copies of such

amendment or supplement as the Underwriters may reasonably request. The Company has given the Representatives notice of any filings made pursuant to the 1934 Act or 1934 Act Regulations as soon as practicable prior to the Applicable Time; the Company will give the Representatives notice of its intention to make any such filing from the Applicable Time to the Closing Time and will furnish the Representatives with copies of any such documents a reasonable amount of time prior to such proposed filing, as the case may be, and will not file or use any such document to which the Representatives or counsel for the Underwriters shall reasonably object.

(c) *Delivery of Registration Statements*. The Company has furnished or will deliver to the Representatives and counsel for the Underwriters, without charge, conformed copies of the Registration Statement as originally filed and each amendment thereto (including exhibits filed therewith) and conformed copies of all consents and certificates of experts. The copies of the Registration Statement and each amendment thereto furnished to the Underwriters will be identical to the electronically transmitted copies thereof filed with the Commission pursuant to EDGAR, except to the extent permitted by Regulation S-T.

(d) *Delivery of Prospectuses*. The Company has delivered to each Underwriter, without charge, as many copies of each preliminary prospectus as such Underwriter reasonably requested, and the Company hereby consents to the use of such copies for purposes permitted by the 1933 Act. The Company will furnish to each Underwriter, without charge, during the period when a prospectus relating to the Securities is (or, but for the exception afforded by Rule 172, would be) required to be delivered under the 1933 Act, such number of copies of the Prospectus (as amended or supplemented) as such Underwriter may reasonably request. The Prospectus and any amendments or supplements thereto furnished to the Underwriters will be identical to the electronically transmitted copies thereof filed with the Commission pursuant to EDGAR, except to the extent permitted by Regulation S-T.

(e) *Blue Sky Qualifications*. The Company will use its reasonable best efforts, in cooperation with the Underwriters, to qualify the Securities for offering and sale under the applicable securities laws of such states and other jurisdictions (domestic or foreign) as the Representatives may designate and to maintain such qualifications in effect so long as required to complete the distribution of the Securities; provided, however, that the Company shall not be obligated to file any general consent to service of process or to qualify as a foreign corporation or as a dealer in securities in any jurisdiction in which it is not so qualified or to subject itself to taxation in respect of doing business in any jurisdiction in which it is not otherwise so subject.

(f) *Rule 158*. The Company will timely file such reports pursuant to the 1934 Act as are necessary in order to make generally available (which may be satisfied by filing with the Commission pursuant to EDGAR) to its securityholders as soon as practicable an earnings statement for the purposes of, and to provide to the Underwriters the benefits contemplated by, the last paragraph of Section 11(a) of the 1933 Act.

(g) *Use of Proceeds*. The Company will use the net proceeds received by it from the sale of the Securities in the manner specified in the Registration Statement, the General Disclosure Package and the Prospectus under “Use of Proceeds.”

(h) *Listing*. The Company will use its reasonable best efforts to effect and maintain the listing of the Common Stock (including the Securities) on The Nasdaq Global Market.

(i) *Restriction on Sale of Securities*. During a period of 180 days from the date of the Prospectus, the Company will not, without the prior written consent of the Representatives, (i) directly or indirectly, offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase or otherwise transfer or dispose of any shares of Common Stock or any securities convertible into or exercisable or exchangeable for Common Stock or file or confidentially submit any registration statement under the 1933 Act with respect to any of the foregoing or (ii) enter into any swap or any other agreement or any transaction that transfers, in whole or in part, directly or indirectly, the economic consequence of ownership of the Common Stock, whether any such swap or transaction described in clause (i) or (ii) above is to be settled by delivery of Common Stock or other securities, in cash or otherwise. The foregoing sentence shall not apply to (A) the Securities to be sold hereunder, (B) any shares of Common Stock issued by the Company upon the exercise (including any net exercise or exercise by delivery of already-owned shares of Common Stock) of an option or warrant or the conversion of a security outstanding on the date hereof and referred to in the Registration Statement, the General Disclosure Package and the Prospectus, (C) any shares of Common Stock issued or options to purchase Common Stock or restricted stock units covering shares of Common Stock granted pursuant to existing employee benefit plans of the Company referred to in the Registration Statement, the General Disclosure Package and the Prospectus, (D) any shares of Common Stock issued or options to purchase shares of Common Stock granted pursuant to any non-employee director compensation plan or dividend reinvestment plan referred to in the Registration Statement, the General Disclosure Package and the Prospectus, (E) the filing by the Company of a registration statement with the Commission on Form S-8 or a successor form thereto with respect to the registration of securities to be offered under any plans or programs referred to in clauses (C) and (D) above and (F) the sale or issuance of or entry into an agreement to sell or issue shares of Common Stock or other securities issued in connection with any (1) merger, (2) acquisition of securities, businesses, properties or other assets, (3) joint venture or (4) strategic alliance or relationship; provided, that the aggregate number of shares issued pursuant to this clause (F) shall not exceed 10.0% of the total number of outstanding shares of Common Stock immediately following the issuance and sale of the Securities; provided further that the recipient of any such shares of Common Stock or securities issued pursuant to clauses (B), (C), (D) and (F) during the 180-day restricted period shall enter into an agreement substantially in the form of Exhibit A hereto with respect to (and not in excess of) the 180-day restricted period and only if such recipient did not previously enter into such an agreement with the Representatives.

(j) *Release*. If the Representatives, in their sole discretion, agree to release or waive the restrictions set forth in a lock-up agreement described in Section 5(i) hereof for an officer or director of the Company and provide the Company with notice of the impending release or waiver at least three business days before the effective date of the release or waiver, the Company agrees to announce the impending release or waiver by a press release substantially in the form of Exhibit B hereto through a major news service at least two business days before the effective date of the release or waiver.

(k) *Reporting Requirements*. The Company, during the period when a Prospectus relating to the Securities is (or, but for the exception afforded by Rule 172, would be) required to be delivered under the 1933 Act, will file all documents required to be filed with the Commission pursuant to the 1934 Act within the time periods required by the 1934 Act and 1934 Act Regulations. Additionally, the Company shall report the use of proceeds from the issuance of the Securities as may be required under Rule 463 under the 1933 Act.

(l) *Issuer Free Writing Prospectuses*. The Company agrees that, unless it obtains the prior written consent of the Representatives, it will not make any offer relating to the Securities that would constitute an Issuer Free Writing Prospectus or that would otherwise constitute a “free writing prospectus,” or a portion thereof, required to be filed by the Company with the Commission or retained by the Company under Rule 433; provided that the Representatives will be deemed to have consented to the Issuer Free Writing Prospectuses listed on Schedule B-2 hereto and any “road show that is a written communication” within the meaning of Rule 433(d)(8)(i) that has been reviewed by the Representatives. The Company represents that it has treated or agrees that it will treat each such free writing prospectus

consented to, or deemed consented to, by the Representatives as an "issuer free writing prospectus," as defined in Rule 433, and that it has complied and will comply with the applicable requirements of Rule 433 with respect thereto, including timely filing with the Commission where required, legending and record keeping. If at any time following issuance of an Issuer Free Writing Prospectus there occurred or occurs an event or development as a result of which such Issuer Free Writing Prospectus conflicted or would conflict with the information contained in the Registration Statement, any preliminary prospectus or the Prospectus or included or would include an untrue statement of a material fact or omitted or would omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances existing at that subsequent time, not misleading, the Company will promptly notify the Representatives and will promptly amend or supplement, at its own expense, such Issuer Free Writing Prospectus to eliminate or correct such conflict, untrue statement or omission.

(m) *Certification Regarding Beneficial Owners*. The Company will deliver to the Representatives, on the date of execution of this Agreement, a properly completed and executed Certification Regarding Beneficial Owners of Legal Entity Customers, together with copies of identifying documentation, and the Company undertakes to provide such additional supporting documentation as the Representatives may reasonably request in connection with the verification of the foregoing certification.

(n) *Testing-the-Waters Materials*. If at any time following the distribution of any Written Testing-the-Waters Communication there occurred or occurs an event or development as a result of which such Written Testing-the-Waters Communication included or would include an untrue statement of a material fact or omitted or would omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances existing at that subsequent time, not misleading, the Company will promptly notify the Representatives and will promptly amend or supplement, at its own expense, such Written Testing-the-Waters Communication to eliminate or correct such untrue statement or omission.

(o) *Emerging Growth Company Status*. The Company will promptly notify the Representatives if the Company ceases to be an Emerging Growth Company at any time prior to the later of (i) completion of the distribution of the Securities within the meaning of the Securities Act and (ii) completion of the 180-day restricted period referred to in Section 3(i).

SECTION 4. Payment of Expenses.

(a) *Expenses*. The Company will pay or cause to be paid all expenses incident to the performance of its obligations under this Agreement including (i) the preparation, printing and filing of the Registration Statement (including financial statements and exhibits) as originally filed and each amendment thereto, (ii) the preparation, printing and delivery to the Underwriters of copies of each preliminary prospectus, each Issuer Free Writing Prospectus and the Prospectus and any amendments or supplements thereto and any costs associated with electronic delivery of any of the foregoing by the Underwriters to investors, (iii) the preparation, issuance and delivery of the certificates or security entitlements for the Securities to the Underwriters, including any stock or other transfer taxes and any stamp or other duties payable upon the sale, issuance or delivery of the Securities to the Underwriters, (iv) the fees and disbursements of the Company's counsel, accountants and other advisors, (v) the qualification of the Securities under securities laws in accordance with the provisions of Section 3(e) hereof, including filing fees and the reasonable fees and disbursements of counsel for the Underwriters in connection therewith and in connection with the preparation of the Blue Sky Survey and any supplement thereto, (vi) the fees and expenses of any transfer agent or registrar for the Securities, (vii) the costs and expenses of the Company relating to investor presentations on any "road show" undertaken in connection with the marketing of the Securities, including without limitation, expenses associated with the production of road show slides and graphics, fees and expenses of any consultants engaged by the

Company or with the Company's prior written consent (which may be by email) in connection with the road show presentations, travel and lodging expenses of the representatives and officers of the Company and any such consultants, and the cost of aircraft and other transportation (provided that the travel and lodging expenses of the Representatives shall be paid for by the Underwriters), and fifty percent (50%) of the cost of any aircraft chartered in connection with the road show (with the Underwriters agreeing to pay for the other fifty percent (50%) of the cost of such chartered aircraft), (viii) the filing fees incident to, and the reasonable fees and disbursements of counsel to the Underwriters in connection with, the review by FINRA of the terms of the sale of the Securities, with such legal fees, taken together with the legal fees described in clause (v) above, not to exceed $40,000; (ix) the fees and expenses incurred in connection with the listing of the Securities on The Nasdaq Global Market and (x) the costs and expenses (including, without limitation, any damages or other amounts payable in connection with legal or contractual liability) associated with the reforming of any contracts for sale of the Securities made by the Underwriters caused by a breach of the representation contained in the third sentence of Section 1(a)(ii). Except as provided in this Section 4, the Underwriters will pay all of their own costs and expenses, including the fees and disbursements of their counsel, stock transfer taxes payable on the resale of any of the Securities by them and any advertising expenses connected with any offers they may make.

(b) *Termination of Agreement*. If this Agreement is terminated by the Representatives in accordance with the provisions of Section 5, Section 9(a)(i) or (iii) or Section 10 hereof, the Company shall reimburse the non-defaulting Underwriters for all of their reasonable out-of-pocket expenses actually incurred, including the reasonable fees and disbursements of counsel for the Underwriters.

SECTION 5. Conditions of Underwriters' Obligations. The obligations of the several Underwriters hereunder are subject to the accuracy of the representations and warranties of the Company contained herein or in certificates of any officer of the Company or any of its subsidiaries delivered pursuant to the provisions hereof, to the performance by the Company of its covenants and other obligations hereunder, and to the following further conditions:

(a) *Effectiveness of Registration Statement; Rule 430A Information*. The Registration Statement, including any Rule 462(b) Registration Statement, has become effective and, at the Closing Time, no stop order suspending the effectiveness of the Registration Statement or any post-effective amendment thereto has been issued under the 1933 Act, no order preventing or suspending the use of any preliminary prospectus or the Prospectus has been issued and no proceedings for any of those purposes have been instituted or are pending or, to the Company's knowledge, contemplated; and the Company has complied with each request (if any) from the Commission for additional information. A prospectus containing the Rule 430A Information shall have been filed with the Commission in the manner and within the time frame required by Rule 424(b) without reliance on Rule 424(b)(8) or a post-effective amendment providing such information shall have been filed with, and declared effective by, the Commission in accordance with the requirements of Rule 430A.

(b) *Opinion and Negative Assurance Letter of Counsel for Company*. At the Closing Time, the Representatives shall have received an opinion and negative assurance letter, dated the Closing Time, of Gibson, Dunn & Crutcher LLP, counsel for the Company, in form and substance satisfactory to counsel for the Underwriters, together with signed or reproduced copies of such letter for each of the other Underwriters.

(c) *Opinion of Intellectual Property Counsel for Company*. At the Closing Time, the Representatives shall have received the favorable opinion, dated the Closing Time, of Greenberg Traurig, LLP, intellectual property counsel for the Company, in form and substance satisfactory to counsel for the Underwriters, together with signed or reproduced copies of such letter for each of the other Underwriters.

(d) *Opinion and Negative Assurance Letter of Counsel for Underwriters*. At the Closing Time, the Representatives shall have received the favorable opinion and negative assurance letter, dated the Closing Time, of Cooley LLP, counsel for the Underwriters, in the form and substance reasonably satisfactory to the Representatives, together with signed or reproduced copies of such letter for each of the other Underwriters.

(e) *Officers' Certificate*. At the Closing Time, there shall not have been, since the date hereof or since the respective dates as of which information is given in the Registration Statement, the General Disclosure Package or the Prospectus, any Material Adverse Effect change, and the Representatives shall have received a certificate of the Chief Executive Officer or the President of the Company and of the chief financial or chief accounting officer of the Company, dated the Closing Time, to the effect that (i) there has been no such material adverse change, (ii) the representations and warranties of the Company in this Agreement are true and correct with the same force and effect as though expressly made at and as of the Closing Time, (iii) the Company has complied in all material respects with all agreements and satisfied all conditions on its part to be performed or satisfied at or prior to the Closing Time, and (iv) no stop order suspending the effectiveness of the Registration Statement under the 1933 Act has been issued, no order preventing or suspending the use of any preliminary prospectus or the Prospectus has been issued and no proceedings for any of those purposes have been instituted or are pending or, to their knowledge, contemplated by the Commission.

(f) *Accountant's Comfort Letter*. At the time of the execution of this Agreement, the Representatives shall have received from Brightman Almagor Zohar & Co., a firm in the Deloitte Global Network, a letter, dated such date, in form and substance satisfactory to the Representatives, together with reproduced copies of such letter for each of the other Underwriters containing statements and information of the type ordinarily included in accountants' "comfort letters" to underwriters with respect to the financial statements and certain financial information contained in the Registration Statement, the General Disclosure Package and the Prospectus.

(g) *Bring-down Comfort Letter*. At the Closing Time, the Representatives shall have received from Brightman Almagor Zohar & Co., a firm in the Deloitte Global Network, a letter, dated as of the Closing Time, to the effect that they reaffirm the statements made in the letter furnished pursuant to subsection (e) of this Section, except that the specified date referred to shall be a date not more than three business days prior to the Closing Time.

(h) *Approval of Listing*. At the Closing Time, the Securities shall have been approved for listing on The Nasdaq Global Market, subject only to official notice of issuance.

(i) *No Objection*. FINRA has confirmed that it has not raised any objection with respect to the fairness and reasonableness of the underwriting terms and arrangements relating to the offering of the Securities.

(j) *Lock-up Agreements*. At the date of this Agreement, the Representatives shall have received an agreement substantially in the form of Exhibit A hereto signed by (i) each of the Company's directors and officers and (ii) each holder of shares of Common Stock or any security convertible or exercisable for shares of Common Stock.

(k) *Maintenance of Rating*. Neither the Company nor its subsidiaries have any debt securities or preferred stock that are rated by any "nationally recognized statistical rating agency" (as defined in Section 3(a)(62) of the 1934 Act).

(l) *Chief Financial Officer Certificate*. On the date of this Agreement and at the Closing Time, as the case may be, the Company shall have furnished to the Representatives a certificate, dated the respective dates of delivery thereof and addressed to the Underwriters, of its chief financial officer with respect to certain financial data contained in the General Disclosure Package and the Prospectus, providing "management comfort" with respect to such information, in form and substance reasonably satisfactory to the Representatives.

(m) *Conditions to Purchase of Option Securities*. In the event that the Underwriters exercise their option provided in Section 2(b) hereof to purchase all or any portion of the Option Securities, the representations and warranties of the Company contained herein and the statements in any certificates furnished by the Company and any of its subsidiaries hereunder shall be true and correct as of each Date of Delivery and, at the relevant Date of Delivery, the Representatives shall have received:

(i) Officers' Certificate. A certificate, dated such Date of Delivery, of the President or a Vice President of the Company and of the chief financial or chief accounting officer of the Company confirming that the certificate delivered at the Closing Time pursuant to Section 5(d) hereof remains true and correct as of such Date of Delivery.

(ii) Opinion and Negative Assurance Letter of Counsel for Company. If requested by the Representatives, the favorable opinion and negative assurance letter of Gibson, Dunn & Crutcher LLP, counsel for the Company, in form and substance satisfactory to counsel for the Underwriters, dated such Date of Delivery, relating to the Option Securities to be purchased on such Date of Delivery and otherwise to the same effect as the opinion required by Section 5(b) hereof.

(iii) Opinion of Intellectual Property Counsel for Company. If requested by the Representatives, the favorable opinion of Greenberg Traurig, LLP, intellectual property counsel for the Company, in form and substance satisfactory to counsel for the Underwriters, dated such Date of Delivery, relating to the Option Securities to be purchased on such Date of Delivery and otherwise to the same effect as the opinion required by Section 5(c) hereof.

(iv) Opinion and Negative Assurance Letter of Counsel for Underwriters. If requested by the Representatives, the favorable opinion and negative assurance letter of Cooley LLP, counsel for the Underwriters, dated such Date of Delivery, relating to the Option Securities to be purchased on such Date of Delivery and otherwise to the same effect as the opinion required by Section 5(e) hereof.

(v) Bring-down Comfort Letter. If requested by the Representatives, a letter from Brightman Almagor Zohar & Co., a firm in the Deloitte Global Network, in form and substance satisfactory to the Representatives and dated such Date of Delivery, substantially in the same form and substance as the letter furnished to the Representatives pursuant to Section 5(e) hereof, except that the "specified date" in the letter furnished pursuant to this paragraph shall be a date not more than three business days prior to such Date of Delivery.

(vi) Chief Financial Officer Certificate. A certificate, dated such Date of Delivery, of the Company's chief financial officer relating to the Option Securities to be purchased on such Date of Delivery and otherwise to the same effect as the certificate required by Section 5(l) hereof.

(n) *Additional Documents*. At the Closing Time and at each Date of Delivery (if any) counsel for the Underwriters shall have been furnished with such documents and opinions as they may reasonably require for the purpose of enabling them to pass upon the issuance and sale of the Securities as herein contemplated, or in order to evidence the accuracy of any of the representations or warranties, or the fulfillment of any of the conditions, herein contained; and all proceedings taken by the Company in connection with the issuance and sale of the Securities as herein contemplated shall be reasonably satisfactory in form and substance to the Representatives and counsel for the Underwriters.

(o) *Termination of Agreement*. If any condition specified in this Section shall not have been fulfilled when and as required to be fulfilled, this Agreement, or, in the case of any condition to the purchase of Option Securities on a Date of Delivery which is after the Closing Time, the obligations of the several Underwriters to purchase the relevant Option Securities, may be terminated by the Representatives by notice to the Company at any time at or prior to Closing Time or such Date of Delivery, as the case may be, and such termination shall be without liability of any party to any other party except as provided in Section 4 and except that Sections 1, 6, 7, 8, 14, 15, 16 and 17 shall survive any such termination and remain in full force and effect.

SECTION 6. Indemnification.

(a) *Indemnification of Underwriters*. The Company agrees to indemnify and hold harmless each Underwriter, its affiliates (as such term is defined in Rule 501(b) under the 1933 Act (each, an "Affiliate")), its selling agents and each person, if any, who controls any Underwriter within the meaning of Section 15 of the 1933 Act or Section 20 of the 1934 Act as follows:

(i) against any and all loss, liability, claim, damage and expense whatsoever, as incurred, arising out of any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement (or any amendment thereto), including the Rule 430A Information, or the omission or alleged omission therefrom of a material fact required to be stated therein or necessary to make the statements therein not misleading or arising out of any untrue statement or alleged untrue statement of a material fact included (A) in any preliminary prospectus, any Issuer Free Writing Prospectus, any Written Testing-the-Waters Communication, the General Disclosure Package or the Prospectus (or any amendment or supplement thereto), or (B) in any materials or information provided to investors by, or with the approval of, the Company in connection with the marketing of the offering of the Securities ("Marketing Materials"), including any road show (as defined in Rule 433(h) under the 1933 Act) or investor presentations made to investors by the Company (whether in person or electronically), or the omission or alleged omission in any preliminary prospectus, Issuer Free Writing Prospectus, any Written Testing-the-Waters Communication, Prospectus or in any Marketing Materials of a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading;

(ii) against any and all loss, liability, claim, damage and expense whatsoever, as incurred, to the extent of the aggregate amount paid in settlement of any litigation, or any investigation or proceeding by any governmental agency or body, commenced or threatened, or of any claim whatsoever based upon any such untrue statement or omission, or any such alleged untrue statement or omission; provided that (subject to Section 6(d) below) any such settlement is effected with the written consent of the Company;

(iii) against any and all expense whatsoever, as incurred (including the fees and disbursements of counsel chosen by the Representatives), reasonably incurred in investigating, preparing or defending against any litigation, or any investigation or proceeding by any governmental agency or body, commenced or threatened, or any claim whatsoever based upon any such untrue statement or omission, or any such alleged untrue statement or omission, to the extent that any such expense is not paid under (i) or (ii) above;

provided, however, that this indemnity agreement shall not apply to any loss, liability, claim, damage or expense to the extent arising out of any untrue statement or omission or alleged untrue statement or omission made in the Registration Statement (or any amendment thereto), including the Rule 430A Information, the General Disclosure Package, any preliminary prospectus, any Issuer Free Writing Prospectus, any Written Testing-the-Waters Communication, any Marketing Materials or the Prospectus (or any amendment or supplement thereto) in reliance upon and in conformity with the Underwriter Information.

(b) *Indemnification of Company, Directors and Officers*. Each Underwriter severally agrees to indemnify and hold harmless the Company, its directors, each of its officers who signed the Registration Statement, and each person, if any, who controls the Company within the meaning of Section 15 of the 1933 Act or Section 20 of the 1934 Act, against any and all loss, liability, claim, damage and expense described in the indemnity contained in subsection (a) of this Section, as incurred, but only with respect to untrue statements or omissions, or alleged untrue statements or omissions, made in the Registration Statement (or any amendment thereto), including the Rule 430A Information, the General Disclosure Package any preliminary prospectus, any Issuer Free Writing Prospectus, any Written Testing-the-Waters Communication, any Marketing Materials or the Prospectus (or any amendment or supplement thereto) in reliance upon and in conformity with the Underwriter Information.

(c) *Actions against Parties; Notification*. Each indemnified party shall give notice as promptly as reasonably practicable to each indemnifying party of any action commenced against it in respect of which indemnity may be sought hereunder, but failure to so notify an indemnifying party shall not relieve such indemnifying party from any liability hereunder to the extent it is not materially prejudiced as a result thereof and in any event shall not relieve it from any liability which it may have otherwise than on account of this indemnity agreement. In the case of parties indemnified pursuant to Section 6(a) above, counsel to the indemnified parties shall be selected by the Representatives, and, in the case of parties indemnified pursuant to Section 6(b) above, counsel to the indemnified parties shall be selected by the Company. An indemnifying party may participate at its own expense in the defense of any such action; provided, however, that counsel to the indemnifying party shall not (except with the consent of the indemnified party) also be counsel to the indemnified party. In no event shall the indemnifying parties be liable for fees and expenses of more than one counsel (in addition to any local counsel) separate from their own counsel for all indemnified parties in connection with any one action or separate but similar or related actions in the same jurisdiction arising out of the same general allegations or circumstances. No indemnifying party shall, without the prior written consent of the indemnified parties, settle or compromise or consent to the entry of any judgment with respect to any litigation, or any investigation or proceeding by any governmental agency or body, commenced or threatened, or any claim whatsoever in respect of which indemnification or contribution could be sought under this Section 6 or Section 7 hereof (whether or not the indemnified parties are actual or potential parties thereto), unless such settlement, compromise or consent (i) includes an unconditional release of each indemnified party from all liability arising out of such litigation, investigation, proceeding or claim and (ii) does not include a statement as to or an admission of fault, culpability or a failure to act by or on behalf of any indemnified party.

(d) *Settlement without Consent if Failure to Reimburse*. If at any time an indemnified party shall have requested an indemnifying party to reimburse the indemnified party for fees and expenses of counsel, such indemnifying party agrees that it shall be liable for any settlement of the nature contemplated by Section 6(a)(ii) or settlement of any claim in connection with any violation referred to in Section 6(e) effected without its written consent if (i) such settlement is entered into more than 45 days after receipt by such indemnifying party of the aforesaid request, (ii) such indemnifying party shall have received notice of the terms of such settlement at least 30 days prior to such settlement being entered into and (iii) such indemnifying party shall not have reimbursed such indemnified party in accordance with such request prior to the date of such settlement.

SECTION 7. Contribution. If the indemnification provided for in Section 6 hereof is for any reason unavailable to or insufficient to hold harmless an indemnified party in respect of any losses, liabilities, claims, damages or expenses referred to therein, then each indemnifying party shall contribute to the aggregate amount of such losses, liabilities, claims, damages and expenses incurred by such indemnified party, as incurred, (i) in such proportion as is appropriate to reflect the relative benefits received by the Company, on the one hand, and the Underwriters, on the other hand, from the offering of the Securities pursuant to this Agreement or (ii) if the allocation provided by clause (i) is not permitted by applicable law, in such proportion as is appropriate to reflect not only the relative benefits referred to in clause (i) above but also the relative fault of the Company, on the one hand, and of the Underwriters, on the other hand, in connection with the statements or omissions which resulted in such losses, liabilities, claims, damages or expenses, as well as any other relevant equitable considerations.

The relative benefits received by the Company, on the one hand, and the Underwriters, on the other hand, in connection with the offering of the Securities pursuant to this Agreement shall be deemed to be in the same respective proportions as the total net proceeds from the offering of the Securities pursuant to this Agreement (after deducting underwriting discounts and commissions but before deducting expenses) received by the Company, on the one hand, and the total underwriting discount received by the Underwriters, on the other hand, in each case as set forth on the cover of the Prospectus, bear to the aggregate initial public offering price of the Securities as set forth on the cover of the Prospectus.

The relative fault of the Company, on the one hand, and the Underwriters, on the other hand, shall be determined by reference to, among other things, whether any such untrue or alleged untrue statement of a material fact or omission or alleged omission to state a material fact relates to information supplied by the Company or by the Underwriters and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such statement or omission.

The Company and the Underwriters agree that it would not be just and equitable if contribution pursuant to this Section 7 were determined by pro rata allocation (even if the Underwriters were treated as one entity for such purpose) or by any other method of allocation which does not take account of the equitable considerations referred to above in this Section 7. The aggregate amount of losses, liabilities, claims, damages and expenses incurred by an indemnified party and referred to above in this Section 7 shall be deemed to include any legal or other expenses reasonably incurred by such indemnified party in investigating, preparing or defending against any litigation, or any investigation or proceeding by any governmental agency or body, commenced or threatened, or any claim whatsoever based upon any such untrue or alleged untrue statement or omission or alleged omission.

Notwithstanding the provisions of this Section 7, no Underwriter shall be required to contribute any amount in excess of the underwriting commissions received by such Underwriter in connection with the Securities underwritten by it and distributed to the public.

No person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the 1933 Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation.

For purposes of this Section 7, each person, if any, who controls an Underwriter within the meaning of Section 15 of the 1933 Act or Section 20 of the 1934 Act and each Underwriter's Affiliates and selling agents shall have the same rights to contribution as such Underwriter, and each director of the Company, each officer of the Company who signed the Registration Statement, and each person, if any, who controls the Company within the meaning of Section 15 of the 1933 Act or Section 20 of the 1934 Act shall have the same rights to contribution as the Company. The Underwriters' respective obligations to contribute pursuant to this Section 7 are several in proportion to the number of Initial Securities set forth opposite their respective names in Schedule A hereto and not joint.

SECTION 8. Representations, Warranties and Agreements to Survive. All representations, warranties and agreements contained in this Agreement or in certificates of officers of the Company or any of its subsidiaries submitted pursuant hereto, shall remain operative and in full force and effect regardless of (i) any investigation made by or on behalf of any Underwriter or its Affiliates or selling agents, any person controlling any Underwriter, its officers or directors or any person controlling the Company and (ii) delivery of and payment for the Securities.

SECTION 9. Termination of Agreement.

(a) *Termination*. The Representatives may terminate this Agreement, by notice to the Company, at any time at or prior to the Closing Time (i) if there has been, in the judgment of the Representatives, since the time of execution of this Agreement or since the respective dates as of which information is given in the Registration Statement, the General Disclosure Package or the Prospectus, any material adverse change in the condition, financial or otherwise, or in the earnings, business affairs or business prospects of the Company and its subsidiaries considered as one enterprise, whether or not arising in the ordinary course of business, or (ii) if there has occurred any material adverse change in the financial markets in the United States or the international financial markets, any outbreak of hostilities or escalation thereof or other calamity or crisis or any change or development involving a prospective change in national or international political, financial or economic conditions, in each case the effect of which is such as to make it, in the judgment of the Representatives, impracticable or inadvisable to proceed with the completion of the offering or to enforce contracts for the sale of the Securities, or (iii) if trading in any securities of the Company has been suspended or materially limited by the Commission or The Nasdaq Global Market, or (iv) if trading generally on the NYSE MKT or the New York Stock Exchange or in The Nasdaq Global Market has been suspended or materially limited, or minimum or maximum prices for trading have been fixed, or maximum ranges for prices have been required, by any of said exchanges or by order of the Commission, FINRA or any other governmental authority, or (v) a material disruption has occurred in commercial banking or securities settlement or clearance services in the United States or with respect to Clearstream or Euroclear systems in Europe, or (vi) if a banking moratorium has been declared by either Federal or New York authorities.

(b) *Liabilities*. If this Agreement is terminated pursuant to this Section, such termination shall be without liability of any party to any other party except as provided in Section 4 hereof, and provided further that Sections 1, 6, 7, 8, 14, 15, 16 and 17 shall survive such termination and remain in full force and effect.

SECTION 10. Default by One or More of the Underwriters. If one or more of the Underwriters shall fail at the Closing Time or a Date of Delivery to purchase the Securities which it or they are obligated to purchase under this Agreement (the "Defaulted Securities"), the Representatives shall have the right, within 24 hours thereafter, to make arrangements for one or more of the non-defaulting Underwriters, or any other underwriters, to purchase all, but not less than all, of the Defaulted Securities in such amounts as may be agreed upon and upon the terms herein set forth; if, however, the Representatives shall not have completed such arrangements within such 24-hour period, then:

(i) if the number of Defaulted Securities does not exceed 10% of the number of Securities to be purchased on such date, each of the non-defaulting Underwriters shall be obligated, severally and not jointly, to purchase the full amount thereof in the proportions that their respective underwriting obligations hereunder bear to the underwriting obligations of all non-defaulting Underwriters, or

(ii) if the number of Defaulted Securities exceeds 10% of the number of Securities to be purchased on such date, this Agreement or, with respect to any Date of Delivery which occurs after the Closing Time, the obligation of the Underwriters to purchase, and the Company to sell, the Option Securities to be purchased and sold on such Date of Delivery shall terminate without liability on the part of any non-defaulting Underwriter.

No action taken pursuant to this Section shall relieve any defaulting Underwriter from liability in respect of its default.

In the event of any such default which does not result in a termination of this Agreement or, in the case of a Date of Delivery which is after the Closing Time, which does not result in a termination of the obligation of the Underwriters to purchase and the Company to sell the relevant Option Securities, as the case may be, either the (i) Representatives or (ii) the Company shall have the right to postpone Closing Time or the relevant Date of Delivery, as the case may be, for a period not exceeding seven days in order to effect any required changes in the Registration Statement, the General Disclosure Package or the Prospectus or in any other documents or arrangements. As used herein, the term "Underwriter" includes any person substituted for an Underwriter under this Section 10.

SECTION 11. Notices. All notices and other communications hereunder shall be in writing and shall be deemed to have been duly given if mailed or transmitted by any standard form of telecommunication. Notices to the Underwriters shall be directed to (i) BofAS at One Bryant Park, New York, New York 10036, attention of Syndicate Department (facsimile: (646) 855-3073), with a copy to ECM Legal (facsimile: (212) 230-8730), (ii) SVB Leerink at One Federal Street, 37th Floor, Boston, Massachusetts, attention of Jack I. Fitzgerald, Esq. (facsimile (617) 918-4664), and (iii) RBC at 200 Vesey Street, 8th Floor, New York, New York 10281, attention of Equity Syndicate Department (facsimile (212) 428-7479); notices to the Company shall be directed to it at 89bio, Inc., 535 Mission Street, 14th Floor, San Francisco, California 94105, attention of Rohan Palekar, Chief Executive Officer.

SECTION 12. No Advisory or Fiduciary Relationship. The Company acknowledges and agrees that (a) the purchase and sale of the Securities pursuant to this Agreement, including the determination of the initial public offering price of the Securities and any related discounts and commissions, is an arm's-length commercial transaction between the Company, on the one hand, and the several Underwriters, on the other hand, (b) in connection with the offering of the Securities and the process leading thereto, each Underwriter is and has been acting solely as a principal and is not the agent or fiduciary of the Company, any of its subsidiaries or their respective stockholders, creditors, employees or any other party, (c) no Underwriter has assumed or will assume an advisory or fiduciary responsibility in favor of the Company with respect to the offering of the Securities or the process leading thereto (irrespective of whether such Underwriter has advised or is currently advising the Company or any of its subsidiaries on other matters) and no Underwriter has any obligation to the Company with respect to the offering of the Securities except the obligations expressly set forth in this Agreement, (d) the Underwriters and their respective affiliates may be engaged in a broad range of transactions that involve interests that differ from those of the Company and (e) the Underwriters have not provided any legal, accounting, regulatory or tax advice with respect to the offering of the Securities and the Company has consulted its own respective legal, accounting, regulatory and tax advisors to the extent it deemed appropriate.

SECTION 13. Recognition of the U.S. Special Resolution Regimes.

(a) In the event that any Underwriter that is a Covered Entity becomes subject to a proceeding under a U.S. Special Resolution Regime, the transfer from such Underwriter of this Agreement, and any interest and obligation in or under this Agreement, will be effective to the same extent as the transfer would be effective under the U.S. Special Resolution Regime if this Agreement, and any such interest and obligation, were governed by the laws of the United States or a state of the United States.

(b) In the event that any Underwriter that is a Covered Entity or a BHC Act Affiliate of such Underwriter becomes subject to a proceeding under a U.S. Special Resolution Regime, Default Rights under this Agreement that may be exercised against such Underwriter are permitted to be exercised to no greater extent than such Default Rights could be exercised under the U.S. Special Resolution Regime if this Agreement were governed by the laws of the United States or a state of the United States.

For purposes of this Section 13, a "BHC Act Affiliate" has the meaning assigned to the term "affiliate" in, and shall be interpreted in accordance with, 12 U.S.C. § 1841(k). "Covered Entity" means any of the following: (i) a "covered entity" as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 252.82(b); (ii) a "covered bank" as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 47.3(b); or (iii) a "covered FSI" as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 382.2(b). **"**Default Right" has the meaning assigned to that term in, and shall be interpreted in accordance with, 12 C.F.R. §§ 252.81, 47.2 or 382.1, as applicable. "U.S. Special Resolution Regime" means each of (i) the Federal Deposit Insurance Act and the regulations promulgated thereunder and (ii) Title II of the Dodd-Frank Wall Street Reform and Consumer Protection Act and the regulations promulgated thereunder.

SECTION 14. Parties. This Agreement shall each inure to the benefit of and be binding upon the Underwriters and the Company and their respective successors. Nothing expressed or mentioned in this Agreement is intended or shall be construed to give any person, firm or corporation, other than the Underwriters and the Company and their respective successors and the controlling persons and officers and directors referred to in Sections 6 and 7 and their heirs and legal representatives, any legal or equitable right, remedy or claim under or in respect of this Agreement or any provision herein contained. This Agreement and all conditions and provisions hereof are intended to be for the sole and exclusive benefit of the Underwriters and the Company and their respective successors, and said controlling persons and officers and directors and their heirs and legal representatives, and for the benefit of no other person, firm or corporation. No purchaser of Securities from any Underwriter shall be deemed to be a successor by reason merely of such purchase.

SECTION 15. Trial by Jury. The Company (on its behalf and, to the extent permitted by applicable law, on behalf of its stockholders and affiliates) and each of the Underwriters hereby irrevocably waives, to the fullest extent permitted by applicable law, any and all right to trial by jury in any legal proceeding arising out of or relating to this Agreement or the transactions contemplated hereby.

SECTION 16. GOVERNING LAW. THIS AGREEMENT AND ANY CLAIM, CONTROVERSY OR DISPUTE ARISING UNDER OR RELATED TO THIS AGREEMENT SHALL BE GOVERNED BY, AND CONSTRUED IN ACCORDANCE WITH THE LAWS OF, THE STATE OF NEW YORK WITHOUT REGARD TO ITS CHOICE OF LAW PROVISIONS.

SECTION 17. Consent to Jurisdiction. Any legal suit, action or proceeding arising out of or based upon this Agreement or the transactions contemplated hereby shall be instituted in (i) the federal courts of the United States of America located in the City and County of New York, Borough of Manhattan or (ii) the courts of the State of New York located in the City and County of New York, Borough of Manhattan (collectively, the "Specified Courts"), and each party irrevocably submits to the exclusive jurisdiction (except for proceedings instituted in regard to the enforcement of a judgment of any such court, as to which such jurisdiction is non-exclusive) of such courts in any such suit, action or proceeding. Service of any process, summons, notice or document by mail to such party's address set forth above shall be effective service of process for any suit, action or other proceeding brought in any such court. The parties irrevocably and unconditionally waive any objection to the laying of venue of any suit, action or other proceeding in the Specified Courts and irrevocably and unconditionally waive and agree not to plead or claim in any such court that any such suit, action or other proceeding brought in any such court has been brought in an inconvenient forum.

SECTION 18. TIME. TIME SHALL BE OF THE ESSENCE OF THIS AGREEMENT. EXCEPT AS OTHERWISE SET FORTH HEREIN, SPECIFIED TIMES OF DAY REFER TO NEW YORK CITY TIME.

SECTION 19. Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed to be an original, but all such counterparts shall together constitute one and the same Agreement.

SECTION 20. Effect of Headings. The section headings herein are for convenience only and shall not affect the construction hereof.

[signature pages follow]

If the foregoing is in accordance with your understanding of our agreement, please sign and return to the Company a counterpart hereof, whereupon this instrument, along with all counterparts, will become a binding agreement among the Underwriters and the Company in accordance with its terms.

Very truly yours,

89BIO, INC.

By _____
Name:
Title:

CONFIRMED AND ACCEPTED,
as of the date first above written:

BOFA SECURITIES, INC.
SVB LEERINK LLC
RBC CAPITAL MARKETS, LLC

By: **BOFA SECURITIES, INC.**

By: _____
Authorized Signatory

By: **SVB LEERINK LLC**

By: _____
Authorized Signatory

By: **RBC CAPITAL MARKETS, LLC**

By: _____
Authorized Signatory

For themselves and as Representatives of the other Underwriters named in Schedule A hereto.

[Signature Page to Underwriting Agreement]

SCHEDULE A

The initial public offering price per share for the Securities shall be $[●].

The purchase price per share for the Securities to be paid by the several Underwriters shall be $[●], being an amount equal to the initial public offering price set forth above less $[●] per share, subject to adjustment in accordance with Section 2(b) for dividends or distributions declared by the Company and payable on the Initial Securities but not payable on the Option Securities.

Name of Underwriter	Number of Initial Securities
BofA Securities, Inc.	
SVB Leerink LLC	
RBC Capital Markets, LLC	
Oppenheimer & Co. Inc.	
Total	

SCHEDULE B-1

Pricing Terms

1. The Company is selling [●] shares of Common Stock.
2. The Company has granted an option to the Underwriters, severally and not jointly, to purchase up to an additional [●] shares of Common Stock.
3. The initial public offering price per share for the Securities shall be $[●].

SCHEDULE B-2

Free Writing Prospectuses

[SPECIFY EACH ISSUER GENERAL USE FREE WRITING PROSPECTUS]

SCHEDULE B-3

Written Testing-the-Waters Communications

Testing the Waters Presentation dated September 2019

Testing the Waters Presentation dated October 2019

EXHIBIT A

Form of Lock-Up from Directors, Officers or other Stockholders
Pursuant to Section 5(j)

_____, 2019

BofA Securities, Inc.
SVB Leerink LLC
RBC Capital Markets, LLC

as Representatives of the several
Underwriters to be named in the
within-mentioned Underwriting Agreement

c/o BofA Securities, Inc.
One Bryant Park
New York, New York 10036

c/o SVB Leerink LLC
255 California Street, 12th Floor
San Francisco, California 94111

c/o RBC Capital Markets, LLC
200 Vesey Street
New York, New York 10281

Re: Proposed Public Offering by 89bio, Inc.

Ladies and Gentlemen:

The undersigned, a securityholder, an officer and/or a director, as applicable, of 89bio, Inc., a Delaware corporation (the "Company"), understands that BofA Securities, Inc. ("BofAS"), SVB Leerink LLC ("SVB Leerink") and RBC Capital Markets, LLC ("RBC," and, collectively with BofAS and SVB Leerink, the "Representatives") propose to enter into an Underwriting Agreement (the "Underwriting Agreement") with the Company, providing for the public offering (the "Public Offering") of shares of the Company's common stock, par value $0.001 per share ("Common Stock"). In recognition of the benefit that the Public Offering will confer upon the undersigned as a securityholder, an officer and/or a director, as applicable, of the Company, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the undersigned agrees with each underwriter to be named in the Underwriting Agreement that, during the period beginning on the date hereof and ending on the date that is 180 days from the date of the Underwriting Agreement (the "Lock-Up Period"), the undersigned will not, without the prior written consent of the Representatives, (i) directly or indirectly, offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase or otherwise transfer or dispose of any shares of Common Stock or any securities convertible into or exercisable or exchangeable for shares of Common Stock, whether now owned or hereafter acquired by the undersigned or with respect to which the undersigned has or hereafter acquires the power of disposition (collectively, the "Lock-Up Securities"), or exercise any right with respect to the registration of any of the Lock-Up Securities, or file, cause to be filed or cause to be confidentially submitted any registration statement in connection therewith, under the Securities Act of

1933, as amended, or (ii) enter into any swap or any other agreement or any transaction that transfers, in whole or in part, directly or indirectly, the economic consequence of ownership of the Lock-Up Securities, whether any such swap or transaction is to be settled by delivery of shares of Common Stock or other securities, in cash or otherwise. If the undersigned is an officer or director of the Company, the undersigned further agrees that the foregoing provisions shall be equally applicable to any issuer-directed Common Stock the undersigned may purchase in the Public Offering.

If the undersigned is an officer or director of the Company, (i) the Representatives agree that, at least three business days before the effective date of any release or waiver of the foregoing restrictions in connection with a transfer of shares of Common Stock, the Representatives will notify the Company of the impending release or waiver, and (ii) the Company has agreed, or will agree, in the Underwriting Agreement to announce the impending release or waiver by press release through a major news service at least two business days before the effective date of the release or waiver. Any release or waiver granted by the Representatives hereunder to any such officer or director shall only be effective two business days after the publication date of such press release. The provisions of this paragraph will not apply if (i) the release or waiver is effected solely to permit a transfer not for consideration and (ii) the transferee has agreed in writing to be bound by the same terms described in this Lock-Up Agreement to the extent and for the duration that such terms remain in effect at the time of the transfer.

Notwithstanding the foregoing, and subject to the conditions below, the undersigned may transfer the Lock-Up Securities without the prior written consent of the Representatives:

(1) as a *bona fide* gift or gifts, *provided* that (i) the Representatives receive a signed lock-up agreement for the balance of the Lock-Up Period from each transferee prior to such transfer, (ii) any such transfer shall not involve a disposition for value, (iii) any such transfer is not required to be publicly filed or reported during the Lock-Up Period, and (iv) the undersigned does not otherwise voluntarily effect any public filing or report regarding such transfers during the Lock-Up Period;

(2) by will or intestate succession upon the death of the undersigned, including to the transferee's nominee or custodian, *provided* that (i) the Representatives receive a signed lock-up agreement for the balance of the Lock-Up Period from each transferee prior to such transfer, (ii) any such transfer shall not involve a disposition for value, (iii) if required, any public filing or report under Section 16 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") during the Lock-Up Period shall clearly indicate in the footnotes thereto that the such transfer is being made pursuant to the circumstances described in this clause, and (iv) no public filings or reports regarding such transfers shall be otherwise voluntarily effected during the Lock-Up Period;

(3) to the immediate family of the undersigned or any trust, partnership or similar entity for the direct or indirect benefit of the undersigned or the immediate family of the undersigned (for purposes of this Lock-Up Agreement, "immediate family" shall mean any relationship by blood, marriage or adoption, not more remote than first cousin) or if the undersigned is a trust, to any beneficiary of the undersigned (including such beneficiary's estate), *provided* that (i) the Representatives receive a signed lock-up agreement for the balance of the Lock-Up Period from each transferee prior to such transfer, (ii) any such transfer shall not involve a disposition for value, (iii) any such transfer is not required to be publicly filed or reported during the Lock-Up Period, and (iv) the undersigned does not otherwise voluntarily effect any public filing or report regarding such transfers during the Lock-Up Period;

(4) if the undersigned is a non-natural person, as a distribution to limited partners, general partners, limited liability company members, stockholders or other equity holders of the undersigned, *provided* that (i) the Representatives receive a signed lock-up agreement for the balance of the Lock-Up Period from each transferee prior to such transfer, (ii) any such transfer shall not involve a disposition for value, (iii) any such transfer is not required to be publicly filed or reported during the Lock-Up Period, and (iv) the undersigned does not otherwise voluntarily effect any public filing or report regarding such transfers during the Lock-Up Period;

(5) to the undersigned's affiliates or to any investment fund or other entity controlled or managed by the undersigned, *provided* that (i) the Representatives receive a signed lock-up agreement for the balance of the Lock-Up Period from each transferee prior to such transfer, (ii) any such transfer shall not involve a disposition for value, (iii) any such transfer is not required to be publicly filed or reported during the Lock-Up Period, and (iv) the undersigned does not otherwise voluntarily effect any public filing or report regarding such transfers during the Lock-Up Period;

(6) to the Company upon exercise of any right in respect of any option granted under any incentive plan of the Company described in the final prospectus relating to the Public Offering including the surrender of shares of Common Stock to the Company in "net" or "cashless" exercise of any option, *provided*, that (i) the shares of Common Stock received by the undersigned upon exercise continue to be subject to the restrictions on transfer set forth in this Lock-Up Agreement, (ii) if required, any public filing or report under Section 16 of the Exchange Act during the Lock-Up Period shall clearly indicate in the footnotes thereto that the filing relates to the exercise of a stock option, that no shares were sold by the reporting person and that the shares received upon exercise of the stock option are subject to this Lock-Up Agreement, and (iii) the undersigned does not otherwise voluntarily effect any public filing or report regarding such transfers during the Lock-Up Period;

(7) pursuant to an order of a court of competent jurisdiction or in connection with a qualified domestic order or divorce settlement, *provided*, that (i) the Representatives receive a signed lock-up agreement for the balance of the Lock-Up Period from each transferee prior to such transfer, (ii) if required, any public filing or report under Section 16 of the Exchange Act during the Lock-Up Period shall clearly indicate in the footnotes thereto that the such transfer is being made pursuant to the circumstances described in this clause, and (iii) the undersigned does not otherwise voluntarily effect any public filing or report regarding such transfers during the Lock-Up Period;

(8) in connection with the conversion of the outstanding preferred stock into shares of Common Stock in connection with the consummation of the Public Offering as described in the final prospectus relating to the Public Offering, *provided* that any shares of Common Stock received upon such conversion remain subject to the terms of this Lock-Up Agreement; or

(9) to a *bona fide* third party pursuant to a merger, consolidation, tender offer or other similar transaction made to all holders of Common Stock and involving a Change of Control of the Company and approved by the Company's board of directors, *provided*, that (i) in the event that such Change of Control is not completed, the undersigned's Lock-Up Securities shall remain subject to the restrictions contained herein, and (ii) any shares of Common Stock not transferred in such merger, consolidation, tender offer or similar transaction shall remain subject to the restrictions contained herein. "Change of Control" shall mean the transfer (whether by tender offer, merger, consolation or other similar transaction), in one transaction or a series of related transactions, to a person or group of affiliated persons (other than an underwriter pursuant to the Public Offering), of the Company's voting securities if, after such transfer, such person or group of affiliated persons would hold more than 50% of the outstanding voting securities of the Company (or the surviving entity).

Furthermore, during the Lock-Up Period, the undersigned may sell shares of Common Stock purchased by the undersigned in the Public Offering or in the open market transactions following the Public Offering if and only if (i) such sales are not required to be publicly filed or reported during the Lock-Up Period and (ii) the undersigned does not otherwise voluntarily effect any public filing or report regarding such sales during the Lock-Up Period.

Nothing herein shall prevent the undersigned from establishing a 10b5-1 trading plan that complies with Rule 10b5-1 under the Exchange Act (a "10b5-1 trading plan") so long as any such plan does not permit sales of Lock-Up Securities during the Lock-Up Period; and *provided* that the establishment of a 10b5-1 trading plan shall only be permitted if (i) the establishment of such plan is not required to be reported in any public filing or report with the Securities and Exchange Commission, or otherwise and (ii) the undersigned does not otherwise voluntarily effect any public filing or report regarding the establishment of such plan during the Lock-Up Period.

The undersigned also agrees and consents to the entry of stop transfer instructions with the Company's transfer agent and registrar against the transfer of the Lock-Up Securities, except in compliance with the foregoing restrictions.

Notwithstanding anything to the contrary contained herein, this Lock-Up Agreement will automatically terminate and the undersigned will be released from all of his, her or its obligations hereunder upon the earliest to occur, if any, of (i) if the Representatives, on the one hand, or the Company, on the other hand, informs the other, prior to the execution of the Underwriting Agreement, that it has determined not to proceed with the Public Offering, (ii) the date the Company files an application with the Securities and Exchange Commission to withdraw the registration statement related to the Public Offering, (iii) the date the Underwriting Agreement is terminated prior to payment for and delivery of the shares of Common Stock to be sold thereunder or (iv) January 31, 2020, in the event that the Underwriting Agreement has not been executed by such date (*provided* that the Company may, by written notice to the undersigned prior to such date, extend such date for a period of up to an additional six months).

[signature page follows]

Very truly yours,

Name of Security Holder *(Print exact name*)

By: _____
(Signature)

If not signing in an individual capacity:

Name of Authorized Signatory *(Print*)

Title of Authorized Signatory *(Print*)

(Indicate capacity of person signing if signing as custodian, trustee, or on behalf of an entity)

EXHIBIT B

Form of Press Release to be Issued
Pursuant to Section 3(j)

89bio, Inc.

[Date]

89bio, Inc. (the "Company") announced today that [BofA Securities, Inc., SVB Leerink LLC and RBC Capital Markets, LLC, the joint book-running managers] in the Company's recent public sale of [●] shares of common stock, are [waiving] [releasing] a lock-up restriction with respect to shares of the Company's common stock held by [certain officers or directors] [an officer or director] of the Company. The [waiver] [release] will take effect on , 20 , and the shares may be sold on or after such date.

This press release is not an offer for sale of the securities in the United States or in any other jurisdiction where such offer is prohibited, and such securities may not be offered or sold in the United States absent registration or an exemption from registration under the United States Securities Act of 1933, as amended.

AMENDED AND RESTATED CERTIFICATE OF INCORPORATION OF 89BIO, INC.

AMENDED AND RESTATED
CERTIFICATE OF INCORPORATION
OF
89BIO, INC.

(Pursuant to Sections 241 and 245 of the
General Corporation Law of the State of Delaware)

89bio, Inc., a corporation organized and existing under and by virtue of the provisions of the General Corporation Law of the State of Delaware (the "**General Corporation Law**"),

DOES HEREBY CERTIFY:

1. That the name of this corporation is 89bio, Inc., and that this corporation was originally incorporated pursuant to the General Corporation Law on June 28, 2019.

2. That as of the date hereof, the corporation has not received payment for any of its stock.

3. That the Board of Directors duly adopted resolutions approving the amendment and restatement of the Certificate of Incorporation of this corporation in accordance with Section 241(b) of the General Corporation Law as follows:

RESOLVED, that the Certificate of Incorporation of this corporation be amended and restated in its entirety to read as follows:

FIRST: The name of this corporation is 89bio, Inc. (the "**Corporation**").

SECOND: The address of the registered office of the Corporation in the State of Delaware is 1209 Orange Street, Wilmington, New Castle County, Delaware 19801. The name of its registered agent at such address is The Corporation Trust Company.

THIRD: The nature of the business or purposes to be conducted or promoted is to engage in any lawful act or activity for which corporations may be organized under the General Corporation Law.

FOURTH: The total number of shares of all classes of stock which the Corporation shall have authority to issue is (i) 72,882,353 shares of Common Stock, $0.001 par value per share ("**Common Stock**") and (ii) 60,000,000 shares of Preferred Stock, $0.001 par value per share ("**Preferred Stock**").

The following is a statement of the designations and the powers, privileges and rights, and the qualifications, limitations or restrictions thereof in respect of each class of capital stock of the Corporation.

A. COMMON STOCK

1. General. The voting, dividend and liquidation rights of the holders of the Common Stock are subject to and qualified by the rights, powers and preferences of the holders of the Preferred Stock set forth herein.

2. Voting. The holders of the Common Stock are entitled to one vote for each share of Common Stock held at all meetings of stockholders (and written actions in lieu of meetings); provided, however, that, except as otherwise required by law, holders of Common Stock, as such, shall not be entitled to vote on any amendment to this Amended and Restated Certificate of Incorporation that relates solely to the terms of one or more outstanding series of Preferred Stock if the holders of such affected series are entitled, either separately or together with the holders of one or more other such series, to vote thereon pursuant to this Amended and Restated Certificate of Incorporation or pursuant to the General Corporation Law. There shall be no cumulative voting. The number of authorized shares of Common Stock may be increased or decreased (but not below the number of shares thereof then outstanding) by (in addition to any vote of the holders of one or more series of Preferred Stock that may be required by the terms of this Amended and Restated Certificate of Incorporation) the affirmative vote of the holders of shares of capital stock of the Corporation representing a majority of the votes represented by all outstanding shares of capital stock of the Corporation entitled to vote, irrespective of the provisions of Section 242(b)(2) of the General Corporation Law.

B. PREFERRED STOCK

60,000,000 shares of the authorized and unissued Preferred Stock of the Corporation are hereby designated "**Series A Preferred Stock**" with the following rights, preferences, powers, privileges and restrictions, qualifications and limitations. Unless otherwise indicated, references to "sections" or "subsections" in this Part B of this Article Fourth refer to sections and subsections of Part B of this Article Fourth.

1. Dividends.

The Corporation shall not declare, pay or set aside any dividends on shares of any other class or series of capital stock of the Corporation (other than dividends on shares of Common Stock payable in shares of Common Stock) unless (in addition to the obtaining of any consents required elsewhere in this Amended and Restated Certificate of Incorporation) the holders of the Series A Preferred Stock then outstanding shall first receive, or simultaneously receive, a dividend on each outstanding share of Series A Preferred Stock in an amount at least equal to $0.08 (as adjusted for any share split, share combination, share dividend, recapitalization or like events) per annum (the "**Preferred Dividends**"). Such Preferred Dividends shall not accrue on an annual basis, but shall only be payable in each year if and as declared by the Board of Directors in such year.

In the event that a dividend declared shall be insufficient for the payment of the Preferred Dividends in full to all of the holders of Series A Preferred Stock, then the dividend amount so payable shall be distributed among the holders of Series A Preferred Stock on a pro rata *pari passu* basis in proportion to the amounts such holders would have been entitled to receive had the dividend amount been sufficient for the distribution of the Preferred Dividends in full. Following the declaration and payment in full of the Preferred Dividends, any other dividends or similar distributions shall be declared and paid to the holders of Series A Preferred Stock and Common Stock on an as converted and pro rata basis.

2. Liquidation, Dissolution or Winding Up; Certain Mergers, Consolidations and Asset Sales.

2.1 Preferential Payments to Holders of Series A Preferred Stock. In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Corporation, the holders of shares of Series A Preferred Stock then outstanding shall be entitled to be paid out of the assets of the Corporation available for distribution to its stockholders, and in the event of a Deemed Liquidation Event (as defined below), the holders of shares of Series A Preferred Stock then outstanding shall be entitled to be paid (i) out of the consideration payable to stockholders in such Deemed Liquidation Event or (ii) the consideration received by the Corporation for such Deemed Liquidation Event (net of any retained liabilities associated with the assets sold or technology licensed, as determined in good faith by the Board of Directors of the Corporation), together with any other assets of the Corporation available for distribution to its stockholders, all to the extent permitted by Delaware law governing distributions to stockholders (the "**Available Proceeds**"), as applicable, before any payment shall be made to the holders of Common Stock by reason of their ownership thereof, an amount per share equal to the Series A Original Issue Price, plus any dividends declared but unpaid thereon and less the amount of distributions actually received in any Deemed Liquidation Event for each such share of Series A Preferred Stock (the "**Series A Liquidation Amount**"). If upon any such liquidation, dissolution or winding up of the Corporation or Deemed Liquidation Event, the assets of the Corporation available for distribution to its stockholders shall be insufficient to pay the holders of shares of Series A Preferred Stock the full amount to which they shall be entitled under this Subsection 2.1, the holders of shares of Series A Preferred Stock shall share ratably in any distribution of the assets available for distribution in proportion to the respective amounts which would otherwise be payable in respect of the shares held by them upon such distribution if all amounts payable on or with respect to such shares were paid in full. The "**Series A Original Issue Price**" shall mean $1.00 per share, subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series A Preferred Stock.

2.2 Distribution of Remaining Assets. In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Corporation, after the payment in full of all Series A Liquidation Amounts required to be paid to the holders of shares of Series A Preferred Stock, the remaining assets of the Corporation available for distribution to its stockholders or, in the case of a Deemed Liquidation Event, the consideration not payable to the holders of shares of Series A Preferred Stock pursuant to Section 2.1 or the remaining Available Proceeds, as the case may be, shall be distributed among the holders of the shares of Series A Preferred Stock and Common Stock, pro rata based on the number of shares held by each such holder, treating for this purpose all such securities as if they had been converted to Common Stock pursuant to the terms of this Amended and Restated Certificate of Incorporation immediately prior to such liquidation, dissolution or winding up of the Corporation.

2.3 Deemed Liquidation Events.

2.3.1 Definition. Each of the following events shall be considered a "**Deemed Liquidation Event**" unless the holders of at least 50% of the then outstanding shares of Series A Preferred Stock, including either OrbiMed Israel Partners II, L.P. ("**OrbiMed IL**") or OrbiMed Private Investments VI, LP ("**OrbiMed US**" and, together with OrbiMed IL, "**OrbiMed**") (the "**Requisite Preferred**"), elect otherwise by written notice sent to the Corporation prior to the effective date of any such event:

(a) a merger or consolidation in which

(i) the Corporation is a constituent party or

(ii) a subsidiary of the Corporation is a constituent party and the Corporation issues shares of its capital stock pursuant to such merger or consolidation,

except any such merger or consolidation involving the Corporation or a subsidiary in which the shares of capital stock of the Corporation outstanding immediately prior to such merger or consolidation continue to represent, or are converted into or exchanged for shares of capital stock that represent, immediately following such merger or consolidation, at least 50% of the voting power, of the capital stock of (1) the surviving or resulting corporation; or (2) if the surviving or resulting corporation is a wholly owned subsidiary of another corporation immediately following such merger or consolidation, the parent corporation of such surviving or resulting corporation; or

(b) (1) the sale, lease, transfer, exclusive license or other disposition, in a single transaction or series of related transactions, by the Corporation or any subsidiary of the Corporation of all or substantially all the assets of the Corporation and its subsidiaries taken as a whole (including, without limitation, the Corporation's intellectual property), or (2) the sale or disposition (whether by merger, consolidation or otherwise, and whether in a single transaction or a series of related transactions) of one or more subsidiaries of the Corporation if substantially all of the assets of the Corporation and its subsidiaries taken as a whole are held by such subsidiary or subsidiaries, except where such sale, lease, transfer, exclusive license or other disposition is to a wholly owned subsidiary of the Corporation.

2.3.2 Effecting a Deemed Liquidation Event.

(a) The Corporation shall not have the power to effect a Deemed Liquidation Event referred to in Subsection 2.3.1(a)(i) unless the agreement or plan of merger or consolidation for such transaction (the "**Merger Agreement**") provides that the consideration payable to the stockholders of the Corporation in such Deemed Liquidation Event shall be paid to the holders of capital stock of the Corporation in accordance with Subsections 2.1 and 2.2.

(b) In the event of a Deemed Liquidation Event referred to in Subsection 2.3.1(a)(ii) or 2.3.1(b), if the Corporation does not effect a dissolution of the Corporation under the General Corporation Law within ninety (90) days after such Deemed Liquidation Event, then (i) the Corporation shall send a written notice to each holder of Series A

Preferred Stock no later than the ninetieth (90th) day after the Deemed Liquidation Event advising such holders of their right (and the requirements to be met to secure such right) pursuant to the terms of the following clause; (ii) to require the redemption of such shares of Series A Preferred Stock, and (iii) if the Requisite Preferred so request in a written instrument delivered to the Corporation not later than one hundred twenty (120) days after such Deemed Liquidation Event, the Corporation shall use the consideration received by the Corporation for such Deemed Liquidation Event (net of any retained liabilities associated with the assets sold or technology licensed, as determined in good faith by the Board of Directors of the Corporation), together with any other assets of the Corporation available for distribution to its stockholders, all to the extent permitted by Delaware law governing distributions to stockholders (the "**Available Proceeds**"), on the one hundred fiftieth (150th) day after such Deemed Liquidation Event, to redeem all outstanding shares of Series A Preferred Stock at a price per share equal to the Series A Liquidation Amount (the "**Redemption Price**"). Notwithstanding the foregoing, in the event of a redemption pursuant to the preceding sentence, if the Available Proceeds are not sufficient to redeem all outstanding shares of Series A Preferred Stock, the Corporation shall redeem a pro rata portion of each holder's shares of Series A Preferred Stock to the fullest extent of such Available Proceeds, based on the respective amounts which would otherwise be payable in respect of the shares to be redeemed if the Available Proceeds were sufficient to redeem all such shares, and shall redeem the remaining shares as soon as it may lawfully do so under Delaware law governing distributions to stockholders. The Corporation shall send written notice of the redemption (the "**Redemption Notice**") to each holder of record of Series A Preferred Stock not less than forty (40) days prior to the intended redemption date (the "**Redemption Date**"). Each Redemption Notice shall state (x) the number of shares of Series A Preferred Stock held by the holder that the Corporation shall redeem on the Redemption Date specified in the Redemption Notice; (y) the Redemption Date and the Redemption Price; and (z) for holders of shares in certificated form, that the holder is to surrender to the Corporation, in the manner and at the place designated, his, her or its certificate or certificates representing the shares of Series A Preferred Stock to be redeemed. Prior to the distribution or redemption provided for in this Subsection 2.3.2(b), the Corporation shall not expend or dissipate the consideration received for such Deemed Liquidation Event, except to discharge expenses incurred in connection with such Deemed Liquidation Event or in the ordinary course of business.

2.3.3 Amount Deemed Paid or Distributed. The amount deemed paid or distributed to the holders of capital stock of the Corporation upon any such merger, consolidation, sale, transfer, exclusive license, other disposition or redemption shall be the cash or the value of the property, rights or securities to be paid or distributed to such holders pursuant to such Deemed Liquidation Event. The value of such property, rights or securities shall be determined in good faith by the Board of Directors of the Corporation, including the approval of the majority of the Preferred Directors; provided, that during such time that the Pontifax Letter Agreement is in effect such majority shall include the OrbiMed Director (the "**Requisite Preferred Directors**"). The "**OrbiMed Director**" means the member of the Board of Directors appointed, removed or replaced by OrbiMed. The "**Pontifax Letter Agreement**" means that certain letter agreement dated April 16, 2018 by and between OrbiMed and Pontifax (China) V L.P., Pontifax (Israel) V Limited Partnership, and Pontifax (Cayman) V L.P. (collectively "**Pontifax**"). The "**Preferred Directors**" means, collectively, (i) the OrbiMed Director and one (1) member of the Board of Directors (the "**OrbiMed Additional Director**") appointed, removed or replaced by OrbiMed; (ii) one (1) member of the Board of Directors (the "**Longitude Director**") appointed, removed or replaced by Longitude Venture Partners III, L.P. ("**Longitude**"); and (iii) one (1) member of the Board of Directors (the "**RA Director**") appointed, removed or replaced by RA Capital Healthcare Fund, L.P.

2.3.4 Allocation of Escrow and Contingent Consideration. In the event of a Deemed Liquidation Event pursuant to Subsection 2.3.1(a)(i), if any portion of the consideration payable to the stockholders of the Corporation is payable only upon satisfaction of contingencies (the "**Additional Consideration**"), the Merger Agreement shall provide that (a) the portion of such consideration that is not Additional Consideration (such portion, the "**Initial Consideration**") shall be allocated among the holders of capital stock of the Corporation in accordance with Subsections 2.1 and 2.2 as if the Initial Consideration were the only consideration payable in connection with such Deemed Liquidation Event; and (b) any Additional Consideration which becomes payable to the stockholders of the Corporation upon satisfaction of such contingencies shall be allocated among the holders of capital stock of the Corporation in accordance with Subsections 2.1 and 2.2 after taking into account the previous payment of the Initial Consideration as part of the same transaction. For the purposes of this Subsection 2.3.4, consideration placed into escrow or retained as a holdback to be available for satisfaction of indemnification or similar obligations in connection with such Deemed Liquidation Event shall be deemed to be Initial Consideration.

3. Voting.

3.1 General. On any matter presented to the stockholders of the Corporation for their action or consideration at any meeting of stockholders of the Corporation (or by written consent of stockholders in lieu of meeting), each holder of outstanding shares of Series A Preferred Stock shall be entitled to cast the number of votes equal to the number of whole shares of Common Stock into which the shares of Series A Preferred Stock held by such holder are convertible as of the record date for determining stockholders entitled to vote on such matter. Except as provided by law or by the other provisions of this Amended and Restated Certificate of Incorporation (including where a separate class vote is specified), holders of Series A Preferred Stock shall vote together with the holders of Common Stock as a single class and on an as-converted to Common Stock basis.

3.2 Election of Directors.

3.2.1 The holders of record of the shares of Series A Preferred Stock, exclusively and as a separate class, shall be entitled to elect six (6) directors of the Corporation (the "**Series A Directors**").

3.2.2 Any director elected as provided in the preceding sentence may be removed without cause by, and only by, the affirmative vote of the holders of the shares of the class or series of capital stock entitled to elect such director or directors, given either at a special meeting of such stockholders duly called for that purpose or pursuant to a written consent of stockholders. If the holders of shares of Series A Preferred Stock fail to elect a sufficient number of directors to fill all directorships for which they are entitled to elect directors, voting exclusively and as a separate class, pursuant to the first sentence of this Subsection 3.2, then any directorship not so filled shall remain vacant until such time as the holders of the Series A Preferred Stock elect a person to fill such directorship by vote or written consent in lieu of a

meeting; and no such directorship may be filled by stockholders of the Corporation other than by the stockholders of the Corporation that are entitled to elect a person to fill such directorship, voting exclusively and as a separate class. At any meeting held for the purpose of electing a director, the presence in person or by proxy of the holders of a majority of the outstanding shares of the class or series entitled to elect such director shall constitute a quorum for the purpose of electing such director. Except as otherwise provided in this Subsection 3.2, a vacancy in any directorship filled by the holders of any class or series shall be filled only by vote or written consent in lieu of a meeting of the holders of such class or series or by any remaining director or directors elected by the holders of such class or series pursuant to this Subsection 3.2.

3.2.3 The holders of record of the shares of Common Stock, exclusively and as a separate class, shall be entitled to elect one director of the Corporation, which shall be the then presiding chief executive officer of the Corporation.

3.2.4 The holders of record of the shares of Common Stock and of any other class or series of voting stock (including the Series A Preferred Stock), exclusively and voting together as a single class, shall be entitled to elect the balance of the total number of directors of the Corporation.

3.3 Series A Preferred Stock Protective Provisions. When shares of Series A Preferred Stock are outstanding, the Corporation shall not, either directly or indirectly by amendment, merger, consolidation or otherwise, do any of the following without (in addition to any other vote required by law or this Amended and Restated Certificate of Incorporation) the written consent or affirmative vote of the Requisite Preferred given in writing or by vote at a meeting, consenting or voting (as the case may be) separately as a class, and any such act or transaction entered into without such consent or vote shall be null and void *ab initio*, and of no force or effect.

3.3.1 liquidate, dissolve or wind-up the business and affairs of the Corporation, effect any merger or consolidation or any other Deemed Liquidation Event, or consent to any of the foregoing;

3.3.2 amend, alter or repeal any provision of this Amended and Restated Certificate of Incorporation or Bylaws of the Corporation;

3.3.3 increase or decrease the authorized number of shares of Common Stock or Preferred Stock;

3.3.4 create, or authorize the creation of, any additional class or series of capital stock unless the same ranks junior to the Series A Preferred Stock;

3.3.5 purchase or redeem (or permit any subsidiary to purchase or redeem) or pay or declare, or take any action that results in the payment or declaration of, any dividend or make any distribution on, any shares of capital stock of the Corporation (other than pursuant to share restriction agreements with founders or pursuant to equity incentive agreements with service providers giving the Corporation the right to repurchase shares upon the termination of services at the lesser of fair market value or cost);

3.3.6 results in any merger, other corporate reorganization, sale of voting control or any transaction in which all or substantially all of the assets of the Corporation are sold;

3.3.7 create, or hold capital stock in, any subsidiary that is not wholly owned (either directly or through one or more other subsidiaries) by the Corporation, or permit any subsidiary to create, or authorize the creation of, or issue or obligate itself to issue, any shares of any class or series of capital stock, or sell, transfer or otherwise dispose of any capital stock of any direct or indirect subsidiary of the Corporation, or permit any direct or indirect subsidiary to sell, lease, transfer, exclusively license or otherwise dispose (in a single transaction or series of related transactions) of all or substantially all of the assets of such subsidiary;

3.3.8 increase or decrease the authorized number of directors constituting the Board of Directors;

3.3.9 sell, assign, license, pledge, or encumber material technology or intellectual property, other than licenses granted in the ordinary course of business;

3.3.10 enter into any corporate strategic relationship involving the payment, contribution, or assignment by the Corporation or to the Corporation of assets greater than $500,000;

3.3.11 incur any aggregate indebtedness in excess of $500,000;

3.3.12 change the number of shares subject to any equity incentive plan or approve the adoption of any equity incentive plan; or

3.3.13 change the principal business of the Corporation, enter new lines of business, or exit any line of business of the Corporation.

4. Optional Conversion.

The holders of the Series A Preferred Stock shall have conversion rights as follows (the "**Conversion Rights**"):

4.1 Right to Convert.

4.1.1 Conversion Ratio. Each share of Series A Preferred Stock shall be convertible, at the option of the holder thereof, at any time and from time to time, and without the payment of additional consideration by the holder thereof, into such number of fully paid and non-assessable shares of Common Stock as is determined by dividing the Series A Original Issue Price by the Series A Conversion Price (as defined below) in effect at the time of conversion. The "**Series A Conversion Price**" shall initially be equal to $1.00. Such initial Series A Conversion Price, and the rate at which shares of Series A Preferred Stock may be converted into shares of Common Stock, shall be subject to adjustment as provided below.

4.2 Fractional Shares.

4.2.1 No fractional shares of Common Stock shall be issued upon conversion of the Series A Preferred Stock. In lieu of any fractional shares to which the holder would otherwise be entitled, the Corporation shall pay cash equal to such fraction multiplied by the fair market value of a share of Common Stock as determined in good faith by the Board of Directors of the Corporation. Whether or not fractional shares would be issuable upon such conversion shall be determined on the basis of the total number of shares of Series A Preferred Stock the holder is at the time converting into Common Stock and the aggregate number of shares of Common Stock issuable upon such conversion.

4.3 Mechanics of Conversion.

4.3.1 Notice of Conversion. In order for a holder of Series A Preferred Stock to voluntarily convert shares of Series A Preferred Stock into shares of Common Stock, such holder shall (a) provide written notice to the Corporation's transfer agent at the office of the transfer agent for the Series A Preferred Stock (or at the principal office of the Corporation if the Corporation serves as its own transfer agent) that such holder elects to convert all or any number of such holder's shares of Series A Preferred Stock and, if applicable, any event on which such conversion is contingent and (b), if such holder's shares are certificated, surrender the certificate or certificates for such shares of Series A Preferred Stock (or, if such registered holder alleges that such certificate has been lost, stolen or destroyed, a lost certificate affidavit and agreement reasonably acceptable to the Corporation to indemnify the Corporation against any claim that may be made against the Corporation on account of the alleged loss, theft or destruction of such certificate), at the office of the transfer agent for the Series A Preferred Stock (or at the principal office of the Corporation if the Corporation serves as its own transfer agent). Such notice shall state such holder's name or the names of the nominees in which such holder wishes the shares of Common Stock to be issued. If required by the Corporation, any certificates surrendered for conversion shall be endorsed or accompanied by a written instrument or instruments of transfer, in form satisfactory to the Corporation, duly executed by the registered holder or his, her or its attorney duly authorized in writing. The close of business on the date of receipt by the transfer agent (or by the Corporation if the Corporation serves as its own transfer agent) of such notice and, if applicable, certificates (or lost certificate affidavit and agreement) shall be the time of conversion (the "**Conversion Time**"), and the shares of Common Stock issuable upon conversion of the specified shares shall be deemed to be outstanding of record as of such date. The Corporation shall, as soon as practicable after the Conversion Time (i) issue and deliver to such holder of Series A Preferred Stock, or to his, her or its nominees, a notice of issuance of uncertificated shares and may, upon written request, issue and deliver a certificate for the number of full shares of Common Stock issuable upon such conversion in accordance with the provisions hereof and, may, if applicable and upon written request, issue and deliver a certificate for the number (if any) of the shares of Series A Preferred Stock represented by any surrendered certificate that were not converted into Common Stock, (ii) pay in cash such amount as provided in Subsection 4.2 in lieu of any fraction of a share of Common Stock otherwise issuable upon such conversion; and (iii) pay all declared but unpaid dividends on the shares of Series A Preferred Stock converted.

4.3.2 Reservation of Shares. The Corporation shall at all times when the Series A Preferred Stock shall be outstanding, reserve and keep available out of its authorized but unissued capital stock, for the purpose of effecting the conversion of the Series A Preferred Stock, such number of its duly authorized shares of Common Stock as shall from time

to time be sufficient to effect the conversion of all outstanding Series A Preferred Stock; and if at any time the number of authorized but unissued shares of Common Stock shall not be sufficient to effect the conversion of all then outstanding shares of the Series A Preferred Stock, the Corporation shall take such corporate action as may be necessary to increase its authorized but unissued shares of Common Stock to such number of shares as shall be sufficient for such purposes, including, without limitation, engaging in best efforts to obtain the requisite stockholder approval of any necessary amendment to this Amended and Restated Certificate of Incorporation. Before taking any action which would cause an adjustment reducing the Series A Conversion Price below the then par value of the shares of Common Stock issuable upon conversion of the Series A Preferred Stock, the Corporation will take any corporate action which may, in the opinion of its counsel, be necessary in order that the Corporation may validly and legally issue fully paid and non-assessable shares of Common Stock at such adjusted Series A Conversion Price.

4.3.3 Effect of Conversion. All shares of Series A Preferred Stock which shall have been surrendered for conversion as herein provided shall no longer be deemed to be outstanding and all rights with respect to such shares shall immediately cease and terminate at the Conversion Time, except only the right of the holders thereof to receive shares of Common Stock in exchange therefor, to receive payment in lieu of any fraction of a share otherwise issuable upon such conversion as provided in Subsection 4.2, and to receive payment of any dividends declared but unpaid thereon. Any shares of Series A Preferred Stock so converted shall be retired and cancelled and may not be reissued as shares of such series, and the Corporation may thereafter take such appropriate action (without the need for stockholder action) as may be necessary to reduce the authorized number of shares of Series A Preferred Stock accordingly.

4.3.4 No Further Adjustment. Upon any such conversion, no adjustment to the Series A Conversion Price shall be made for any declared but unpaid dividends on the Series A Preferred Stock surrendered for conversion or on the Common Stock delivered upon conversion.

4.3.5 Taxes. The Corporation shall pay any and all issue and other similar taxes that may be payable in respect of any issuance or delivery of shares of Common Stock upon conversion of shares of Series A Preferred Stock pursuant to this Section 4. The Corporation shall not, however, be required to pay any tax which may be payable in respect of any transfer involved in the issuance and delivery of shares of Common Stock in a name other than that in which the shares of Series A Preferred Stock so converted were registered, and no such issuance or delivery shall be made unless and until the person or entity requesting such issuance has paid to the Corporation the amount of any such tax or has established, to the satisfaction of the Corporation, that such tax has been paid.

4.4 Adjustments to Series A Conversion Price for Diluting Issues.

4.4.1 Special Definitions. For purposes of this Article Fourth, the following definitions shall apply:

(a) "**Option**" shall mean rights, options or warrants to subscribe for, purchase or otherwise acquire Common Stock or Convertible Securities.

(b) "**Series A Original Issue Date**" shall mean the date on which the first share of Series A Preferred Stock was issued.

(c) "**Convertible Securities**" shall mean any evidences of indebtedness, shares or other securities directly or indirectly convertible into or exchangeable for Common Stock, but excluding Options.

(d) "**Additional Shares of Common Stock**" shall mean all shares of Common Stock issued (or, pursuant to Subsection 4.4.3 below, deemed to be issued) by the Corporation after the Series A Original Issue Date, other than (1) the following shares of Common Stock and (2) shares of Common Stock deemed issued pursuant to the following Options and Convertible Securities (clauses (1) and (2), collectively, "**Exempted Securities**"):

(i) shares of Common Stock, Options or Convertible Securities issued as a dividend or distribution on Series A Preferred Stock;

(ii) shares of Common Stock or Options issued to officers, employees or directors of, or consultants to, the Corporation or any of its subsidiaries pursuant to a plan, agreement or arrangement approved by the Board of Directors of the Corporation, including the approval of the Requisite Preferred Directors;

(iii) shares of Common Stock, Options or Convertible Securities issued by reason of a dividend, stock split, split-up or other distribution on shares of Common Stock that is covered by Subsection 4.5, 4.6, 4.7 or 4.8 and approved by the Board of Directors of the Corporation, including the approval of the Requisite Preferred Directors**;**

(iv) shares of Common Stock or Options issued in connection with a Qualified Public Offering;

(v) if explicitly determined in writing by the Requisite Preferred to be "Exempted Securities" (and such determination must state the purposes for which such shares shall be "Exempted Securities");

(vi) shares of Common Stock or Convertible Securities actually issued upon the exercise of Options or shares of Common Stock actually issued upon the conversion or exchange of Convertible Securities, in each case provided such issuance is pursuant to the terms of such Option or Convertible Security;

(vii) shares of Common Stock, Options or Convertible Securities issued to banks, equipment lessors or other financial institutions, or to real property lessors, pursuant to a debt financing, equipment leasing or real property leasing transaction approved by the Board of Directors of the Corporation, including the approval of Requisite Preferred Directors; or

(viii) shares of Common Stock, Options or Convertible Securities issued as acquisition consideration pursuant to the acquisition of another corporation by the Corporation by merger, purchase of substantially all of the assets or other reorganization or to a joint venture agreement approved by the Board of Directors of the Corporation, including the approval of the Requisite Preferred Directors.

4.4.2 No Adjustment of Series A Conversion Price. No adjustment in the Series A Conversion Price shall be made as the result of the issuance or deemed issuance of Additional Shares of Common Stock if the Corporation receives written notice from the Requisite Preferred agreeing that no such adjustment shall be made as the result of the issuance or deemed issuance of such Additional Shares of Common Stock.

4.4.3 Deemed Issue of Additional Shares of Common Stock.

(a) If the Corporation at any time or from time to time after the Series A Original Issue Date shall issue any Options or Convertible Securities (excluding Options or Convertible Securities which are themselves Exempted Securities) or shall fix a record date for the determination of holders of any class of securities entitled to receive any such Options or Convertible Securities, then the maximum number of shares of Common Stock (as set forth in the instrument relating thereto, assuming the satisfaction of any conditions to exercisability, convertibility or exchangeability but without regard to any provision contained therein for a subsequent adjustment of such number) issuable upon the exercise of such Options or, in the case of Convertible Securities and Options therefor, the conversion or exchange of such Convertible Securities, shall be deemed to be Additional Shares of Common Stock issued as of the time of such issue or, in case such a record date shall have been fixed, as of the close of business on such record date.

(b) If the terms of any Option or Convertible Security, the issuance of which resulted in an adjustment to the Series A Conversion Price pursuant to the terms of Subsection 4.4.4, are revised as a result of an amendment to such terms or any other adjustment pursuant to the provisions of such Option or Convertible Security (but excluding automatic adjustments to such terms pursuant to anti-dilution or similar provisions of such Option or Convertible Security) to provide for either (1) any increase or decrease in the number of shares of Common Stock issuable upon the exercise, conversion and/or exchange of any such Option or Convertible Security or (2) any increase or decrease in the consideration payable to the Corporation upon such exercise, conversion and/or exchange, then, effective upon such increase or decrease becoming effective, the Series A Conversion Price computed upon the original issue of such Option or Convertible Security (or upon the occurrence of a record date with respect thereto) shall be readjusted to such Series A Conversion Price as would have obtained had such revised terms been in effect upon the original date of issuance of such Option or Convertible Security. Notwithstanding the foregoing, no readjustment pursuant to this clause (b) shall have the effect of increasing the Series A Conversion Price to an amount which exceeds the lower of (i) the Series A Conversion Price in effect immediately prior to the original adjustment made as a result of the issuance of such Option or Convertible Security, or (ii) the Series A Conversion Price that would have resulted from any issuances of Additional Shares of Common Stock (other than deemed issuances of Additional Shares of Common Stock as a result of the issuance of such Option or Convertible Security) between the original adjustment date and such readjustment date.

(c) If the terms of any Option or Convertible Security (excluding Options or Convertible Securities which are themselves Exempted Securities), the issuance of which did not result in an adjustment to the Series A Conversion Price pursuant to the terms of Subsection 4.4.4 (either because the consideration per share (determined pursuant to Subsection 4.4.5) of the Additional Shares of Common Stock subject thereto was equal to or greater than the Series A Conversion Price then in effect, or because such Option or Convertible Security was issued before the Series A Original Issue Date), are revised after the Series A Original Issue Date as a result of an amendment to such terms or any other adjustment pursuant to the provisions of such Option or Convertible Security (but excluding automatic adjustments to such terms pursuant to anti-dilution or similar provisions of such Option or Convertible Security) to provide for either (1) any increase in the number of shares of Common Stock issuable upon the exercise, conversion or exchange of any such Option or Convertible Security or (2) any decrease in the consideration payable to the Corporation upon such exercise, conversion or exchange, then such Option or Convertible Security, as so amended or adjusted, and the Additional Shares of Common Stock subject thereto (determined in the manner provided in Subsection 4.4.3(a)) shall be deemed to have been issued effective upon such increase or decrease becoming effective.

(d) Upon the expiration or termination of any unexercised Option or unconverted or unexchanged Convertible Security (or portion thereof) which resulted (either upon its original issuance or upon a revision of its terms) in an adjustment to the Series A Conversion Price pursuant to the terms of Subsection 4.4.4, the Series A Conversion Price shall be readjusted to such Series A Conversion Price as would have obtained had such Option or Convertible Security (or portion thereof) never been issued.

(e) If the number of shares of Common Stock issuable upon the exercise, conversion and/or exchange of any Option or Convertible Security, or the consideration payable to the Corporation upon such exercise, conversion and/or exchange, is calculable at the time such Option or Convertible Security is issued or amended but is subject to adjustment based upon subsequent events, any adjustment to the Series A Conversion Price provided for in this Subsection 4.4.3 shall be effected at the time of such issuance or amendment based on such number of shares or amount of consideration without regard to any provisions for subsequent adjustments (and any subsequent adjustments shall be treated as provided in clauses (b) and (c) of this Subsection 4.4.3). If the number of shares of Common Stock issuable upon the exercise, conversion and/or exchange of any Option or Convertible Security, or the consideration payable to the Corporation upon such exercise, conversion and/or exchange, cannot be calculated at all at the time such Option or Convertible Security is issued or amended, any adjustment to the Series A Conversion Price that would result under the terms of this Subsection 4.4.3 at the time of such issuance or amendment shall instead be effected at the time such number of shares and/or amount of consideration is first calculable (even if subject to subsequent adjustments), assuming for purposes of calculating such adjustment to the Series A Conversion Price that such issuance or amendment took place at the time such calculation can first be made.

4.4.4 Adjustment of Series A Conversion Price Upon Issuance of Additional Shares of Common Stock. In the event the Corporation shall at any time after the Series A Original Issue Date but prior to the Closing of a Qualified Public Offering issue Additional Shares of Common Stock (including Additional Shares of Common Stock deemed to be issued pursuant to Subsection 4.4.3), without consideration or for a consideration per share less than the Series A Conversion Price in effect immediately prior to such issuance or deemed issuance, then the Series A Conversion Price shall be reduced, concurrently with such issue, to a price (calculated to the nearest one-hundredth of a cent) determined in accordance with the following formula:

$$CP_2 = CP_1 * (A + B) \div (A + C).$$

For purposes of the foregoing formula, the following definitions shall apply:

(a) "CP_2" shall mean the Series A Conversion Price in effect immediately after such issuance or deemed issuance of Additional Shares of Common Stock

(b) "CP_1" shall mean the Series A Conversion Price in effect immediately prior to such issuance or deemed issuance of Additional Shares of Common Stock;

(c) "A" shall mean the number of shares of Common Stock outstanding immediately prior to such issuance or deemed issuance of Additional Shares of Common Stock (treating for this purpose as outstanding all shares of Common Stock issuable upon exercise of Options outstanding immediately prior to such issuance or deemed issuance or upon conversion or exchange of Convertible Securities (including the Series A Preferred Stock) outstanding (assuming exercise of any outstanding Options therefor) immediately prior to such issue);

(d) "B" shall mean the number of shares of Common Stock that would have been issued if such Additional Shares of Common Stock had been issued or deemed issued at a price per share equal to CP_1 (determined by dividing the aggregate consideration received by the Corporation in respect of such issue by CP_1); and

(e) "C" shall mean the number of such Additional Shares of Common Stock issued in such transaction.

No adjustment of the Series A Conversion Price pursuant to this Subsection 4.4.4 shall be made if it has the effect of increasing the Series A Conversion Price of the Series A Preferred Stock above the Series A Conversion Price in effect immediately prior to such adjustment. In addition, no adjustments of the Series A Conversion Price shall be made in an amount less than one hundredth (1/100) of one cent ($0.0001) per share; provided, that any adjustments that are not required to be made by reason of this sentence shall be carried forward and shall be either taken into account in any subsequent adjustment made prior to three (3) years from the date of the event giving rise to the adjustment being carried forward, or shall be made at the end of three (3) years from the date of the event giving rise to the adjustment being carried forward.

4.4.5 Determination of Consideration. For purposes of this Subsection 4.4, the consideration received by the Corporation for the issuance or deemed issuance of any Additional Shares of Common Stock shall be computed as follows:

(a) Cash and Property: Such consideration shall:

(i) insofar as it consists of cash, be computed at the aggregate amount of cash received by the Corporation;

(ii) insofar as it consists of property other than cash, be computed at the fair market value thereof at the time of such issue, as determined in good faith by the Board of Directors of the Corporation (including the Requisite Preferred Directors); and

(iii) in the event Additional Shares of Common Stock are issued together with other shares or securities or other assets of the Corporation for consideration which covers both, be the proportion of such consideration so received, computed as provided in clauses (i) and (ii) above, as determined in good faith by the Board of Directors of the Corporation (including the Requisite Preferred Directors).

(b) Options and Convertible Securities. The consideration per share received by the Corporation for Additional Shares of Common Stock deemed to have been issued pursuant to Subsection 4.4.3, relating to Options and Convertible Securities, shall be determined by dividing:

(i) The total amount, if any, received or receivable by the Corporation as consideration for the issue of such Options or Convertible Securities, plus the minimum aggregate amount of additional consideration (as set forth in the instruments relating thereto, without regard to any provision contained therein for a subsequent adjustment of such consideration) payable to the Corporation upon the exercise of such Options or the conversion or exchange of such Convertible Securities, or in the case of Options for Convertible Securities, the exercise of such Options for Convertible Securities and the conversion or exchange of such Convertible Securities, by

(ii) the maximum number of shares of Common Stock (as set forth in the instruments relating thereto, without regard to any provision contained therein for a subsequent adjustment of such number) issuable upon the exercise of such Options or the conversion or exchange of such Convertible Securities, or in the case of Options for Convertible Securities, the exercise of such Options for Convertible Securities and the conversion or exchange of such Convertible Securities.

4.4.6 Multiple Closing Dates. In the event the Corporation shall issue on more than one date Additional Shares of Common Stock that are a part of one transaction or a series of related transactions and that would result in an adjustment to the Series A Conversion Price pursuant to the terms of Subsection 4.4.4 then, upon the final such issuance, the Series A Conversion Price shall be readjusted to give effect to all such issuances as if they occurred on the date of the first such issuance (and without giving effect to any additional adjustments as a result of any such subsequent issuances within such period).

4.5 Adjustment for Stock Splits and Combinations. If the Corporation shall at any time or from time to time after the Series A Original Issue Date effect a subdivision of the outstanding Common Stock, the Series A Conversion Price in effect immediately before that subdivision shall be proportionately decreased so that the number of shares of Common Stock issuable on conversion of each share of such series shall be increased in proportion to such increase in the aggregate number of shares of Common Stock outstanding. If the Corporation shall at any time or from time to time after the Series A Original Issue Date combine the

outstanding shares of Common Stock, the Series A Conversion Price in effect immediately before the combination shall be proportionately increased so that the number of shares of Common Stock issuable on conversion of each share of such series shall be decreased in proportion to such decrease in the aggregate number of shares of Common Stock outstanding. Any adjustment under this subsection shall become effective at the close of business on the date the subdivision or combination becomes effective.

4.6 Adjustment for Certain Dividends and Distributions. In the event the Corporation at any time or from time to time after the Series A Original Issue Date shall make or issue, or fix a record date for the determination of holders of Common Stock entitled to receive, a dividend or other distribution payable on the Common Stock in additional shares of Common Stock, then and in each such event the Series A Conversion Price in effect immediately before such event shall be decreased as of the time of such issuance or, in the event such a record date shall have been fixed, as of the close of business on such record date, by multiplying the Series A Conversion Price then in effect by a fraction:

(1) the numerator of which shall be the total number of shares of Common Stock issued and outstanding immediately prior to the time of such issuance or the close of business on such record date, and

(2) the denominator of which shall be the total number of shares of Common Stock issued and outstanding immediately prior to the time of such issuance or the close of business on such record date plus the number of shares of Common Stock issuable in payment of such dividend or distribution.

Notwithstanding the foregoing (a) if such record date shall have been fixed and such dividend is not fully paid or if such distribution is not fully made on the date fixed therefor, the Series A Conversion Price shall be recomputed accordingly as of the close of business on such record date and thereafter the Series A Conversion Price shall be adjusted pursuant to this subsection as of the time of actual payment of such dividends or distributions; and (b) that no such adjustment shall be made if the holders of Series A Preferred Stock simultaneously receive a dividend or other distribution of shares of Common Stock in a number equal to the number of shares of Common Stock as they would have received if all outstanding shares of Series A Preferred Stock had been converted into Common Stock on the date of such event.

4.7 Adjustments for Other Dividends and Distributions. In the event the Corporation at any time or from time to time after the Series A Original Issue Date shall make or issue, or fix a record date for the determination of holders of Common Stock entitled to receive, a dividend or other distribution payable in securities of the Corporation (other than a distribution of shares of Common Stock in respect of outstanding shares of Common Stock) or in other property and the provisions of Section 1 do not apply to such dividend or distribution, then and in each such event the holders of Series A Preferred Stock shall receive, simultaneously with the distribution to the holders of Common Stock, a dividend or other distribution of such securities or other property in an amount equal to the amount of such securities or other property as they would have received if all outstanding shares of Series A Preferred Stock had been converted into Common Stock on the date of such event.

4.8 Adjustment for Merger or Reorganization, etc. Subject to the provisions of Subsection 2.3, if there shall occur any reorganization, recapitalization, reclassification, consolidation or merger involving the Corporation in which the Common Stock (but not the Series A Preferred Stock) is converted into or exchanged for securities, cash or other property (other than a transaction covered by Subsections 4.4, 4.6 or 4.7), then, following any such reorganization, recapitalization, reclassification, consolidation or merger, each share of Series A Preferred Stock shall thereafter be convertible in lieu of the Common Stock into which it was convertible prior to such event into the kind and amount of securities, cash or other property which a holder of the number of shares of Common Stock of the Corporation issuable upon conversion of one share of Series A Preferred Stock immediately prior to such reorganization, recapitalization, reclassification, consolidation or merger would have been entitled to receive pursuant to such transaction; and, in such case, appropriate adjustment (as determined in good faith by the Board of Directors of the Corporation) shall be made in the application of the provisions in this Section 4 with respect to the rights and interests thereafter of the holders of the Series A Preferred Stock, to the end that the provisions set forth in this Section 4 (including provisions with respect to changes in and other adjustments of the Series A Conversion Price) shall thereafter be applicable, as nearly as reasonably may be, in relation to any securities or other property thereafter deliverable upon the conversion of the Series A Preferred Stock.

4.9 Certificate as to Adjustments. Upon the occurrence of each adjustment or readjustment of the Series A Conversion Price pursuant to this Section 4, the Corporation at its expense shall, as promptly as reasonably practicable, compute such adjustment or readjustment in accordance with the terms hereof and furnish to each holder of Series A Preferred Stock a certificate setting forth such adjustment or readjustment (including the kind and amount of securities, cash or other property into which the Series A Preferred Stock is convertible) and showing in detail the facts upon which such adjustment or readjustment is based. The Corporation shall, as promptly as reasonably practicable after the written request at any time of any holder of Series A Preferred Stock, furnish or cause to be furnished to such holder a certificate setting forth (i) the Series A Conversion Price then in effect, and (ii) the number of shares of Common Stock and the amount, if any, of other securities, cash or property which then would be received upon the conversion of Series A Preferred Stock.

4.10 Notice of Record Date. In the event:

(a) the Corporation shall take a record of the holders of its Common Stock (or other capital stock or securities at the time issuable upon conversion of the Series A Preferred Stock) for the purpose of entitling or enabling them to receive any dividend or other distribution, or to receive any right to subscribe for or purchase any shares of capital stock of any class or any other securities, or to receive any other security; or

(b) of any capital reorganization of the Corporation, any reclassification of the Common Stock of the Corporation, or any Deemed Liquidation Event; or

(c) of the voluntary or involuntary dissolution, liquidation or winding-up of the Corporation,

then, and in each such case, the Corporation will send or cause to be sent to the holders of the Series A Preferred Stock a notice specifying, as the case may be, (i) the record date for such dividend, distribution or right, and the amount and character of such dividend, distribution or right, or (ii) the effective date on which such reorganization, reclassification, consolidation, merger, transfer, dissolution, liquidation or winding-up is proposed to take place, and the time, if any is to be fixed, as of which the holders of record of Common Stock (or such other capital stock or securities at the time issuable upon the conversion of the Series A Preferred Stock) shall be entitled to exchange their shares of Common Stock (or such other capital stock or securities) for securities or other property deliverable upon such reorganization, reclassification, consolidation, merger, transfer, dissolution, liquidation or winding-up, and the amount per share and character of such exchange applicable to the Series A Preferred Stock and the Common Stock. Such notice shall be sent at least seven (7) days prior to the record date or effective date for the event specified in such notice.

4.11 No Impairment. The Corporation will not, by amendment of its Certificate of Incorporation or through any reorganization, recapitalization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms to be observed or performed hereunder by the Corporation, but will at all times in good faith assist in the carrying out of all the provisions of this Article Fourth and in the taking of all such action as may be necessary or appropriate in order to protect the conversion rights of the holders of the Series A Preferred Stock against impairment.

5. Mandatory Conversion.

5.1 Trigger Events. Upon either (a) the closing of the sale of shares of Common Stock to the public at a price of at least $5.00 per share (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Common Stock), in a firm-commitment underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, resulting in at least $50,000,000 of gross proceeds to the Corporation (a "**Qualified Public Offering**") or (b) the date and time, or the occurrence of an event, specified by vote or written consent of the Requisite Preferred (the time of such closing or the date and time specified or the time of the event specified in such vote or written consent is referred to herein as the "**Mandatory Conversion Time**"), then (i) all outstanding shares of Series A Preferred Stock shall automatically be converted into shares of Common Stock, at the then effective conversion rate as calculated pursuant to Subsection 4.1.1 and (ii) such shares may not be reissued by the Corporation.

5.2 Procedural Requirements. All holders of record of shares of Series A Preferred Stock shall be sent written notice of the Mandatory Conversion Time and the place designated for mandatory conversion of all such shares of Series A Preferred Stock pursuant to this Section 5. Such notice need not be sent in advance of the occurrence of the Mandatory Conversion Time. Upon receipt of such notice, each holder of shares of Series A Preferred Stock in certificated form shall surrender his, her or its certificate or certificates for all such shares (or, if such holder alleges that such certificate has been lost, stolen or destroyed, a lost certificate affidavit and agreement reasonably acceptable to the Corporation to indemnify the Corporation against any claim that may be made against the Corporation on account of the alleged loss, theft

or destruction of such certificate) to the Corporation at the place designated in such notice. If so required by the Corporation, any certificates surrendered for conversion shall be endorsed or accompanied by written instrument or instruments of transfer, in form satisfactory to the Corporation, duly executed by the registered holder or by his, her or its attorney duly authorized in writing. All rights with respect to the Series A Preferred Stock converted pursuant to Subsection 5.1, including the rights, if any, to receive notices and vote (other than as a holder of Common Stock), will terminate at the Mandatory Conversion Time (notwithstanding the failure of the holder or holders thereof to surrender any certificates at or prior to such time), except only the rights of the holders thereof, upon surrender of any certificate or certificates of such holders (or lost certificate affidavit and agreement) therefor, to receive the items provided for in the next sentence of this Subsection 5.2. As soon as practicable after the Mandatory Conversion Time and, if applicable, the surrender of any certificate or certificates (or lost certificate affidavit and agreement) for Series A Preferred Stock, the Corporation shall (a) issue and deliver to such holder, or to his, her or its nominees, a notice of issuance of uncertificated shares and may, upon written request, issue and deliver a certificate for the number of full shares of Common Stock issuable on such conversion in accordance with the provisions hereof and (b) pay cash as provided in Subsection 4.2 in lieu of any fraction of a share of Common Stock otherwise issuable upon such conversion and for the payment of any declared but unpaid dividends on the shares of Series A Preferred Stock converted. Such converted Series A Preferred Stock shall be retired and cancelled and may not be reissued as shares of such series, and the Corporation may thereafter take such appropriate action (without the need for stockholder action) as may be necessary to reduce the authorized number of shares of Series A Preferred Stock accordingly.

5A. Special Mandatory Conversion.

5A.1. Trigger Event. In the event that any holder of shares of Series A Preferred Stock is deemed a Breaching Investor (as defined in the Series A Preferred Share Purchase Agreement, dated April 16, 2018), then, unless otherwise waived in writing by the Requisite Preferred who are not Breaching Investors, all of such Breaching Investor's Series A Preferred Stock and/or Common Stock issued upon conversion of Series A Preferred Stock (the "**Forfeited Shares**"), shall automatically, and without any further action on the part of such holder, be converted into shares of Common Stock at a conversion ratio of ten (10) Forfeited Shares to one (1) share of Common Stock (a "**Special Mandatory Conversion**"). In the event of a Special Mandatory Conversion, such Breaching Investor will lose any right it may have as a holder of shares of Series A Preferred Stock and all rights and preferences originally conferred to the Series A Preferred Stock.

5A.2. Procedural Requirements. Upon a Special Mandatory Conversion, each holder of shares of Series A Preferred Stock converted pursuant to Subsection 5A.1 shall be sent written notice of such Special Mandatory Conversion and the place designated for mandatory conversion of all such shares of Series A Preferred Stock pursuant to this Section 5A. Upon receipt of such notice, each holder of such shares of Series A Preferred Stock in certificated form shall surrender his, her or its certificate or certificates for all such shares (or, if such holder alleges that any such certificate has been lost, stolen or destroyed, a lost certificate affidavit and agreement reasonably acceptable to the Corporation to indemnify the Corporation against any claim that may be made against the Corporation on account of the alleged loss, theft or destruction of such certificate) to the Corporation at the place designated in such notice. If so required by the Corporation, any certificates surrendered for conversion shall be endorsed or

accompanied by written instrument or instruments of transfer, in form satisfactory to the Corporation, duly executed by the registered holder or by his, her or its attorney duly authorized in writing. All rights with respect to the Series A Preferred Stock converted pursuant to Subsection 5A.1, including the rights, if any, to receive notices and vote (other than as a holder of Common Stock), will terminate at the time of the Special Mandatory Conversion (notwithstanding the failure of the holder or holders thereof to surrender any certificates for such shares at or prior to such time), except only the rights of the holders thereof, upon surrender of any certificate or certificates of such holders therefor (or lost certificate affidavit and agreement), to receive the items provided for in the next sentence of this Subsection 5A.2. As soon as practicable after the Special Mandatory Conversion and, if applicable, the surrender of any certificate or certificates (or lost certificate affidavit and agreement) for Series A Preferred Stock so converted, the Corporation shall (a) issue and deliver to such holder, or to his, her or its nominees, a notice of issuance of uncertificated shares and may, upon written request, issue and deliver a certificate or certificates for the number of full shares of Common Stock issuable upon such conversion in accordance with the provisions hereof and (b) may, if applicable and upon written request, issue and deliver a new certificate for the number of shares, if any, of Series A Preferred Stock represented by such surrendered certificate and not converted pursuant to Subsection 5A.1.

5A.3. Such converted Series A Preferred Stock shall be retired and cancelled and may not be reissued as shares of such series, and the Corporation may thereafter take such appropriate action (without the need for stockholder action) as may be necessary to reduce the authorized number of shares of Series A Preferred Stock accordingly.

6. Redeemed or Otherwise Acquired Shares. Any shares of Series A Preferred Stock that are redeemed or otherwise acquired by the Corporation or any of its subsidiaries shall be automatically and immediately cancelled and retired and shall not be reissued, sold or transferred. Neither the Corporation nor any of its subsidiaries may exercise any voting or other rights granted to the holders of Series A Preferred Stock following redemption.

7. Waiver. Any of the rights, powers, preferences and other terms of the Series A Preferred Stock set forth herein may be waived on behalf of all holders of Series A Preferred Stock by the Requisite Preferred.

8. Notices. Any notice required or permitted by the provisions of this Article Fourth to be given to a holder of shares of Series A Preferred Stock shall be mailed, postage prepaid, to the post office address last shown on the records of the Corporation, or given by electronic communication in compliance with the provisions of the General Corporation Law, and shall be deemed sent upon such mailing or electronic transmission.

FIFTH: Subject to any additional vote required by this Amended and Restated Certificate of Incorporation or Bylaws, in furtherance and not in limitation of the powers conferred by statute, the Board of Directors is expressly authorized to make, repeal, alter, amend and rescind any or all of the Bylaws of the Corporation.

SIXTH: Subject to any additional vote required by this Amended and Restated Certificate of Incorporation, the number of directors of the Corporation shall be determined in the manner set forth in the Bylaws of the Corporation. Each director shall be entitled to one vote on each matter presented to the Board of Directors; provided, however, that, so long as the holders of Series A Preferred Stock are entitled to elect Series A Directors, the affirmative vote of the Requisite Preferred Directors shall be required for the authorization by the Board of Directors of any of the matters set forth in Section 5.4 of the Investors' Rights Agreement, dated as of September 17, 2019, by and among the Corporation and the other parties thereto, as such agreement may be amended from time to time.

SEVENTH: Elections of directors need not be by written ballot unless the Bylaws of the Corporation shall so provide.

EIGHTH: Meetings of stockholders may be held within or without the State of Delaware, as the Bylaws of the Corporation may provide. The books of the Corporation may be kept outside the State of Delaware at such place or places as may be designated from time to time by the Board of Directors or in the Bylaws of the Corporation.

NINTH: To the fullest extent permitted by law, a director of the Corporation shall not be personally liable to the Corporation or its stockholders for monetary damages for breach of fiduciary duty as a director. If the General Corporation Law or any other law of the State of Delaware is amended after approval by the stockholders of this Article Ninth to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director of the Corporation shall be eliminated or limited to the fullest extent permitted by the General Corporation Law as so amended.

Any repeal or modification of the foregoing provisions of this Article Ninth by the stockholders of the Corporation shall not adversely affect any right or protection of a director of the Corporation existing at the time of, or increase the liability of any director of the Corporation with respect to any acts or omissions of such director occurring prior to, such repeal or modification.

TENTH: The following indemnification provisions shall apply to the persons enumerated below.

1. Right to Indemnification of Directors and Officers. The Corporation shall indemnify and hold harmless, to the fullest extent permitted by applicable law as it presently exists or may hereafter be amended, any person (an "**Indemnified Person**") who was or is made or is threatened to be made a party or is otherwise involved in any action, suit or proceeding, whether civil, criminal, administrative or investigative (a "**Proceeding**"), by reason of the fact that such person, or a person for whom such person is the legal representative, is or was a director or officer of the Corporation or, while a director or officer of the Corporation, is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation or of a partnership, joint venture, limited liability company, trust, enterprise or nonprofit entity, including service with respect to employee benefit plans, against all liability and loss suffered and expenses (including attorneys' fees) reasonably incurred by such Indemnified Person in such Proceeding. Notwithstanding the preceding sentence, except as otherwise provided in Section 3 of this Article Tenth the Corporation shall be required to indemnify an Indemnified Person in connection with a Proceeding (or part thereof) commenced by such Indemnified Person only if the commencement of such Proceeding (or part thereof) by the Indemnified Person was authorized in advance by the Board of Directors.

2. Prepayment of Expenses of Directors and Officers. The Corporation shall pay the expenses (including attorneys' fees) incurred by an Indemnified Person in defending any Proceeding in advance of its final disposition, provided, however, that, to the extent required by law, such payment of expenses in advance of the final disposition of the Proceeding shall be made only upon receipt of an undertaking by the Indemnified Person to repay all amounts advanced if it should be ultimately determined that the Indemnified Person is not entitled to be indemnified under this Article Tenth or otherwise.

3. Claims by Directors and Officers. If a claim for indemnification or advancement of expenses under this Article Tenth is not paid in full within thirty (30) days after a written claim therefor by the Indemnified Person has been received by the Corporation, the Indemnified Person may file suit to recover the unpaid amount of such claim and, if successful in whole or in part, shall be entitled to be paid the expense of prosecuting such claim. In any such action the Corporation shall have the burden of proving that the Indemnified Person is not entitled to the requested indemnification or advancement of expenses under applicable law.

4. Indemnification of Employees and Agents. The Corporation may indemnify and advance expenses to any person who was or is made or is threatened to be made or is otherwise involved in any Proceeding by reason of the fact that such person, or a person for whom such person is the legal representative, is or was an employee or agent of the Corporation or, while an employee or agent of the Corporation, is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation or of a partnership, joint venture, limited liability company, trust, enterprise or nonprofit entity, including service with respect to employee benefit plans, against all liability and loss suffered and expenses (including attorneys' fees) reasonably incurred by such person in connection with such Proceeding. The ultimate determination of entitlement to indemnification of persons who are non-director or officer employees or agents shall be made in such manner as is determined by the Board of Directors in its sole discretion. Notwithstanding the foregoing sentence, the Corporation shall not be required to indemnify a person in connection with a Proceeding initiated by such person if the Proceeding was not authorized in advance by the Board of Directors.

5. Advancement of Expenses of Employees and Agents. The Corporation may pay the expenses (including attorneys' fees) incurred by an employee or agent in defending any Proceeding in advance of its final disposition on such terms and conditions as may be determined by the Board of Directors.

6. Non-Exclusivity of Rights. The rights conferred on any person by this Article Tenth shall not be exclusive of any other rights which such person may have or hereafter acquire under any statute, provision of this Amended and Restated Certificate of Incorporation, the Bylaws of the Corporation, or any agreement, or pursuant to any vote of stockholders or disinterested directors or otherwise.

7. Other Indemnification. The Corporation's obligation, if any, to indemnify any person who was or is serving at its request as a director, officer or employee of another Corporation, partnership, limited liability company, joint venture, trust, organization or other enterprise shall be reduced by any amount such person may collect as indemnification from such other Corporation, partnership, limited liability company, joint venture, trust, organization or other enterprise.

8. Insurance. The Board of Directors may, to the full extent permitted by applicable law as it presently exists, or may hereafter be amended from time to time, authorize an appropriate officer or officers to purchase and maintain at the Corporation's expense insurance: (a) to indemnify the Corporation for any obligation which it incurs as a result of the indemnification of directors, officers and employees under the provisions of this Article Tenth; and (b) to indemnify or insure directors, officers and employees against liability in instances in which they may not otherwise be indemnified by the Corporation under the provisions of this Article Tenth.

9. Amendment or Repeal. Any repeal or modification of the foregoing provisions of this Article Tenth shall not adversely affect any right or protection hereunder of any person in respect of any act or omission occurring prior to the time of such repeal or modification. The rights provided hereunder shall inure to the benefit of any Indemnified Person and such person's heirs, executors and administrators.

ELEVENTH: The Corporation renounces, to the fullest extent permitted by law, any interest or expectancy of the Corporation in, or in being offered an opportunity to participate in, any Excluded Opportunity. An "**Excluded Opportunity**" is any matter, transaction or interest that is presented to, or acquired, created or developed by, or which otherwise comes into the possession of (i) any director of the Corporation who is not an employee of the Corporation or any of its subsidiaries, or (ii) any holder of Series A Preferred Stock or any partner, member, director, stockholder, employee, affiliate or agent of any such holder, other than someone who is an employee of the Corporation or any of its subsidiaries (collectively, the persons referred to in clauses (i) and (ii) are "**Covered Persons**"), unless such matter, transaction or interest is presented to, or acquired, created or developed by, or otherwise comes into the possession of, a Covered Person expressly and solely in such Covered Person's capacity as a director of the Corporation while such Covered Person is performing services in such capacity. Any repeal or modification of this Article Eleventh will only be prospective and will not affect the rights under this Article Eleventh in effect at the time of the occurrence of any actions or omissions to act giving rise to liability. Notwithstanding anything to the contrary contained elsewhere in this Amended and Restated Certificate of Incorporation, the affirmative vote of the holders of at least 50% of the shares of Series A Preferred Stock then outstanding, will be required to amend or repeal, or to adopt any provisions inconsistent with this Article Eleventh.

TWELFTH: Unless the Corporation consents in writing to the selection of an alternative forum, the Court of Chancery in the State of Delaware shall be the sole and exclusive forum for any stockholder (including a beneficial owner) to bring (i) any derivative action or proceeding brought on behalf of the Corporation, (ii) any action asserting a claim of breach of fiduciary duty owed by any director, officer or other employee of the Corporation to the Corporation or the Corporation's stockholders, (iii) any action asserting a claim against the Corporation, its directors, officers or employees arising pursuant to any provision of the Delaware General Corporation Law or the Corporation's certificate of incorporation or bylaws or (iv) any action asserting a claim against the

Corporation, its directors, officers or employees governed by the internal affairs doctrine, except for, as to each of (i) through (iv) above, any claim as to which the Court of Chancery determines that there is an indispensable party not subject to the jurisdiction of the Court of Chancery (and the indispensable party does not consent to the personal jurisdiction of the Court of Chancery within ten days following such determination), which is vested in the exclusive jurisdiction of a court or forum other than the Court of Chancery, or for which the Court of Chancery does not have subject matter jurisdiction. If any provision or provisions of this Article Twelfth shall be held to be invalid, illegal or unenforceable as applied to any person or entity or circumstance for any reason whatsoever, then, to the fullest extent permitted by law, the validity, legality and enforceability of such provisions in any other circumstance and of the remaining provisions of this Article Twelfth (including, without limitation, each portion of any sentence of this Article Twelfth containing any such provision held to be invalid, illegal or unenforceable that is not itself held to be invalid, illegal or unenforceable) and the application of such provision to other persons or entities and circumstances shall not in any way be affected or impaired thereby.

THIRTEENTH: For purposes of Section 500 of the California Corporations Code (to the extent applicable), in connection with any repurchase of shares of Common Stock permitted under this Amended and Restated Certificate of Incorporation from employees, officers, directors or consultants of the Corporation in connection with a termination of employment or services pursuant to agreements or arrangements approved by the Board of Directors (in addition to any other consent required under this Amended and Restated Certificate of Incorporation), such repurchase may be made without regard to any "preferential dividends arrears amount" or "preferential rights amount" (as those terms are defined in Section 500 of the California Corporations Code). Accordingly, for purposes of making any calculation under California Corporations Code Section 500 in connection with such repurchase, the amount of any "preferential dividends arrears amount" or "preferential rights amount" (as those terms are defined therein) shall be deemed to be zero (0).

* * *

4. That the foregoing amendment and restatement was approved by the Board of Directors in accordance with Section 241(b) of the General Corporation Law.

5. That this Certificate of Incorporation, which restates and integrates and further amends the provisions of this Corporation's Certificate of Incorporation, has been duly adopted in accordance with Section 245 of the General Corporation Law.

IN WITNESS WHEREOF, this Amended and Restated Certificate of Incorporation has been executed by a duly authorized officer of this corporation on this 17th day of September, 2019.

By: /s/ Rohan A. Palekar
Chief Executive Officer

[Signature Page – Amended and Restated Certificate of Incorporation]

CERTIFICATE OF AMENDMENT TO THE
AMENDED AND RESTATED
CERTIFICATE OF INCORPORATION
OF
89BIO, INC.

(Pursuant to Sections 242 of the
General Corporation Law of the State of Delaware)

89bio, Inc. (the "Corporation"), a corporation organized and existing under and by virtue of the provisions of the General Corporation Law of the State of Delaware (the "General Corporation Law"):

DOES HEREBY CERTIFY:

1. That the name of this corporation is 89bio, Inc., and that this corporation was originally incorporated pursuant to the General Corporation Law on June 28, 2019.

2. That the Certificate of Incorporation of the Corporation was amended and restated on September 17, 2019 (as so amended, the "Amended and Restated Certificate of Incorporation").

3. This Certificate of Amendment to the Amended and Restated Certificate of Incorporation (the "Certificate of Amendment") has been duly adopted in accordance with Section 242 of the General Corporation Law and amends the provisions of the Corporation's Amended and Restated Certificate of Incorporation (the "Restated Certificate").

4. This Certificate of Amendment has been approved and duly adopted by the Board of Directors of the Corporation.

5. The terms and provisions of this Certificate of Amendment have been duly approved by written consent of the required number of shares of outstanding stock of the Corporation in accordance with Sections 228 and 242 of the General Corporation Law.

6. The following is hereby inserted into paragraph A of Article FOURTH of the Restated Certificate immediately before the first sentence therein:

"Effective upon the filing of this Certificate of Amendment to the Amended and Restated Certificate of Incorporation with the Secretary of State of the State of Delaware (the "Effective Time"), every 6.217 shares of Common Stock then issued and outstanding or held in the treasury of the Corporation immediately prior to the Effective Time shall automatically be split into one (1) share of Common Stock, without any further action by the holders of such shares (the "Stock Split"). The Stock Split shall occur automatically without any further action by the holders of the shares of Common Stock and Preferred Stock affected thereby. All rights, preferences and privileges of the Common Stock and the Preferred Stock shall be appropriately adjusted to reflect the Stock Split in accordance with this Amended and Restated Certificate of Incorporation."

[*Remainder of page intentionally left blank*]

IN WITNESS WHEREOF, this Certificate of Amendment has been executed by a duly authorized officer of this corporation on this 25th day of October, 2019.

By: /s/ Rohan Palekar
Rohan Palekar
Chief Executive Officer

[*Signature Page – Certificate of Amendment*]

SECOND AMENDED AND RESTATED CERTIFICATE OF INCORPORATION

OF

89BIO, INC.
(a Delaware corporation)

89bio, Inc., a corporation organized and existing under the laws of the State of Delaware (the "Corporation"), hereby certifies as follows:

1. The name of the Corporation is 89bio, Inc. The date of the filing of its original Certificate of Incorporation with the Secretary of State of the State of Delaware was June 28, 2019.

2. This Second Amended and Restated Certificate of Incorporation amends, restates and integrates provisions of the First Amended and Restated Certificate of Incorporation that was filed with the Secretary of State of Delaware on September 17, 2019 (the "First Amended and Restated Certificate"), and was duly adopted in accordance with the provisions of Sections 228, 242 and 245 of the General Corporation Law of the State of Delaware (the "DGCL").

3. The text of the First Amended and Restated Certificate is hereby amended and restated in its entirety to provide as herein set forth in full.

ARTICLE I
NAME

The name of the Corporation is 89bio, Inc.

ARTICLE II
AGENT

The address of the Corporation's registered office in the State of Delaware is 1209 Orange Street, Wilmington, New Castle County, Delaware 19801. The name of its registered agent at such address is The Corporation Trust Company.

ARTICLE III
PURPOSE

The purpose of the Corporation is to engage in any lawful act or activity for which corporations may be organized under the DGCL.

ARTICLE IV
STOCK

Section 4.1 Authorized Stock. The total number of shares that the Corporation shall have authority to issue is 110,000,000, of which 100,000,000 shall be designated as common stock, par value $0.001 per share (the "Common Stock"), and 10,000,000 shall be designated as preferred stock, par value $0.001 per share (the "Preferred Stock").

Section 4.2 Common Stock.

(a) Voting Rights. Each holder of Common Stock, as such, shall be entitled to one vote for each share of Common Stock held of record by such holder on all matters on which stockholders generally are entitled to vote; provided, however, that, except as otherwise required by law, holders of Common Stock, as such, shall not be entitled to vote on any amendment to this Certificate of Incorporation, including any certificate of designations relating to any series of Preferred Stock (each hereinafter referred to as a "Preferred Stock Designation"), that relates solely to the terms of one or more outstanding series of Preferred Stock if the holders of such affected series are entitled, either separately or together with the holders of one or more other such series, to vote thereon pursuant to this Certificate of Incorporation (including any Preferred Stock Designation).

(b) Dividends. Subject to the rights of the holders of any outstanding series of Preferred Stock, the holders of shares of Common Stock shall be entitled to receive any dividends to the extent permitted by law when, as and if declared by the board of directors of the Corporation (the "Board").

(c) Liquidation. Upon the dissolution, liquidation or winding up of the Corporation, subject to the rights of the holders of any outstanding series of Preferred Stock, the holders of shares of Common Stock shall be entitled to receive the assets of the Corporation available for distribution to its stockholders ratably in proportion to the number of shares held by them.

Section 4.3 Preferred Stock. The Preferred Stock may be issued from time to time in one or more series. Subject to limitations prescribed by law and the provisions of this Article (including any Preferred Stock Designation), the Board is hereby authorized to provide by resolution and by causing the filing of a Preferred Stock Designation for the issuance of the shares of Preferred Stock in one or more series, and to establish from time to time the number of shares to be included in each such series, and to fix the designations, powers, preferences, and relative, participating, optional or other rights, if any, and the qualifications, limitations or restrictions, if any, of the shares of each such series.

Section 4.4 No Class Vote on Changes in Authorized Number of Shares of Stock. Subject to the rights of the holders of any outstanding series of Preferred Stock, the number of authorized shares of Common Stock or Preferred Stock may be increased or decreased (but not below the number of shares thereof then outstanding) by the affirmative vote of at least a majority of the voting power of the stock outstanding and entitled to vote thereon irrespective of the provisions of Section 242(b)(2) of the DGCL.

ARTICLE V
BOARD OF DIRECTORS

Section 5.1 Number. The number of directors of the Corporation shall be fixed solely by resolution adopted from time to time by the Board by a majority of the directors then in office.

Section 5.2 Classification.

(a) Except as may be otherwise provided with respect to directors elected by the holders of any series of Preferred Stock provided for or fixed pursuant to the provisions of Article IV hereof (including any Preferred Stock Designation) (the "Preferred Stock Directors"), the Board shall be divided into three classes designated Class I, Class II and Class III. Class I directors shall initially serve until the first annual meeting of stockholders following the initial effectiveness of this Section; Class II directors shall initially serve until the second annual meeting of stockholders following the initial effectiveness of this Section; and Class III directors shall initially serve until the third annual meeting of stockholders following the initial effectiveness of this Section. Commencing with the first annual meeting of stockholders following the initial effectiveness of this Section, directors of each class the term of which shall then expire shall be elected to hold office for a three-year term and until the election and qualification of their respective successors in office. The Board is authorized to assign members of the Board already in office to Class I, Class II or Class III, with such assignment becoming effective as of the initial effectiveness of this Section.

(b) Subject to the rights of the holders of any outstanding series of Preferred Stock, and unless otherwise required by law, newly created directorships resulting from any increase in the authorized number of directors and any vacancies in the Board resulting from death, resignation, retirement, disqualification, removal from office or other cause shall be filled solely by the affirmative vote of a majority of the remaining directors then in office, even though less than a quorum of the Board, or by the sole remaining director. Any director so chosen shall hold office until the next election of the class for which such director shall have been chosen and until his or her successor shall have been duly elected and qualified. No decrease in the authorized number of directors shall shorten the term of any incumbent director.

(c) Any director, or the entire Board, may be removed from office at any time, but only for cause and only by the affirmative vote of at least 66⅔% of the voting power of the stock outstanding and entitled to vote thereon.

(d) During any period when the holders of any series of Preferred Stock have the right to elect additional directors as provided for or fixed pursuant to the provisions of Article IV hereof (including any Preferred Stock Designation), and upon commencement and for the duration of the period during which such right continues: (i) the then otherwise total authorized number of directors of the Corporation shall automatically be increased by such number of directors that the holders of any series of Preferred Stock have a right to elect, and the holders of such Preferred Stock shall be entitled to elect the additional directors so provided for or fixed pursuant to said provisions; and (ii) each Preferred Stock Director shall serve until such Preferred Stock Director's successor shall have been duly elected and qualified, or until such director's

right to hold such office terminates pursuant to said provisions, whichever occurs earlier, subject to his or her earlier death, disqualification, resignation or removal. Except as otherwise provided for or fixed pursuant to the provisions of Article IV hereof (including any Preferred Stock Designation), whenever the holders of any series of Preferred Stock having such right to elect additional directors are divested of such right pursuant to said provisions, the terms of office of all Preferred Stock Directors elected by the holders of such Preferred Stock, or elected to fill any vacancies resulting from the death, resignation, disqualification or removal of such additional directors, shall forthwith terminate (in which case each such Preferred Stock Director shall cease to be qualified as a director and shall cease to be a director) and the total authorized number of directors of the Corporation shall be automatically reduced accordingly.

Section 5.3 Powers. Except as otherwise required by the DGCL or as provided in this Certificate of Incorporation (including any Preferred Stock Designation), the business and affairs of the Corporation shall be managed by or under the direction of the Board.

Section 5.4 Election; Notice of Nominations and Business.

(a) Ballot Not Required. The directors of the Corporation need not be elected by written ballot unless the Bylaws of the Corporation (the "Bylaws") so provide.

(b) Notice. Advance notice of nominations for the election of directors, and of business other than nominations, to be proposed by stockholders for consideration at a meeting of stockholders of the Corporation shall be given in the manner and to the extent provided in or contemplated by the Bylaws.

(c) Annual Meeting. The annual meeting of stockholders, for the election of directors to succeed those whose terms expire and for the transaction of such other business as may properly come before the meeting, shall be held at such place, if any, either within or without the State of Delaware, on such date, and at such time as the Board shall fix.

ARTICLE VI
STOCKHOLDER ACTION

Section 6.1 No Action Without Meeting. Except as otherwise provided for or fixed with respect to actions required or permitted to be taken solely by holders of Preferred Stock pursuant to the provisions of Article IV hereof (including any Preferred Stock Designation), no action that is required or permitted to be taken by the stockholders of the Corporation may be effected by consent of stockholders in lieu of a meeting of stockholders.

Section 6.2 Special Meetings. Except as otherwise required by law, and except as otherwise provided for or fixed pursuant to the provisions of Article IV hereof (including any Preferred Stock Designation), a special meeting of the stockholders of the Corporation may be called at any time only by the Board. Only such business shall be conducted at a special meeting of stockholders as shall have been brought before the meeting by or at the direction of the Board.

ARTICLE VII
EXISTENCE

The Corporation shall have perpetual existence.

ARTICLE VIII
AMENDMENT

Section 8.1 Amendment of Certificate of Incorporation. The Corporation reserves the right, at any time and from time to time, to amend, alter, change or repeal any provision contained in this Certificate of Incorporation (including any Preferred Stock Designation), and to add or insert other provisions authorized by the laws of the State of Delaware at the time in force, in the manner now or hereafter prescribed by the laws of the State of Delaware. All powers, preferences and rights of any nature conferred upon stockholders, directors or any other persons by and pursuant to this Certificate of Incorporation (including any Preferred Stock Designation) in its present form or as hereafter amended are granted subject to this reservation; provided, however, that, except as otherwise provided in this Certificate of Incorporation (including any provision of a Preferred Stock Designation that provides for a greater or lesser vote) and in addition to any other vote required by law, the affirmative vote of at least 66⅔% of the voting power of the stock outstanding and entitled to vote thereon, voting together as a single class, shall be required to amend or repeal, or adopt any provision inconsistent with, Section 5.2 of Article V, Article VI, Article VIII or Article IX.

Section 8.2 Amendment of Bylaws. In furtherance and not in limitation of the powers conferred by the laws of the State of Delaware, but subject to the terms of any series of Preferred Stock then outstanding, the Board is expressly authorized to adopt, amend or repeal the Bylaws. Except as otherwise provided in this Certificate of Incorporation (including the terms of any Preferred Stock Designation that require an additional vote) or the Bylaws, and in addition to any requirements of law, the affirmative vote of at least 66⅔% of the voting power of the stock outstanding and entitled to vote thereon, voting together as a single class, shall be required for the stockholders to adopt, amend or repeal any provision of the Bylaws.

ARTICLE IX
LIABILITY OF DIRECTORS

Section 9.1 No Personal Liability. To the fullest extent permitted by the DGCL as the same exists or as may hereafter be amended, no director of the Corporation shall be personally liable to the Corporation or its stockholders for monetary damages for breach of fiduciary duty as a director.

Section 9.2 Amendment or Repeal. Any amendment, alteration or repeal of this Article that adversely affects any right of a director shall be prospective only and shall not limit or eliminate any such right with respect to any proceeding involving any occurrence or alleged occurrence of any action or omission to act that took place prior to such amendment, alteration or repeal.

ARTICLE X
FORUM FOR ADJUDICATION OF DISPUTES

Section 10.1 Forum. Unless the Corporation, in writing, selects or consents to the selection of an alternative forum, the sole and exclusive forum for any current or former stockholder (including any current or former beneficial owner) to bring Internal Corporate Claims (as defined below), to the fullest extent permitted by law, and subject to applicable jurisdictional requirements, shall be the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have, or declines to accept, jurisdiction, another state court or a federal court located within the State of Delaware). For purposes of this Article, "Internal Corporate Claims" means claims, including claims in the right of the Corporation: (a) that are based on an actual or alleged violation of a duty by a current or former director, officer, employee or stockholder in such capacity; or (b) as to which the DGCL confers jurisdiction upon the Court of Chancery. Notwithstanding anything herein to the contrary, and for the avoidance of doubt: (y) this Article shall not apply to suits brought to enforce a duty or liability created by the Securities Exchange Act of 1934, as amended; and (z) unless the Corporation consents in writing to the selection of an alternative forum, the federal district courts of the United States of America shall be the sole and exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act of 1933, as amended, subject to and contingent upon a final adjudication in the State of Delaware of the enforceability of such exclusive forum provision.

Section 10.2 Consent to Jurisdiction. If any action, the subject matter of which is within the scope of this Article, is filed in a court other than the Court of Chancery (or, if the Court of Chancery does not have, or declines to accept, jurisdiction, another state court or a federal court located within the State of Delaware) (a "Foreign Action") by any current or former stockholder (including any current or former beneficial owner), such stockholder shall be deemed to have consented to: (a) the personal jurisdiction of the Court of Chancery (or such other state or federal court located within the State of Delaware, as applicable) in connection with any action brought in any such court to enforce this Article; and (b) having service of process made upon such stockholder in any such action by service upon such stockholder's counsel in the Foreign Action as agent for such stockholder.

Section 10.3 Enforceability. If any provision of this Article shall be held to be invalid, illegal or unenforceable as applied to any person or entity or circumstance for any reason whatsoever, then, to the fullest extent permitted by law, the validity, legality and enforceability of such provision in any other circumstance and of the remaining provisions of this Article (including, without limitation, each portion of any sentence of this Article containing any such provision held to be invalid, illegal or unenforceable that is not itself held to be invalid, illegal or unenforceable), and the application of such provision to other persons or entities or circumstances shall not in any way be affected or impaired thereby.

IN WITNESS WHEREOF, this Second Amended and Restated Certificate of Incorporation has been executed by a duly authorized officer of this corporation on this ____ day of _____, 2019.

By: _____
Chief Executive Officer

[*Signature Page – Second Amended and Restated Certificate of Incorporation*]

SECOND AMENDED AND RESTATED BYLAWS

OF

89bio, Inc.
(a Delaware corporation)

ARTICLE I
CORPORATE OFFICES

Section 1.1 Registered Office. The registered office of 89bio, Inc. (the "Corporation") shall be fixed in the Certificate of Incorporation of the Corporation.

Section 1.2 Other Offices. The Corporation may also have an office or offices, and keep the books and records of the Corporation, except as otherwise required by law, at such other place or places, either within or without the State of Delaware, as the Corporation may from time to time determine or the business of the Corporation may require.

ARTICLE II
MEETINGS OF STOCKHOLDERS

Section 2.1 Annual Meeting. The annual meeting of stockholders, for the election of directors to succeed those whose terms expire and for the transaction of such other business as may properly come before the meeting, shall be held at such place, if any, either within or without the State of Delaware, on such date, and at such time as the Board of Directors shall fix. The Board of Directors may postpone, reschedule or cancel any annual meeting of stockholders previously scheduled by the Board of Directors.

Section 2.2 Special Meeting. Except as otherwise required by law, and except as otherwise provided for or fixed pursuant to the Certificate of Incorporation, including any certificate of designations relating to any series of Preferred Stock (each hereinafter referred to as a "Preferred Stock Designation"), a special meeting of the stockholders of the Corporation may be called at any time only by the Board of Directors. The Board of Directors may postpone, reschedule or cancel any special meeting of stockholders previously scheduled by the Board of Directors. Only such business shall be conducted at a special meeting of stockholders as shall have been brought before the meeting by or at the direction of the Board of Directors.

Section 2.3 Notice of Stockholders' Meetings.

(a) Whenever stockholders are required or permitted to take any action at a meeting, notice of the place, if any, date, and time of the meeting of stockholders, the record date for determining the stockholders entitled to vote at the meeting (if such date is different from the record date for determining the stockholders entitled to notice of the meeting), the means of remote communications, if any, by which stockholders and proxyholders may be deemed to be present in person and vote at such meeting and, if the meeting is to be held solely by means of remote communications, the means for accessing the list of stockholders contemplated by Section 2.5 of these Bylaws, shall be given. The notice shall be given not less than 10 nor more

than 60 days before the date on which the meeting is to be held, to each stockholder entitled to vote at such meeting as of the record date for determining the stockholders entitled to notice of the meeting, except as otherwise provided by law, the Certificate of Incorporation (including any Preferred Stock Designation) or these Bylaws. In the case of a special meeting, the purpose or purposes for which the meeting is called also shall be set forth in the notice.

(b) Except as otherwise required by law, notice may be given in writing directed to a stockholder's mailing address as it appears on the records of the Corporation and shall be given: (i) if mailed, when notice is deposited in the U.S. mail, postage prepaid; and (ii) if delivered by courier service, the earlier of when the notice is received or left at such stockholder's address.

(c) So long as the Corporation is subject to the Securities and Exchange Commission's proxy rules set forth in Regulation 14A under the Securities Exchange Act of 1934 (the "Exchange Act"), notice shall be given in the manner required by such rules. To the extent permitted by such rules, notice may be given by electronic transmission directed to the stockholder's electronic mail address, and if so given, shall be given when directed to such stockholder's electronic mail address unless the stockholder has notified the Corporation in writing or by electronic transmission of an objection to receiving notice by electronic mail or such notice is prohibited by Section 232(e) of the General Corporation Law of the State of Delaware (the "DGCL"). If notice is given by electronic mail, such notice shall comply with the applicable provisions of Sections 232(a) and 232(d) of the DGCL.

(d) Notice may be given by other forms of electronic transmission with the consent of a stockholder in the manner permitted by Section 232(b) of the DGCL, and shall be deemed given as provided therein.

(e) An affidavit that notice has been given, executed by the Secretary of the Corporation, Assistant Secretary or any transfer agent or other agent of the Corporation, shall be *prima facie* evidence of the facts stated in the notice in the absence of fraud. Notice shall be deemed to have been given to all stockholders who share an address if notice is given in accordance with the "householding" rules set forth in Rule 14a-3(e) under the Exchange Act and Section 233 of the DGCL.

(f) When a meeting is adjourned to another time or place, notice need not be given of the adjourned meeting if the place, if any, date and time thereof, and the means of remote communications, if any, by which stockholders and proxyholders may be deemed to be present in person and vote at such adjourned meeting are announced at the meeting at which the adjournment is taken; provided, however, that if the adjournment is for more than 30 days, a notice of the adjourned meeting shall be given to each stockholder of record entitled to vote at the meeting. If after the adjournment a new record date for stockholders entitled to vote is fixed for the adjourned meeting, the Board of Directors shall fix a new record date for notice of such adjourned meeting in accordance with Section 7.6(a), and shall give notice of the adjourned meeting to each stockholder of record entitled to vote at such adjourned meeting as of the record date fixed for notice of such adjourned meeting.

Section 2.4 Organization.

(a) Unless otherwise determined by the Board of Directors, meetings of stockholders shall be presided over by the Chairman of the Board of Directors, or in his or her absence, by the Chief Executive Officer or, in his or her absence, by another person designated by the Board of Directors. The Secretary of the Corporation, or in his or her absence, an Assistant Secretary, or in the absence of the Secretary and all Assistant Secretaries, a person whom the chairman of the meeting shall appoint, shall act as secretary of the meeting and keep a record of the proceedings thereof.

(b) The date and time of the opening and the closing of the polls for each matter upon which the stockholders shall vote at a meeting of stockholders shall be announced at the meeting. The Board of Directors may adopt such rules and regulations for the conduct of any meeting of stockholders as it shall deem appropriate. Except to the extent inconsistent with such rules and regulations as adopted by the Board of Directors, the chairman of the meeting shall have the authority to adopt and enforce such rules and regulations for the conduct of any meeting of stockholders and the safety of those in attendance as, in the judgment of the chairman, are necessary, appropriate or convenient for the conduct of the meeting. Rules and regulations for the conduct of meetings of stockholders, whether adopted by the Board of Directors or by the chairman of the meeting, may include, without limitation, establishing: (i) an agenda or order of business for the meeting; (ii) rules and procedures for maintaining order at the meeting and the safety of those present; (iii) limitations on attendance at or participation in the meeting to stockholders entitled to vote at the meeting, their duly authorized and constituted proxies and such other persons as the chairman of the meeting shall permit; (iv) restrictions on entry to the meeting after the time fixed for the commencement thereof; (v) limitations on the time allotted for consideration of each agenda item and for questions and comments by participants; (vi) regulations for the opening and closing of the polls for balloting and matters which are to be voted on by ballot (if any); and (vii) procedures (if any) requiring attendees to provide the Corporation advance notice of their intent to attend the meeting. Subject to any rules and regulations adopted by the Board of Directors, the chairman of the meeting may convene and, for any or no reason, from time to time, adjourn and/or recess any meeting of stockholders pursuant to Section 2.7. The chairman of the meeting, in addition to making any other determinations that may be appropriate to the conduct of the meeting, shall have the power to declare that a nomination or other business was not properly brought before the meeting if the facts warrant (including if a determination is made, pursuant to Section 2.10(c)(i) of these Bylaws, that a nomination or other business was not made or proposed, as the case may be, in accordance with Section 2.10 of these Bylaws), and if such chairman should so declare, such nomination shall be disregarded or such other business shall not be transacted.

Section 2.5 List of Stockholders. The Corporation shall prepare, at least 10 days before every meeting of stockholders, a complete list of the stockholders entitled to vote at the meeting; provided, however, that if the record date for determining the stockholders entitled to vote is less than 10 days before the date of the meeting, the list shall reflect the stockholders entitled to vote as of the 10th day before the meeting date. Such list shall be arranged in alphabetical order and shall show the address of each stockholder and the number of shares registered in the name of each stockholder. Nothing in this Section 2.5 shall require the Corporation to include electronic mail addresses or other electronic contact information on such

list. Such list shall be open to the examination of any stockholder, for any purpose germane to the meeting at least 10 days prior to the meeting: (a) on a reasonably accessible electronic network, provided that the information required to gain access to such list is provided with the notice of meeting; or (b) during ordinary business hours at the principal place of business of the Corporation. In the event that the Corporation determines to make the list available on an electronic network, the Corporation may take reasonable steps to ensure that such information is available only to stockholders of the Corporation. If the meeting is to be held at a place, then a list of stockholders entitled to vote at the meeting shall be produced and kept at the time and place of the meeting during the whole time thereof and may be examined by any stockholder who is present. If the meeting is to be held solely by means of remote communication, then the list shall also be open to the examination of any stockholder during the whole time of the meeting on a reasonably accessible electronic network, and the information required to access such list shall be provided with the notice of the meeting. Except as otherwise required by law, the stock ledger shall be the only evidence as to who are the stockholders entitled to examine the list of stockholders required by this Section 2.5 or to vote in person or by proxy at any meeting of stockholders.

Section 2.6 Quorum. Except as otherwise required by law, the Certificate of Incorporation (including any Preferred Stock Designation) or these Bylaws, at any meeting of stockholders, a majority of the voting power of the stock outstanding and entitled to vote at the meeting, present in person or represented by proxy, shall constitute a quorum for the transaction of business; provided, however, that where a separate vote by a class or series or classes or series is required, a majority of the voting power of the stock of such class or series or classes or series outstanding and entitled to vote on that matter, present in person or represented by proxy, shall constitute a quorum entitled to take action with respect to such matter. If a quorum is not present or represented at any meeting of stockholders, then the chairman of the meeting, or a majority of the voting power of the stock present in person or represented by proxy at the meeting and entitled to vote thereon, shall have power to adjourn or recess the meeting from time to time in accordance with Section 2.7, until a quorum is present or represented. Subject to applicable law, if a quorum initially is present at any meeting of stockholders, the stockholders may continue to transact business until adjournment or recess, notwithstanding the withdrawal of enough stockholders to leave less than a quorum, but if a quorum is not present at least initially, no business other than adjournment or recess may be transacted.

Section 2.7 Adjourned or Recessed Meeting. Any annual or special meeting of stockholders, whether or not a quorum is present, may be adjourned or recessed for any or no reason from time to time by the chairman of the meeting, subject to any rules and regulations adopted by the Board of Directors pursuant to Section 2.4(b). Any such meeting may be adjourned for any or no reason (and may be recessed if a quorum is not present or represented) from time to time by a majority of the voting power of the stock present in person or represented by proxy at the meeting and entitled to vote thereon. At any such adjourned or recessed meeting at which a quorum is present, any business may be transacted that might have been transacted at the meeting as originally called.

Section 2.8 Voting.

(a) Except as otherwise required by law or the Certificate of Incorporation (including any Preferred Stock Designation), each holder of stock of the Corporation entitled to vote at any meeting of stockholders shall be entitled to one vote for each share of such stock held of record by such holder that has voting power upon the subject matter in question.

(b) Except as otherwise required by law, the Certificate of Incorporation (including any Preferred Stock Designation), these Bylaws or any law, rule or regulation applicable to the Corporation or its securities, at each meeting of stockholders at which a quorum is present, all corporate actions to be taken by vote of the stockholders shall be authorized by the affirmative vote of at least a majority of the voting power of the stock present in person or represented by proxy and entitled to vote on the subject matter, and where a separate vote by a class or series or classes or series is required, if a quorum of such class or series or classes or series is present, such act shall be authorized by the affirmative vote of at least a majority of the voting power of the stock of such class or series or classes or series present in person or represented by proxy and entitled to vote on the subject matter. Voting at meetings of stockholders need not be by written ballot.

Section 2.9 Proxies. Every stockholder entitled to vote for directors, or on any other matter, shall have the right to do so either in person or by one or more persons authorized to act for such stockholder by proxy, but no such proxy shall be voted or acted upon after three years from its date, unless the proxy provides for a longer period. A proxy shall be irrevocable if it states that it is irrevocable and if, and only as long as, it is coupled with an interest sufficient in law to support an irrevocable power. A proxy may be made irrevocable regardless of whether the interest with which it is coupled is an interest in the stock itself or an interest in the Corporation generally. A stockholder may revoke any proxy which is not irrevocable by attending the meeting and voting in person or by delivering to the Secretary of the Corporation a revocation of the proxy or an executed new proxy bearing a later date.

Section 2.10 Notice of Stockholder Business and Nominations.

(a) Annual Meeting.

(i) Nominations of persons for election to the Board of Directors and the proposal of business other than nominations to be considered by the stockholders may be made at an annual meeting of stockholders only: (A) pursuant to the Corporation's notice of meeting (or any supplement thereto); (B) by or at the direction of the Board of Directors (or any authorized committee thereof); or (C) by any stockholder of the Corporation who is a stockholder of record at the time the notice provided for in this Section 2.10(a) is delivered to the Secretary of the Corporation, who is entitled to vote at the meeting and who complies with the notice procedures set forth in this Section 2.10(a). For the avoidance of doubt, the foregoing clause (C) shall be the exclusive means for a stockholder to make nominations or propose other business at an annual meeting of stockholders (other than a proposal included in the Corporation's proxy statement pursuant to and in compliance with Rule 14a-8 under the Exchange Act).

(ii) For nominations or other business to be properly brought before an annual meeting by a stockholder pursuant to clause (C) of the foregoing paragraph, the stockholder must have given timely notice thereof in writing to the Secretary of the Corporation and, in the case of business other than nominations, such business must be a proper subject for stockholder action. To be timely, a stockholder's notice must be delivered to the Secretary at the principal executive offices of the Corporation not later than the close of business (as defined in Section 2.10(c)(ii) below) on the 90th day nor earlier than the close of business on the 120th day prior to the first anniversary of the preceding year's annual meeting; provided, however, that in the event that the date of the annual meeting is more than 30 days before or more than 60 days after such anniversary date, or if no annual meeting was held in the preceding year, notice by the stockholder to be timely must be so delivered not earlier than the close of business on the 120th day prior to such annual meeting and not later than the close of business on the later of the 90th day prior to such annual meeting or the 10th day following the date on which public announcement (as defined in Section 2.10(c)(ii) below) of the date of such meeting is first made by the Corporation. In no event shall an adjournment or recess of an annual meeting, or a postponement of an annual meeting for which notice of the meeting has already been given to stockholders or a public announcement of the meeting date has already been made, commence a new time period (or extend any time period) for the giving of a stockholder's notice as described above. The number of nominees a stockholder may nominate for election at the annual meeting (or in the case of a stockholder giving the notice on behalf of a beneficial owner, the number of nominees a stockholder may nominate for election at the annual meeting on behalf of the beneficial owner) shall not exceed the number of directors to be elected at such annual meeting. For purposes of this Section 2.10, the 2019 annual meeting of stockholders shall be deemed to have been held on May 30, 2019. Such stockholder's notice shall set forth:

(A) as to each person whom the stockholder proposes to nominate for election or re-election as a director: (1) all information relating to such person that is required to be disclosed in solicitations of proxies for election of directors in an election contest, or is otherwise required, in each case pursuant to and in accordance with Regulation 14A under the Exchange Act; and (2) such person's written consent to serving as a director, if elected, for the full term for which such person is standing for election; provided, however, that, in addition to the information required in the stockholder's notice pursuant to this Section 2.10(a)(ii)(A), such person shall also provide the Corporation such other information that the Corporation may reasonably request and that is necessary to permit the Corporation to determine the eligibility of such person to serve as a director of the Corporation, including information relevant to a determination whether such person can be considered an independent director;

(B) as to any other business that the stockholder proposes to bring before the meeting, a brief description of the business desired to be brought before the meeting, the text of the proposal or business (including the text of any resolutions proposed for consideration and in the event that such business includes a proposal to amend the Bylaws of the Corporation, the language of the proposed amendment), the reasons for conducting such business at the meeting and any substantial interest (within the meaning of Item 5 of Schedule 14A under the Exchange Act) in such business of such stockholder and the beneficial owner (within the meaning of Section 13(d) of the Exchange Act), if any, on whose behalf the proposal is made;

(C) as to the stockholder giving the notice and the beneficial owner, if any, on whose behalf the nomination is made or the other business is proposed:

(1) the name and address of such stockholder, as they appear on the Corporation's books, and the name and address of such beneficial owner;

(2) the class or series and number of shares of stock of the Corporation which are owned of record by such stockholder and such beneficial owner as of the date of the notice, and a representation that the stockholder will notify the Corporation in writing within five business days after the record date for such meeting of the class or series and number of shares of stock of the Corporation owned of record by the stockholder and such beneficial owner as of the record date for the meeting; and

(3) a representation that the stockholder (or a qualified representative of the stockholder) intends to appear at the meeting to make such nomination or propose such business;

(D) as to the stockholder giving the notice or, if the notice is given on behalf of a beneficial owner on whose behalf the nomination is made or the other business is proposed, as to such beneficial owner, and if such stockholder or beneficial owner is an entity, as to each director, executive, managing member or control person of such entity (any such individual or control person, a "control person"):

(1) the class or series and number of shares of stock of the Corporation which are beneficially owned (as defined in Section 2.10(c)(ii) below) by such stockholder or beneficial owner and by any control person as of the date of the notice, and a representation that the stockholder will notify the Corporation in writing within five business days after the record date for such meeting of the class or series and number of shares of stock of the Corporation beneficially owned by such stockholder or beneficial owner and by any control person as of the record date for the meeting;

(2) a description of any agreement, arrangement or understanding with respect to the nomination or other business between or among such stockholder, beneficial owner or control person and any other person, including, without limitation any agreements that would be required to be disclosed pursuant to Item 5 or Item 6 of Exchange Act Schedule 13D (regardless of whether the requirement to file a Schedule 13D is applicable) and a representation that the stockholder will notify the Corporation in writing within five business days after the record date for such meeting of any such agreement, arrangement or understanding in effect as of the record date for the meeting;

(3) a description of any agreement, arrangement or understanding (including, without limitation, any derivative or short positions, profit interests, options, hedging transactions, and borrowed or loaned shares) that has been entered into as of the date of the stockholder's notice by, or on behalf of, such stockholder, beneficial owner or control person, the effect or intent of which is to mitigate loss, manage risk or benefit from changes in the share price of any class or series of the Corporation's stock, or maintain, increase or decrease the voting power of the stockholder, beneficial owner or control person with respect to securities

of the Corporation, and a representation that the stockholder will notify the Corporation in writing within five business days after the record date for such meeting of any such agreement, arrangement or understanding in effect as of the record date for the meeting; and

(4) a representation whether the stockholder or the beneficial owner, if any, will engage in a solicitation with respect to the nomination or other business and, if so, the name of each participant in such solicitation (as defined in Item 4 of Schedule 14A under the Exchange Act) and whether such person intends or is part of a group which intends to deliver a proxy statement and/or form of proxy to holders of shares representing at least 50% of the voting power of the stock entitled to vote generally in the election of directors in the case of a nomination, or holders of at least the percentage of the Corporation's stock required to approve or adopt the business to be proposed in the case of other business.

(iii) Notwithstanding anything in Section 2.10(a)(ii) above or Section 2.10(b) below to the contrary, if the record date for determining the stockholders entitled to vote at any meeting of stockholders is different from the record date for determining the stockholders entitled to notice of the meeting, a stockholder's notice required by this Section 2.10 shall set forth a representation that the stockholder will notify the Corporation in writing within five business days after the record date for determining the stockholders entitled to vote at the meeting, or by the opening of business on the date of the meeting (whichever is earlier), of the information required under clauses (ii)(C)(2) and (ii)(D)(1)-(3) of this Section 2.10(a), and such information when provided to the Corporation shall be current as of the record date for determining the stockholders entitled to vote at the meeting.

(iv) This Section 2.10(a) shall not apply to a proposal proposed to be made by a stockholder if the stockholder has notified the Corporation of his or her intention to present the proposal at an annual or special meeting only pursuant to and in compliance with Rule 14a-8 under the Exchange Act and such proposal has been included in a proxy statement that has been prepared by the Corporation to solicit proxies for such meeting.

(v) Notwithstanding anything in this Section 2.10(a) to the contrary, in the event that the number of directors to be elected to the Board of Directors at an annual meeting is increased and there is no public announcement by the Corporation naming all of the nominees for directors or specifying the size of the increased Board of Directors made by the Corporation at least 10 days prior to the last day a stockholder may deliver a notice in accordance with Section 2.10(a)(ii) above, a stockholder's notice required by this Section 2.10(a) shall also be considered timely, but only with respect to nominees for any new positions created by such increase, if it shall be delivered to the Secretary of the Corporation at the principal executive offices of the Corporation not later than the close of business on the 10th day following the day on which such public announcement is first made by the Corporation.

(b) Special Meeting. Nominations of persons for election to the Board of Directors may be made at a special meeting of stockholders at which directors are to be elected pursuant to the Corporation's notice of meeting: (i) by or at the direction of the Board of Directors (or any authorized committee thereof); or (ii) provided that one or more directors are to be elected at such meeting, by any stockholder of the Corporation who is a stockholder of record at the time the notice provided for in this Section 2.10(b) is delivered to the Secretary of the

Corporation, who is entitled to vote at the meeting and upon such election and who delivers notice thereof in writing setting forth the information required by Section 2.10(a) above. In the event the Corporation calls a special meeting of stockholders for the purpose of electing one or more directors to the Board of Directors, any stockholder entitled to vote in such election of directors may nominate a person or persons (as the case may be) for election to such position(s) as specified in the Corporation's notice of meeting, if the notice required by this Section 2.10(b) shall be delivered to the Secretary at the principal executive offices of the Corporation not earlier than the close of business on the 120th day prior to such special meeting and not later than the close of business on the later of the 90th day prior to such special meeting or the 10th day following the date on which public announcement of the date of the special meeting and of the nominees proposed by the Board of Directors to be elected at such meeting is first made by the Corporation. The number of nominees a stockholder may nominate for election at the special meeting (or in the case of a stockholder giving the notice on behalf of a beneficial owner, the number of nominees a stockholder may nominate for election at the annual meeting on behalf of such beneficial owner) shall not exceed the number of directors to be elected at such special meeting. In no event shall an adjournment, recess or postponement of a special meeting commence a new time period (or extend any time period) for the giving of a stockholder's notice as described above.

(c) General.

(i) Except as otherwise required by law, only such persons who are nominated in accordance with the procedures set forth in this Section 2.10 shall be eligible to be elected at any meeting of stockholders of the Corporation to serve as directors and only such other business shall be conducted at a meeting of stockholders as shall have been brought before the meeting in accordance with the procedures set forth in this Section 2.10. Except as otherwise required by law, each of the Chairman of the Board of Directors or the chairman of the meeting shall have the power to determine whether a nomination or any other business proposed to be brought before the meeting was made or proposed, as the case may be, in accordance with the procedures set forth in this Section 2.10 (including whether a stockholder or beneficial owner solicited (or is part of a group which solicited) or did not so solicit, as the case may be, proxies in compliance with such stockholder's representation as required by clause (a)(ii)(D)(4) of this Section 2.10). If any proposed nomination or other business is not in compliance with this Section 2.10, then except as otherwise required by law, the chairman of the meeting shall have the power to declare that such nomination shall be disregarded or that such other business shall not be transacted. Notwithstanding the foregoing provisions of this Section 2.10, unless otherwise required by law, or otherwise determined by the Chairman of the Board of Directors or the chairman of the meeting, if the stockholder does not provide the information required under clauses (a)(ii)(C)(2) and (a)(ii)(D)(1)-(3) of this Section 2.10 to the Corporation within the time frames specified herein, any such nomination shall be disregarded and any such other business shall not be transacted, notwithstanding that proxies in respect of such vote may have been received by the Corporation. Notwithstanding the foregoing provisions of this Section 2.10, unless otherwise required by law, or otherwise determined by the Chairman of the Board of Directors or the chairman of the meeting, if the stockholder (or a qualified representative of the stockholder) does not appear at the annual or special meeting of stockholders of the Corporation to present a nomination or other business (whether pursuant to the requirements of these Bylaws or in accordance with Rule 14a-8 under the Exchange Act), such nomination shall be disregarded

and such other business shall not be transacted, notwithstanding that proxies in respect of such vote may have been received by the Corporation. To be considered a qualified representative of a stockholder pursuant to the preceding sentence, a person must be a duly authorized officer, manager or partner of such stockholder or authorized by a writing executed by such stockholder (or a reliable reproduction of the writing) delivered to the Corporation prior to the making of such nomination or proposal at such meeting (and in any event not fewer than five days before the meeting) stating that such person is authorized to act for such stockholder as proxy at the meeting of stockholders.

(ii) For purposes of this Section 2.10, the "close of business" shall mean 6:00 p.m. local time at the principal executive offices of the Corporation on any calendar day, whether or not the day is a business day, and a "public announcement" shall mean disclosure in a press release reported by the Dow Jones News Service, Associated Press or a comparable national news service or in a document publicly filed by the Corporation with the Securities and Exchange Commission pursuant to Sections 13, 14 or 15(d) of the Exchange Act. For purposes of clause (a)(ii)(D)(1) of this Section 2.10, shares shall be treated as "beneficially owned" by a person if the person beneficially owns such shares, directly or indirectly, for purposes of Section 13(d) of the Exchange Act and Regulations 13D and 13G thereunder or has or shares pursuant to any agreement, arrangement or understanding (whether or not in writing): (A) the right to acquire such shares (whether such right is exercisable immediately or only after the passage of time or the fulfillment of a condition or both); (B) the right to vote such shares, alone or in concert with others; and/or (C) investment power with respect to such shares, including the power to dispose of, or to direct the disposition of, such shares.

(iii) Nothing in this Section 2.10 shall be deemed to affect any rights of the holders of any series of Preferred Stock to elect directors pursuant to any applicable provisions of the Certificate of Incorporation (including any Preferred Stock Designation).

Section 2.11 No Action by Written Consent.

Except as otherwise provided for or fixed pursuant to the Certificate of Incorporation (including any Preferred Stock Designation), no action that is required or permitted to be taken by the stockholders of the Corporation may be effected by consent of stockholders in lieu of a meeting of stockholders.

Section 2.12 Inspectors of Election. Before any meeting of stockholders, the Corporation may, and shall if required by law, appoint one or more inspectors of election to act at the meeting and make a written report thereof. Inspectors may be employees of the Corporation. The Corporation may designate one or more persons as alternate inspectors to replace any inspector who fails to act. If no inspector or alternate is able to act at a meeting of stockholders, the chairman of the meeting may, and shall if required by law, appoint one or more inspectors to act at the meeting. Each inspector, before entering upon the discharge of his or her duties, shall take and sign an oath faithfully to execute the duties of inspector with strict impartiality and according to the best of his or her ability. Inspectors need not be stockholders. No director or nominee for the office of director at an election shall be appointed as an inspector at such election.

Such inspectors shall:

(a) determine the number of shares outstanding and the voting power of each, the number of shares represented at the meeting, the existence of a quorum, and the validity of proxies and ballots;

(b) determine and retain for a reasonable period a record of the disposition of any challenges made to any determination by the inspectors;

(c) count and tabulate all votes and ballots; and

(d) certify their determination of the number of shares represented at the meeting, and their count of all votes and ballots.

Section 2.13 Meetings by Remote Communications. The Board of Directors may, in its sole discretion, determine that a meeting of stockholders shall not be held at any place, but may instead be held solely by means of remote communication in accordance with Section 211(a)(2) of the DGCL. If authorized by the Board of Directors in its sole discretion, and subject to such guidelines and procedures as the Board of Directors may adopt, stockholders and proxyholders not physically present at a meeting of stockholders may, by means of remote communication: (a) participate in a meeting of stockholders; and (b) be deemed present in person and vote at a meeting of stockholders whether such meeting is to be held at a designated place or solely by means of remote communication, provided that: (i) the Corporation shall implement reasonable measures to verify that each person deemed present and permitted to vote at the meeting by means of remote communication is a stockholder or proxyholder; (ii) the Corporation shall implement reasonable measures to provide such stockholders and proxyholders a reasonable opportunity to participate in the meeting and to vote on matters submitted to the stockholders, including an opportunity to read or hear the proceedings of the meeting substantially concurrently with such proceedings; and (iii) if any stockholder or proxyholder votes or takes other action at the meeting by means of remote communication, a record of such vote or other action shall be maintained by the Corporation.

Section 2.14 Delivery to the Corporation. Whenever this Article II requires one or more persons (including a record or beneficial owner of stock) to deliver a document or information to the Corporation or any officer, employee or agent thereof (including any notice, request, questionnaire, revocation, representation or other document or agreement), the Corporation shall not be required to accept delivery of such document or information unless the document or information is in writing exclusively (and not in an electronic transmission) and delivered exclusively by hand (including, without limitation, overnight courier service) or by certified or registered mail, return receipt requested.

ARTICLE III
DIRECTORS

Section 3.1 Powers. Except as otherwise required by the DGCL or as provided in the Certificate of Incorporation (including any Preferred Stock Designation), the business and affairs of the Corporation shall be managed by or under the direction of the Board of Directors. In addition to the powers and authorities these Bylaws expressly confer upon it, the Board of

Directors may exercise all such powers of the Corporation and do all such lawful acts and things as are not by law, the Certificate of Incorporation (including any Preferred Stock Designation) or these Bylaws required to be exercised or done by the stockholders.

Section 3.2 Number, Term of Office and Election. The number of directors of the Corporation shall be fixed solely by resolution adopted from time to time by a majority of the directors then in office. The directors shall hold office in the manner provided in the Certificate of Incorporation. At any meeting of stockholders at which directors are to be elected, directors shall be elected by a plurality of the votes cast. Directors need not be stockholders unless so required by the Certificate of Incorporation (including any Preferred Stock Designation) or these Bylaws, wherein other qualifications for directors may be prescribed.

Section 3.3 Vacancies and Newly Created Directorships. Subject to the rights of the holders of any outstanding series of Preferred Stock, and unless otherwise required by law newly created directorships resulting from any increase in the authorized number of directors and any vacancies in the Board of Directors resulting from death, resignation, retirement, disqualification, removal from office or other cause shall be filled solely by the affirmative vote of a majority of the remaining directors then in office, even though less than a quorum, or by the sole remaining director, and any director so chosen shall hold office until the next election of the class for which such director shall have been chosen and until his or her successor shall have been duly elected and qualified. No decrease in the authorized number of directors shall shorten the term of any incumbent director.

Section 3.4 Resignations and Removal.

(a) Any director may resign at any time upon notice given in writing or by electronic transmission to the Board of Directors, the Chairman of the Board of Directors or the Secretary of the Corporation. Such resignation shall take effect upon delivery, unless the resignation specifies a later effective date or time or an effective date or time determined upon the happening of an event or events. Unless otherwise specified therein, the acceptance of such resignation shall not be necessary to make it effective.

(b) Except for such additional directors, if any, as are elected by the holders of any series of Preferred Stock as provided for or fixed pursuant to the Certificate of Incorporation (including any Preferred Stock Designation), any director, or the entire Board of Directors, may be removed from office at any time, but only for cause and only by the affirmative vote of at least 66⅔% of the voting power of the stock outstanding and entitled to vote thereon.

Section 3.5 Regular Meetings. Regular meetings of the Board of Directors shall be held at such place or places, within or without the State of Delaware, on such date or dates and at such time or times, as shall have been established by the Board of Directors and publicized among all directors. A notice of each regular meeting shall not be required.

Section 3.6 Special Meetings. Special meetings of the Board of Directors for any purpose or purposes may be called at any time by the Chairman of the Board of Directors, the Chief Executive Officer or a majority of the directors then in office. The person or persons authorized to call special meetings of the Board of Directors may fix the place, within or without

the State of Delaware, date and time of such meetings. Notice of each such meeting shall be given to each director, if by mail, addressed to such director at his or her residence or usual place of business, at least five days before the day on which such meeting is to be held, or shall be sent to such director by electronic transmission, or be delivered personally or by telephone, in each case at least 24 hours prior to the time set for such meeting. A notice of special meeting need not state the purpose of such meeting, and, unless indicated in the notice thereof, any and all business may be transacted at a special meeting.

Section 3.7 Participation in Meetings by Conference Telephone. Members of the Board of Directors, or of any committee thereof, may participate in a meeting of such Board of Directors or committee by means of conference telephone or other communications equipment by means of which all persons participating in the meeting can hear each other, and such participation shall constitute presence in person at such meeting.

Section 3.8 Quorum and Voting. Except as otherwise required by law, the Certificate of Incorporation or these Bylaws, a majority of the total number of directors then authorized shall constitute a quorum for the transaction of business at any meeting of the Board of Directors, and the vote of a majority of the directors present at a duly held meeting at which a quorum is present shall be the act of the Board of Directors. The chairman of the meeting or a majority of the directors present may adjourn the meeting to another time and place whether or not a quorum is present. At any adjourned meeting at which a quorum is present, any business may be transacted which might have been transacted at the meeting as originally called.

Section 3.9 Board of Directors Action by Written Consent Without a Meeting. Unless otherwise restricted by the Certificate of Incorporation or these Bylaws, any action required or permitted to be taken at any meeting of the Board of Directors, or any committee thereof, may be taken without a meeting, provided that all members of the Board of Directors or committee, as the case may be, consent in writing or by electronic transmission to such action. After an action is taken, the consent or consents relating thereto shall be filed with the minutes or proceedings of the Board of Directors or committee in the same paper or electronic form as the minutes are maintained. Any person (whether or not then a director) may provide, whether through instruction to an agent or otherwise, that a consent to action shall be effective at a future time (including a time determined upon the happening of an event), no later than 60 days after such instruction is given or such provision is made and such consent shall be deemed to have been given at such effective time so long as such person is then a director and did not revoke the consent prior to such time. Any such consent shall be revocable prior to its becoming effective.

Section 3.10 Chairman of the Board. The Chairman of the Board shall preside at meetings of stockholders (unless otherwise determined by the Board of Directors) and at meetings of directors and shall perform such other duties as the Board of Directors may from time to time determine. If the Chairman of the Board is not present at a meeting of the Board of Directors, another director chosen by the Board of Directors shall preside.

Section 3.11 Rules and Regulations. The Board of Directors may adopt such rules and regulations not inconsistent with the provisions of law, the Certificate of Incorporation or these Bylaws for the conduct of its meetings and management of the affairs of the Corporation as the Board of Directors shall deem proper.

Section 3.12 Fees and Compensation of Directors. Unless otherwise restricted by the Certificate of Incorporation, directors may receive such compensation, if any, for their services on the Board of Directors and its committees, and such reimbursement of expenses, as may be fixed or determined by resolution of the Board of Directors.

Section 3.13 Emergency Bylaws. In the event of any emergency, disaster or catastrophe, as referred to in Section 110 of the DGCL, or other similar emergency condition, as a result of which a quorum of the Board of Directors or a standing committee of the Board of Directors cannot readily be convened for action, then the director or directors in attendance at the meeting shall constitute a quorum. Such director or directors in attendance may further take action to appoint one or more of themselves or other directors to membership on any standing or temporary committees of the Board of Directors as they shall deem necessary and appropriate.

ARTICLE IV
COMMITTEES

Section 4.1 Committees of the Board of Directors. The Board of Directors may designate one or more committees, each such committee to consist of one or more of the directors of the Corporation. The Board of Directors may designate one or more directors as alternate members of any committee to replace any absent or disqualified member at any meeting of the committee. In the absence or disqualification of a member of a committee, the member or members present at any meeting and not disqualified from voting, whether or not he, she or they constitute a quorum, may unanimously appoint another member of the Board of Directors to act at the meeting in the place of any such absent or disqualified member. Any such committee, to the extent permitted by law and provided in the resolution of the Board of Directors establishing such committee, shall have and may exercise all the powers and authority of the Board of Directors in the management of the business and affairs of the Corporation, and may authorize the seal of the Corporation to be affixed to all papers which may require it; but no such committee shall have the power or authority in reference to the following matters: (a) approving or adopting, or recommending to the stockholders, any action or matter (other than the election or removal of directors) expressly required by the DGCL to be submitted to stockholders for approval; or (b) adopting, amending or repealing any bylaw of the Corporation. All committees of the Board of Directors shall keep minutes of their meetings and shall report their proceedings to the Board of Directors when requested or required by the Board of Directors.

Section 4.2 Meetings and Action of Committees. Unless the Board of Directors provides otherwise by resolution, any committee of the Board of Directors may adopt, alter and repeal such rules and regulations not inconsistent with the provisions of law, the Certificate of Incorporation or these Bylaws for the conduct of its meetings as such committee may deem proper. A majority of the directors then serving on a committee shall constitute a quorum for the transaction of business by the committee except as otherwise required by law, the Certificate of Incorporation or these Bylaws, and except as otherwise provided in a resolution of the Board of Directors; provided, however, that in no case shall a quorum be less than one-third of the directors then serving on the committee. Unless the Certificate of Incorporation, these Bylaws or a resolution of the Board of Directors requires a greater number, the vote of a majority of the members of a committee present at a meeting at which a quorum is present shall be the act of the committee.

ARTICLE V
OFFICERS

Section 5.1 Officers. The officers of the Corporation shall consist of a Chief Executive Officer, a President, a Chief Financial Officer, a Secretary, a Treasurer, a Controller and such other officers as the Board of Directors may from time to time determine, each of whom shall be elected by the Board of Directors, each to have such authority, functions or duties as set forth in these Bylaws or as determined by the Board of Directors. Each officer shall be elected by the Board of Directors and shall hold office for such term as may be prescribed by the Board of Directors and until such person's successor shall have been duly elected and qualified, or until such person's earlier death, disqualification, resignation or removal. Any number of offices may be held by the same person; provided, however, that no officer shall execute, acknowledge or verify any instrument in more than one capacity if such instrument is required by law, the Certificate of Incorporation or these Bylaws to be executed, acknowledged or verified by two or more officers. The Board of Directors may require any officer, agent or employee to give security for the faithful performance of his or her duties.

Section 5.2 Compensation. The salaries of the officers of the Corporation and the manner and time of the payment of such salaries shall be fixed and determined by the Board of Directors or by a duly authorized officer and may be altered by the Board of Directors from time to time as it deems appropriate, subject to the rights, if any, of such officers under any contract of employment.

Section 5.3 Removal, Resignation and Vacancies. Any officer of the Corporation may be removed, with or without cause, by the Board of Directors or by a duly authorized officer, without prejudice to the rights, if any, of such officer under any contract to which it is a party. Any officer may resign at any time upon notice given in writing or by electronic transmission to the Corporation, without prejudice to the rights, if any, of the Corporation under any contract to which such officer is a party. If any vacancy occurs in any office of the Corporation, the Board of Directors may elect a successor to fill such vacancy for the remainder of the unexpired term and until a successor shall have been duly elected and qualified.

Section 5.4 Chief Executive Officer. The Chief Executive Officer shall have general supervision and direction of the business and affairs of the Corporation, shall be responsible for corporate policy and strategy, and shall report directly to the Board of Directors. Unless otherwise provided in these Bylaws or determined by the Board of Directors, all other officers of the Corporation shall report directly to the Chief Executive Officer or as otherwise determined by the Chief Executive Officer. The Chief Executive Officer shall, if present and in the absence of the Chairman of the Board of Directors, preside at meetings of the stockholders.

Section 5.5 President. The President shall be the chief operating officer of the Corporation, with general responsibility for the management and control of the operations of the Corporation. The President shall, when requested, counsel with and advise the other officers of the Corporation and shall perform such other duties as the Board of Directors or the Chief Executive Officer may from time to time determine.

Section 5.6 Chief Financial Officer. The Chief Financial Officer shall exercise all the powers and perform the duties of the office of the chief financial officer and in general have overall supervision of the financial operations of the Corporation. The Chief Financial Officer shall, when requested, counsel with and advise the other officers of the Corporation and shall perform such other duties as the Board of Directors or the Chief Executive Officer may from time to time determine.

Section 5.7 Treasurer. The Treasurer shall supervise and be responsible for all the funds and securities of the Corporation, the deposit of all moneys and other valuables to the credit of the Corporation in depositories of the Corporation, borrowings and compliance with the provisions of all indentures, agreements and instruments governing such borrowings to which the Corporation is a party, the disbursement of funds of the Corporation and the investment of its funds, and in general shall perform all of the duties incident to the office of the Treasurer. The Treasurer shall, when requested, counsel with and advise the other officers of the Corporation and shall perform such other duties as the Board of Directors, the Chief Executive Officer or the Chief Financial Officer may from time to time determine.

Section 5.8 Controller. The Controller shall be the chief accounting officer of the Corporation. The Controller shall, when requested, counsel with and advise the other officers of the Corporation and shall perform such other duties as the Board of Directors, the Chief Executive Officer or the Chief Financial Officer may from time to time determine.

Section 5.9 Secretary. The powers and duties of the Secretary are: (i) to act as Secretary at all meetings of the Board of Directors, of the committees of the Board of Directors and of the stockholders and to record the proceedings of such meetings in a book or books to be kept for that purpose; (ii) to see that all notices required to be given by the Corporation are duly given and served; (iii) to act as custodian of the seal of the Corporation and affix the seal or cause it to be affixed to all certificates of stock of the Corporation and to all documents, the execution of which on behalf of the Corporation under its seal is duly authorized in accordance with the provisions of these Bylaws; (iv) to have charge of the books, records and papers of the Corporation and see that the reports, statements and other documents required by law to be kept and filed are properly kept and filed; and (v) to perform all of the duties incident to the office of Secretary. The Secretary shall, when requested, counsel with and advise the other officers of the Corporation and shall perform such other duties as the Board of Directors, the Chief Executive Officer or the President may from time to time determine.

Section 5.10 Additional Matters. The Chief Executive Officer and the Chief Financial Officer of the Corporation shall have the authority to designate employees of the Corporation to have the title of Vice President, Assistant Vice President, Assistant Treasurer or Assistant Secretary. Any employee so designated shall have the powers and duties determined by the officer making such designation. The persons upon whom such titles are conferred shall not be deemed officers of the Corporation unless elected by the Board of Directors.

Section 5.11 Checks; Drafts; Evidences of Indebtedness. From time to time, the Board of Directors shall determine the method, and designate (or authorize officers of the Corporation to designate) the person or persons who shall have authority, to sign or endorse all checks, drafts, other orders for payment of money and notes, bonds, debentures or other evidences of indebtedness that are issued in the name of or payable by the Corporation, and only the persons so authorized shall sign or endorse such instruments.

Section 5.12 Corporate Contracts and Instruments; How Executed. Except as otherwise provided in these Bylaws, the Board of Directors may determine the method, and designate (or authorize officers of the Corporation to designate) the person or persons who shall have authority to enter into any contract or execute any instrument in the name of and on behalf of the Corporation. Such authority may be general or confined to specific instances. Unless so authorized, or within the power incident to a person's office or other position with the Corporation, no person shall have any power or authority to bind the Corporation by any contract or engagement or to pledge its credit or to render it liable for any purpose or for any amount.

Section 5.13 Signature Authority. Unless otherwise determined by the Board of Directors or otherwise provided by law or these Bylaws, contracts, evidences of indebtedness and other instruments or documents of the Corporation may be executed, signed or endorsed: (i) by the Chief Executive Officer or the President; or (ii) by the Chief Financial Officer, Treasurer, Secretary or Controller, in each case only with regard to such instruments or documents that pertain to or relate to such person's duties or business functions.

Section 5.14 Action with Respect to Securities of Other Corporations or Entities. The Chief Executive Officer or any other officer of the Corporation authorized by the Board of Directors or the Chief Executive Officer is authorized to vote, represent, and exercise on behalf of the Corporation all rights incident to any and all shares or other equity interests of any other corporation or entity or corporations or entities, standing in the name of the Corporation. The authority herein granted may be exercised either by such person directly or by any other person authorized to do so by proxy or power of attorney duly executed by the person having such authority.

Section 5.15 Delegation. The Board of Directors may from time to time delegate the powers or duties of any officer to any other officers or agents, notwithstanding the foregoing provisions of this Article V.

ARTICLE VI
INDEMNIFICATION AND ADVANCEMENT OF EXPENSES

Section 6.1 Right to Indemnification. Each person who was or is a party or is threatened to be made a party to, or was or is otherwise involved in, any action, suit, arbitration, alternative dispute resolution mechanism, investigation, inquiry, judicial, administrative or legislative hearing, or any other threatened, pending or completed proceeding, whether brought by or in the right of the Corporation or otherwise, including any and all appeals, whether of a civil, criminal, administrative, legislative, investigative or other nature (hereinafter a "proceeding"), by reason of the fact that he or she is or was a director or an officer (which means, for purposes of this Article VI, any individual designated by the Board of Directors as an officer for purposes of Section 16 of the Exchange Act) of the Corporation or while a director or officer of the Corporation is or was serving at the request of the Corporation as a director, officer, employee, agent or trustee of another corporation or of a partnership, joint venture, trust or other enterprise, including service with respect to an employee benefit plan (hereinafter an

"indemnitee"), or by reason of anything done or not done by him or her in any such capacity, shall be indemnified and held harmless by the Corporation to the fullest extent authorized by the DGCL, as the same exists or may hereafter be amended, against all expense, liability and loss (including attorneys' fees, judgments, fines, ERISA excise taxes, penalties and amounts paid in settlement by or on behalf of the indemnitee) actually and reasonably incurred by such indemnitee in connection therewith, all on the terms and conditions set forth in these Bylaws; provided, however, that, except as otherwise required by law or provided in Section 6.3 with respect to suits to enforce rights under this Article VI, the Corporation shall indemnify any such indemnitee in connection with a proceeding, or part thereof, voluntarily initiated by such indemnitee (including claims and counterclaims, whether such counterclaims are asserted by: (i) such indemnitee; or (ii) the Corporation in a proceeding initiated by such indemnitee) only if such proceeding, or part thereof, was authorized or ratified by the Board of Directors or the Board of Directors otherwise determines that indemnification or advancement of expenses is appropriate.

Section 6.2 Right to Advancement of Expenses.

(a) In addition to the right to indemnification conferred in Section 6.1, an indemnitee shall, to the fullest extent permitted by law, also have the right to be paid by the Corporation the expenses (including attorneys' fees) incurred in defending any proceeding in advance of its final disposition (hereinafter an "advancement of expenses"); provided, however, that an advancement of expenses shall be made only upon delivery to the Corporation of an undertaking (hereinafter an "undertaking"), by or on behalf of such indemnitee, to repay all amounts so advanced if it shall ultimately be determined by final judicial decision of a court of competent jurisdiction from which there is no further right to appeal (hereinafter a "final adjudication") that such indemnitee is not entitled to be indemnified for such expenses under this Article VI or otherwise.

(b) Notwithstanding the foregoing Section 6.2(a), the Corporation shall not make or continue to make advancements of expenses to an indemnitee if a determination is reasonably made that the facts known at the time such determination is made demonstrate clearly and convincingly that the indemnitee acted in bad faith or in a manner that the indemnitee did not reasonably believe to be in or not opposed to the best interests of the Corporation, or, with respect to any criminal proceeding, that the indemnitee had reasonable cause to believe his or her conduct was unlawful. Such determination shall be made: (i) by the Board of Directors by a majority vote of directors who are not parties to such proceeding, whether or not such majority constitutes a quorum; (ii) by a committee of such directors designated by a majority vote of such directors, whether or not such majority constitutes a quorum; or (iii) if there are no such directors, or if such directors so direct, by independent legal counsel in a written opinion to the Board of Directors, a copy of which shall be delivered to the indemnitee.

Section 6.3 Right of Indemnitee to Bring Suit. If a request for indemnification under Section 6.1 is not paid in full by the Corporation within 60 days, or if a request for an advancement of expenses under Section 6.2 is not paid in full by the Corporation within 20 days, after a written request has been received by the Secretary of the Corporation, the indemnitee may at any time thereafter bring suit against the Corporation in a court of competent jurisdiction in the State of Delaware seeking an adjudication of entitlement to such indemnification or

advancement of expenses. If successful in whole or in part in any such suit, or in a suit brought by the Corporation to recover an advancement of expenses pursuant to the terms of an undertaking, the indemnitee shall be entitled to be paid also the expense of prosecuting or defending such suit to the fullest extent permitted by law. In any suit brought by the indemnitee to enforce a right to indemnification hereunder (but not in a suit brought by the indemnitee to enforce a right to an advancement of expenses) it shall be a defense that the indemnitee has not met any applicable standard of conduct for indemnification set forth in the DGCL. Further, in any suit brought by the Corporation to recover an advancement of expenses pursuant to the terms of an undertaking, the Corporation shall be entitled to recover such expenses upon a final adjudication that the indemnitee has not met any applicable standard of conduct for indemnification set forth in the DGCL. Neither the failure of the Corporation (including its directors who are not parties to such action, a committee of such directors, independent legal counsel or its stockholders) to have made a determination prior to the commencement of such suit that indemnification of the indemnitee is proper in the circumstances because the indemnitee has met the applicable standard of conduct set forth in the DGCL, nor an actual determination by the Corporation (including its directors who are not parties to such action, a committee of such directors, independent legal counsel or its stockholders) that the indemnitee has not met such applicable standard of conduct, shall create a presumption that the indemnitee has not met the applicable standard of conduct or, in the case of such a suit brought by the indemnitee, be a defense to such suit. In any suit brought by the indemnitee to enforce a right to indemnification or to an advancement of expenses hereunder, or brought by the Corporation to recover an advancement of expenses pursuant to the terms of an undertaking, the burden of proving that the indemnitee is not entitled to be indemnified, or to such advancement of expenses, under applicable law, this Article VI or otherwise shall be on the Corporation.

Section 6.4 Non-Exclusivity of Rights. The rights to indemnification and to the advancement of expenses conferred in this Article VI shall not be exclusive of any other right which any person may have or hereafter acquire under any law, agreement, vote of stockholders or disinterested directors, provisions of a certificate of incorporation or bylaws, or otherwise.

Section 6.5 Insurance. The Corporation may maintain insurance, at its expense, to protect itself and any director, officer, employee or agent of the Corporation or another corporation, partnership, joint venture, trust or other enterprise against any expense, liability or loss, whether or not the Corporation would have the power to indemnify such person against such expense, liability or loss under the DGCL.

Section 6.6 Indemnification of Employees and Agents of the Corporation. The Corporation may, to the extent and in the manner permitted by law, and to the extent authorized from time to time, grant rights to indemnification and to the advancement of expenses to any employee or agent of the Corporation.

Section 6.7 Nature of Rights. The rights conferred upon indemnitees in this Article VI shall be contract rights and such rights shall continue as to an indemnitee who has ceased to be a director or officer and shall inure to the benefit of the indemnitee’s heirs, executors and administrators. Any amendment, alteration or repeal of this Article VI that adversely affects any right of an indemnitee or its successors shall be prospective only and shall not limit or eliminate any such right with respect to any proceeding involving any occurrence or alleged occurrence of any action or omission to act that took place prior to such amendment, alteration or repeal.

Section 6.8 Settlement of Claims. Notwithstanding anything in this Article VI to the contrary, the Corporation shall not be liable to indemnify any indemnitee under this Article VI for any amounts paid in settlement of any proceeding effected without the Corporation's written consent, which consent shall not be unreasonably withheld.

Section 6.9 Subrogation. In the event of payment under this Article VI, the Corporation shall be subrogated to the extent of such payment to all of the rights of recovery of the indemnitee (excluding insurance obtained on the indemnitee's own behalf), and the indemnitee shall execute all papers required and shall do everything that may be necessary to secure such rights, including the execution of such documents necessary to enable the Corporation effectively to bring suit to enforce such rights.

Section 6.10 Severability. If any provision or provisions of this Article VI shall be held to be invalid, illegal or unenforceable as applied to any person or entity or circumstance for any reason whatsoever, then, to the fullest extent permitted by law: (a) the validity, legality and enforceability of such provision in any other circumstance and of the remaining provisions of this Article VI (including, without limitation, all portions of any paragraph of this Article VI containing any such provision held to be invalid, illegal or unenforceable, that are not by themselves invalid, illegal or unenforceable) and the application of such provision to other persons or entities or circumstances shall not in any way be affected or impaired thereby; and (b) to the fullest extent possible, the provisions of this Article VI (including, without limitation, all portions of any paragraph of this Article VI containing any such provision held to be invalid, illegal or unenforceable, that are not themselves invalid, illegal or unenforceable) shall be construed so as to give effect to the intent of the parties that the Corporation provide protection to the indemnitee to the fullest extent set forth in this Article VI.

ARTICLE VII
CAPITAL STOCK

Section 7.1 Certificates of Stock. The shares of the Corporation shall be represented by certificates; provided, however, that the Board of Directors may provide by resolution or resolutions that some or all of any or all classes or series of stock shall be uncertificated shares. Any such resolution shall not apply to shares represented by a certificate until such certificate is surrendered to the Corporation. Every holder of stock represented by certificates shall be entitled to have a certificate signed by or in the name of the Corporation by any two authorized officers of the Corporation, including, without limitation, the Chief Executive Officer, the President, the Chief Financial Officer, the Treasurer, the Controller, the Secretary, or an Assistant Treasurer or Assistant Secretary, of the Corporation certifying the number of shares owned by such holder in the Corporation. Any or all such signatures may be facsimiles. In case any officer, transfer agent or registrar who has signed or whose facsimile signature has been placed upon a certificate has ceased to be such officer, transfer agent or registrar before such certificate is issued, it may be issued by the Corporation with the same effect as if such person were such officer, transfer agent or registrar at the date of issue.

Section 7.2 Special Designation on Certificates. If the Corporation is authorized to issue more than one class of stock or more than one series of any class, then the powers, the designations, the preferences, and the relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights shall be set forth in full or summarized on the face or back of the certificate that the Corporation shall issue to represent such class or series of stock; provided, however, that, except as otherwise provided in Section 202 of the DGCL, in lieu of the foregoing requirements there may be set forth on the face or back of the certificate that the Corporation shall issue to represent such class or series of stock a statement that the Corporation will furnish without charge to each stockholder who so requests the powers, the designations, the preferences, and the relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights. Within a reasonable time after the issuance or transfer of uncertificated stock, the registered owner thereof shall be given a notice, in writing or by electronic transmission, containing the information required to be set forth or stated on certificates pursuant to this Section 7.2 or Sections 151, 156, 202(a) or 218(a) of the DGCL or with respect to this Section 7.2 and Section 151 of the DGCL a statement that the Corporation will furnish without charge to each stockholder who so requests the powers, the designations, the preferences, and the relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights. Except as otherwise expressly provided by law, the rights and obligations of the holders of uncertificated stock and the rights and obligations of the holders of certificates representing stock of the same class and series shall be identical.

Section 7.3 Transfers of Stock. Transfers of shares of stock of the Corporation shall be made only on the books of the Corporation upon authorization by the registered holder thereof or by such holder's attorney thereunto authorized by a power of attorney duly executed and filed with the Secretary of the Corporation or a transfer agent for such stock, and if such shares are represented by a certificate, upon surrender of the certificate or certificates for such shares properly endorsed or accompanied by a duly executed stock transfer power and the payment of any taxes thereon; provided, however, that the Corporation shall be entitled to recognize and enforce any lawful restriction on transfer. Transfers may also be made in any manner authorized by the Corporation (or its authorized transfer agent) and permitted by Section 224 of the DGCL.

Section 7.4 Lost Certificates. The Corporation may issue a new share certificate or uncertificated shares in the place of any certificate theretofore issued by it, alleged to have been lost, stolen or destroyed, and the Corporation may require the owner of the lost, stolen or destroyed certificate or the owner's legal representative to give the Corporation a bond (or other adequate security) sufficient to indemnify it against any claim that may be made against it (including any expense or liability) on account of the alleged loss, theft or destruction of any such certificate or the issuance of such new certificate or uncertificated shares. The Board of Directors may adopt such other provisions and restrictions with reference to lost certificates, not inconsistent with applicable law, as it shall in its discretion deem appropriate.

Section 7.5 Registered Stockholders. The Corporation shall be entitled to recognize the exclusive right of a person registered on its books as the owner of shares to receive dividends, and to vote as such owner, and shall not be bound to recognize any equitable or other claim to or interest in such share or shares on the part of any other person, whether or not it shall have express or other notice thereof, except as otherwise required by law.

Section 7.6 Record Date for Determining Stockholders.

(a) In order that the Corporation may determine the stockholders entitled to notice of any meeting of stockholders or any adjourned meeting, the Board of Directors may fix a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted by the Board of Directors, and which record date shall, unless otherwise required by law, not be more than 60 nor less than 10 days before the date of such meeting. If the Board of Directors so fixes a date, such date shall also be the record date for determining the stockholders entitled to vote at such meeting unless the Board of Directors determines, at the time it fixes such record date, that a later date on or before the date of the meeting shall be the date for making such determination. If no record date is fixed by the Board of Directors, the record date for determining stockholders entitled to notice of and to vote at a meeting of stockholders shall be at the close of business on the day next preceding the day on which notice is given, or, if notice is waived, at the close of business on the day next preceding the day on which the meeting is held. A determination of stockholders of record entitled to notice of or to vote at a meeting of stockholders shall apply to any adjourned meeting; provided, however, that the Board of Directors may fix a new record date for the determination of stockholders entitled to vote at the adjourned meeting, and in such case shall also fix as the record date for stockholders entitled to notice of such adjourned meeting the same or an earlier date as that fixed for determination of stockholders entitled to vote in accordance herewith at the adjourned meeting.

(b) In order that the Corporation may determine the stockholders entitled to receive payment of any dividend or other distribution or allotment of any rights, or entitled to exercise any rights in respect of any change, conversion or exchange of stock or for the purpose of any other lawful action, the Board of Directors may fix a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted by the Board of Directors, and which record date shall not be more than 60 days prior to such action. If no such record date is fixed, the record date for determining stockholders for any such purpose shall be at the close of business on the day on which the Board of Directors adopts the resolution relating thereto.

Section 7.7 Regulations. To the extent permitted by applicable law, the Board of Directors may make such additional rules and regulations as it may deem expedient concerning the issue, transfer and registration of shares of stock of the Corporation.

Section 7.8 Waiver of Notice. Whenever notice is required to be given under any provision of the DGCL or the Certificate of Incorporation or these Bylaws, a written waiver, signed by the person entitled to notice, or a waiver by electronic transmission by the person entitled to notice, whether before or after the time stated therein, shall be deemed equivalent to notice. Attendance of a person at a meeting shall constitute a waiver of notice of such meeting, except when the person attends a meeting for the express purpose of objecting at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened. Neither the business to be transacted at, nor the purpose of, any regular or special meeting of the stockholders, the Board of Directors or a committee of the Board of Directors need be specified in any written waiver of notice or any waiver by electronic transmission unless so required by the Certificate of Incorporation or these Bylaws.

ARTICLE VIII
GENERAL MATTERS

Section 8.1 Fiscal Year. The fiscal year of the Corporation shall begin on the first day of January of each year and end on the last day of December of the same year, or shall extend for such other 12 consecutive months as the Board of Directors may designate.

Section 8.2 Corporate Seal. The Board of Directors may provide a suitable seal, containing the name of the Corporation, which seal shall be in the charge of the Secretary of the Corporation. If and when so directed by the Board of Directors or a committee thereof, duplicates of the seal may be kept and used by the Treasurer or by an Assistant Secretary or Assistant Treasurer.

Section 8.3 Reliance Upon Books, Reports and Records. Each director and each member of any committee designated by the Board of Directors shall, in the performance of his or her duties, be fully protected in relying in good faith upon the books of account or other records of the Corporation and upon such information, opinions, reports or statements presented to the Corporation by any of its officers or employees, or committees of the Board of Directors so designated, or by any other person as to matters which such director or committee member reasonably believes are within such other person's professional or expert competence and who has been selected with reasonable care by or on behalf of the Corporation.

Section 8.4 Subject to Law and Certificate of Incorporation. All powers, duties and responsibilities provided for in these Bylaws, whether or not explicitly so qualified, are qualified by the Certificate of Incorporation (including any Preferred Stock Designation) and applicable law.

Section 8.5 Electronic Signatures, etc. Except as otherwise required by the Certificate of Incorporation (including as otherwise required by any Preferred Stock Designation) or these Bylaws (including, without limitation, as otherwise required by Section 2.14), any document, including, without limitation, any consent, agreement, certificate or instrument, required by the DGCL, the Certificate of Incorporation (including any Preferred Stock Designation) or these Bylaws to be executed by any officer, director, stockholder, employee or agent of the Corporation may be executed using a facsimile or other form of electronic signature to the fullest extent permitted by applicable law. All other contracts, agreements, certificates or instruments to be executed on behalf of the Corporation may be executed using a facsimile or other form of electronic signature to the fullest extent permitted by applicable law. The terms "electronic mail," "electronic mail address," "electronic signature" and "electronic transmission" as used herein shall have the meanings ascribed thereto in the DGCL.

ARTICLE IX
AMENDMENTS

Section 9.1 Amendments. In furtherance and not in limitation of the powers conferred by the laws of the State of Delaware, the Board of Directors is expressly authorized to adopt, amend or repeal these Bylaws. Except as otherwise provided in the Certificate of Incorporation (including the terms of any Preferred Stock Designation that provides for a greater or lesser vote) or these Bylaws, and in addition to any other vote required by law, the affirmative vote of at least 66⅔% of the voting power of the stock outstanding and entitled to vote thereon, voting together as a single class, shall be required for the stockholders to adopt, amend or repeal, or adopt any provision inconsistent with, any provision of these Bylaws.

The foregoing Second Amended and Restated Bylaws were adopted by the Board of Directors on September 17, 2019 and approved by the stockholders on October 24, 2019 subject to and effective upon the effectiveness of the Corporation's Registration Statement on Form S-1 for its initial public offering.

NUMBER

SHARES
SPECIMEN

COMMON STOCK

89bio

INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE

SEE REVERSE FOR CERTAIN DEFINITIONS

CUSIP 282559 10 3

THIS CERTIFIES THAT:

SPECIMEN - NOT NEGOTIABLE

IS THE OWNER OF

FULLY PAID AND NON-ASSESSABLE SHARES OF COMMON STOCK OF $0.001 PAR VALUE EACH OF

89BIO, INC.

transferable on the books of the Corporation by the holder hereof in person or by duly authorized attorney upon surrender of this certificate duly endorsed. This certificate and the shares represented hereby are subject to the laws of the State of Delaware, and to the Certificate of Incorporation and Bylaws of the Corporation, as now in effect or as hereafter amended.

This certificate is not valid until countersigned and registered by the Transfer Agent and Registrar.

WITNESS the facsimile seal of the Corporation and the facsimile signatures of its duly authorized officers.

DATED:

SPECIMEN
NOT NEGOTIABLE

89BIO, INC. CORPORATE SEAL 2019 DELAWARE

CHIEF EXECUTIVE OFFICER

SECRETARY

COUNTERSIGNED AND REGISTERED:
AMERICAN STOCK TRANSFER & TRUST COMPANY, LLC
BROOKLYN, NY

BY

TRANSFER AGENT AND REGISTRAR

AUTHORIZED SIGNATURE

THE CORPORATION WILL FURNISH TO ANY STOCKHOLDER, UPON REQUEST AND WITHOUT CHARGE, A FULL STATEMENT OF THE DESIGNATIONS, RELATIVE RIGHTS, PREFERENCES AND LIMITATIONS OF THE SHARES OF EACH CLASS AND SERIES AUTHORIZED TO BE ISSUED, SO FAR AS THE SAME HAVE BEEN DETERMINED, AND OF THE AUTHORITY, IF ANY, OF THE BOARD TO DIVIDE THE SHARES INTO CLASSES OR SERIES AND TO DETERMINE AND CHANGE THE RELATIVE RIGHTS, PREFERENCES AND LIMITATIONS OF ANY CLASS OR SERIES. SUCH REQUEST MAY BE MADE TO THE SECRETARY OF THE CORPORATION OR TO THE TRANSFER AGENT NAMED ON THIS CERTIFICATE.

The following abbreviations, when used in the inscription on the face of this certificate, shall be construed as though they were written out in full according to applicable laws or regulations:

TEN COM	*as tenants in common*	*UNIF GIFT MIN ACT -*	*.....Custodian.....*
TEN ENT	*as tenants by the entireties*	*(Cust)*	*(Minor)*
JT TEN	*as joint tenants with right of survivorship and not as tenants in common*	*under Uniform Gifts to Minors Act.....*	
		(State)	

Additional abbreviations may also be used though not in the above list.

For Value Received, _____ *hereby sell, assign and transfer unto*

PLEASE INSERT SOCIAL SECURITY OR OTHER IDENTIFYING NUMBER OF ASSIGNEE

_____

(PLEASE PRINT OR TYPEWRITE NAME AND ADDRESS, INCLUDING ZIP CODE, OF ASSIGNEE)

_____

_____

_____ *Shares of the stock represented by the within Certificate, and do hereby irrevocably constitute and appoint*

_____ *Attorney to transfer the said stock on the books of the within named Corporation with full power of substitution in the premises.*

Dated _____

NOTICE: THE SIGNATURE(S) TO THIS ASSIGNMENT MUST CORRESPOND WITH THE NAME(S) AS WRITTEN UPON THE FACE OF THE CERTIFICATE, IN EVERY PARTICULAR, WITHOUT ALTERATION OR ENLARGEMENT OR ANY CHANGE WHATSOEVER.

Signature(s) Guaranteed

By _____

The Signature(s) must be guaranteed by an eligible guarantor institution (Banks, Stockbrokers, Savings and Loan Associations and Credit Unions with membership in an approved Signature Guarantee Medallion Program), pursuant to SEC Rule 17Ad-15.

Exhibit 5.1

GIBSON DUNN

Gibson, Dunn & Crutcher LLP

555 Mission Street
San Francisco, CA 94105-0921
Tel 415.393.8200
www.gibsondunn.com

Client: 26925-00003

October 28, 2019

89bio, Inc.
535 Mission Street, 14th Floor
San Francisco, CA 94105

Re: *89bio, Inc.*
Registration Statement on Form S 1 (File No. 333-234174)

Ladies and Gentlemen:

We have examined the Registration Statement on Form S-1, File No. 333-234174, as amended (the "Registration Statement"), of 89bio, Inc., a Delaware corporation (the "Company"), filed with the Securities and Exchange Commission (the "Commission") pursuant to the Securities Act of 1933, as amended (the "Securities Act"), in connection with the offering by the Company of up to 5,031,250 shares of the Company's common stock, par value $0.001 per share, (the "Shares").

In arriving at the opinion expressed below, we have examined originals, or copies certified or otherwise identified to our satisfaction as being true and complete copies of the originals, of specimen Common Stock certificates and such other documents, corporate records, certificates of officers of the Company and of public officials and other instruments as we have deemed necessary or advisable to enable us to render the opinions set forth below. In our examination, we have assumed without independent investigation the genuineness of all signatures, the legal capacity and competency of all natural persons, the authenticity of all documents submitted to us as originals and the conformity to original documents of all documents submitted to us as copies.

Based upon the foregoing, and subject to the assumptions, exceptions, qualifications and limitations set forth herein, we are of the opinion that the Shares, when issued against payment therefor as set forth in the Registration Statement, will be validly issued, fully paid and non-assessable.

We consent to the filing of this opinion as an exhibit to the Registration Statement, and we further consent to the use of our name under the caption "Legal Matters" in the Registration Statement and the prospectus that forms a part thereof. In giving these consents, we do not thereby admit that we are within the category of persons whose consent is required under Section 7 of the Securities Act or the Rules and Regulations of the Commission.

Very truly yours,

Sincerely,

/s/ Gibson, Dunn & Crutcher LLP

89BIO, INC.

2019 AMENDED AND RESTATED EQUITY INCENTIVE PLAN

ORIGINALLY ADOPTED BY THE BOARD: SEPTEMBER 17, 2019
ORIGINALLY APPROVED BY THE STOCKHOLDERS: SEPTEMBER 17, 2019
AMENDED AND RESTATED PLAN ADOPTED BY THE BOARD: OCTOBER 24, 2019
AMENDED AND RESTATED PLAN APPROVED BY THE STOCKHOLDERS: OCTOBER 24, 2019
EFFECTIVE DATE: SEPTEMBER 17, 2019
AMENDED AND RESTATED EFFECTIVE DATE: OCTOBER 24, 2019

1. GENERAL.

(a) **Successor to Prior Plan**. This Plan is the successor to the 89Bio Ltd. 2018 Equity Incentive Plan, as amended and together with any attachments thereto (the "**Prior Plan**"). From and after 12:01 a.m. Eastern time on the Effective Date, no additional stock awards will be granted under the Prior Plan. In addition, all stock awards granted under the Prior Plan prior to the Effective Date that remain outstanding on the Effective Date shall be cancelled and replaced with equivalent Awards under this Plan. All Awards granted on or after 12:01 a.m. Eastern Time on the Effective Date are subject to the terms of this Plan.

(b) **Eligible Award Recipients**. Employees, Directors and Consultants are eligible to receive Awards.

(c) **Available Awards**. This Plan provides for the grant of the following Awards: (i) Incentive Stock Options; (ii) Nonstatutory Stock Options; (iii) Stock Appreciation Rights; (iv) Restricted Stock Awards; (v) Restricted Stock Unit Awards; (vi) Performance Stock Awards; and (vii) Performance Cash Awards.

(d) **Purpose**. This Plan, through the granting of Awards, is intended to help the Company secure and retain the services of eligible award recipients, provide incentives for such persons to exert maximum efforts for the success of the Company and any Affiliate and provide a means by which the eligible award recipients may benefit from increases in the value of the Common Stock.

2. ADMINISTRATION.

(a) **Administration by Board**. The Board will administer this Plan. The Board may delegate administration of this Plan to a Committee or Committees, as provided in Section 2(c).

(b) **Powers of Board**. The Board will have the power, subject to, and within the limitations of, the express provisions of this Plan:

(i) To determine: (A) who will be granted Awards; (B) when and how each Award will be granted; (C) what type of Award will be granted; (D) the provisions of each Award (which need not be identical), including when a person will be permitted to exercise or otherwise receive cash or Common Stock under the Award; (E) the number of shares of Common Stock subject to, or the cash value of, an Award; and (F) the Fair Market Value applicable to a Stock Award.

(ii) To construe and interpret this Plan and Awards granted under it, and to establish, amend and revoke rules and regulations for administration of this Plan and Awards. The Board, in the exercise of these powers, may correct any defect, omission or inconsistency in this Plan or in any Award Document or in the written terms of a Performance Cash Award, in a manner and to the extent it will deem necessary or expedient to make this Plan or Award fully effective.

(iii) To settle all controversies regarding this Plan and Awards granted under it.

(iv) To accelerate, in whole or in part, or to extend, in whole or in part, the time during which an Award may be exercised or vest, or at which cash or shares of Common Stock may be issued.

(v) To suspend or terminate this Plan at any time. Except as otherwise provided in this Plan or an Award Document, suspension or termination of this Plan will not materially impair a Participant's rights under his or her then-outstanding Award without his or her written consent except as provided in subsection (viii) below.

(vi) To amend this Plan in any respect the Board deems necessary or advisable, including, without limitation, adopting amendments relating to Incentive Stock Options and nonqualified deferred compensation under Section 409A of the Code and/or making this Plan or Awards granted under this Plan exempt from or compliant with the requirements for Incentive Stock Options or exempt from or compliant with the requirements for nonqualified deferred compensation under Section 409A of the Code, subject to the limitations, if any, of applicable law. If required by applicable law or listing requirements, and except as provided in Section 9(a) relating to Capitalization Adjustments, the Company will seek stockholder approval of any amendment of this Plan that (A) materially increases the number of shares of Common Stock available for issuance under this Plan, (B) materially expands the class of individuals eligible to receive Awards under this Plan, (C) materially increases the benefits accruing to Participants under this Plan, (D) materially reduces the price at which shares of Common Stock may be issued or purchased under this Plan, (E) materially extends the term of this Plan, or (F) materially expands the types of Awards available for issuance under this Plan. Except as otherwise provided in this Plan (including subsection (viii) below) or an Award Document, no amendment of this Plan will materially impair a Participant's rights under an outstanding Award without the Participant's written consent.

(vii) To submit any amendment to this Plan for stockholder approval, including, but not limited to, amendments to this Plan intended to satisfy the requirements of (A) Section 422 of the Code regarding "incentive stock options" or (B) Rule 16b-3 of the Exchange Act or any successor rule, if applicable.

(viii) To approve forms of Award Documents for use under this Plan and to amend the terms of any one or more outstanding Awards, including, but not limited to, amendments to provide terms more favorable to the Participant than previously provided in the Award Documents for such Awards, subject to any specified limits in this Plan that are not subject to Board discretion. A Participant's rights under any Award will not be impaired by any such amendment unless the Company requests the consent of the affected Participant, and the Participant consents in writing. However, a Participant's rights will not be deemed to have been impaired by any such amendment if the Board, in its sole discretion, determines that the amendment, taken as a whole, does not materially impair the Participant's rights. In addition, subject to the limitations of applicable law, if any, the Board may amend the terms of any one or more Awards without the affected Participant's consent (A) to maintain the qualified status of the Award as an Incentive Stock Option under Section 422 of the Code, (B) to change the terms of an Incentive Stock Option, if such change results in impairment of the Award solely because it impairs the qualified status of the Award as an Incentive Stock Option under Section 422 of the Code, (C) to clarify the manner of exemption from, or to bring the Award into compliance with, Section 409A of the Code, or (D) to comply with other applicable laws or listing requirements.

(ix) Generally, to exercise such powers and to perform such acts as the Board deems necessary or expedient to promote the best interests of the Company and that are not in conflict with the provisions of this Plan and/or Award Documents.

(x) To adopt such procedures and sub-plans as are necessary or appropriate (A) to permit or facilitate participation in this Plan by persons eligible to receive Awards under this Plan who are not citizens of, subject to taxation by, or employed outside, the United States or (B) to allow Awards to qualify for special tax treatment in a jurisdiction other than the United States. Board approval will not be necessary for immaterial modifications to this Plan or any Award Document that are required for compliance with the laws of the relevant jurisdiction.

(xi) To effect, with the consent of any adversely affected Participant, (A) the reduction of the exercise, purchase or strike price of any outstanding Stock Award; (B) the cancellation of any outstanding Stock Award and the grant in substitution therefore of a new (1) Option or SAR, (2) Restricted Stock Award, (3) Restricted Stock Unit Award, (4) cash award and/or (5) award of other valuable consideration determined by the Board, in its sole discretion, with any such substituted award (x) covering the same or a different number of shares of Common Stock as the cancelled Stock Award and (y) granted under this Plan or another equity or compensatory plan of the Company; or (C) any other action that is treated as a repricing under generally accepted accounting principles.

(c) **Delegation to Committee**.

(i) General. The Board may delegate some or all of the administration of this Plan to a Committee or Committees. If administration of this Plan is delegated to a Committee, the Committee will have, in connection with the administration of this Plan, the powers theretofore possessed by the Board that have been delegated to the Committee, including the power to delegate to a subcommittee of the Committee any of the administrative powers the Committee is authorized to exercise (and references in this Plan to the Board will thereafter be to the Committee or subcommittee). Any delegation of administrative powers will be reflected in the charter of the Committee to which the delegation is made, or resolutions, not inconsistent with the provisions of this Plan, adopted from time to time by the Board or Committee (as applicable). The Committee may, at any time, abolish the subcommittee and/or revest in the Committee any powers delegated

to any subcommittee. Unless otherwise provided by the Board, delegation of authority by the Board to a Committee, or to an Officer or employee pursuant to Section 2(d), does not limit the authority of the Board, which may continue to exercise any authority so delegated and may concurrently administer this Plan with the Committee and may, at any time, revest in the Board some or all of the powers previously delegated.

(ii) Rule 16b-3 Compliance. The Committee may consist solely of two or more Non-Employee Directors, in accordance with Rule 16b-3 of the Exchange Act.

(d) **Delegation to an Officer**. The Board may delegate to one (1) or more Officers the authority to do one or both of the following, to the maximum extent permitted by applicable law: (i) designate Employees who are not Officers to be recipients of Stock Awards and the terms of such Stock Awards; and (ii) determine the number of shares of Common Stock to be subject to such Stock Awards granted to such Employees; provided, however, that the Board resolutions regarding such delegation will specify the total number of shares of Common Stock that may be subject to the Stock Awards granted by such Officer and that such Officer may not grant a Stock Award to himself or herself. Any such Stock Awards will be granted on a form that is substantially the same as the form of Stock Award Document approved by the Committee or the Board for use in connection with such Stock Awards, unless otherwise provided for in the resolutions approving the delegation authority.

(e) **Effect of Board's Decision**. All determinations, interpretations and constructions made by the Board (or a duly authorized Committee, subcommittee or Officer exercising powers delegated by the Board under this Section 2) in good faith will not be subject to review by any person and will be final, binding and conclusive on all persons.

3. SHARES SUBJECT TO THIS PLAN.

(a) **Share Reserve**.

(i) Subject to Section 9(a) relating to Capitalization Adjustments, the aggregate maximum number of shares of Common Stock that may be issued pursuant to Stock Awards from and after the Effective Date will not exceed 2,844,193 shares of Common Stock (the "**Share Reserve**") plus any shares of Common Stock added as a result of the "evergreen" provision in Section 3(a)(ii).

(ii) The Share Reserve will automatically increase on January 1st of each year beginning in 2020 and ending with a final increase on January 1, 2029, in an amount equal to four percent (4%) of the total number of shares of Capital Stock outstanding on December 31st of the preceding calendar year. The Board may provide that there will be no January 1st increase in the Share Reserve for any such year or that the increase in the Share Reserve for any such year will be a smaller number of shares of Common Stock than would otherwise occur pursuant to the preceding sentence.

(iii) For clarity, the Share Reserve is a limitation on the number of shares of Common Stock that may be issued under this Plan. As a single share may be subject to grant more than once (e.g., if a share subject to a Stock Award is forfeited, it may be made subject to grant again as provided in Section 3(b) below), the Share Reserve is not a limit on the number of Stock Awards that can be granted.

(iv) Shares may be issued under the terms of this Plan in connection with a merger or acquisition as permitted by NASDAQ Listing Rule 5635(c), NYSE Listed Company Manual Section 303A.08, AMEX Company Guide Section 711 or other applicable rule, and such issuance will not reduce the number of shares available for issuance under this Plan.

(b) **Reversion of Shares to the Share Reserve**. If a Stock Award or any portion of a Stock Award (i) expires, is cancelled or forfeited or otherwise terminates without all of the shares covered by the Stock Award having been issued or (ii) is settled in cash (i.e., the Participant receives cash rather than stock), such expiration, cancellation, forfeiture, termination or settlement will not reduce (or otherwise offset) the number of shares of Common Stock that are available for issuance under this Plan. If any shares of Common Stock issued under a Stock Award are forfeited back to, reacquired at no cost by, or repurchased at cost by the Company because of the failure to meet a contingency or condition required to vest such shares in the Participant, then the shares that are forfeited, reacquired or repurchased will revert to and again become available for issuance under this Plan. Any shares retained and not issued by the Company in satisfaction of tax withholding obligations on a Stock Award or as consideration for the exercise or purchase price of a Stock Award will not reduce (or otherwise offset) the number of shares of Common Stock that are available for issuance under this Plan. Any shares reacquired by the Company (as distinguished from being retained without issuance by the Company) in satisfaction of tax withholding obligations on a Stock Award, as consideration for the exercise or purchase price of a Stock Award, or with the proceeds paid by the Participant under the terms of a Stock Award, will again become available for issuance under this Plan, but only if such reacquisition occurs during the period beginning on the Effective Date and ending on the tenth (10th) anniversary of the date on which the Company's stockholders initially approved this Plan.

(c) **Incentive Stock Option Limit**. Subject to Section 9(a) relating to Capitalization Adjustments, the aggregate maximum number of shares of Common Stock that may be issued on the exercise of Incentive Stock Options will be 2,844,193 shares of Common Stock.

(d) **Source of Shares**. The stock issuable under this Plan will be shares of authorized but unissued or reacquired Common Stock, including shares repurchased by the Company on the open market or otherwise or shares classified as treasury shares.

4. ELIGIBILITY.

(a) **Eligibility for Specific Stock Awards**. Incentive Stock Options may be granted only to employees of the Company or a "parent corporation" or "subsidiary corporation" thereof (as such terms are defined in Sections 424(e) and 424(f) of the Code). Stock Awards other than Incentive Stock Options may be granted to Employees, Directors and Consultants.

(b) **Ten Percent Stockholders**. A Ten Percent Stockholder will not be granted an Incentive Stock Option unless the exercise price of such Option is at least 110% of the Fair Market Value on the date of grant and the Option is not exercisable after the expiration of five (5) years from the date of grant.

5. PROVISIONS RELATING TO OPTIONS AND STOCK APPRECIATION RIGHTS.

Each Option or SAR will be in such form and will contain such terms and conditions as the Board deems appropriate. All Options will be separately designated Incentive Stock Options or Nonstatutory Stock Options at the time of grant, and, if certificates are issued, a separate certificate or certificates will be issued for shares of Common Stock purchased on exercise of each type of Option. If an Option is not specifically designated as an Incentive Stock Option, or if an Option is designated as an Incentive Stock Option but some portion or all of the Option fails to qualify as an Incentive Stock Option under the applicable rules, then the Option (or portion thereof) will be a Nonstatutory Stock Option. The provisions of separate Options or SARs need not be identical; provided, however, that each Award Document will conform to (through incorporation of provisions hereof by reference in the applicable Award Document or otherwise) the substance of each of the following provisions:

(a) **Term**. Subject to Section 4(b) regarding Ten Percent Stockholders, no Option or SAR will be exercisable after the expiration of 10 years from the date of its grant or such shorter period specified in the Award Document.

(b) **Exercise Price**. Subject to Section 4(b) regarding Ten Percent Stockholders, the exercise or strike price of each Option or SAR will be not less than 100% of the Fair Market Value of the Common Stock subject to the Option or SAR on the date the Award is granted. Notwithstanding the foregoing, an Option or SAR may be granted with an exercise or strike price lower than 100% of the Fair Market Value of the Common Stock subject to the Award if such Award is granted pursuant to an assumption of or substitution for another option or stock appreciation right pursuant to a corporate transaction and in a manner consistent with the provisions of Section 409A of the Code and, if applicable, Section 424(a) of the Code (including, but not limited to, Options or SARs issued in substitution for awards outstanding under the Prior Plan on the Effective Date). Each SAR will be denominated in shares of Common Stock equivalents.

(c) **Purchase Price for Options**. The purchase price of Common Stock acquired pursuant to the exercise of an Option may be paid, to the extent permitted by applicable law and as determined by the Board in its sole discretion, by any combination of the methods of payment set forth below. The Board will have the authority to grant Options that do not permit all of the following methods of payment (or otherwise restrict the ability to use certain methods) and to grant Options that require the consent of the Company to use a particular method of payment. The purchase price shall be denominated in U.S. dollars. The permitted methods of payment are as follows:

(i) by cash, check, bank draft or money order payable to the Company;

(ii) pursuant to a program developed under Regulation T as promulgated by the United States Federal Reserve Board or a successor regulation, or a similar rule in a foreign jurisdiction of domicile of a Participant, that, prior to or contemporaneously with the issuance of the stock subject to the Option, results in either the receipt of cash (or check) by the Company or the receipt of irrevocable instructions to pay the aggregate exercise price to the Company from the proceeds of sale of such stock;

(iii) by delivery to the Company (either by actual delivery or attestation) of shares of Common Stock;

(iv) by a "net exercise" arrangement pursuant to which the Company will reduce the number of shares of Common Stock issuable upon exercise by the largest whole number of shares with a Fair Market Value that does not exceed the aggregate exercise price; provided, however, that the Company will accept cash or other payment from the Participant to the extent of any remaining balance of the aggregate exercise price not satisfied by such reduction in the number of whole shares to be issued. Shares of Common Stock will no longer be subject to an Option and will not be exercisable thereafter to the extent that (A) shares issuable upon exercise are used to pay the exercise price pursuant to the "net exercise," (B) shares are delivered to the Participant as a result of such exercise, and (C) shares are withheld to satisfy tax withholding obligations; or

(v) in any other form of legal consideration that may be acceptable to the Board and specified in the applicable Award Document.

(d) **Exercise and Payment of a SAR**. To exercise any outstanding SAR, the Participant must provide written notice of exercise to the Company in compliance with the provisions of the Stock Appreciation Right Award Document evidencing such SAR. The appreciation distribution payable on the exercise of a SAR will be not greater than an amount equal to the excess of (A) the aggregate Fair Market Value (on the date of the exercise of the SAR) of a number of shares of Common Stock equal to the number of Common Stock equivalents in which the Participant is vested under such SAR (with respect to which the Participant is exercising the SAR on such date), over (B) the aggregate strike price of the number of Common Stock equivalents with respect to which the Participant is exercising the SAR on such date. The appreciation distribution may be paid in Common Stock, in cash, in any combination of the two or in any other form of consideration, as determined by the Board and contained in the Award Document evidencing such SAR.

(e) **Transferability of Options and SARs**. The Board may, in its sole discretion, impose such limitations on the transferability of Options and SARs as the Board determines. In the absence of such a determination by the Board to the contrary, the following restrictions on the transferability of Options and SARs will apply:

(i) Restrictions on Transfer. An Option or SAR will not be transferable except by will or by the laws of descent and distribution (or pursuant to subsections (ii) and (iii) below), and will be exercisable during the lifetime of the Participant only by the Participant. The Board may permit transfer of the Option or SAR in a manner that is not prohibited by applicable tax and securities laws. Except as explicitly provided herein, neither an Option nor a SAR may be transferred for consideration.

(ii) Domestic Relations Orders. Subject to the approval of the Board or a duly authorized Officer, an Option or SAR may be transferred pursuant to the terms of a domestic relations order, official marital settlement agreement or other divorce or separation instrument as permitted by U.S. Treasury Regulation 1.421-1(b)(2) or other applicable law. If an Option is an Incentive Stock Option, such Option may be deemed to be a Nonstatutory Stock Option as a result of such transfer.

(iii) Beneficiary Designation. Subject to the approval of the Board or a duly authorized Officer, a Participant may, by delivering written notice to the Company, in a form approved by the Company (or the designated broker), designate a third party who, on the death of the Participant, will thereafter be entitled to exercise the Option or SAR and receive the Common Stock or other consideration resulting from such exercise. In the absence of such a designation, the executor or administrator of the Participant's estate will be entitled to exercise the Option or SAR and receive the Common Stock or other consideration resulting from such exercise. However, the Company may prohibit designation of a beneficiary at any time, including due to any conclusion by the Company that such designation would be inconsistent with the provisions of applicable laws.

(f) **Vesting Generally**. The total number of shares of Common Stock subject to an Option or SAR may vest and therefore become exercisable in periodic installments that may or may not be equal. The Option or SAR may be subject to such other terms and conditions on the time or times when it may or may not be exercised (which may be based on the satisfaction of performance goals or other criteria) as the Board may deem appropriate. The vesting provisions of individual Options or SARs may vary. The provisions of this Section 5(f) are subject to any Option or SAR provisions governing the minimum number of shares of Common Stock as to which an Option or SAR may be exercised.

(g) **Termination of Continuous Service**. Except as otherwise provided in the applicable Award Document, or other agreement between the Participant and the Company, if a Participant's Continuous Service terminates (other than for Cause and other than upon the Participant's death or Disability), the Participant may exercise his or her Option or SAR (to the extent that the Participant was entitled to exercise such Award as of the date of termination of Continuous Service) within the period of time ending on the earlier of (i) the date three (3) months following the termination of the Participant's Continuous Service and (ii) the expiration of the term of the Option or SAR as set forth in the applicable Award Document. If, after termination of Continuous Service, the Participant does not exercise his or her Option or SAR within the applicable time frame, the Option or SAR will terminate.

(h) **Extension of Termination Date**. Except as otherwise provided in the applicable Award Document, or other agreement between the Participant and the Company, if the exercise of an Option or SAR following the termination of the Participant's Continuous Service (other than for Cause and other than upon the Participant's death or Disability) would be prohibited at any time solely because the issuance of shares of Common Stock would violate the registration requirements under the Securities Act, then the Option or SAR will terminate on the earlier of (i) the expiration of a total period of three (3) months (that need not be consecutive) after the termination of the Participant's Continuous Service during which the exercise of the Option or SAR would not be in violation of such registration requirements, and (ii) the expiration of the term of the Option or SAR as set forth in the applicable Award Document. In addition, unless otherwise provided in a Participant's applicable Award Document, or other agreement between the Participant and the Company, if the sale of any Common Stock received upon exercise of an

Option or SAR following the termination of the Participant's Continuous Service (other than for Cause) would violate the Company's insider trading policy, and the Company does not waive the potential violation of the policy or otherwise permit the sale, or allow the Participant to surrender shares of Common Stock to the Company in satisfaction of any exercise price and/or any withholding obligations under Section 9(h), then the Option or SAR will terminate on the earlier of (i) the expiration of a period of months (that need not be consecutive) equal to the applicable post-termination exercise period after the termination of the Participant's Continuous Service during which the sale of the Common Stock received upon exercise of the Option or SAR would not be in violation of the Company's insider trading policy, or (ii) the expiration of the term of the Option or SAR as set forth in the applicable Award Document.

(i) **Disability of Participant**. Except as otherwise provided in the applicable Award Document, or other agreement between the Participant and the Company, if a Participant's Continuous Service terminates as a result of the Participant's Disability, the Participant may exercise his or her Option or SAR (to the extent that the Participant was entitled to exercise such Option or SAR as of the date of termination of Continuous Service), but only within such period of time ending on the earlier of (i) the date 12 months following such termination of Continuous Service, and (ii) the expiration of the term of the Option or SAR as set forth in the applicable Award Document. If, after termination of Continuous Service, the Participant does not exercise his or her Option or SAR within the applicable time frame, the Option or SAR (as applicable) will terminate.

(j) **Death of Participant**. Except as otherwise provided in the applicable Award Document, or other agreement between the Participant and the Company, if (i) a Participant's Continuous Service terminates as a result of the Participant's death, or (ii) the Participant dies within the period (if any) specified in this Plan or the applicable Award Document, or other agreement between the Participant and the Company, for exercisability after the termination of the Participant's Continuous Service (for a reason other than death), then the Option or SAR may be exercised (to the extent the Participant was entitled to exercise such Option or SAR as of the date of death) by the Participant's estate, by a person who acquired the right to exercise the Option or SAR by bequest or inheritance or by a person designated to exercise the Option or SAR upon the Participant's death, but only within the period ending on the earlier of (i) the date 18 months following the date of death, and (ii) the expiration of the term of such Option or SAR as set forth in the applicable Award Document. If, after the Participant's death, the Option or SAR is not exercised within the applicable time frame, the Option or SAR will terminate.

(k) **Termination for Cause**. Except as explicitly provided otherwise in a Participant's Award Document or other individual written agreement between the Company or any Affiliate and the Participant, if a Participant's Continuous Service is terminated for Cause, the Option or SAR will terminate upon the date on which the event giving rise to the termination for Cause first occurred, and the Participant will be prohibited from exercising his or her Option or SAR from and after the date on which the event giving rise to the termination for Cause first occurred (or, if required by law, the date of termination of Continuous Service). If a Participant's Continuous Service is suspended pending an investigation of the existence of Cause, all of the Participant's rights under the Option or SAR will also be suspended during the investigation period.

(i) **Non-Exempt Employees**. If an Option or SAR is granted to an Employee who is a non-exempt employee for purposes of the U.S. Fair Labor Standards Act of 1938, as amended, the Option or SAR will not be first exercisable for any shares of Common Stock until at least 6 months following the date of grant of the Option or SAR (although the Award may vest prior to such date). Consistent with the provisions of the U.S. Worker Economic Opportunity Act, (i) if such non-exempt Employee dies or suffers a Disability, (ii) upon a Change in Control in which such Option or SAR is not assumed, continued, or substituted, or (iii) upon the non-exempt Employee's retirement (as such term may be defined in the non-exempt Employee's applicable Award Document, in another agreement between the non-exempt Employee and the Company, or, if no such definition, in accordance with the Company's then current employment policies and guidelines), the vested portion of any Options and SARs may be exercised earlier than 6 months following the date of grant. The foregoing provision is intended to operate so that any income derived by a non-exempt Employee in connection with the exercise or vesting of an Option or SAR will be exempt from his or her regular rate of pay. To the extent permitted and/or required for compliance with the U.S. Worker Economic Opportunity Act to ensure that any income derived by a non-exempt Employee in connection with the exercise, vesting or issuance of any shares under any other Stock Award will be exempt from such employee's regular rate of pay, the provisions of this paragraph will apply to all Stock Awards and are hereby incorporated by reference into such Stock Award Documents.

6. PROVISIONS OF STOCK AWARDS OTHER THAN OPTIONS AND SARS.

(a) **Restricted Stock Awards**. Each Restricted Stock Award Document will be in such form and will contain such terms and conditions as the Board deems appropriate. To the extent consistent with the Company's bylaws, at the Board's election, shares of Common Stock may be (x) held in book entry form subject to the Company's instructions until any restrictions relating to the Restricted Stock Award lapse, or (y) evidenced by a certificate, which certificate will be held in such form and manner as determined by the Board. The terms and conditions of Restricted Stock Award Documents may change from time to time, and the terms and conditions of separate Restricted Stock Award Documents need not be identical. Each Restricted Stock Award Document will conform to (through incorporation of the provisions hereof by reference in the agreement or otherwise) the substance of each of the following provisions:

(i) Consideration. A Restricted Stock Award may be awarded in consideration for (A) cash, check, bank draft or money order payable to the Company, (B) past services to the Company or an Affiliate, or (C) any other form of legal consideration (including future services) that may be acceptable to the Board, in its sole discretion, and permissible under applicable law.

(ii) Vesting. Shares of Common Stock awarded under the Restricted Stock Award Document may be subject to forfeiture to the Company in accordance with a vesting schedule and subject to such conditions as may be determined by the Board.

(iii) Termination of Participant's Continuous Service. If a Participant's Continuous Service terminates, the Company may receive through a forfeiture condition or a repurchase right, any or all of the shares of Common Stock held by the Participant that have not vested as of the date of termination of Continuous Service under the terms of the Restricted Stock Award Document.

(iv) Transferability. Common Stock issued pursuant to an Award, and rights to acquire shares of Common Stock under the Restricted Stock Award Document, will be transferable by the Participant only upon such terms and conditions as are set forth in the Restricted Stock Award Document, as the Board determines in its sole discretion, so long as such Common Stock remains subject to the terms of the Restricted Stock Award Document.

(v) Dividends. Any dividends paid on Restricted Stock will be subject to the same vesting and forfeiture restrictions as apply to the shares subject to the Restricted Stock Award to which they relate.

(b) **Restricted Stock Unit Awards**. Each Restricted Stock Unit Award Document will be in such form and will contain such terms and conditions as the Board deems appropriate. The terms and conditions of Restricted Stock Unit Award Documents may change from time to time, and the terms and conditions of separate Restricted Stock Unit Award Documents need not be identical. Each Restricted Stock Unit Award Document will conform to (through incorporation of the provisions hereof by reference in the Agreement or otherwise) the substance of each of the following provisions:

(i) Consideration. At the time of grant of a Restricted Stock Unit Award, the Board will determine the consideration, if any, to be paid by the Participant upon delivery of each share of Common Stock subject to the Restricted Stock Unit Award. The consideration to be paid (if any) by the Participant for each share of Common Stock subject to a Restricted Stock Unit Award may be paid in any form of legal consideration that may be acceptable to the Board, in its sole discretion, and permissible under applicable law.

(ii) Vesting. At the time of the grant of a Restricted Stock Unit Award, the Board may impose such restrictions on or conditions to the vesting of the Restricted Stock Unit Award as it, in its sole discretion, deems appropriate.

(iii) Payment. A Restricted Stock Unit Award may be settled by the delivery of shares of Common Stock, their cash equivalent, any combination thereof or in any other form of consideration, as determined by the Board and contained in the Restricted Stock Unit Award Document.

(iv) Additional Restrictions. At the time of the grant of a Restricted Stock Unit Award, the Board, as it deems appropriate, may impose such restrictions or conditions that delay the delivery of the shares of Common Stock (or their cash equivalent) subject to a Restricted Stock Unit Award to a time after the vesting of such Restricted Stock Unit Award.

(v) Dividend Equivalents. Dividend equivalents may be credited in respect of shares of Common Stock covered by a Restricted Stock Unit Award, as determined by the Board and contained in the Restricted Stock Unit Award Document. At the sole discretion of the Board, such dividend equivalents may be converted into additional shares of Common Stock covered by the Restricted Stock Unit Award in such manner as determined by the Board. Any dividend equivalents and/or additional shares covered by the Restricted Stock Unit Award credited by reason of such dividend equivalents will be subject to all of the same terms and conditions of the underlying Restricted Stock Unit Award Document to which they relate.

(vi) Termination of Participant's Continuous Service. Except as otherwise provided in the applicable Restricted Stock Unit Award Document, or other agreement between the Participant and the Company, such portion of the Restricted Stock Unit Award that has not vested will be forfeited upon the Participant's termination of Continuous Service.

(c) **Performance Awards**.

(i) Performance Stock Awards. A Performance Stock Award is a Stock Award that is payable (including that may be granted, vest or exercised) contingent upon the attainment during a Performance Period of the achievement of certain performance goals. A Performance Stock Award may, but need not, require the completion of a specified period of Continuous Service. The length of any Performance Period, the performance goals to be achieved during the Performance Period, and the measure of whether and to what degree such performance goals have been attained will be conclusively determined by the Committee, the Board, or an authorized Officer, in its sole discretion. In addition, to the extent permitted by applicable law and the applicable Award Document, the Board may determine that cash may be used in payment of Performance Stock Awards.

(ii) Performance Cash Awards. A Performance Cash Award is a cash award that is granted and/or becomes payable contingent upon the attainment during a Performance Period of the achievement of certain performance goals. A Performance Cash Award may also require the completion of a specified period of Continuous Service. At the time of grant of a Performance Cash Award, the length of any Performance Period, the performance goals to be achieved during the Performance Period, and the measure of whether and to what degree such performance goals have been attained will be conclusively determined by the Committee, the Board, or an authorized Officer, in its sole discretion. The Board may specify the form of payment of Performance Cash Awards, which may be cash or other property, or may provide for a Participant to have the option for his or her Performance Cash Award, or such portion thereof as the Board may specify, to be paid in whole or in part in cash or other property.

(iii) Board Discretion. The Committee, the Board, or an authorized Officer, as the case may be, retains the discretion to reduce or eliminate the compensation or economic benefit due upon attainment of performance goals and to define the manner of calculating the performance criteria it selects to use for a Performance Period.

7. COVENANTS OF THE COMPANY.

(a) **Availability of Shares**. The Company will keep available at all times the number of shares of Common Stock reasonably required to satisfy then-outstanding Stock Awards.

(b) **Securities Law Compliance**. The Company will seek to obtain from each regulatory commission or agency having jurisdiction over this Plan such authority as may be required to grant Stock Awards and to issue and sell shares of Common Stock upon exercise of the Stock Awards; provided, however, that this undertaking will not require the Company to register under the Securities Act this Plan, any Stock Award or any Common Stock issued or issuable pursuant to any such Stock Award. If, after reasonable efforts and at a reasonable cost, the Company is unable to obtain from any such regulatory commission or agency the authority

that counsel for the Company deems necessary for the lawful issuance and sale of Common Stock under this Plan, the Company will be relieved from any liability for failure to issue and sell Common Stock upon exercise of such Stock Awards unless and until such authority is obtained. A Participant will not be eligible for the grant of an Award or the subsequent issuance of cash or Common Stock pursuant to the Award if such grant or issuance would be in violation of any applicable securities law.

(c) **No Obligation to Notify or Minimize Taxes**. The Company will have no duty or obligation to any Participant to advise such holder as to the time or manner of exercising such Stock Award. Furthermore, the Company will have no duty or obligation to warn or otherwise advise such holder of a pending termination or expiration of an Award or a possible period in which the Award may not be exercised. The Company has no duty or obligation to, and does not undertake to, provide tax advice or to minimize the tax consequences of an Award to the holder of such Award.

8. MISCELLANEOUS.

(a) **Use of Proceeds from Sales of Common Stock**. Proceeds from the sale of shares of Common Stock pursuant to Stock Awards will constitute general funds of the Company.

(b) **Corporate Action Constituting Grant of Awards**. Corporate action constituting a grant by the Company of an Award to any Participant will be deemed completed as of the latest date that all necessary corporate action has occurred and all material terms of the Award (including, in the case of stock options, the exercise price thereof) are fixed, unless otherwise determined by the Board, regardless of when the documentation evidencing the Award is communicated to, or actually received or accepted by, the Participant. In the event that the corporate records (e.g., Board consents, resolutions or minutes) documenting the corporate action constituting the grant contain terms (e.g., exercise price, vesting schedule or number of shares) that are inconsistent with those in the Award Document as a result of a clerical error in the papering of the Award Document, the corporate records will control and the Participant will have no legally binding right to the incorrect term in the Award Document.

(c) **Stockholder Rights**. No Participant will be deemed to be the holder of, or to have any of the rights of a holder with respect to, any shares of Common Stock subject to a Stock Award unless and until (i) such Participant has satisfied all requirements for exercise of, or the issuance of shares of Common Stock under, the Stock Award pursuant to its terms, and (ii) the issuance of the Common Stock subject to such Stock Award has been entered into the books and records of the Company.

(d) **No Employment or Other Service Rights**. Nothing in this Plan, any Award Document or any other instrument executed thereunder or in connection with any Award granted pursuant thereto will confer upon any Participant any right to continue to serve the Company or an Affiliate in the capacity in effect at the time the Award was granted or any other capacity or will affect the right of the Company or an Affiliate to terminate (i) the employment of an Employee with or without notice and with or without cause, including, but not limited to, Cause, (ii) the service of a Consultant pursuant to the terms of such Consultant's agreement with the Company or an Affiliate, or (iii) the service of a Director pursuant to the organizational documents of the Company or an Affiliate (including articles of incorporation and bylaws), and any applicable provisions of the corporate law of the state in which the Company or the Affiliate is incorporated, as the case may be.

(e) **Change in Time Commitment**. In the event a Participant's regular level of time commitment in the performance of his or her services for the Company and any Affiliates is reduced (for example, and without limitation, if the Participant is an Employee of the Company and the Employee has a change in status from a full-time Employee to a part-time Employee or takes an extended leave of absence), or the Participant's role or primary responsibilities are changed to a level that, in the Board's determination does not justify the Participant's unvested Awards, and such reduction or change occurs after the date of grant of any Award to the Participant, the Board has the right in its sole discretion to (i) make a corresponding reduction in the number of shares or cash amount subject to any portion of such Award that is scheduled to vest or become payable after the date of such change in time commitment, and (ii) in lieu of or in combination with such a reduction, extend the vesting or payment schedule applicable to such Award. In the event of any such reduction, the Participant will have no right with respect to any portion of the Award that is so reduced or extended.

(f) **Incentive Stock Option Limitations**. To the extent that the aggregate Fair Market Value (determined at the time of grant) of Common Stock with respect to which Incentive Stock Options are exercisable for the first time by any Optionholder during any calendar year (under all plans of the Company and any Affiliates) exceeds USD$100,000 (or such other limit established in the Code) or otherwise does not comply with the rules governing Incentive Stock Options, the Options or portions thereof that exceed such limit (according to the order in which they were granted) or otherwise do not comply with such rules will be treated as Nonstatutory Stock Options, notwithstanding any contrary provision of the applicable Option Agreement(s).

(g) **Investment Assurances**. The Company may require a Participant, as a condition of exercising or acquiring Common Stock under any Stock Award, (i) to give written assurances satisfactory to the Company as to the Participant's knowledge and experience in financial and business matters and/or to employ a purchaser representative reasonably satisfactory to the Company who is knowledgeable and experienced in financial and business matters and that he or she is capable of evaluating, alone or together with the purchaser representative, the merits and risks of exercising the Stock Award, and (ii) to give written assurances satisfactory to the Company stating that the Participant is acquiring Common Stock subject to the Stock Award for the Participant's own account and not with any present intention of selling or otherwise distributing the Common Stock. The foregoing requirements, and any assurances given pursuant to such requirements, will be inoperative if (i) the issuance of the shares upon the exercise of a Stock Award or acquisition of Common Stock under the Stock Award has been registered under a then currently effective registration statement under the Securities Act, or (ii) as to any particular requirement, a determination is made by counsel for the Company that such requirement need not be met in the circumstances under the then applicable securities laws. The Company may, upon advice of counsel to the Company, place legends on stock certificates issued under this Plan as such counsel deems necessary or appropriate in order to comply with applicable securities laws, including, but not limited to, legends restricting the transfer of the Common Stock.

(h) **Withholding Obligations**. Unless prohibited by the terms of an Award Document, the Company may, in its sole discretion, satisfy any national, state, local or other tax withholding obligation relating to an Award by any of the following means or by a combination of such means: (i) causing the Participant to tender a cash payment; (ii) withholding shares of Common Stock from the shares of Common Stock issued or otherwise issuable to the Participant in connection with the Award (only up to the amount permitted that will not cause an adverse accounting consequence or cost); (iii) withholding cash from an Award settled in cash; (iv) withholding payment from any amounts otherwise payable to the Participant, including proceeds from the sale of shares of Common Stock issued pursuant to a Stock Award; or (v) by such other method as may be set forth in the Award Document.

(i) **Electronic Delivery**. Any reference herein to a "written" agreement or document will include any agreement or document delivered electronically, filed publicly at www.sec.gov (or any successor website thereto), or posted on the Company's intranet (or other shared electronic medium controlled by the Company to which the Participant has access).

(j) **Deferrals**. To the extent permitted by applicable law, the Board, in its sole discretion, may determine that the delivery of Common Stock or the payment of cash, upon the exercise, vesting or settlement of all or a portion of any Award may be deferred and may establish programs and procedures for deferral elections to be made by Participants. Deferrals by Participants will be made in accordance with Section 409A of the Code (to the extent applicable to a Participant). Consistent with Section 409A of the Code, the Board may provide for distributions while a Participant is still an employee or otherwise providing services to the Company. The Board is authorized to make deferrals of Awards and determine when, and in what annual percentages, Participants may receive payments, including lump sum payments, following the Participant's termination of Continuous Service, and implement such other terms and conditions consistent with the provisions of this Plan and in accordance with applicable law.

(k) **Compliance with Section 409A**. Unless otherwise expressly provided for in an Award Document, or other agreement between the Participant and the Company, this Plan and Award Documents will be interpreted to the greatest extent possible in a manner that makes this Plan and the Awards granted hereunder exempt from Section 409A of the Code, to the extent that Section 409A of the Code is applicable to an Award, and, to the extent not so exempt, in compliance with Section 409A of the Code. If the Board determines that any Award granted hereunder is subject to Section 409A of the Code, the Award Document evidencing such Award will incorporate the terms and conditions necessary to avoid the consequences specified in Section 409A(a)(1) of the Code, and to the extent an Award Document is silent on terms necessary for compliance, such terms are hereby incorporated by reference into the Award Document. Notwithstanding anything to the contrary in this Plan (and unless the Award Document specifically provides otherwise), if the shares of Common Stock are publicly traded, and if a Participant holding an Award that constitutes "deferred compensation" under Section 409A of the Code is a "specified employee" for purposes of Section 409A of the Code and the Participant is otherwise subject to Section 409A of the Code, no distribution or payment of any amount that is due because of a "separation from service" (as defined in Section 409A of the Code without regard to alternative definitions thereunder) will be issued or paid before the date that is six (6) months following the date of such Participant's "separation from service" or, if earlier, the date of the Participant's death, unless such distribution or payment can be made in a manner that complies with Section 409A of the Code, and any amounts so deferred will be paid in a lump sum on the day after such six (6) month period elapses, with the balance paid thereafter on the original schedule.

(i) **Clawback/Recovery**. All Awards granted under this Plan will be subject to recoupment in accordance with any clawback policy that the Company is required to adopt pursuant to the listing standards of any national securities exchange or association on which the Company's securities are listed or as is otherwise required by the Dodd-Frank Wall Street Reform and Consumer Protection Act or other applicable law. In addition, the Board may impose such other clawback, recovery or recoupment provisions in an Award Document as the Board determines necessary or appropriate, including, but not limited to, a reacquisition right in respect of previously acquired shares of Common Stock or other cash or property upon the occurrence of Cause. No recovery of compensation under such a clawback policy will be an event giving rise to a right to resign for "good reason" or "constructive termination" (or similar term) under any agreement with the Company or an Affiliate.

9. ADJUSTMENTS UPON CHANGES IN COMMON STOCK; OTHER CORPORATE EVENTS.

(a) **Capitalization Adjustments**. In the event of a Capitalization Adjustment, the Board will appropriately and proportionately adjust: (i) the class(es) and maximum number of securities subject to this Plan pursuant to Section 3(a); (ii) the class(es) and maximum number of securities that may be issued pursuant to the exercise of Incentive Stock Options pursuant to Section 3(c); and (iii) the class(es) and number of securities or other property and value (including price per share of stock) subject to outstanding Stock Awards. The Board will make such adjustments, and its determination will be final, binding and conclusive.

(b) **Dissolution or Liquidation**. Except as otherwise provided in the Stock Award Document, or other agreement between the Participant and the Company, in the event of a dissolution or liquidation of the Company, all outstanding Stock Awards (other than Stock Awards consisting of vested and outstanding shares of Common Stock not subject to a forfeiture condition or the Company's right of repurchase) will terminate immediately prior to the completion of such dissolution or liquidation, and the shares of Common Stock subject to the Company's repurchase rights or subject to a forfeiture condition may be repurchased or reacquired by the Company notwithstanding the fact that the holder of such Stock Award is providing Continuous Service; provided, however, that the Board may, in its sole discretion, cause some or all Stock Awards to become fully vested, exercisable and/or no longer subject to repurchase or forfeiture (to the extent such Stock Awards have not previously expired or terminated) before the dissolution or liquidation is completed but contingent on its completion.

(c) **Change in Control**. The following provisions will apply to Awards in the event of a Change in Control unless otherwise provided in the instrument evidencing the Award or any other written agreement between the Company or any Affiliate and the Participant or unless otherwise expressly provided by the Board at the time of grant of an Award. In the event of a Change in Control, then, notwithstanding any other provision of this Plan, the Board will take one or more of the following actions with respect to each outstanding Award, contingent upon the closing or completion of the Change in Control:

(i) arrange for the surviving corporation or acquiring corporation (or the surviving or acquiring corporation's parent company) to assume or continue the Award or to substitute a similar award for the Award (including, but not limited to, an award to acquire the same consideration per share paid to the stockholders of the Company pursuant to the Change in Control);

(ii) arrange for the assignment of any reacquisition or repurchase rights held by the Company in respect of Common Stock issued pursuant to the Award to the surviving corporation or acquiring corporation (or the surviving or acquiring corporation's parent company);

(iii) accelerate the vesting, in whole or in part, of the Award (and, if applicable, the time at which the Award may be exercised) to a date prior to the effective time of such Change in Control as the Board will determine (or, if the Board will not determine such a date, to the date that is 5 days prior to the effective date of the Change in Control), with such Award terminating if not exercised (if applicable) at or prior to the effective time of the Change in Control, and with such exercise reversed if the Change in Control does not become effective;

(iv) arrange for the lapse, in whole or in part, of any reacquisition or repurchase rights held by the Company with respect to the Award;

(v) cancel or arrange for the cancellation of the Award, to the extent not vested or not exercised prior to the effective time of the Change in Control, in exchange for such cash consideration, if any, as the Board, in its reasonable determination, may consider appropriate as an approximation of the value of the canceled Award, taking into account the value of the Common Stock subject to the canceled Award, the possibility that the Award might not otherwise vest in full, and such other factors as the Board deems relevant; and

(vi) cancel or arrange for the cancellation of the Award, to the extent not vested or not exercised prior to the effective time of the Change in Control, in exchange for a payment, in such form as may be determined by the Board equal to the excess, if any, of (A) the value in the Change in Control of the property the Participant would have received upon the exercise of the Award immediately prior to the effective time of the Change in Control, over (B) any exercise price payable by such holder in connection with such exercise.

The Board need not take the same action or actions with respect to all Awards or portions thereof or with respect to all Participants. The Board may take different actions with respect to the vested and unvested portions of an Award.

In the absence of any affirmative determination by the Board at the time of a Change in Control, each outstanding Award will be assumed or an equivalent Award will be substituted by such successor corporation or a parent or subsidiary of such successor corporation (the "**Successor Corporation**"), unless the Successor Corporation does not agree to assume the Award or to substitute an equivalent Award, in which case the vesting of such Award will accelerate in its entirety (along with, if applicable, the time at which the Award may be exercised) to a date prior to the effective time of such Change in Control as the Board will determine (or, if the Board will not determine such a date, to the date that is 5 days prior to the effective date of the Change in Control), with such Award terminating if not exercised (if applicable) at or prior to the effective time of the Change in Control, and with such exercise reversed if the Change in Control does not become effective.

(d) **Acceleration of Awards upon a Change in Control**. An Award may be subject to additional acceleration of vesting and exercisability upon or after a Change in Control as may be provided in the Award Document for such Award or as may be provided in any other written agreement between the Company or any Affiliate and the Participant, but in the absence of such provision, no such acceleration will occur.

10. TERMINATION OR SUSPENSION OF THIS PLAN.

The Board or the Compensation Committee may suspend or terminate this Plan at any time. This Plan will have no fixed expiration date; provided, however, that no Incentive Stock Option may be granted more than 10 years after the later of (i) the Adoption Date and (ii) the adoption by the Board of any amendment to this Plan that constitutes the adoption of a new plan for purposes of Section 422 of the Code. No Awards may be granted under this Plan while this Plan is suspended or after it is terminated.

11. EFFECTIVE DATE OF PLAN; TIMING OF FIRST GRANT OR EXERCISE.

This Plan shall come into existence on the Effective Date and no Award may be granted under this Plan prior to the Effective Date. In addition, no Stock Award may be exercised (or, in the case of a Restricted Stock Award, Restricted Stock Unit Award, or Performance Stock Award, may be granted) and no Performance Cash Award may be settled unless and until this Plan has been approved by the stockholders of the Company, which approval will be within 12 months before or after the Adoption Date.

12. CHOICE OF LAW.

The laws of the State of Delaware will govern all questions concerning the construction, validity and interpretation of this Plan, without regard to that state's conflict of laws rules.

13. DEFINITIONS.

As used in this Plan, the following definitions will apply to the capitalized terms indicated below:

(a) "**Adoption Date**" means the date this Plan is originally adopted by the Board.

(b) "**Affiliate**" means, at the time of determination, any "parent" or "subsidiary" of the Company, as such terms are defined in Rule 405 of the Securities Act. The Board will have the authority to determine the time or times at which "parent" or "subsidiary" status is determined within the foregoing definition.

(c) "**Award**" means a Stock Award or a Performance Cash Award.

(d) "**Award Document**" means a written agreement between the Company and a Participant, or a written notice issued by the Company to a Participant, evidencing the terms and conditions of an Award.

(e) "**Board**" means the Board of Directors of the Company.

(f) "**Capital Stock**" means each and every class of common stock of the Company, regardless of the number of votes per share.

(g) "**Capitalization Adjustment**" means any change that is made in, or other events that occur with respect to, the Common Stock subject to this Plan or subject to any Stock Award after the Adoption Date without the receipt of consideration by the Company through merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, large nonrecurring cash dividend, stock split, reverse stock split, liquidating dividend, combination of shares, exchange of shares, change in corporate structure or other similar equity restructuring transaction, as that term is used in Financial Accounting Standards Board Accounting Standards Codification Topic 718 (or any successor thereto). Notwithstanding the foregoing, the conversion of any convertible securities of the Company will not be treated as a Capitalization Adjustment.

(h) "**Cause**" will have the meaning ascribed to such term in any written agreement between the Participant and the Company or any Affiliate defining such term and, in the absence of such agreement, such term means, with respect to a Participant, the occurrence of any of the following events: (i) Participant's failure substantially to perform his or her duties and responsibilities to the Company or any Affiliate or violation of a policy of the Company or any Affiliate; (ii) Participant's commission of any act of fraud, embezzlement, dishonesty or any other misconduct that has caused or is reasonably expected to result in injury to the Company or any Affiliate; (iii) unauthorized use or disclosure by Participant of any proprietary information or trade secrets of the Company or any other party to whom the Participant owes an obligation of nondisclosure as a result of his or her relationship with the Company or any Affiliate; or (iv) Participant's breach of any of his or her obligations under any written agreement or covenant with the Company or any Affiliate. The determination as to whether a Participant is being terminated for Cause will be made in good faith by the Company and will be final and binding on the Participant. Any determination by the Company that the Continuous Service of a Participant was terminated with or without Cause for the purposes of outstanding Awards held by such Participant will have no effect upon any determination of the rights or obligations of the Company, any Affiliate or such Participant for any other purpose.

(i) "**Change in Control**" means the occurrence, in a single transaction or in a series of related transactions, of any one or more of the following events:

(i) any Exchange Act Person becomes the Owner, directly or indirectly, of securities of the Company representing more than 50% of the combined voting power of the Company's then outstanding securities other than by virtue of a merger, consolidation or similar transaction. Notwithstanding the foregoing, a Change in Control will not be deemed to occur (A) on account of the acquisition of securities of the Company directly from the Company, (B) on account of the acquisition of securities of the Company by an investor, any affiliate thereof or any

other Exchange Act Person that acquires the Company's securities in a transaction or series of related transactions the primary purpose of which is to obtain financing for the Company through the issuance of equity securities or (C) solely because the level of Ownership held by any Exchange Act Person (the "**Subject Person**") exceeds the designated percentage threshold of the outstanding voting securities as a result of a repurchase or other acquisition of voting securities by the Company reducing the number of shares outstanding, provided that if a Change in Control would occur (but for the operation of this sentence) as a result of the acquisition of voting securities by the Company, and after such share acquisition, the Subject Person becomes the Owner of any additional voting securities that, assuming the repurchase or other acquisition had not occurred, increases the percentage of the then outstanding voting securities Owned by the Subject Person over the designated percentage threshold, then a Change in Control will be deemed to occur;

(ii) there is consummated a merger, consolidation or similar transaction involving (directly or indirectly) the Company and, immediately after the consummation of such merger, consolidation or similar transaction, the stockholders of the Company immediately prior thereto do not Own, directly or indirectly, either (A) outstanding voting securities representing 50% or more of the combined outstanding voting power of the surviving Entity in such merger, consolidation or similar transaction or (B) 50% or more of the combined outstanding voting power of the parent of the surviving Entity in such merger, consolidation or similar transaction, in each case in substantially the same proportions as their Ownership of the outstanding voting securities of the Company immediately prior to such transaction;

(iii) there is consummated a sale, lease, license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries, other than a sale, lease, license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries to an Entity, more than 50% of the combined voting power of the voting securities of which are Owned by stockholders of the Company in substantially the same proportions as their Ownership of the outstanding voting securities of the Company immediately prior to such sale, lease, license or other disposition; or

(iv) individuals who, on the Adoption Date, are members of the Board (the "**Incumbent Board**") cease for any reason to constitute at least a majority of the members of the Board; provided, however, that if the appointment or election (or nomination for election) of any new Board member was approved or recommended by a majority vote of the members of the Incumbent Board then still in office, such new member will, for purposes of this Plan, be considered as a member of the Incumbent Board.

Notwithstanding the foregoing definition or any other provision of this Plan, (A) the term Change in Control will not include a sale of assets, merger or other transaction effected exclusively for the purpose of changing the domicile of the Company, and (B) the definition of Change in Control (or any analogous term) in an individual written agreement between the Company or any Affiliate and the Participant will supersede the foregoing definition with respect to Awards subject to such agreement; provided, however, that if no definition of Change in Control or any analogous term is set forth in such an individual written agreement, the foregoing definition will apply.

If required for compliance with Section 409A of the Code, in no event will a Change in Control be deemed to have occurred if such transaction is not also a "change in the ownership or effective control of" the Company or "a change in the ownership of a substantial portion of the assets of" the Company as determined under U.S. Treasury Regulation Section 1.409A-3(i)(5) (without regard to any alternative definition thereunder). The Board may, in its sole discretion and without a Participant's consent, amend the definition of "Change in Control" to conform to the definition of "Change in Control" under Section 409A of the Code, and the regulations thereunder.

(j) "**Code**" means the U.S. Internal Revenue Code of 1986, as amended, including any applicable regulations and guidance thereunder.

(k) "**Committee**" means a committee of one (1) or more Directors to whom authority has been delegated by the Board in accordance with Section 2(c).

(l) "**Compensation Committee**" means the Compensation Committee of the Board.

(m) "**Common Stock**" means the common stock of the Company.

(n) "**Company**" 89bio, Inc., a Delaware corporation.

(o) "**Consultant**" means any person, including an advisor, who is (i) engaged by the Company or an Affiliate to render consulting or advisory services and is compensated for such services, or (ii) serving as a member of the board of directors of an Affiliate and is compensated for such services. However, service solely as a Director, or payment of a fee for such service, will not cause a Director to be considered a "Consultant" for purposes of this Plan. Notwithstanding the foregoing, a person is treated as a Consultant under this Plan only if a Form Registration Statement on Form S-8 or a successor form under the Securities Act is available to register either the offer or the sale of the Company's securities to such person.

(p) "**Continuous Service**" means that the Participant's service with the Company or an Affiliate, whether as an Employee, Director or Consultant, is not interrupted or terminated. A change in the capacity in which the Participant renders service to the Company or an Affiliate as an Employee, Consultant or Director or a change in the Entity for which the Participant renders such service, provided that there is no interruption or termination of the Participant's service with the Company or an Affiliate, will not terminate a Participant's Continuous Service. For example, a change in status from an Employee of the Company to a Consultant of an Affiliate or to a Director will not constitute an interruption of Continuous Service. If the Entity for which a Participant is rendering services ceases to qualify as an Affiliate, as determined by the Board in its sole discretion, such Participant's Continuous Service will be considered to have terminated on the date such Entity ceases to qualify as an Affiliate. To the extent permitted by law, the Board or the chief executive officer of the Company, in that party's sole discretion, may determine whether Continuous Service will be considered interrupted in the case of (i) any leave of absence approved by the Board or chief executive officer, including sick leave, military leave or any other personal leave, or (ii) transfers between the Company, an Affiliate, or their successors. In addition, if required for exemption from or compliance with Section 409A of the Code, the determination of whether there has been a termination of Continuous Service will be made, and such term will be construed, in a manner that is consistent with the definition of "separation from service" as defined under U.S. Treasury Regulation Section 1.409A-1(h) (without regard to any alternative definition thereunder). A leave of absence will be treated as Continuous Service for purposes of vesting in a Stock Award only to such extent as may be provided in the applicable Award Document, the Company's leave of absence policy, in the written terms of any leave of absence agreement or policy applicable to the Participant, or as otherwise required by law.

(q) "**Director**" means a member of the Board.

(r) "**Disability**" means, with respect to a Participant, the inability of such Participant to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment that can be expected to result in death or that has lasted or can be expected to last for a continuous period of not less than 12 months as provided in Sections 22(e)(3) and 409A(a)(2)(C)(i) of the Code, and will be determined by the Board on the basis of such medical evidence as the Board deems warranted under the circumstances.

(s) "**Effective Date**" means September 17, 2019.

(t) "**Employee**" means any person providing services as an employee of the Company or an Affiliate. However, service solely as a Director, or payment of a fee for such services, will not cause a Director to be considered an "Employee" for purposes of this Plan.

(u) "**Entity**" means a corporation, partnership, limited liability company or other entity.

(v) "**Exchange Act**" means the U.S. Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

(w) "**Exchange Act Person**" means any natural person, Entity or "group" (within the meaning of Section 13(d) or 14(d) of the Exchange Act), except that "Exchange Act Person" will not include (i) the Company or any Subsidiary of the Company, (ii) any employee benefit plan of the Company or any Subsidiary of the Company or any trustee or other fiduciary holding securities under an employee benefit plan of the Company or any Subsidiary of the Company, (iii) an underwriter temporarily holding securities pursuant to a registered public offering of such securities, (iv) an Entity Owned, directly or indirectly, by the stockholders of the Company in substantially the same proportions as their Ownership of stock of the Company, or (v) any natural person, Entity or "group" (within the meaning of Section 13(d) or 14(d) of the Exchange Act) that, as of the Effective Date, is the Owner, directly or indirectly, of securities of the Company representing more than 50% of the combined voting power of the Company's then outstanding securities.

(x) "**Fair Market Value**" means, as of any date, the value of the Common Stock determined as follows:

(i) If the Common Stock is listed on any established stock exchange or traded on any established market, the Fair Market Value of a share of Common Stock as of any date of determination will be, unless otherwise determined by the Board, the closing sales price for such stock as quoted on such exchange or market (or the exchange or market with the greatest volume of trading in the Common Stock) on the date of determination, as reported in a source the Board deems reliable.

(ii) Unless otherwise provided by the Board, if there is no closing sales price for the Common Stock on the date of determination, then the Fair Market Value will be the closing selling price on the last preceding date for which such quotation exists.

(iii) In the absence of such markets for the Common Stock, the Fair Market Value will be determined by the Board in good faith and in a manner that complies with Sections 409A and 422 of the Code.

(y) "**Incentive Stock Option**" means an option granted pursuant to Section 5 of this Plan that is intended to be, and that qualifies as, an "incentive stock option" within the meaning of Section 422 of the Code.

(z) "**Non-Employee Director**" means a Director who either (i) is not a current employee or officer of the Company or an Affiliate, does not receive compensation, either directly or indirectly, from the Company or an Affiliate for services rendered as a consultant or in any capacity other than as a Director (except for an amount as to which disclosure would not be required under Item 404(a) of Regulation S-K promulgated pursuant to the Securities Act ("**Regulation S-K**")), does not possess an interest in any other transaction for which disclosure would be required under Item 404(a) of Regulation S-K, and is not engaged in a business relationship for which disclosure would be required pursuant to Item 404(b) of Regulation S-K; or (ii) is otherwise considered a "non-employee director" for purposes of Rule 16b-3 of the Exchange Act.

(aa) "**Nonstatutory Stock Option**" means any option granted pursuant to Section 5 of this Plan that does not qualify as an Incentive Stock Option.

(bb) "**Officer**" means a person who is an officer of the Company within the meaning of Section 16 of the Exchange Act.

(cc) "**Option**" means an Incentive Stock Option or a Nonstatutory Stock Option to purchase shares of Common Stock granted pursuant to this Plan.

(dd) "**Option Agreement**" means an Award Document evidencing the terms and conditions of an Option grant. Each Option Agreement will be subject to the terms and conditions of this Plan.

(ee) "**Optionholder**" means a person to whom an Option is granted pursuant to this Plan or, if applicable, such other person who holds an outstanding Option.

(ff) "**Own**," "**Owned**," "**Owner**," "**Ownership**" means a person or Entity will be deemed to "Own," to have "Owned," to be the "Owner" of, or to have acquired "Ownership" of securities if such person or Entity, directly or indirectly, through any contract, arrangement, understanding, relationship or otherwise, has or shares voting power, which includes the power to vote or to direct the voting, with respect to such securities.

(gg) "**Participant**" means a person to whom an Award is granted pursuant to this Plan or, if applicable, such other person who holds an outstanding Stock Award.

(hh) "**Performance Cash Award**" means an award of cash granted pursuant to the terms and conditions of Section 6(c)(ii).

(ii) "**Performance Period**" means the period of time selected by the Board over which the attainment of one or more performance goals will be measured for the purpose of determining a Participant's right to and the payment of a Stock Award or a Performance Cash Award. Performance Periods may be of varying and overlapping duration, at the sole discretion of the Board.

(jj) "**Performance Stock Award**" means a Stock Award granted under the terms and conditions of Section 6(c)(i).

(kk) "**Plan**" means this 2019 Equity Incentive Plan of 89bio, Inc., as amended and restated from time to time.

(ll) "**Restricted Stock Award**" means an award of shares of Common Stock which is granted pursuant to the terms and conditions of Section 6(a).

(mm) "**Restricted Stock Award Document**" means an Award Document evidencing the terms and conditions of a Restricted Stock Award grant. Each Restricted Stock Award Document will be subject to the terms and conditions of this Plan.

(nn) "**Restricted Stock Unit Award**" means a right to receive shares of Common Stock which is granted pursuant to the terms and conditions of Section 6(b).

(oo) "**Restricted Stock Unit Award Document**" means an Award Document evidencing the terms and conditions of a Restricted Stock Unit Award grant. Each Restricted Stock Unit Award Document will be subject to the terms and conditions of this Plan.

(pp) "**Securities Act**" means the U.S. Securities Act of 1933, as amended.

(qq) "**Stock Appreciation Right**" or "**SAR**" means a right to receive the appreciation on Common Stock that is granted pursuant to the terms and conditions of Section 5.

(rr) "**Stock Appreciation Right Award Document**" means an Award Document evidencing the terms and conditions of a Stock Appreciation Right grant. Each Stock Appreciation Right Award Document will be subject to the terms and conditions of this Plan.

(ss) "**Stock Award**" means any right to receive Common Stock granted under this Plan, including an Incentive Stock Option, a Nonstatutory Stock Option, a Restricted Stock Award, a Restricted Stock Unit Award, a Stock Appreciation Right, or a Performance Stock Award.

(tt) "**Stock Award Document**" means an Award Document evidencing the terms and conditions of a Stock Award grant. Each Stock Award Document will be subject to the terms and conditions of this Plan.

(uu) "**Subsidiary**" means, with respect to the Company, (i) any corporation of which more than 50% of the outstanding capital stock having ordinary voting power to elect a majority of the board of directors of such corporation (irrespective of whether, at the time, stock of any other class or classes of such corporation will have or might have voting power by reason of the happening of any contingency) is at the time, directly or indirectly, Owned by the Company, and (ii) any partnership, limited liability company or other entity in which the Company has a direct or indirect interest (whether in the form of voting or participation in profits or capital contribution) of more than 50%.

(vv) "**Ten Percent Stockholder**" means a person who Owns (or is deemed to Own pursuant to Section 424(d) of the Code) stock possessing more than 10% of the total combined voting power of all classes of stock of the Company or any Affiliate.

END OF DOCUMENT

89BIO, INC.

2019 EQUITY INCENTIVE PLAN
NOTICE OF GRANT OF STOCK OPTION
(UNITED STATES AWARD AGREEMENT)

Name of Optionee: _____

Notice of Grant

89bio, Inc. (the "Company") hereby grants to the Optionee named above the option to purchase shares (the "Option Shares") of the Company's common stock, par value $0.001 per share (the "Common Stock") upon the terms and subject to the conditions set forth in this Grant Notice, the 89bio, Inc. 2019 Equity Incentive Plan (the "Plan") and the Stock Option Agreement promulgated under such Plan, each as amended from time to time. This award of Option Shares is granted pursuant to the Plan and is subject to and qualified in its entirety by the Stock Option Agreement.

Grant Date:	[_____]
Vesting Commencement Date:	[_____]
Exercise Price:	[_____]
Option Shares:	[_____]
Expiration Date:	[_____] (subject to earlier expiration in accordance with the terms of the Stock Option Agreement)
Type of Option	[__] Incentive Stock Option
	[__] Nonstatutory Stock Option

Vesting Schedule

These Option Shares shall become vested and exercisable on the following basis:

- [_____]

subject in each case to Continuous Service through each such vesting date. If Optionee ceases Continuous Service for any or no reason before Optionee vests in any portion of the Stock Option, the unvested portion of the Stock Option and Optionee's right to acquire any shares of Common Stock pursuant to the unvested portion of the Stock Option will immediately terminate. However, notwithstanding anything herein to the contrary, the vesting of the Stock Option shall be subject to any vesting acceleration provisions applicable to the Stock Option contained in the Plan and/or any employment or service agreement, offer letter, severance agreement, or any other agreement between Optionee and the Company or any Affiliate or Subsidiary (such agreement, a "Separate Agreement").

Agreements

By your signature and the Company's signature below, you and the Company agree that this Stock Option is granted under and governed by the terms of the Plan and the Stock Option Agreement, all of which are attached hereto and incorporated herein by this reference. Capitalized terms used but not defined herein shall have the meanings given to them in the Plan or the Stock Option Agreement, as the case may be.

You further acknowledge that your rights to any Option Shares will be earned and become vested only as you provide Continuous Service to the Company over time, that the grant of this Stock Option is not consideration for service you rendered to the Company prior to the Grant Date, and that nothing herein or the attached documents confers upon you any right to continue your employment or other service relationship with the Company or any Affiliate or Subsidiary for any period of time, nor does it interfere in any way with your right or the Company's (or any Affiliate's or Subsidiary's) right to terminate that relationship at any time, for any reason or no reason, with or without Cause, and with or without advance notice, except as may be required by the terms of a Separate Agreement or in compliance with governing public law.

Except as otherwise set forth in the Stock Option Agreement, the vested portion of this Stock Option may be exercised for three months after termination of your Continuous Service to the Company (but in no event later than the Expiration Date). You are responsible for keeping track of these exercise periods following termination for any reason of your Continuous Service to the Company. The Company is not obligated to provide further notice of such periods.

"COMPANY"

89bio, Inc.

_____

[Name]
[Title]

"OPTIONEE"

_____

Name

_____

Signature

_____

Address

_____

Address

89BIO, INC.
2019 EQUITY INCENTIVE PLAN
STOCK OPTION AGREEMENT
(UNITED STATES AWARD AGREEMENT)

This Stock Option Agreement is made and entered into by and between 89bio, Inc., a Delaware corporation ("Company"), and the Optionee identified in the Notice of Grant of Stock Option ("Grant Notice") which is attached hereto ("Optionee").

1. **Grant of Stock Option.** Subject to the terms and conditions set forth herein, the Company hereby grants to Optionee a stock option (the "Stock Option") to purchase from the Company, at the Exercise Price set forth in the Grant Notice, the number of Option Shares set forth in the Grant Notice. This Option is intended to be an Incentive Stock Option or a Nonstatutory Stock Option as set forth on the Grant Notice. Capitalized terms not otherwise defined herein shall have the meanings set forth in the Plan or the Grant Notice.

2. **Incentive Stock Option.** If, and only to the extent, that this Stock Option is identified as an Incentive Stock Option on the Grant Notice, it is intended to qualify as an "incentive stock option" under Section 422 of the United States Internal Revenue Code of 1986, as amended (the "Code") provided, however (a) this Stock Option shall cease to qualify as an Incentive Stock Option under the Code to the extent it is exercised (i) more than three months after the date the Optionee ceases to be an Employee for any reason other than death or permanent and total disability (as defined in Section 22(e)(3) of the Code), (ii) more than 12 months after the date the Optionee ceases to be an Employee by reason of such permanent and total disability or (iii) after the Optionee has been on a leave of absence for more than three months, unless the Optionee's reemployment rights are guaranteed by statute or by contract; and (b) to the extent that the Stock Option (together with all other Company Incentive Stock Options held by Optionee) becomes exercisable for the first time during any calendar year for shares having a Fair Market Value greater than $100,000, the portion of such options which exceeds such amount will be treated as Nonstatutory Stock Options. If the Code is amended to provide for a different limitation from that set forth in this Section, such different limitation shall be deemed incorporated herein effective as of the date required or permitted by such amendment to the Code.

3. **Expiration of Stock Option.** The Stock Option shall expire and cease to be exercisable as of the earlier of (i) the Expiration Date set forth in the Grant Notice or (ii) the date specified below in connection with the Optionee's termination of Continuous Service:

(a) If the Optionee's Continuous Service terminates by reason of death or Disability, the Optionee (or the Optionee's estate, beneficiary or legal representative, as applicable) may exercise any portion of the Stock Option that is vested and exercisable at the time of such termination until the date that is twelve (12) months following the date of such termination. Any portion of the Stock Option that is not vested and exercisable at the time of such termination shall be forfeited and canceled as of the date of such termination.

(b) If the Optionee's Continuous Service terminates for any reason other than death, Disability, or Cause, the Optionee may exercise any portion of the Stock Option that is vested and exercisable at the time of such termination until the date that is three (3) months following the date of such termination. Any portion of the Stock Option that is not vested and exercisable at the time of such termination shall be forfeited and canceled as of the date of such termination.

(d) If the Optionee's Continuous Service is terminated by the Company for Cause, the entire Stock Option, whether or not then vested and exercisable, shall be immediately forfeited and canceled as of the date of such termination.

4. **Exercise.**

4.1 **Exercisability.** Subject to the terms and conditions of this Stock Option Agreement, the Stock Option shall become exercisable at such time or times, during such period and for such number of Option Shares as is set forth in the Grant Notice. Upon the expiration of the applicable exercise period or (if earlier) upon the expiration of the Stock Option term, the Stock Option shall terminate and cease to be outstanding for any Option Shares for which the Stock Option has not been exercised.

4.2 **Exercise Agreement.** Optionee may exercise the Stock Option by delivering to the Company, either in person or by certified or registered mail or such other manner as approved by the Company, a duly executed exercise agreement in a form approved by the Company from time to time for such exercises (the "Exercise Agreement"), and payment in full of the purchase price as provided in Section 4.3 of this Stock Option Agreement. A copy of the Exercise Agreement will be provided by the Company to Optionee upon request, and no exercise of this Stock Option may be effected without the Optionee's execution of such Exercise Agreement in the form approved by the Company and containing the provisions noted above.

4.3 **Payment of Purchase Price.** The purchase price for any Option Shares for which this Stock Option is exercised shall be paid in full in United States dollars at the time Optionee delivers to the Company the Exercise Agreement. The purchase price shall be paid in one or a combination of the following, to the extent permitted by the Company: (a) cash, check, bank draft or money order payable to the Company; (b) Common Stock; (c) through the delivery of a notice that Optionee has placed a market sell order with a broker acceptable to the Company with respect to shares of Common Stock then issuable upon exercise of the Stock Option, and that the broker has been directed to pay a sufficient portion of the net proceeds of the sale to the Company in satisfaction of the purchase price; *provided* that payment of such proceeds is then made to the Company at such time as may be required by the Company, but in any event not later than the settlement of such sale; or (d) net exercise (solely in the case of a Nonstatutory Stock Option). In addition to the purchase price, the Optionee shall pay the amount of tax required to be withheld (if any) by the Company or any Affiliate or Subsidiary as a result of the exercise of the Stock Option. The Optionee acknowledges that the Company shall have the right to deduct any taxes required to be withheld by law in connection with the exercise of the Stock Option from any amounts payable by it to the Optionee (including, without limitation, future cash wages).

4.4 **Issuance of Shares.** Fractional shares may not be exercised. Shares of Common Stock will be issued as soon as practical after exercise. Notwithstanding the above, the Company shall not be obligated to deliver any shares of Common Stock during any period when the Company determines that the exercisability of the Stock Option or the delivery of shares of Common Stock hereunder would violate any federal, state or other applicable laws. Until the consummation of an initial public offering of the Company's Common Stock ("IPO"), any shares of Common Stock acquired upon the exercise of the Stock Options shall be voted by an irrevocable proxy, in the form attached hereto as Exhibit A. Such proxy shall be signed by the Optionee as a pre-condition to the exercise of any portion of the Stock Options by the Optionee.

5. **Change in Control**. Unless otherwise provided in a Separate Agreement, upon the occurrence of a Change in Control, Sections 9(c) and 9(d) of the Plan shall control.

6. **Restrictions on Resales.** The Company may impose such restrictions, conditions or limitations as it determines appropriate as to the timing and manner of any resales by the Optionee or other subsequent transfers by the Optionee of any shares of Common Stock issued as a result of the exercise of the Stock Option, including without limitation (a) restrictions under an insider trading policy, (b) restrictions designed to delay and/or coordinate the timing and manner of sales by Optionee and other optionholders and (c) restrictions as to the use of a specified brokerage firm for such resales or other transfers.

7. **Rights as a Stockholder.** Optionee shall have no rights as a stockholder of the Company with respect to any Option Shares until the issuance of the Common Stock subject to the Stock Option has been entered into the books and records of the Company.

8. **No Transfer of Stock Option.** Except as permitted by the Board or as permitted under the Plan, the Optionee may not assign or transfer the Stock Option to anyone other than by will or the laws of descent and distribution and the Stock Option shall be exercisable only by the Optionee during his or her lifetime.

9. **Other Agreements Superseded.** The Grant Notice, this Stock Option Agreement, the Plan and any Separate Agreement, if applicable, constitute the entire understanding between the Optionee and the Company regarding the Stock Option. Any prior agreements, commitments or negotiations concerning the Stock Option are superseded.

10. **Limitation in Interest in Shares Subject to Stock Option.** Neither the Optionee (individually or as a member of a group) nor any beneficiary or other person claiming under or through the Optionee shall have any right, title, interest, or privilege in or to any shares of Common Stock allocated or reserved for the purpose of the Plan or subject to the Grant Notice or this Stock Option Agreement except as to such shares of Common Stock, if any, as shall have been issued to such person upon exercise of the Stock Option or any part of it. Nothing in the Plan, in the Grant Notice, this Stock Option Agreement or any other instrument executed pursuant to the Plan shall confer upon the Optionee any right to continue in the Company's employ or service nor limit in any way the Company's right to terminate the Optionee's employment or other service at any time for any reason.

11. **No Liability of Company.** The Company and any Affiliate or Subsidiary which is in existence or hereafter comes into existence shall not be liable to the Optionee or any other person as to: (a) the non-issuance or sale of shares of Common Stock as to which the Company has been unable to obtain from any regulatory body having jurisdiction the authority deemed by the Company's counsel to be necessary to the lawful issuance and sale of any shares hereunder; and (b) any tax consequence expected, but not realized, by the Optionee or other person due to the receipt, exercise or settlement of any Stock Option granted hereunder.

12. **Market Stand-Off.** In connection with any public offering of the Company's equity securities, pursuant to an effective registration statement, for such period as the Company or its underwriters may request, the Optionee shall not, directly or indirectly, sell, make any short sale of, loan, hypothecate, pledge, offer, grant or sell any option or other contract for the purchase of, purchase any option or other contract for the sale of, or otherwise dispose of or transfer, or agree to engage in any of the foregoing transactions with respect to, any shares of Common Stock acquired under the Plan without the prior written consent of the Company or its underwriters.

13. **General Provisions.**

13.1 **Tax Withholding**. Whenever Option Shares are to be issued hereunder, the Company may require the Optionee to remit to the Company an amount sufficient to satisfy any national, state and local or other withholding tax requirements prior to the delivery of Option Shares.

13.2 **Governing Plan Document**. The Stock Option is subject to all the provisions of the Plan, the provisions of which are hereby made a part of the Stock Option, and is further subject to all interpretations, amendments, rules and regulations, which may from time to time be promulgated and adopted pursuant to the Plan.

13.3 **Governing Law.** This Stock Option Agreement shall be governed by, and construed in accordance with, the laws of the State of Delaware, without regard to principles of conflicts of law.

13.4 **Electronic Delivery.** By executing the Grant Notice, the Optionee hereby consents to the delivery of information (including, without limitation, information required to be delivered to the Optionee pursuant to applicable securities laws) regarding the Company and its Affiliates or Subsidiaries, the Plan, the Stock Option and the Common Stock via Company web site or other electronic delivery.

13.5 **Notices.** Any notice required or permitted to be delivered under this Stock Option Agreement shall be in writing (which shall include electronic transmission) and shall be deemed received (i) the business day following electronic verification of receipt if sent electronically, (ii) upon personal delivery to the party to whom the notice is directed, (iii) the business day following deposit with a reputable overnight courier (or the second business day following deposit in the case of an international delivery), or (iv) five days after deposit in the U.S. Mail, First Class with postage prepaid. Notice shall be addressed to the Company at its principal executive office and to the Optionee at the address that he or she most recently provided to the Company. The recipient may acknowledge actual receipt at a time earlier than the deemed receipt set forth herein or by a means other than that set forth herein.

13.6 **Successors/Assigns.** This Stock Option Agreement shall inure to the benefit of and be binding upon the parties hereto and their respective permitted heirs, beneficiaries, successors and assigns.

13.7 **Severability.** If one or more provisions of this Stock Option Agreement are held to be unenforceable under applicable law, such provision shall be excluded from this Stock Option Agreement, and the balance of the Stock Option Agreement shall be interpreted as if such provision were so excluded and shall be enforceable in accordance with its terms. The parties agree to replace such illegal, void, invalid or unenforceable provision of this Stock Option Agreement with a legal, valid and enforceable provision that will achieve, to the extent possible, the economic, business and other purposes of such illegal, void, invalid or unenforceable provision.

Exhibit A

PROXY

89BIO, INC.
2019 EQUITY INCENTIVE PLAN AND THE SUBPLAN FOR SERVICE PROVIDERS IN ISRAEL
NOTICE OF GRANT OF STOCK OPTION
(ISRAELI PARTICIPANT AWARD AGREEMENT)

Name of Optionee: _____

Notice of Grant

89bio, Inc. (the "Company") hereby grants to the Optionee named above the option to purchase shares (the "Option Shares") of the Company's common stock, par value $0.001 per share (the "Common Stock") upon the terms and subject to the conditions set forth in this Grant Notice, the 89bio, Inc. 2019 Equity Incentive Plan, including the Subplan to the 2019 Equity Incentive Plan for Service Providers in Israel (the "Master Plan" and the "Israeli Subplan", respectively, and together, the "Plan"), the trust deed by and between the Trustee and the Company and/or its Affiliate (the "Trust Deed") and the Stock Option Agreement promulgated under such Plan, each as amended from time to time. This award of Option Shares is granted pursuant to the Plan and is subject to and qualified in its entirety by the Stock Option Agreement.

Grant Date:	[_____]
Vesting Commencement Date:	[_____]
Exercise Price:	[_____]
Option Shares:	[_____]
Expiration Date:	[_____] (subject to earlier expiration in accordance with the terms of the Stock Option Agreement)
Type of Award	[__] 102 Capital Gain Award
	[__] 102 Ordinary Income Award

Vesting Schedule

These Option Shares shall become vested and exercisable on the following basis:

- [_____]

subject in each case to Continuous Service through each such vesting date. If Optionee ceases Continuous Service for any or no reason before Optionee vests in any portion of the Stock Option, the unvested portion of the Stock Option and Optionee's right to acquire any shares of Common Stock pursuant to the unvested portion of the Stock Option will immediately terminate. However, notwithstanding anything herein to the contrary, the vesting of the Stock Option shall be subject to any vesting acceleration provisions applicable to the Stock Option contained in the Plan and/or any employment or service agreement, offer letter, severance agreement, or any other agreement between Optionee and the Company or any Affiliate or Subsidiary (such agreement, a "Separate Agreement").

Agreements

By your signature and the Company's signature below, you and the Company agree that this Stock Option is granted under and governed by the terms of the Plan, the Stock Option Agreement and the Trust Deed, all of which are attached hereto and incorporated herein by this reference. Capitalized terms used but not defined herein shall have the meanings given to them in the Plan or the Stock Option Agreement, as the case may be.

You further acknowledge that your rights to any Option Shares will be earned and become vested only as you provide Continuous Service to the Company over time, that the grant of this Stock Option is not consideration for service you rendered to the Company prior to the Grant Date, and that nothing herein or the attached documents confers upon you any right to continue your employment or other service relationship with the Company or any Affiliate or Subsidiary for any period of time, nor does it interfere in any way with your right or the Company's (or any Affiliate's or Subsidiary's) right to terminate that relationship at any time, for any reason or no reason, with or without Cause, and with or without advance notice, except as may be required by the terms of a Separate Agreement or in compliance with governing public law.

Except as otherwise set forth in the Stock Option Agreement, the vested portion of this Stock Option may be exercised for three months after termination of your Continuous Service to the Company (but in no event later than the Expiration Date). You are responsible for keeping track of these exercise periods following termination for any reason of your Continuous Service to the Company. The Company is not obligated to provide further notice of such periods.

"COMPANY"

89bio, Inc.

_____

[Name]
[Title]

"OPTIONEE"

_____

Name

_____

Signature

_____

Address

_____

Address

89BIO, INC.
2019 EQUITY INCENTIVE PLAN AND THE SUBPLAN FOR SERVICE PROVIDERS IN ISRAEL
STOCK OPTION AGREEMENT
(ISRAELI PARTICIPANT AWARD AGREEMENT)

This Stock Option Agreement is made and entered into by and between 89bio, Inc., a Delaware corporation ("Company"), and the Optionee identified in the Notice of Grant of Stock Option ("Grant Notice") which is attached hereto ("Optionee").

1. **Grant of Stock Option.** Subject to the terms and conditions set forth herein, the Company hereby grants to Optionee a stock option (the "Stock Option") to purchase from the Company, at the Exercise Price set forth in the Grant Notice, the number of Option Shares set forth in the Grant Notice. This Option is intended to be an Approved 102 Award as set forth on the Grant Notice and is subject to the provisions of Section 102 and the rules and regulations promulgated thereunder, as now in effect or as amended or replaced from time to time. Capitalized terms not otherwise defined herein shall have the meanings set forth in the Plan or the Grant Notice.

2. **Approved 102 Award.**

(a) The classification of the Stock Option as Approved 102 Award is conditioned upon the approval (or the deemed approval pursuant to the provisions of section 102(a) of the Ordinance) of the Plan and the Trustee by the ITA. In the event that such approval is not granted, regardless of reason, then the Stock Option shall be deemed to be Unapproved 102 Award, unless otherwise determined by the ITA.

(b) The Stock Option will be issued to the Trustee. The Trustee will hold in trust the Stock Option, and any Common Stock to be issued upon exercise of the Option, and all other securities received following any exercise or realization of rights, including without limitation bonus stock, until the later to occur of: (i) the lapse of the minimum Holding Period as required under Section 102, or (ii) the full payment of all requisite taxes by the Participant, as shall be determined by the Company, its Affiliate and/or the Trustee, at their sole discretion. The administration of the Stock Option and any Common Stock covered thereby by the Trustee shall be in accordance with the provisions and processes agreed upon by the Company and/or its Affiliate and the Trustee.

3. **Expiration of Stock Option.** The Stock Option shall expire and cease to be exercisable as of the earlier of (i) the Expiration Date set forth in the Grant Notice or (ii) the date specified below in connection with the Optionee's termination of Continuous Service:

(a) If the Optionee's Continuous Service terminates by reason of death or Disability, the Optionee (or the Optionee's estate, beneficiary or legal representative, as applicable) may exercise any portion of the Stock Option that is vested and exercisable at the time of such termination until the date that is twelve (12) months following the date of such termination. Any portion of the Stock Option that is not vested and exercisable at the time of such termination shall be forfeited and canceled as of the date of such termination.

(b) If the Optionee's Continuous Service terminates for any reason other than death, Disability, or Cause, the Optionee may exercise any portion of the Stock Option that is vested and exercisable at the time of such termination until the date that is three (3) months following the date of such termination. Any portion of the Stock Option that is not vested and exercisable at the time of such termination shall be forfeited and canceled as of the date of such termination.

(d) If the Optionee's Continuous Service is terminated by the Company for Cause, the entire Stock Option, whether or not then vested and exercisable, shall be immediately forfeited and canceled as of the date of such termination.

4. **Exercise.**

4.1 **Exercisability.** Subject to the terms and conditions of this Stock Option Agreement, the Stock Option shall become exercisable at such time or times, during such period and for such number of Option Shares as is set forth in the Grant Notice. Upon the expiration of the applicable exercise period or (if earlier) upon the expiration of the Stock Option term, the Stock Option shall terminate and cease to be outstanding for any Option Shares for which the Stock Option has not been exercised.

4.2 **Exercise Agreement.** Optionee may exercise the Stock Option by delivering to the Company, either in person or by certified or registered mail or such other manner as approved by the Company, a duly executed exercise agreement in a form approved by the Company from time to time for such exercises (the "Exercise Agreement"), and payment in full of the purchase price as provided in Section 4.3 of this Stock Option Agreement. A copy of the Exercise Agreement will be provided by the Company to Optionee upon request, and no exercise of this Stock Option may be effected without the Optionee's execution of such Exercise Agreement in the form approved by the Company and containing the provisions noted above.

4.3 **Payment of Purchase Price.** The purchase price for any Option Shares for which this Stock Option is exercised shall be paid in full in United States dollars at the time Optionee delivers to the Company the Exercise Agreement. The purchase price shall be paid in one or a combination of the following, to the extent permitted by the Company: (a) cash, check, bank draft or money order payable to the Company; (b) Common Stock; (c) through the delivery of a notice that Optionee has placed a market sell order with a broker acceptable to the Company with respect to shares of Common Stock then issuable upon exercise of the Stock Option, and that the broker has been directed to pay a sufficient portion of the net proceeds of the sale to the Company in satisfaction of the purchase price; *provided* that payment of such proceeds is then made to the Company at such time as may be required by the Company, but in any event not later than the settlement of such sale; or (d) net exercise. In addition to the purchase price, the Optionee shall pay the amount of tax required to be withheld (if any) by the Company or any Affiliate or Subsidiary as a result of the exercise of the Stock Option.

4.4 **Issuance of Shares.** Fractional shares may not be exercised. Shares of Common Stock will be issued as soon as practical after exercise. Notwithstanding the above, the Company shall not be obligated to deliver any shares of Common Stock during any period when the Company determines that the exercisability of the Stock Option or the delivery of shares of Common Stock hereunder would violate any federal, state or other applicable laws. Until the

consummation of an initial public offering of the Company's Common Stock ("IPO"), any shares of Common Stock acquired upon the exercise of the Stock Options shall be voted by an irrevocable proxy, in the form attached hereto as Exhibit A. Such proxy shall be signed by the Optionee as a pre-condition to the exercise of any portion of the Stock Options by the Optionee.

5. **Change in Control**. Unless otherwise provided in a Separate Agreement, upon the occurrence of a Change in Control, Sections 9(c) and 9(d) of the Master Plan shall control.

6. **Restrictions on Resales.**

(a) Any transfer or other disposition of the shares of Common Stock to be issued upon exercise of the Stock Option (and/or any securities of the Company received subsequently following any realization of rights, including without limitation, bonus stock), shall be subject to the limitations set forth in the Plan and this Stock Option Agreement; (ii) the Company's articles of incorporation and bylaws (as amended from time to time); (iii) any stockholders' agreement to which the holders of Common Stock of the Company may be bound; (iv) restrictions included in the Company's insider trading policy, or similar document, if any; (v) any applicable law (including securities law of any applicable jurisdiction); and (vi) the signing of an irrevocable proxy by the transferee in the form attached hereto as Exhibit A, *mutatis mutandis*.

(b) Notwithstanding the foregoing, as long as the Option and any rights and interests with respect thereto are held by the Trustee on behalf of the Participant, all rights of the Participant over the Stock Option, the Common Stock covered thereby and any rights thereto are personal, cannot be transferred, assigned, pledged or mortgaged, other than by will or laws of descent and distribution.

7. **Rights as a Stockholder.** Optionee shall have no rights as a stockholder of the Company with respect to any Option Shares until the issuance of the Common Stock subject to the Stock Option has been entered into the books and records of the Company.

8. **No Transfer of Stock Option.** Except as permitted by the Board or as permitted under the Plan, the Optionee may not assign or transfer the Stock Option to anyone other than by will or the laws of descent and distribution and the Stock Option shall be exercisable only by the Optionee during his or her lifetime.

9. **Other Agreements Superseded.** The Grant Notice, this Stock Option Agreement, the Plan, the Trust Deed and any Separate Agreement, if applicable, constitute the entire understanding between the Optionee and the Company regarding the Stock Option. Any prior agreements, commitments or negotiations concerning the Stock Option are superseded.

10. **Limitation in Interest in Shares Subject to Stock Option.** Neither the Optionee (individually or as a member of a group) nor any beneficiary or other person claiming under or through the Optionee shall have any right, title, interest, or privilege in or to any shares of Common Stock allocated or reserved for the purpose of the Plan or subject to the Grant Notice or this Stock Option Agreement except as to such shares of Common Stock, if any, as shall have been issued to such person upon exercise of the Stock Option or any part of it. Nothing in the Plan, in the Grant Notice, this Stock Option Agreement or any other instrument executed pursuant to the Plan shall confer upon the Optionee any right to continue in the Company's employ or service nor limit in any way the Company's right to terminate the Optionee's employment or other service at any time for any reason.

11. **No Liability of Company.** The Company and any Affiliate or Subsidiary which is in existence or hereafter comes into existence shall not be liable to the Optionee or any other person as to: (a) the non-issuance or sale of shares of Common Stock as to which the Company has been unable to obtain from any regulatory body having jurisdiction the authority deemed by the Company's counsel to be necessary to the lawful issuance and sale of any shares hereunder; and (b) any tax consequence expected, but not realized, by the Optionee or other person due to the receipt, exercise or settlement of any Stock Option granted hereunder.

12. **Market Stand-Off.** In connection with any public offering of the Company's equity securities, pursuant to an effective registration statement, for such period as the Company or its underwriters may request, the Optionee shall not, directly or indirectly, sell, make any short sale of, loan, hypothecate, pledge, offer, grant or sell any option or other contract for the purchase of, purchase any option or other contract for the sale of, or otherwise dispose of or transfer, or agree to engage in any of the foregoing transactions with respect to, any shares of Common Stock acquired under the Plan without the prior written consent of the Company or its underwriters.

13. **General Provisions.**

13.1 **Tax Matters**.

(a) The Company does not represent or warrant that the Stock Option (or the purchase or sale of the shares of Common Stock subject hereto) will be subject to particular tax treatment. The receipt of the Stock Option, the exercise thereof or the disposal of the Stock Option or the shares of Common Stock covered thereby may result in tax and/or other mandatory payment consequences. The Participant acknowledges that he/she should review with his/her own tax advisors the tax treatment of the Stock Option (including the purchase and sale of shares of Common Stock subject hereto) and should rely solely on those advisors in that regard.

(b) Any tax arising with respect to the grant or exercise of the Stock Option, the payment for, or disposition of, shares of Common Stock covered thereby, or from any other event or act in connection therewith (of the Company, its Affiliates, the Trustee or the Participant, including without limitation, in the event that the Stock Option does not qualify under the tax classification/tax track in which it was intended), shall be borne solely by the Participant. The Company, its Affiliates, and the Trustee shall be entitled to withhold taxes according to the requirements of any applicable laws, rules, and regulations, including withholding taxes at source. The Participant shall indemnify the Company, its Affiliates, and the Trustee, as the case may be, and hold each of them harmless against and from any and all liability for any such tax or interest or penalty thereon, including without limitation, liabilities relating to the necessity to withhold, or to have withheld, any such tax from any payment made to the Participant. The Company or any Affiliate thereof may exercise such indemnification by deducting the taxes subject to indemnification from Participant's salaries or remunerations.

(c) Notwithstanding anything to the contrary, the Board, or when applicable, the Trustee shall not release the Stock Option or any Common Stock allocated or issued upon exercise of the Stock Option (including rights or bonus stock) prior to the full payment of the Participant's tax liabilities arising from the Stock Option which was granted to him/her and/or any Common Stock allocated or issued upon exercise of such Stock Option, or the sale or other disposition of such Common Stock.

(d) The Participant hereby acknowledges that he or she is familiar with the provisions of Section 102 and the regulations and rules promulgated thereunder, including without limitations the type of Award granted hereunder and the tax implications applicable to such grant.

(e) In the event that the requirements for the Approved 102 Award are not met, then this Stock Option shall be regarded as Unapproved 102 Award.

13.2 **Governing Plan Document**. The Stock Option is subject to all the provisions of the Plan, the provisions of which are hereby made a part of the Stock Option, and is further subject to all interpretations, amendments, rules and regulations, which may from time to time be promulgated and adopted pursuant to the Plan.

13.3 **Governing Law.** This Stock Option Agreement shall be governed by, and construed in accordance with, the laws of the State of Delaware, without regard to principles of conflicts of law, provided, however, that all questions concerning the construction, validity and interpretation of this Stock Option Agreement in connection with tax matters shall be governed by, and construed in accordance with, the laws of the State of Israel, without regard to principles of conflicts of law.

13.4 **Electronic Delivery.** By executing the Grant Notice, the Optionee hereby consents to the delivery of information (including, without limitation, information required to be delivered to the Optionee pursuant to applicable securities laws) regarding the Company and its Affiliates or Subsidiaries, the Plan, the Stock Option and the Common Stock via Company web site or other electronic delivery.

13.5 **Privacy Protection**. The Participant hereby authorizes the Company and any Affiliate thereof to provide the Trustee with any information required for the purpose of administering the Plan, including executing its obligations according to Section 102 and the trust agreement, including without limitation information about the Participant's Stock Option, shares of Common Stock, income tax rates, salary bank account, contact details and identification number

13.6 **Notices.** Any notice required or permitted to be delivered under this Stock Option Agreement shall be in writing (which shall include electronic transmission) and shall be deemed received (i) the business day following electronic verification of receipt if sent electronically, (ii) upon personal delivery to the party to whom the notice is directed, or (iii) the business day following deposit with a reputable overnight courier (or the second business day following deposit in the case of an international delivery). Notice shall be addressed to the Company at its principal executive office and to the Optionee at the address that he or she most recently provided to the Company. The recipient may acknowledge actual receipt at a time earlier than the deemed receipt set forth herein or by a means other than that set forth herein.

13.7 **Successors/Assigns.** This Stock Option Agreement shall inure to the benefit of and be binding upon the parties hereto and their respective permitted heirs, beneficiaries, successors and assigns.

13.8 **Severability.** If one or more provisions of this Stock Option Agreement are held to be unenforceable under applicable law, such provision shall be excluded from this Stock Option Agreement, and the balance of the Stock Option Agreement shall be interpreted as if such provision were so excluded and shall be enforceable in accordance with its terms. The parties agree to replace such illegal, void, invalid or unenforceable provision of this Stock Option Agreement with a legal, valid and enforceable provision that will achieve, to the extent possible, the economic, business and other purposes of such illegal, void, invalid or unenforceable provision.

Exhibit A

PROXY

Exhibit 10.3

89BIO, INC.

2019 EMPLOYEE STOCK PURCHASE PLAN

Section 1. PURPOSE

The purpose of this Employee Stock Purchase Plan (the "Plan") is to provide an opportunity for Employees of 89bio, Inc., a Delaware corporation ("Sponsor") and its Participating Subsidiaries (collectively Sponsor and its Participating Subsidiaries shall be referred to as the "Company"), to purchase Common Stock of Sponsor and thereby to have an additional incentive to contribute to the prosperity of the Company. It is the intention of the Company that the Plan (excluding any sub-plans thereof except as expressly provided in the terms of such sub-plan) qualify as an "Employee Stock Purchase Plan" under Section 423 of the U.S. Internal Revenue Code of 1986, as amended (the "Code"), and the Plan shall be administered in accordance with this intent. In addition, the Plan authorizes the grant of options pursuant to sub-plans or special rules adopted by the Committee designed to achieve desired tax or other objectives in particular locations outside of the United States or to achieve other business objectives in the determination of the Committee, which sub-plans shall not be required to comply with the requirements of Section 423 of the Code or all of the specific provisions of the Plan, including but not limited to terms relating to eligibility, Offering Periods or Purchase Price.

Section 2. DEFINITIONS

(a) "Applicable Law" shall mean the legal requirements relating to the administration of an employee stock purchase plan under applicable U.S. state corporate laws, U.S. federal and applicable state securities laws, the Code, any stock exchange rules or regulations and the applicable laws of any other country or jurisdiction, as such laws, rules, regulations and requirements shall be in place from time to time.

(b) "Board" shall mean the Board of Directors of Sponsor.

(c) "Code" shall mean the Internal Revenue Code of 1986, as such is amended from time to time, and any reference to a section of the Code shall include any successor provision of the Code.

(d) "Commencement Date" shall mean, with respect to a given Offering Period, the first Trading Day during such Offering Period.

(e) "Committee" shall mean the Compensation Committee of the Board or the officer, officers or committee appointed by the Compensation Committee in accordance with Section 15 of the Plan (to the extent of the duties and responsibilities delegated by the Compensation Committee of the Board).

(f) "Common Stock" shall mean the common stock of Sponsor, par value $0.001 per share, or any securities into which such Common Stock may be converted.

(g) "Compensation" shall mean the total compensation paid by the Company to an Employee with respect to an Offering Period, including salary, commissions, overtime, shift differentials and all or any portion of any item of compensation considered by the Company to be part of the Employee's regular earnings, but excluding items not considered by the Company to be part of the Employee's regular earnings. Items excluded from the definition of "Compensation" include but are not limited to such items as relocation bonuses, MBO bonuses and similar incentive bonuses, expense reimbursements, certain bonuses paid in connection with mergers and acquisitions, author incentives, recruitment and referral bonuses, foreign service premiums, differentials and allowances, imputed income pursuant to Section 79 of the Code, income realized as a result of participation in any stock option, restricted stock, restricted stock unit, stock purchase or similar equity plan maintained by Sponsor or a Participating Subsidiary, and tuition and other reimbursements. The Committee shall have the authority to determine and approve all forms of pay to be included in the definition of Compensation and may change the definition on a prospective basis.

(h) "Effective Date" shall mean the date of the underwriting agreement between the Company and the underwriters(s) managing the initial public offering of the Common Stock, pursuant to which the Common Stock is priced for the initial public offering of the Company's securities pursuant to a registration statement filed and declared effective pursuant to the Securities Act.

(i) "Employee" shall mean an individual classified as an employee (within the meaning of Code Section 3401(c) and the regulations thereunder) by Sponsor or a Participating Subsidiary on Sponsor's or such Participating Subsidiary's payroll records during the relevant participation period. Notwithstanding the foregoing, no employee of Sponsor or a Participating Subsidiary shall be included within the definition of "Employee" if such person's customary employment is for less than twenty (20) hours per week or for less than five (5) months per year. Individuals classified as independent contractors, consultants, advisers, or members of the Board are not considered "Employees."

(j) "Enrollment Period" shall mean, with respect to a given Offering Period, that period established by the Committee prior to the commencement of such Offering Period during which Employees may elect to participate in order to purchase Common Stock at the end of that Offering Period in accordance with the terms of this Plan.

(k) "Exchange Act" shall mean the Securities Exchange Act of 1934, as amended from time to time, and any reference to a section of the Exchange Act shall include any successor provision of the Exchange Act.

(l) "Market Value" on a given date of determination (e.g., a Commencement Date or Purchase Date, as appropriate) means, as of any date, the value of the Common Stock determined as follows:

(i) If the Common Stock is listed on any established stock exchange or traded on any established market, the Market Value of a share of Common Stock as of any date of determination will be, unless otherwise determined by the Board or Committee, the closing sales price for such stock as quoted on such exchange or market (or the exchange or market with the greatest volume of trading in the Common Stock) on the date of determination, as reported in a source the Board or Committee deems reliable.

(ii) Unless otherwise provided by the Board or Committee, if there is no closing sales price for the Common Stock on the date of determination, then the Market Value will be the closing selling price on the last preceding date for which such quotation exists.

(iii) In the absence of such markets for the Common Stock, the Market Value will be determined by the Board or Committee in good faith.

(m) "Offering Period" shall mean a period of no more than twenty-seven (27) months at the end of which an option granted pursuant to the Plan shall be exercised. The Plan shall be implemented by a series of Offering Periods with terms established by the Committee in accordance with the Plan. Once established, the duration and timing of Offering Periods may be changed or modified by the Committee as permitted by the Plan. If the Committee does not establish different rules with respect to an Offering Period, then the duration of an Offering Period shall be six (6) months and there shall be no overlapping Offering Periods.

(n) "Offering Price" shall mean the Market Value of a share of Common Stock on the Commencement Date for a given Offering Period.

(o) "Participant" shall mean a participant in the Plan as described in Section 5 of the Plan.

(p) "Participating Subsidiary" shall mean a Subsidiary that has been designated by the Committee in its sole discretion as eligible to participate in the Plan with respect to its Employees.

(q) "Plan" shall mean this 2019 Employee Stock Purchase Plan, including any sub-plans or appendices hereto.

(r) "Purchase Date" shall mean the last Trading Day of each Offering Period.

(s) "Purchase Price" shall have the meaning set out in Section 8(b).

(t) "Securities Act" shall mean the U.S. Securities Act of 1933, as amended, as amended from time to time, and any reference to a section of the Securities Act shall include any successor provision of the Securities Act.

(u) "Stockholder" shall mean a record holder of shares entitled to vote such shares of Common Stock under Sponsor's by-laws.

(v) "Subsidiary" shall mean any entity treated as a corporation (other than Sponsor) in an unbroken chain of corporations beginning with Sponsor, within the meaning of Code Section 424(f), whether or not such corporation now exists or is hereafter organized or acquired by Sponsor or a Subsidiary.

(w) "Trading Day" shall mean a day on which U.S. national stock exchanges are open for trading and the Common Stock is being publicly traded on one or more of such markets.

Section 3. ELIGIBILITY

(a) Any Employee employed by Sponsor or by any Participating Subsidiary at the beginning of an Enrollment Period for a given Offering Period shall be eligible to participate in the Plan with respect to such Offering Period and future Offering Periods, provided that the Committee may establish administrative rules requiring that employment commence some minimum period (not to exceed 90 days) prior to an Enrollment Period and/or that customary employment exceed a specified number of hours or period during a calendar year (not to exceed 20 hours per week or 5 months in a calendar year) to be eligible to participate with respect to the associated Offering Period. The Committee may also determine that a designated group of highly compensated Employees is ineligible to participate in the Plan so long as the excluded category fits within the definition of "highly compensated employee" in Code Section 414(q). If the Committee does not establish different rules with respect to an Offering Period, the minimum period of employment that must be completed prior to the beginning of an Enrollment Period shall be five (5) working days.

(b) No Employee may participate in the Plan if immediately after an option is granted the Employee owns or is considered to own (within the meaning of Code Section 424(d)) shares of Common Stock, including Common Stock which the Employee may purchase by conversion of convertible securities or under outstanding options granted by Sponsor or its Subsidiaries, possessing five percent (5%) or more of the total combined voting power or value of all classes of stock of Sponsor or of any of its Subsidiaries. All Employees who participate in the Plan shall have the same rights and privileges under the Plan, except for differences that may be mandated by local law and that are consistent with Code Section 423(b)(5); provided that individuals participating in a sub-plan adopted pursuant to Section 16 which is not designed to qualify under Code Section 423 need not have the same rights and privileges as Employees participating in the Code Section 423 Plan. No Employee may participate in more than one Offering Period at a time.

Section 4. OFFERING PERIODS

The Plan shall be implemented by a series of Offering Periods, which shall possess terms specified by the Committee in accordance with the terms of the Plan. Offering Periods shall continue until the Plan is terminated pursuant to Section 14 hereof. Once established, the Committee shall have the authority to change the frequency and/or duration of Offering Periods (including the Commencement Dates thereof) with respect to future Offering Periods if such change is announced prior to the scheduled occurrence of the Enrollment Period for the first Offering Period to be affected thereafter. If the Committee does not establish different rules with respect to an Offering Period, then the duration of an Offering Period shall be six (6) months and there shall be no overlapping Offering Periods.

Section 5. PARTICIPATION

(a) An Employee who is eligible to participate in the Plan in accordance with its terms at the beginning of an Enrollment Period for an Offering Period and elects to participate in such Offering Period shall automatically receive an option in accordance with Section 8(a). Such an Employee shall become a Participant by completing and submitting, on or before the date prescribed by the Committee with respect to a given Offering Period, a completed payroll deduction authorization and Plan enrollment form provided by Sponsor or its Participating Subsidiaries or by following an electronic or other enrollment process as prescribed by the Committee. An eligible Employee may authorize payroll deductions at the rate of any whole percentage of the Employee's Compensation, not to be less than one percent (1.0%) and not to exceed fifteen percent (15.0%) of the Employee's Compensation (or such other percentages as the Committee may establish from time to time before an Enrollment Period for a future Offering Period) of such Employee's Compensation on each payday during the Offering Period. All payroll deductions will be held in a general corporate account or a trust account. No interest shall be paid or credited to the Participant with respect to such payroll deductions. Sponsor shall maintain or cause to be maintained a separate bookkeeping account for each Participant under the Plan and the amount of each Participant's payroll deductions shall be credited to such account. A Participant may not make any additional payments into such account, unless payroll deductions are prohibited under Applicable Law, in which case the provisions of Section 5(b) of the Plan shall apply.

(b) Notwithstanding any other provisions of the Plan to the contrary, in locations where local law prohibits payroll deductions, an eligible Employee may elect to participate through contributions to his or her account under the Plan in a form acceptable to the Committee. In such event, any such Employees shall be deemed to be participating in a sub-plan, unless the Committee otherwise expressly provides that such Employees shall be treated as participating in the Plan.

(c) Under procedures and at times established by the Committee, a Participant may withdraw from the Plan during an Offering Period, by completing and filing a new payroll deduction authorization and Plan enrollment form with the Company or by following electronic or other procedures prescribed by the Committee. If a Participant withdraws from the Plan during an Offering Period, his or her accumulated payroll deductions will be refunded to the Participant without interest, his or her right to participate in the current Offering Period will be automatically terminated and no further payroll deductions for the purchase of Common Stock will be made during the Offering Period. Any Participant who wishes to withdraw from the Plan during an Offering Period, must complete the withdrawal procedures prescribed by the Committee, subject to any rules established by the Committee, or changes to such rules, pertaining to the timing of withdrawals, limiting the frequency with which Participants may withdraw and re-enroll in the Plan, or imposing a waiting period on Participants wishing to re-enroll following withdrawal.

(d) A Participant may not increase his or her rate of contribution through payroll deductions or otherwise during a given Offering Period. A Participant may decrease his or her rate of contribution through payroll deductions during a given Offering Period during such times specified by the Committee by filing a new payroll deduction authorization and Plan enrollment

form or by following electronic or other procedures prescribed by the Committee. If a Participant has not followed such procedures to change the rate of contribution, the rate of contribution shall continue at the originally elected rate throughout the Offering Period and future Offering Periods. Notwithstanding the foregoing, to the extent necessary to comply with Section 423(b)(8) of the Code for a given calendar year, the Committee may reduce a Participant's payroll deductions to zero percent (0%) at any time during an Offering Period scheduled to end during such calendar year. Payroll deductions shall re-commence at the rate provided in such Participant's enrollment form at the beginning of the first Offering Period which is scheduled to end in the following calendar year, unless terminated by the Participant as provided in Section 5(c).

Section 6. TERMINATION OF EMPLOYMENT

In the event any Participant terminates employment with Sponsor and its Participating Subsidiaries for any reason (including death) prior to the expiration of an Offering Period, the Participant's participation in the Plan shall terminate and all amounts credited to the Participant's account shall be paid to the Participant or, in the case of death, to the Participant's heirs or estate, without interest. Whether a termination of employment has occurred shall be determined by the Committee. If a Participant's termination of employment occurs within a certain period of time as specified by the Committee (not to exceed 30 days) prior to the Purchase Date of the Offering Period then in progress, his or her option for the purchase of shares of Common Stock will be exercised on such Purchase Date in accordance with Section 9 as if such Participant were still employed by the Company. If the Committee does not establish different rules with respect to an Offering Period, then if a Participant's termination of employment occurs on or after the fifth (5th) working day preceding the Purchase Date of an Offering Period, then his or her option for the purchase of shares of Common Stock will be exercised on such Purchase Date in accordance with Section 9 as if such Participant were still employed by the Company. Following the purchase of shares on such Purchase Date, the Participant's participation in the Plan shall terminate and all amounts credited to the Participant's account shall be paid to the Participant or, in the case of death, to the Participant's heirs or estate, without interest. The Committee may also establish rules regarding when leaves of absence or changes of employment status will be considered to be a termination of employment, including rules regarding transfer of employment among Participating Subsidiaries, Subsidiaries and Sponsor, and the Committee may establish termination-of-employment procedures for this Plan that are independent of similar rules established under other benefit plans of Sponsor and its Subsidiaries; provided that such procedures are not in conflict with the requirements of Section 423 of the Code.

Section 7. STOCK

Subject to adjustment as set forth in Section 11 and the "evergreen" provision in this Section 7, the aggregate number of shares of Common Stock which may be issued pursuant to the Plan shall not exceed 225,188 shares (the "Share Reserve"). The Share Reserve will automatically increase on January 1st of each calendar year, for ten years, commencing on January 1 of the calendar year following the Effective Date, in an amount equal to one percent (1%) of the total number of shares of Common Stock outstanding on December 31st of the preceding calendar year. The Board may act prior to January 1st of a given year to provide that there will be no January 1st increase of the Share Reserve for such year or that the increase in the Share Reserve for such year will be a smaller number of shares of Common Stock than would otherwise occur pursuant to the preceding sentence.

Notwithstanding the above, subject to adjustment as set forth in Section 11, the maximum number of shares of Common Stock that may be issued to any Employee in a given Offering Period shall be 1,666. The Committee may change this limitation at any time on a prospective basis to apply to future Offering Periods. If, on a given Purchase Date, the number of shares with respect to which options are to be exercised exceeds either maximum, the Committee shall make, as applicable, such adjustment or pro rata allocation of the shares remaining available for purchase in as uniform a manner as shall be practicable and as it shall determine to be equitable.

Section 8. OFFERING

(a) On the Commencement Date relating to each Offering Period, each eligible Employee, whether or not such Employee has elected to participate as provided in Section 5(a), shall be granted an option to purchase that number of whole shares of Common Stock (as adjusted as set forth in Section 11) not to exceed that number of shares of Common Stock determined in accordance with the last paragraph of Section 7 above (or such lower number of shares as determined by the Committee), which may be purchased with the payroll deductions accumulated on behalf of such Employee during each Offering Period at the purchase price specified in Section 8(b) below, subject to the additional limitation that no Employee participating in the Plan shall be granted an option to purchase Common Stock under the Plan if such option would permit his or her rights to purchase stock under all employee stock purchase plans (described in Section 423 of the Code) of Sponsor and its Subsidiaries to accrue at a rate which exceeds Twenty-Five Thousand Dollars (USD$25,000) of the Market Value of such Common Stock (determined at the time such option is granted) for each calendar year in which such option is outstanding at any time. For purposes of the Plan, an option is "granted" on a Participant's Commencement Date. An option will expire upon the earliest to occur of (i) the termination of a Participant's participation in the Plan or such Offering Period, (ii) the beginning of a subsequent Offering Period in which such Participant is participating, or (iii) the termination of the Offering Period. This Section 8(a) shall be interpreted so as to comply with Code Section 423(b)(8).

(b) The Purchase Price under each option shall be with respect to an Offering Period the lower of (i) a percentage (not less than eighty-five percent (85%)) ("Designated Percentage") of the Offering Price, or (ii) the Designated Percentage of the Market Value of a share of Common Stock on the Purchase Date on which the Common Stock is purchased; provided that the Purchase Price may be adjusted by the Committee pursuant to Sections 11 or 12 in accordance with Section 424(a) of the Code. For a given Offering Period, the Designated Percentage shall be established no later than the beginning of the Enrollment Period for such Offering Period. The Committee may change the Designated Percentage with respect to any future Offering Period, but not to below eighty-five percent (85%), and the Committee may determine with respect to any prospective Offering Period that the Purchase Price shall be the Designated Percentage of the Market Value of a share of the Common Stock solely on the Purchase Date. If the Committee does not established the Designated Percentage prior to the beginning of the Enrollment Period for a given Offering Period, the Designated Percentage for such Offering Period shall be eighty-five percent (85%).

Section 9. PURCHASE OF STOCK

Unless a Participant withdraws from the Plan as provided in Section 5(c), terminates employment prior to the end of an Offering Period as provided in Section 6, or except as provided in Sections 7, 12 or 14(b), upon the expiration of each Offering Period, a Participant's option shall be exercised automatically for the purchase of that number of whole shares of Common Stock which the accumulated payroll deductions credited to the Participant's account at that time shall purchase at the applicable price specified in Section 8(b) in accordance with the terms of the Plan, including Section 7. If a Participant's contributions are collected in a currency other than U.S. Dollars, then unless otherwise provided by the Committee with respect to an Offering Period, such contributions shall be converted into U.S. Dollars using an exchange rate prevailing on the Purchase Date as selected in the reasonable determination of the Sponsor. Notwithstanding the foregoing, Sponsor or its Participating Subsidiary may make such provisions and take such action as it deems necessary or appropriate for the withholding of taxes and/or social insurance and/or other amounts which Sponsor or its Participating Subsidiary determines is required by Applicable Law. Each Participant, however, shall be responsible for payment of all individual tax liabilities arising under the Plan. The shares of Common Stock purchased upon exercise of an option hereunder shall be considered for tax purposes to be sold to the Participant on the Purchase Date. A Participant's option to purchase shares of Common Stock hereunder is exercisable only by him or her.

Section 10. PAYMENT AND DELIVERY

As soon as practicable after the exercise of an option, Sponsor shall deliver or cause to have delivered to the Participant a record of the Common Stock purchased and the balance of any amount of payroll deductions credited to the Participant's account not used for the purchase of Common Stock, except as specified below. The Committee may permit or require that shares be deposited directly with a broker designated by the Committee or to a designated agent of the Company, and the Committee may utilize electronic or automated methods of share transfer. The Committee may require that shares be retained with such broker or agent for a designated period of time and/or may establish other procedures to permit tracking of disqualifying dispositions of such shares. Sponsor or its Participating Subsidiary shall retain the amount of payroll deductions used to purchase Common Stock as full payment for the Common Stock and the Common Stock shall then be fully paid and non-assessable. No Participant shall have any voting, dividend, or other Stockholder rights with respect to shares subject to any option granted under the Plan until the shares subject to the option have been purchased and delivered to the Participant as provided in this Section 10. The Committee may in its discretion direct Sponsor to retain in a Participant's account for the subsequent Offering Period any payroll deductions which are not sufficient to purchase a whole share of Common Stock or return such amount to the Participant. Any other amounts left over in a Participant's account after a Purchase Date shall be returned to the Participant. If the Committee does not establish different rules with respect to an Offering Period, then all amounts left over in a Participant's account after a Purchase Date shall be returned to the Participant.

Section 11. RECAPITALIZATION

Subject to any required action by the Stockholders of Sponsor, if there is any change in the outstanding shares of Common Stock or other securities of Sponsor because of a merger, consolidation, spin-off, reorganization, recapitalization, dividend in property other than cash, extraordinary dividend whether in cash and/or other property, stock split, reverse stock split, stock dividend, liquidating dividend, combination or reclassification of the Common Stock or other securities (including any such change in the number of shares of Common Stock or other securities effected in connection with a change in domicile of Sponsor), or any other increase or decrease in the number of shares of Common Stock or other securities effected without receipt of consideration by Sponsor, provided that conversion of any convertible securities of Sponsor shall not be deemed to have been "effected without receipt of consideration," the type and number of securities covered by each option under the Plan which has not yet been exercised and the type and number of securities which have been authorized and remain available for issuance under the Plan, as well as the maximum number of securities which may be purchased by a Participant in an Offering Period, and the price per share covered by each option under the Plan which has not yet been exercised, shall be appropriately and proportionally adjusted by the Board, and the Board shall take any further actions which, in the exercise of its discretion, may be necessary or appropriate under the circumstances. The Board's determinations under this Section 11 shall be conclusive and binding on all parties.

Section 12. MERGER, LIQUIDATION, OTHER CORPORATE TRANSACTIONS

(a) In the event of the proposed liquidation or dissolution of Sponsor, the Offering Period will terminate immediately prior to the consummation of such proposed transaction, unless otherwise provided by the Board in its sole discretion, and all outstanding options shall automatically terminate and the amounts of all payroll deductions will be refunded without interest to the Participants.

(b) In the event of a proposed sale of all or substantially all of the assets of Sponsor, or the merger or consolidation or similar combination of Sponsor with or into another entity, then in the sole discretion of the Board, (1) each option shall be assumed or an equivalent option shall be substituted by the successor corporation or parent or subsidiary of such successor entity, (2) on a date established by the Board on or before the date of consummation of such merger, consolidation, combination or sale, such date shall be treated as a Purchase Date, and all outstanding options shall be exercised on such date, (3) all outstanding options shall terminate and the accumulated payroll deductions will be refunded without interest to the Participants, or (4) outstanding options shall continue unchanged.

Section 13. TRANSFERABILITY

Neither payroll deductions credited to a Participant's bookkeeping account nor any rights to exercise an option or to receive shares of Common Stock under the Plan may be voluntarily or involuntarily assigned, transferred, pledged, or otherwise disposed of in any way, and any attempted assignment, transfer, pledge, or other disposition shall be null and void and without effect. If a Participant in any manner attempts to transfer, assign or otherwise encumber his or her rights or interests under the Plan, other than as permitted by the Code, such act shall be treated as an election by the Participant to discontinue participation in the Plan pursuant to Section 5(c).

Section 14. AMENDMENT OR TERMINATION OF THE PLAN

(a) The Plan shall continue from the Effective Date until the time that the Plan is terminated in accordance with Section 14(b).

(b) The Board or the Committee may, in its sole discretion, insofar as permitted by law, terminate or suspend the Plan, or revise or amend it in any respect whatsoever, except that, without approval of the Stockholders, no such revision or amendment shall increase the number of shares subject to the Plan, other than an adjustment under Section 11 of the Plan, or make other changes for which Stockholder approval is required under Applicable Law. Upon a termination or suspension of the Plan, the Board may in its discretion (i) return without interest, the payroll deductions credited to Participants' accounts to such Participants or (ii) set an earlier Purchase Date with respect to an Offering Period then in progress.

Section 15. ADMINISTRATION

(a) The Board has appointed the Compensation Committee of the Board to administer the Plan (the "Committee"), who will serve for such period of time as the Board may specify and whom the Board may remove at any time. The Committee will have the authority and responsibility for the day-to-day administration of the Plan, the authority and responsibility specifically provided in this Plan and any additional duty, responsibility and authority delegated to the Committee by the Board, which may include any of the functions assigned to the Board in this Plan. The Committee may delegate to a sub-committee and/or to officers or employees of Sponsor the day-to-day administration of the Plan. The Committee shall have full power and authority to adopt, amend and rescind any rules and regulations which it deems desirable and appropriate for the proper administration of the Plan, to construe and interpret the provisions and supervise the administration of the Plan, to make factual determinations relevant to Plan entitlements and to take all action in connection with administration of the Plan as it deems necessary or advisable, consistent with the delegation from the Board. Decisions of the Committee shall be final and binding upon all Participants. Any decision reduced to writing and signed by a majority of the members of the Committee shall be fully effective as if it had been made at a meeting of the Committee duly held. The Company shall pay all expenses incurred in the administration of the Plan.

(b) In addition to such other rights of indemnification as they may have as members of the Board or officers or employees of the Company, members of the Board and of the Committee and their delegates shall be indemnified by the Company against all reasonable expenses, including attorneys' fees, actually and necessarily incurred in connection with the defense of any action, suit or proceeding, or in connection with any appeal therein, to which they or any of them may be a party by reason of any action taken or failure to act under or in connection with the Plan, or any right granted under the Plan, and against all amounts paid by them in settlement thereof (provided such settlement is approved by independent legal counsel selected by the Sponsor) or paid by them in satisfaction of a judgment in any such action, suit or proceeding, except in relation to matters as to which it shall be adjudged in such action, suit or proceeding that such person is liable for gross negligence, bad faith or intentional misconduct in duties; provided, however, that within sixty (60) days after the institution of such action, suit or proceeding, such person shall offer to the Company, in writing, the opportunity at its own expense to handle and defend the same.

Section 16. COMMITTEE RULES FOR JURISDICTIONS OTHER THAN THE UNITED STATES

The Committee may adopt rules or procedures relating to the operation and administration of the Plan to accommodate the specific requirements of the laws and procedures of jurisdictions outside of the United States. Without limiting the generality of the foregoing, the Committee is specifically authorized to adopt rules and procedures regarding handling of payroll deductions or other contributions by Participants, payment of interest, conversion of local currency, data privacy security, payroll tax, withholding procedures and handling of stock certificates which vary with local requirements; however, if such varying provisions are not in accordance with the provisions of Section 423(b) of the Code, including but not limited to the requirement of Section 423(b)(5) of the Code that all options granted under the Plan shall have the same rights and privileges unless otherwise provided under the Code and the regulations promulgated thereunder, then the individuals affected by such varying provisions shall be deemed to be participating under a sub-plan and not in the Plan. The Committee may also adopt sub-plans applicable to particular Subsidiaries or locations, which sub-plans may be designed to be outside the scope of Code Section 423 and shall be deemed to be outside the scope of Code Section 423 unless the terms of the sub-plan provide to the contrary. The rules of such sub-plans may take precedence over other provisions of this Plan, with the exception of Section 7, but unless otherwise superseded by the terms of such sub-plan, the provisions of this Plan shall govern the operation of such sub-plan. The Committee shall not be required to obtain the approval of the Stockholders prior to the adoption, amendment or termination of any sub-plan unless required by the laws of the jurisdiction in which Employees participating in the sub-plan are located.

Section 17. SECURITIES LAWS REQUIREMENTS

(a) No option granted under the Plan may be exercised to any extent unless the shares to be issued upon such exercise under the Plan are covered by an effective registration statement pursuant to the Securities Act and the Plan is in material compliance with all applicable provisions of any applicable national, regional, state, local or other jurisdiction, including, without limitation, the Securities Act, the Exchange Act, the rules and regulations promulgated thereunder, applicable state and foreign securities laws and the requirements of any stock exchange upon which the Shares may then be listed, subject to the approval of counsel for the Company with respect to such compliance. If on a Purchase Date in any Offering Period hereunder, the Plan is not so registered or in such compliance, options granted under the Plan which are not in material compliance shall not be exercised on such Purchase Date, and the Purchase Date shall be delayed until the Plan is subject to such an effective registration statement and such compliance, except that the Purchase Date shall not be delayed more than twelve (12) months and the Purchase Date shall in no event be more than twenty-seven (27) months from the Commencement Date relating to such Offering Period. If, on the Purchase Date of any offering hereunder, as delayed to the maximum extent permissible, the Plan is not registered and in such

compliance, options granted under the Plan which are not in material compliance shall not be exercised and all payroll deductions accumulated during the Offering Period (reduced to the extent, if any, that such deductions have been used to acquire shares of Common Stock) shall be returned to the Participants, without interest. The provisions of this Section 17 shall comply with the requirements of Section 423(b)(5) of the Code to the extent applicable.

(b) As a condition to the exercise of an option, Sponsor may require the person exercising such option to represent and warrant at the time of any such exercise that the Shares are being purchased only for investment and without any present intention to sell or distribute such Shares if, in the opinion of counsel for Sponsor, such a representation is required by any of the aforementioned applicable provisions of law.

Section 18. GOVERNMENTAL REGULATIONS

This Plan and Sponsor's obligation to sell and deliver shares of its stock under the Plan shall be subject to the approval of any governmental authority required in connection with the Plan or the authorization, issuance, sale, or delivery of stock hereunder.

Section 19. NO ENLARGEMENT OF EMPLOYEE RIGHTS

Nothing contained in this Plan shall be deemed to give any Employee or other individual the right to be retained in the employ or service of Sponsor or any Participating Subsidiary or to interfere with the right of Sponsor or Participating Subsidiary to discharge any Employee or other individual at any time, for any reason or no reason, with or without notice.

Section 20. GOVERNING LAW

This Plan shall be governed by applicable laws of the State of Delaware without regard for the conflicts of laws provisions thereof, and other applicable law.

Section 21. EFFECTIVE DATE

This Plan shall be effective on the Effective Date, subject to approval of the Stockholders of Sponsor within twelve (12) months before or after its date of adoption by the Board.

Section 22. REPORTS

Individual accounts shall be maintained for each Participant in the Plan. Statements of account shall be made available to Participants at least annually, which statements shall set forth the amounts of payroll deductions, the Purchase Price, the number of shares of Common Stock purchased and the remaining cash balance, if any.

Section 23. DESIGNATION OF BENEFICIARY FOR OWNED SHARES

With respect to shares of Common Stock purchased by the Participant pursuant to the Plan and held in an account maintained by Sponsor or its assignee on the Participant's behalf, the Participant may be permitted to file a written designation of beneficiary, who is to receive any shares and cash, if any, from the Participant's account under the Plan in the event of such

Participant's death subsequent to the end of an Offering Period but prior to delivery to him or her of such shares and cash. In addition, a Participant may file a written designation of a beneficiary who is to receive any cash from the Participant's account under the Plan in the event of such Participant's death prior to the Purchase Date of an Offering Period. If a Participant is married and the designated beneficiary is not the spouse, spousal consent shall be required for such designation to be effective to the extent required by local law. The Participant (and if required under the preceding sentence, his or her spouse) may change such designation of beneficiary at any time by written notice. Subject to local legal requirements, in the event of a Participant's death, Sponsor or its assignee shall deliver any shares of Common Stock and/or cash to the designated beneficiary. Subject to local law, in the event of the death of a Participant and in the absence of a beneficiary validly designated who is living at the time of such Participant's death, Sponsor shall deliver such shares of Common Stock and/or cash to the executor or administrator of the estate of the Participant, or if no such executor or administrator has been appointed (to the knowledge of Sponsor), Sponsor in its sole discretion, may deliver (or cause its assignee to deliver) such shares of Common Stock and/or cash to the spouse, or to any one or more dependents or relatives of the Participant, or if no spouse, dependent or relative is known to Sponsor, then to such other person as Sponsor may determine. The provisions of this Section 23 shall in no event require Sponsor to violate local law, and Sponsor shall be entitled to take whatever action it reasonably concludes is desirable or appropriate in order to transfer the assets allocated to a deceased Participant's account in compliance with local law.

Section 24. ADDITIONAL RESTRICTIONS OF RULE 16b-3.

The terms and conditions of options granted hereunder to, and the purchase of shares of Common Stock by, persons subject to Section 16 of the Exchange Act shall comply with the applicable provisions of Rule 16b-3. This Plan shall be deemed to contain, and such options shall contain, and the shares of Common Stock issued upon exercise thereof shall be subject to, such additional conditions and restrictions, if any, as may be required by Rule 16b-3 to qualify for the maximum exemption from Section 16 of the Exchange Act with respect to Plan transactions.

Section 25. NOTICES

All notices or other communications by a Participant to Sponsor or the Committee under or in connection with the Plan shall be deemed to have been duly given when received in the form specified by Sponsor or the Committee at the location, or by the person, designated by Sponsor for the receipt thereof.

NON-EMPLOYEE DIRECTOR COMPENSATION POLICY

The purpose of this Non-Employee Director Compensation Policy (the "Policy") of 89bio, Inc. (the "Company"), is to provide a compensation package that enables the Company to attract and retain high-caliber directors and aligns their interests with the interests of the Company's shareholders.

1. ELIGIBILITY

The Policy applies to all members of the Company's Board of Directors (the "Board") who are not employees or officers of the Company or its subsidiaries. Directors who are employees or officers of the Company or its subsidiaries do not receive compensation for their service on the Board.

2. CASH RETAINERS

The Company shall pay cash retainers as set forth below, such retainers to be: (i) paid for the directors' general availability and participation in regularly scheduled and specially called meetings and conference calls; (ii) paid quarterly in arrears; and (iii) pro-rated based on the number of actual days served by the director on the Board or applicable committee during such calendar quarter or year.

Annual retainer for Board membership	$40,000
Additional annual retainer for service as a committee chair*	$10,000
Additional annual retainer for service as Chairman of the Board	$60,000

**Applies with respect to each of the Audit, Compensation, and Nominating and Corporate Governance Committees*

3. EQUITY AWARDS

The Compensation Committee of the Board may in its discretion grant equity awards to any or all non-employee directors under the 89Bio Inc. 2019 Equity Incentive Plan. Such awards may include: (i) an initial, one-time equity award granted to a new non-employee director upon his or her election to the Board; (ii) equity awards granted to non-employee directors on an annual basis for their service on the Board; and/or (iii) equity awards granted to non-employee directors on an annual basis for their service in a Board leadership role or on a committee. Pursuant to its charter, the Compensation Committee may engage outside compensation consultants to assist in determining the appropriate form, amounts and terms of any such equity awards.

4. EXPENSES

The Company shall reimburse all necessary and reasonable out-of-pocket expenses (including, but not limited to, travel, food and lodging) incurred by non-employee directors in attending meetings of the Board or any committee or otherwise in connection with their service on the Board, subject to any applicable Company policies that may be in effect from time to time.

5. ADMINISTRATION

The Board, with the assistance of the Compensation Committee, administers the Policy and may amend the Policy at any time in its sole discretion. A non-employee director may decline all or any portion of his or her compensation by giving notice to the Company prior to, as the case may be, the date cash is to be paid or equity awards are to be granted.

Policy adopted on October 24, 2019
(effective upon and subject to the completion of the Company's underwritten initial public offering)

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the use in this Amendment No. 1 to registration statement No. 333-234174 on Form S-1, of 89bio, Inc. of our report dated September 19, 2019 (October 28, 2019 as to the retroactive effect of the reverse stock split and the Reorganization as described in Note 2 and Note 4, respectively) on our audit of the financial statement of 89Bio Inc. as of June 28, 2019, and the reference to us under the caption "Experts."

/s/ Brightman Almagor Zohar & Co.
A Firm in the Deloitte Global Network

Tel Aviv, Israel

October 28, 2019

Exhibit 23.2

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the use in this Amendment No. 1 to registration statement No. 333-234174 on Form S-1, of 89bio, Inc. of our report dated August 15, 2019 (October 28, 2019 as to the retroactive effect of the reverse stock split and the Reorganization as described in Note 2 and Note 13, respectively) on our audit of the consolidated financial statements of 89Bio Ltd. as of December 31, 2018, and the related statements of operations and comprehensive loss, change in convertible preferred shares and shareholders' deficit and cash flows from inception January 18, 2018 through December 31, 2018 (which report expresses an unqualified opinion and includes an explanatory paragraph regarding the Company's ability to continue as a going concern), and the reference to us under the caption "Experts."

/s/ Brightman Almagor Zohar & Co.
A Firm in the Deloitte Global Network

Tel Aviv, Israel

October 28, 2019