UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended March 31, 2021

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____to _____

Commission File Number: 001-39122

89bio, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**36-4946844**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
142 Sansome Street, Second Floor San Francisco, California 94104	**94104**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (415) 500-4614

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value $0.001 per share	ETNB	Nasdaq Global Market

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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.

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 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Sections 12, 13 or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court. Yes ☒ No ☐

As of May 7, 2021, the registrant had 20,060,268 shares of common stock, $0.001 par value per share, outstanding.

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

89bio, Inc.
Condensed Consolidated Balance Sheets
(In thousands)

	March 31, 2021 (Unaudited)	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 68,007	$ 98,183
Restricted cash	25	25
Short-term available-for-sale securities	121,618	106,446
Prepaid and other current assets	8,286	5,548
Total current assets	197,936	210,202
Property and equipment, net	161	166
Other assets	557	706
Total assets	$ 198,654	$ 211,074
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 4,521	$ 2,065
Accrued expenses	3,938	6,048
Total current liabilities	8,459	8,113
Commitments and contingencies (Note 5)		
Stockholders' equity:		
Common stock	20	20
Additional paid-in capital	328,055	326,046
Accumulated other comprehensive loss	(3)	(10)
Accumulated deficit	(137,877)	(123,095)
Total stockholders' equity	190,195	202,961
Total liabilities and stockholders' equity	$ 198,654	$ 211,074

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

89bio, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2021	**2020**
Operating expenses:		
Research and development	$ 10,131	$ 7,778
General and administrative	4,608	2,924
Total operating expenses	14,739	10,702
Loss from operations	(14,739)	(10,702)
Other (expenses) income, net	(43)	157
Net loss before tax	(14,782)	(10,545)
Income tax benefit	—	1
Net loss	$ (14,782)	$ (10,544)
Other comprehensive income (loss):		
Unrealized loss on available-for-sale securities	(4)	—
Foreign currency translation adjustments	11	—
Total other comprehensive income	$ 7	$ —
Comprehensive loss	$ (14,775)	$ (10,544)
Net loss per share, basic and diluted	$ 0.74	$ 0.76
Weighted-average shares used to compute net loss per share, basic and diluted	20,010,412	13,789,786

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

89bio, Inc.
Condensed Consolidated Statements of Stockholders' Equity
For the Three Months Ended March 31, 2021 and 2020
(Unaudited)
(In thousands, except share amounts)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance as of December 31, 2020	19,931,660	$ 20	$ 326,046	$ (10)	$ (123,095)	$ 202,961
Issuance of common stock upon exercise of stock options	103,170	—	216	—	—	216
Stock-based compensation	—	—	1,793	—	—	1,793
Net loss	—	—	—	—	(14,782)	(14,782)
Other comprehensive income	—	—	—	7	—	7
Balance as of March 31, 2021	20,034,830	$ 20	$ 328,055	$ (3)	$ (137,877)	$ 190,195

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance as of December 31, 2019	13,788,982	$ 14	$ 163,526	$ —	$ (73,596)	$ 89,944
Issuance of common stock upon exercise of stock options	4,876	—	9	—	—	9
Stock-based compensation	—	—	493	—	—	493
Net loss	—	—	—	—	(10,544)	(10,544)
Balance as of March 31, 2020	13,793,858	$ 14	$ 164,028	$ —	$ (84,140)	$ 79,902

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

89bio, Inc.
Condensed Consolidated Statements of Cash Flows
(Unaudited)
(In thousands)

	Three Months Ended March 31,	
	2021	**2020**
Cash flows from operating activities:		
Net loss	$ (14,782)	$ (10,544)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	15	12
Stock-based compensation	1,793	493
Amortization of premium on available-for-sale securities	229	—
Amortization of debt issuance costs	77	—
Changes in operating assets and liabilities:		
Prepaid and other current assets	(2,726)	109
Other assets	72	—
Accounts payable	2,450	3,066
Accrued expenses	(2,110)	(888)
Net cash used in operating activities	(14,982)	(7,752)
Cash flows from investing activities:		
Purchases of available-for-sale securities	(45,302)	—
Proceeds from maturities of available-for-sale securities	29,896	—
Purchases of property and equipment	(4)	(61)
Net cash used in investing activities	(15,410)	(61)
Cash flows from financing activities:		
Proceeds from issuance of common stock upon stock option exercises	216	9
Net cash provided by financing activities	216	9
Net decrease in cash and cash equivalents, and restricted cash	(30,176)	(7,804)
Cash and cash equivalents, and restricted cash at beginning of period	98,208	93,360
Cash and cash equivalents, and restricted cash at end of period	$ 68,032	$ 85,556
Components of cash and cash equivalents, and restricted cash:		
Cash and cash equivalents	$ 68,007	$ 85,532
Restricted cash	25	24
Total cash and cash equivalents, and restricted cash	$ 68,032	$ 85,556
Supplemental cash flow disclosures:		
Property and equipment purchases included in accounts payable and accrued expenses	$ 6	$ 54
Cash paid for taxes	$ 154	$ —

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

1. Organization and Basis of Presentation

Description of Business

89bio, Inc. ("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 and for the treatment of severe hypertriglyceridemia.

89bio, Inc. was formed as a Delaware corporation in June 2019, for the purpose of completing an initial public offering and related transactions in order to carry on the business of 89Bio Ltd., which was incorporated in Israel in January 2018.

Public Offerings

In July 2020, the Company completed an underwritten public offering of 3,047,040 shares of its common stock, at the public offering price of $27.50 per share. The Company raised a total of $78.2 million in net proceeds after deducting underwriting discounts and commissions of $5.0 million and offering costs of approximately $0.6 million.

In September 2020, the Company completed an underwritten public offering of 3,025,000 shares of its common stock, at a public offering price of $28.00 per share. The Company raised a total of $79.5 million in net proceeds after deducting underwriting discounts and commissions of $4.6 million and offering costs of approximately $0.6 million.

Liquidity

The accompanying condensed consolidated financial statements have been 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. The Company had cash, cash equivalents and short-term available-for-sale securities of $189.6 million as of March 31, 2021.

The Company expects that its cash, cash equivalents and short-term available-for-sale securities as of March 31, 2021, together with proceeds available from the Company's term loan (see Note 6), will be sufficient to fund operating expenses and capital expenditure requirements for a period of at least one year from the date these unaudited condensed consolidated financial statements are filed with the Securities and Exchange Commission ("SEC").

2. Summary of Significant Accounting Policies

Unaudited Condensed Consolidated Financial Statements

The accompanying interim unaudited condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States ("U.S. GAAP") and applicable rules and regulations of the SEC regarding interim financial reporting.

The accompanying interim condensed consolidated financial statements are unaudited. The interim unaudited condensed consolidated financial statements have been prepared on the same basis as the audited consolidated financial statements as of and for the year ended December 31, 2020 and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary to present fairly the Company's consolidated financial position, results of operations and comprehensive loss, and cash flows. The results of operations for the three months ended March 31, 2021 are not necessarily indicative of the results to be expected for the year ending December 31, 2021 or for any other future annual or interim period. The condensed consolidated balance sheet as of December 31, 2020 was derived from the audited financial statements as of that date. These condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements included in the Annual Report on Form 10-K for the year ended December 31, 2020, which was filed with the SEC on March 25, 2021.

Principles of Consolidation

The accompanying condensed 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 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 and certain accrued expenses. 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 condensed consolidated balance sheets. The carrying values of Company's financial assets and liabilities, including cash and cash equivalents, restricted cash, prepaid and other current assets, accounts payable, and accrued expenses approximate to their fair value due to the short-term nature 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 or 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.

Risks and Uncertainties

The ongoing COVID-19 pandemic has disrupted and may continue to disrupt the Company's business and delay its preclinical and clinical programs and timelines. The Company does not yet know the full extent of potential delays to clinical trials, which could prevent or delay the Company from obtaining approval for BIO89-100. The extent to which the COVID-19 pandemic may impact the Company's future operating results and financial condition is uncertain.

Cash and Cash Equivalents

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 funds and commercial paper that are stated at fair value.

Investments

Investments have been classified as available-for-sale and are carried at estimated fair value as determined based upon quoted market prices or pricing models for similar securities. Management determines the appropriate classification of its available-for-sale investments in debt securities at the time of purchase. Generally, investments with original maturities beyond three months at the date of purchase are classified as short-term because it is management's intent to use the investments to fund current operations or to make them available for current operations.

Unrealized gains and losses are excluded from earnings and are reported as a component of comprehensive loss. The Company periodically evaluates whether declines in fair values of its available-for-sale securities below their book value are other-than-temporary. This evaluation consists of several qualitative and quantitative factors regarding the severity and duration of the unrealized loss as well as the Company's ability and intent to hold the available-for-sale security until a forecasted recovery occurs. Additionally, the Company assesses whether it has plans to sell the security or it is more likely than not it will be required to sell any available-for-sale securities before recovery of its amortized cost basis. Realized gains and losses and declines in fair value judged to be other than temporary, if any, on available-for-sale securities are included in other (expenses) income, net. The cost of investments sold is based on the specific-identification method. There are no material realized gains or losses on investments for the periods presented. Interest on available-for-sale securities is included in other (expenses) income, net.

Comprehensive Loss

The Company's comprehensive loss is comprised of changes in unrealized gains or losses on available-for-sale securities and foreign currency translation adjustments.

Recent Accounting Pronouncements

In February 2016, the Financial Standards Accounting Board (the "FASB") issued Accounting Standards Update ("ASU") 2016-02—*Leases* ("ASU 2016-02"), 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, 2021. As an emerging growth company, ASU 2016-02 is effective for the Company for the year ending December 31, 2022 and interim periods within the year ending December 31, 2023. The Company is currently evaluating the impact of this standard on its consolidated financial statements and related disclosures.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments—Credit Losses (Topic 326)*: *Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"), which replaces the existing incurred loss impairment model with an expected credit loss model and requires a financial asset measured at amortized cost to be presented at the net amount expected to be collected. The standard is effective for public entities for fiscal years beginning after December 15, 2019 and for nonpublic entities for fiscal years beginning after December 15, 2022. As an emerging growth company, ASU 2016-13 is effective for the Company for the year ending December 31, 2023 and interim periods within that fiscal year and must be adopted using a modified retrospective approach, with certain exceptions. The Company is currently evaluating the impact of this standard on its consolidated financial statements and related disclosures.

3. Fair Value Measurements

The following table presents the Company's financial assets measured at fair value on a recurring basis by level within the fair value hierarchy as of March 31, 2021 (in thousands):

		March 31, 2021			
	Valuation Hierarchy	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Money market funds	Level 1	$ 53,011	$ —	$ —	$ 53,011
Commercial paper	Level 2	74,420	—	(6)	74,414
Agency bonds	Level 2	21,367	14	—	21,381
Corporate debt securities	Level 2	18,794	1	(9)	18,786
Municipal bonds	Level 2	6,241	2	—	6,243
U.S. government bonds	Level 2	5,554	2	—	5,556
Non-U.S. debt securities	Level 2	2,537	—	—	2,537
Total cash equivalents and available-for-sale securities		$ 181,924	$ 19	$ (15)	$ 181,928
Classified as:					
Cash equivalents					$ 60,310
Short-term available-for-sale securities					121,618
Total cash equivalents and available-for-sale securities					$ 181,928

The following table summarizes the Company's available-for-sale securities by contractual maturity as of March 31, 2021 (in thousands):

	March 31, 2021
Within one year	$ 173,388
After one year through two years	8,540
Total cash equivalents and available-for-sale securities	$ 181,928

The following table presents the Company's financial assets measured at fair value on a recurring basis by level within the fair value hierarchy as of December 31, 2020 (in thousands):

		December 31, 2020			
	Valuation Hierarchy	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Money market funds	Level 1	$ 46,134	$ —	$ —	$ 46,134
Commercial paper	Level 2	76,605	—	(2)	76,603
Agency bonds	Level 2	29,654	15	—	29,669
Corporate debt securities	Level 2	11,890	—	(6)	11,884
U.S. government bonds	Level 2	7,093	—	—	7,093
Municipal bonds	Level 2	5,592	2	(1)	5,593
U.S. treasury bills	Level 2	4,680	—	—	4,680
Agency discount securities	Level 2	200	—	—	200
Total cash equivalents and available-for-sale securities		$ 181,848	$ 17	$ (9)	$ 181,856
Classified as:					
Cash equivalents					$ 75,410
Short-term available-for-sale securities					106,446
Total cash equivalents and available-for-sale securities					$ 181,856

The following table summarizes the Company's available-for-sale securities by contractual maturity as of December 31, 2020 (in thousands):

	December 31, 2020
Within one year	$ 160,304
After one year through two years	21,552
Total cash equivalents and available-for-sale securities	$ 181,856

4. Accrued Expenses

Accrued expenses consist of the following as of the periods indicted (in thousands):

	March 31, 2021	December 31, 2020
Accrued research and development expense	$ 2,121	$ 2,884
Accrued employee and related expenses	1,067	2,552
Accrued professional and legal fees	543	453
Accrued other expenses	207	159
Total accrued expenses	$ 3,938	$ 6,048

5. Commitments and Contingencies

Leases

Future minimum lease payments under the Company's non-cancellable operating lease obligations as of March 31, 2021, are as follows (in thousands):

	March 31, 2021
Remainder of 2021	$ 166
2022	8
Total future minimum annual payments	$ 174

Rent expense was $73,000 and $60,000 for the three months ended March 31, 2021 and 2020, respectively.

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.

During the three months ended March 31, 2021 and 2020, there were no license payment expenses related to the Teva Agreements.

6. Term Loan

Loan and Security Agreement

In April 2020, the Company and certain of its subsidiaries entered into a Loan and Security Agreement, (as amended, the "Loan Agreement") with the lenders referred to therein (the "Lenders"), and Silicon Valley Bank, as collateral agent. The Loan Agreement provides for (i) a secured term A loan facility (the "Term A Loan Facility") of up to $10.0 million and (ii) a secured term B loan facility (the "Term B Loan Facility") of up to $5.0 million that became available upon the satisfaction of certain milestones, each of which is available to be drawn through May 31, 2021 (see Note 9). The Term A Loan Facility matures on November 1, 2022, provided, that if the Term B Loan Facility is funded, the facilities instead mature on September 1, 2023. The loans will bear interest at the greater of (i) 4.50% and (ii) the sum of (a) the Prime Rate as reported in The Wall Street Journal plus (b) 1.25%. As of March 31, 2021, the Company had not drawn any amount under the Loan Agreement.

In April 2020, in connection with the execution of the Loan Agreement, the Company issued Silicon Valley Bank a warrant to purchase 25,000 shares of the Company's common stock with a warrant exercise price of $22.06 per share that is immediately exercisable. The initial expiration date of April 7, 2030 was changed to June 30, 2025 in connection with the July 2020 offering. The Company determined the fair value of the warrant at the issuance date by using the Black-Scholes option-pricing model with the following assumptions: risk-free interest rate of 0.75%, no dividends, expected volatility of 92.30% and expected term of 10.0 years. Upon issuance, the fair value allocated to the warrant of $0.6 million was recorded as a debt issuance cost and classified within other assets and met the requirements for equity classification within additional paid-in capital on the condensed consolidated balance sheets. An additional warrant to purchase 8,333 shares of the Company's common stock will be issued in connection with the Term B Loan Facility, if funded, with the exercise price determined on the Company's stock price at the time of issuance.

Additionally, the Company incurred $0.2 million in closing costs that were recorded as debt issuance costs and classified within other assets on the condensed consolidated balance sheets.

The deferred assets related to the debt issuance cost and warrant are recognized as interest expense over the duration of the Loan Agreement and are recorded within other (expenses) income, net on the condensed consolidated statements of operations and comprehensive loss. As of March 31, 2021, the remaining unamortized debt issuance costs classified within other assets on the condensed consolidated balance sheet is $0.5 million.

7. Stockholders' Equity

Equity Incentive Plan

The Company's board of directors approved the 2019 Equity Incentive Plan (the "2019 Plan"), which became effective in September 2019.

The Company initially reserved 2,844,193 shares of common stock for issuance under the 2019 Plan. In addition, the number of shares of common stock reserved for issuance under the 2019 Plan will automatically increase on the first day of January for a period of up to ten years, commencing on January 1, 2020, in an amount equal to 4% of the total number of shares of the Company's capital stock outstanding on the immediately preceding December 31, or a lesser number of shares determined by the Company's board of directors. As of March 31, 2021, there were 1,633,644 shares of common stock available for issuance as future option grants under the 2019 Plan.

Employee Stock Purchase Plan

In October 2019, the Company adopted the 2019 Employee Stock Purchase Plan ("ESPP"), which became effective in November 2019. The Company initially reserved 225,188 shares of common stock for purchase under the ESPP. The number of shares of common stock reserved for issuance under the ESPP will automatically increase on the first day of January for a period of up to ten years, in an amount equal to 1% of the total number of shares of the Company's common stock outstanding on the immediately preceding December 31, or a lesser number of shares determined by the Company's board of directors. Purchases will be accomplished through the participation of discrete offering periods and each offering is expected to be 6 months long. For each offering period, ESPP participants will purchase shares of common stock at a price per share equal to 85% of the lesser of the fair market value of the Company's common stock on (1) the first trading day of the applicable offering period or (2) the last trading day of the applicable offering period. The first six month offering period under the ESPP commenced on January 1, 2020.

As of March 31, 2021, there were 555,122 shares of common stock available for issuance under the ESPP.

The Company recorded stock-based compensation for the periods indicated as follows (in thousands):

	Three Months Ended March 31,	
	2021	2020
Research and development	$ 639	$ 192
General and administrative	1,154	301
Total stock-based compensation	$ 1,793	$ 493

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:

	Three Months Ended March 31,	
	2021	2020
Stock Options		
Expected term (years)	6.1	6.0-6.1
Contractual term (years)	10.0	10.0
Expected volatility	97.5-97.6 %	86.4-87.5 %
Risk-free interest rate	0.7-0.8 %	0.5-1.5 %
Expected dividend	—	—

The following table summarizes stock option activity for the three months ended March 31, 2021:

	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, 2020	1,898,395	$ 12.79	8.60	$ 25,918
Granted	538,613	23.04		
Exercised	(103,170)	2.09		
Cancelled	(52,728)	16.42		
Balance outstanding as of March 31, 2021	2,281,110	15.61	8.65	$ 22,657
Exercisable as of March 31, 2021	627,372	$ 8.06	7.87	$ 10,725

Restricted Stock Units ("RSUs")

In February 2021, the Company granted 56,545 service based RSUs to its employees with a total grant date fair value of $1.3 million. The RSUs vest annually over a three-year period. The Company recognized $0.1 million of compensation expense related to the service based RSUs in the three months ended March 31, 2021.

In February 2021, the Company granted 61,500 performance based RSUs to certain executives, one-third of which vest on each one-year anniversary date subject to achievement of a development milestone and continued service to the Company. The performance based RSUs have a total grant date fair value of $1.4 million. The Company recognized $0.1 million of compensation expense, using the accelerated attribution method, related to the performance based RSUs in the three months ended March 31, 2021.

8. Net Loss Per Share

Basic net loss per share is computed by dividing net loss by the weighted-average number of shares of common stock outstanding for the period. Since the Company was in a loss position for all periods presented, diluted net loss per share is the same as basic net loss per share for all periods as the inclusion of all potential shares of common stock outstanding would have been anti-dilutive.

The following outstanding potentially dilutive common stock equivalents have been excluded from the calculation of diluted net loss per share for the periods presented due to their anti-dilutive effect:

	Three Months Ended March 31,	
	2021	2020
Stock options to purchase common stock	2,281,110	1,714,685
Shares available for future option grants	1,633,644	1,676,191
Unvested restricted stock units	111,728	—
Employee stock purchase plan	2,357	1,735
Total	4,028,839	3,392,611

9. Subsequent Event

In April 2021, the Company entered into an amendment to the Loan and Security Agreement with Silicon Valley Bank to extend the draw period for both the Term Loan A Facility and Term Loan B Facility to May 31, 2021.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

Forward Looking Statements

You should read the following discussion and analysis of our financial condition and results of operations together with our unaudited condensed consolidated financial statements and related notes and other financial information included elsewhere in this Quarterly Report on Form 10-Q and our consolidated financial statements and related notes and other financial information included in our Annual Report on Form 10-K for the year ended December 31, 2020. Some of the information contained in this discussion and analysis 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 Quarterly Report on Form 10-Q.

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 and for the treatment of SHTG. 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. In September 2020, we announced positive topline data from the Phase 1b/2a trial of BIO89-100 in NASH. In December 2020, we initiated a paired-biopsy open-label cohort as part of the Phase 1b/2a trial in NASH patients assessing histology endpoints with topline data anticipated by the end of 2021. In April 2021, we announced that we received written guidance from the U.S. Food and Drug Administration ("FDA") on the design of our planned Phase 2b trial ENLIVEN evaluating BIO89-100 for the treatment of patients with fibrosis stage 2 or 3 NASH, including agreement on the use of a liquid formulation. A total of approximately 200 patients will receive either one of two different weekly doses or an every two-week dose of BIO89-100 or placebo for 24 weeks followed by a blinded extension phase of an additional 24 weeks for a total treatment period of 48 weeks. The primary efficacy outcome measures at Week 24 will include the two key histology-based endpoints of NASH resolution without worsening of fibrosis and the improvement of fibrosis ≥ 1 stage without worsening of NASH. We plan to initiate the ENLIVEN trial in the second quarter of 2021.

SHTG is 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 initiated our Phase 2 trial (ENTRIGUE) in SHTG patients in the third quarter of 2020 and expect to report topline data in the second half of 2021.

We commenced operations in 2018 and have devoted substantially all of our resources to raising capital, acquiring our initial product candidate, identifying and developing BIO89-100, licensing certain related technology, conducting research and development activities (including preclinical studies and clinical trials) and providing general and administrative support for these operations. Prior to our initial public offering ("IPO"), we had funded our operations primarily from the issuance and sale of capital stock. In November 2019, we completed our IPO pursuant to which we issued 6,100,390 shares of our common stock at a price of $16.00 per share. We received net proceeds of $87.7 million from the IPO.

In July 2020, we completed an underwritten public offering of 3,047,040 shares of our common stock at a public offering price of $27.50 per share. We received net proceeds of $78.2 million after deducting underwriters' discounts and commissions of $5.0 million and offering costs of approximately $0.6 million.

In September 2020, we completed an underwritten public offering of 3,025,000 shares of our common stock, at a public offering price of $28.00 per share. We received net proceeds of $79.5 million after deducting underwriting discounts and commissions of $4.6 million and offering costs of approximately $0.6 million.

As of March 31, 2021, our cash, cash equivalents and short-term available-for-sale securities totaled $189.6 million. Based on our current operating plan, we believe that our cash, cash equivalents and short-term available-for-sale securities, together with the proceeds available under our term loan facility, will be sufficient to meet our anticipated cash requirements for a period of at least one year from the date this Quarterly Report on Form 10-Q is filed with the Securities and Exchange Commission ("SEC").

We have incurred net losses since our inception. Our net losses for the three months ended March 31, 2021 and 2020 were $14.8 million and $10.5 million, respectively. As of March 31, 2021, we had an accumulated deficit of $137.9 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.

Impact of COVID-19 Pandemic

The ongoing COVID-19 pandemic has disrupted and may continue to disrupt our business and delay our preclinical and clinical programs and timelines. The extent to which the COVID-19 pandemic may impact our future operating results and financial condition is uncertain. We initiated our Phase 2 trial (ENTRIGUE) in SHTG patients in the third quarter of 2020 as well as a new paired-biopsy open-label histology cohort as part of the Phase 1b/2a trial in the fourth quarter of 2020. The COVID-19 surge observed late in the fourth quarter of 2020 and in the first quarter of 2021 has adversely impacted enrollment in these studies. While the recent COVID-19 surge in Europe has also resulted in enrollment challenges in certain geographies, we are working closely with our CRO and remain optimistic that enrollment will pick up in the trial.

We plan to initiate a Phase 2b trial (ENLIVEN) in NASH patients in the second quarter of 2021. We do not yet know the full extent of potential delays, which could prevent or delay us from obtaining approval for BIO89-100. For more information regarding risks related to the ongoing COVID-19 pandemic, please see the risk factor entitled “The ongoing COVID-19 pandemic has resulted and may in the future result in significant disruptions to our clinical trials or other business operations, which could have a material adverse effect on our business,” in Part II. Item 1A of this Quarterly Report on Form 10-Q. To the extent the ongoing COVID-19 pandemic adversely affects our business and financial results, it may also have the effect of heightening many of the other risks set forth under “Risk Factors” in this Quarterly Report on Form 10-Q.

Components of Results of Operations

Research and Development Expenses

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 stock-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 accrued expenses 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.

General and Administrative Expenses

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 stock-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.

Other (Expenses) Income, Net

Other (expenses) income, net primarily consists of interest on available-for-sale securities and amortization of deferred debt issuance costs.

Results of Operations

Three Months Ended March 31, 2021 and 2020

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

	Three Months Ended March 31,		
	2021	2020	Change
Operating expenses:			
Research and development	$ 10,131	$ 7,778	$ 2,353
General and administrative	4,608	2,924	1,684
Total operating expenses	14,739	10,702	4,037
Loss from operations	(14,739)	(10,702)	(4,037)
Other (expenses) income, net	(43)	157	(200)
Income tax benefit	—	1	(1)
Net loss	$ (14,782)	$ (10,544)	$ (4,238)

Research and Development Expenses

The following table summarizes the period-over-period changes in research and development expenses for the periods presented (in thousands):

	Three Months Ended March 31,		
	2021	2020	Change
Clinical development	$ 3,681	$ 4,348	$ (667)
Contract manufacturing	3,389	1,191	2,198
Personnel-related expenses	2,584	1,403	1,181
Preclinical costs	135	656	(521)
Other expenses	342	180	162
Total research and development expenses	$ 10,131	$ 7,778	$ 2,353

Research and development expenses increased by $2.4 million, or 30%, to $10.1 million for the three months ended March 31, 2021 from $7.8 million for the three months ended March 31, 2020. The change was primarily due to an increase of $2.2 million in contract manufacturing costs as a result of the manufacture of additional supplies for our ongoing clinical trials, including our clinical trials initiated in the second half of 2020 and an increase of $1.2 million in personnel-related costs, including stock-based compensation, due to higher headcount. The increases were partially offset by a decrease of $0.7 million in clinical development costs and a decrease of $0.5 million in preclinical costs. The timing of such costs is dependent upon the status and stage of our clinical trials.

General and Administrative Expenses

General and administrative expenses increased by $1.7 million, or 58%, to $4.6 million for the three months ended March 31, 2021 from $2.9 million for the three months ended March 31, 2020. The change was primarily due to an increase of $1.1 million in personnel-related costs, including stock-based compensation, driven by higher headcount, an increase of $0.5 million in insurance related costs and an increase of $0.1 million in professional services including legal and accounting consulting service fees.

Other (Expenses) Income, Net

Other (expenses) income, net changed by $0.2 million to net expense of $43,000 for the three months ended March 31, 2021 from net income of $0.2 million for the three months ended March 31, 2020. The change was primarily due to amortization of deferred debt issuance costs in 2021 offset by interest income.

Liquidity and Capital Resources

To date, we have incurred significant net losses and negative cash flows from operations. As of March 31, 2021, we had available cash and cash equivalents and short-term available-for-sale securities of $189.6 million and an accumulated deficit of $137.9 million. Prior to our IPO, we funded our operations from the issuance and sale of capital stock. In connection with our IPO, we issued and sold an aggregate of 6,100,390 shares of common stock at a price of $16.00 per share. We received proceeds of $87.7 million, net of underwriting discounts and commissions and estimated offering costs.

In April 2020, we entered into a secured term loan facility with an aggregate committed principal amount of up to $15.0 million. In March 2021 and April 2021, the Company entered into amendments to the Loan Agreement to extend the draw period for the Term A Loan Facility and the Term B Loan Facility from March 31, 2021 to May 31, 2021. As of March 31, 2021, we have not drawn any amount under the term loan facility.

In July 2020, we completed an underwritten public offering of 3,047,040 shares of our common stock, at a public offering price of $27.50 per share. Upon completion of the offering, we received proceeds of $78.2 million, net of underwriting discounts and commissions and offering expenses.

In September 2020, we completed an underwritten public offering of 3,025,000 shares of our common stock, at a public offering price of $28.00 per share. Upon completion of the offering, we received proceeds of $79.5 million, net of underwriting discounts and commissions and offering expenses.

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 research and development plans, we expect that our existing cash, cash equivalents and short-term available-for-sale securities, together with the proceeds available under our term loan facility, will be sufficient to fund our operations for a period of at least one year from the date this Quarterly Report on Form 10-Q is filed with the SEC. 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 to advance our current product candidate through clinical development, to develop, acquire or in-license other potential product candidates and to fund operations for the foreseeable future. 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. Any failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies.

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.

Cash Flows

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

	Three Months Ended March 31,	
	2021	2020
Net cash used in operating activities	$ (14,982)	$ (7,752)
Net cash used in investing activities	(15,410)	(61)
Net cash provided by financing activities	216	9
Net decrease in cash and cash equivalents, and restricted cash	$ (30,176)	$ (7,804)

Net Cash Used in Operating Activities

During the three months ended March 31, 2021, net cash used in operating activities was $15.0 million, which consisted of a net loss of $14.8 million and a net change of $2.3 million in our net operating assets and liabilities, partially offset by non-cash charges of $2.1 million. The non-cash charges are primarily comprised of $1.8 million in stock-based compensation, $0.2 million in amortization of premium on available-for-sale securities and $0.1 million in amortization of debt issuance costs. The change in our operating assets and liabilities was primarily due to a $2.7 million increase in prepaid and other current assets due to the timing of payments, offset in part by a $0.3 million increase in accounts payable and accrued expenses due to increased activities.

During the three months ended March 31, 2020, net cash used in operating activities was $7.8 million, which consisted of a net loss of $10.5 million, partially offset by non-cash charges of $0.5 million and a net change of $2.3 million in our net operating assets and liabilities. The non-cash charges are primarily comprised of $0.5 million in stock-based compensation. The change in our operating assets and liabilities was primarily due to a $2.2 million increase in accounts payable and accrued expenses as we grew our operations and a $0.1 million decrease in other current assets due to the timing of payments.

Net Cash Used in Investing Activities

During the three months ended March 31, 2021, net cash used in investing activities was $15.4 million, which consisted of $45.3 million in purchases of available-for-sale securities, offset in part by $29.9 million in proceeds from maturities of available-for-sale securities.

During the three months ended March 31, 2020, net cash used in investing activities consisted of purchases of fixed assets.

Net Cash Provided by Financing Activities

During the three months ended March 31, 2021 and 2020, net cash provided by financing activities consisted of proceeds from the issuance of common stock upon exercise of stock options.

Contractual Obligations and Other Commitments

We are a smaller reporting company, as defined by Rule 12b-2 under the Securities and Exchange Act of 1934 and in Item 10(f)(1) of Regulation S-K, and are not required to provide the information under this item.

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.

Critical Accounting Polices and Estimates

There have been no significant changes in our critical accounting policies and estimates as compared to the critical accounting policies and estimates disclosed our Annual Report on Form 10-K for the year ended December 31, 2020.

Recent Accounting Pronouncements

See Note 2 to our condensed consolidated financial statements for more information.

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.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are a smaller reporting company, as defined by Rule 12b-2 under the Securities and Exchange Act of 1934 and in Item 10(f)(1) of Regulation S-K, and are not required to provide the information under this item.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

As of March 31, 2021, our management, with the participation and supervision of our principal executive officer and our principal financial officer, evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the Company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost benefit relationship of possible controls and procedures. Based on this evaluation, our principal executive officer and our principal financial officer concluded that our disclosure controls and procedures were effective as of March 31, 2021 to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and our principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the quarter ended March 31, 2021 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. 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.

Item 1A. 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 make an investment decision with respect to shares of our common stock. You should also refer to the other information contained in this Quarterly Report on Form 10-Q, including "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our unaudited condensed consolidated financial statements and related notes. 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. We caution you that the risks, uncertainties and other factors referred to below and elsewhere in this Quarterly Report on Form 10-Q 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.

Risk Factor Summary

Investing in our common stock involves significant risks. You should carefully consider the risks described below before making a decision to invest in our common stock. If we are unable to successfully address these risks and challenges, our business, financial condition, results of operations, or prospects could be materially adversely affected. In such case, the trading price of our common stock would likely decline, and you may lose all or part of your investment. Below is a summary of some of the risks we face.

- 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.
- The ongoing COVID-19 pandemic has resulted and may in the future result in significant disruptions to our clinical trials or other business operations, which could have a material adverse effect on our business.
- Our business depends on the success of BIO89-100, our only product candidate under clinical development, which 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.
- If we experience delays in clinical testing, our commercial prospects will be adversely affected, our costs may increase and our business may be harmed.
- If we encounter difficulties in enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.
- 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 are 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.
- 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.
- 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.

- 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 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.
- 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.
- We face substantial competition, which may result in others discovering, developing or commercializing competing products before or more successfully than us.
- Unstable market and economic conditions may have serious adverse consequences on our business and financial condition.
- Our Loan and Security Agreement with Silicon Valley Bank contains certain covenants that could adversely affect our operations and, if an event of default were to occur, we could be forced to repay any outstanding indebtedness sooner than planned and possibly at a time when we do not have sufficient capital to meet this obligation.
- 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.
- 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 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.

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 focused on organizing and staffing our company, raising capital, acquiring our initial product candidate, BIO89-100 and licensing certain related technology, conducting research and development activities, including preclinical studies and 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.

BIO89-100 is in development and, 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 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.

We are not profitable and have incurred net losses since our inception. 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 clinical trial and manufacturing activities increase. 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. 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. 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.

The ongoing COVID-19 pandemic has resulted and may in the future result in significant disruptions to our clinical trials or other business operations, which could have a material adverse effect on our business.

Our business and its operations, including but not limited to our research and development activities, could be adversely affected by health epidemics in regions where we have business operations, and such health epidemics could cause significant disruption in the operations of third parties upon whom we rely. In response to public health directives and orders related to COVID-19 and based on guidance from public health officials, we have implemented and continue to implement work-from-home policies for our employees on an office-by-office basis. The effects of executive and similar government orders, shelter-in-place orders and our work-from-home policies may negatively impact our growth, including our ability to recruit and onboard new employees, and productivity, disrupt our business and delay our preclinical and clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. These and similar, and perhaps more severe, disruptions in our operations could negatively impact our business, operating results and financial condition.

Our clinical trials have been and may continue to be affected by the COVID-19 pandemic. For example, while we initiated the Phase 2 trial (ENTRIGUE) of BIO89-100 for the treatment of SHTG and a paired-biopsy histology cohort as part of the Phase 1b/2a trial of BIO89-100 in NASH in 2020, our successful completion of these trials will depend on the external environment with respect to COVID-19 remaining conducive to executing the trial safely and effectively. The COVID-19 surge observed late in the fourth quarter of 2020 and in the first quarter of 2021 has adversely impacted enrollment in these studies. While the recent COVID-19 surge in Europe has also resulted in enrollment challenges in certain geographies, we are working closely with our CRO and remain optimistic that enrollment will pick up in the trial. Similarly, while we expect to initiate the Phase 2b trial (ENLIVEN) of BIO89-100 in NASH patients in the second quarter of 2021, we may be delayed in the initiation of such trial due to COVID-19 or related government restrictions.

In addition, quarantines, shelter-in-place, executive and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, related to COVID-19 or other infectious diseases, have impacted and may continue to impact personnel at third-party manufacturing facilities in the United States, Europe and other countries, or the availability or cost of materials we use or require to conduct our business, including product development, which would disrupt our supply chain. Furthermore, some of our manufacturers and suppliers are in Europe and may be impacted by port closures and other restrictions resulting from the COVID-19 pandemic, which may disrupt our supply chain or limit our ability to obtain sufficient materials for our drug products. In particular, BTPH, our sole source supplier for BIO89-100, has missed certain project deadlines for our manufacturing scale-up due to quarantine orders and has forecasted other delays due to COVID-19-related impacts on their suppliers. However, we have not experienced and do not expect to experience any delays to the overall timeline for the delivery of clinical supplies.

If COVID-19 continues to spread in the United States and elsewhere, we may experience additional disruptions that could severely impact our business, preclinical studies and clinical trials, including: delays in receiving authorization from local regulatory authorities to initiate our planned clinical trials; delays or difficulties in enrolling patients in our clinical trials; delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff; delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials; changes in local regulations as part of a response to the COVID-19 pandemic which may require us to change the ways in which our clinical trials are conducted and result in unexpected costs, or discontinuing our clinical trials altogether; a diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials; interruption of key clinical trial activities, such as clinical trial site monitoring and data entry and verification, due to limitations on travel imposed or recommended by federal or state governments, employers and others, or interruption of clinical trial subject visits and study procedures, the occurrence of which could affect the completeness and integrity of clinical trial data and, as a result, determine the outcomes of the trial; the risk that participants enrolled in our clinical trials will acquire COVID-19 while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events; the risk that participants enrolled in our clinical trials will not be able to travel to our clinical trial sites as a result of quarantines or other restrictions resulting from COVID-19 or comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services; interruptions or delays in preclinical studies due to restricted or limited operations at our research and development laboratory facilities; limitations in employee resources that would otherwise be focused on the conduct of our clinical trials; the refusal of the FDA to accept data from clinical trials in affected geographies; and interruption or delays to our clinical activities.

The COVID-19 pandemic continues to evolve rapidly. The ultimate impact of the COVID-19 pandemic or a similar public health emergency is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, healthcare systems, or the global economy as a whole. However, any one or a combination of these events could have an adverse effect on the operation of and results from our clinical trials and on our other business operations, including preventing or delaying approval for BIO89-100.

Our business depends on the success of BIO89-100, our only product candidate under clinical development, which 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 that 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.

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.

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. We may be unable to design and execute a clinical trial to support regulatory approval. Even if a current clinical trial is successful, it may 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 and Phase 1b/2a clinical trials have involved small patient populations and, because of the small sample size in such trials, the results of these clinical trials may be subject to substantial variability and may not be indicative of either future interim results or final results in future trials of 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.

We cannot guarantee that we will be able to initiate and complete clinical trials and successfully accomplish all required regulatory activities or other activities necessary to gain approval and commercialize BIO89-100 or any future product candidates. We

currently have two active investigational new drug ("IND") applications with the FDA in the United States for BIO89-100. In the future, we may file an additional IND with another division for any future indications or future product candidates. 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. As a result, 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. 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 including, for example, a new formulation, 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 future 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 identifying SHTG patients, and the significant competition for recruiting NASH and SHTG 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. 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. 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. 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.

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. As with other drugs, we have seen evidence of adverse effects in animal and human studies and it is possible that other adverse effects will become apparent in ongoing or future animal or human safety studies. 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. Further, we expect that BIO89-100 will require multiple administrations via subcutaneous injection in the course of a clinical trial. This chronic administration increases the risk that rare adverse events or chance findings are discovered in the commercial setting, where BIO89-100 would be administered to more patients or for greater periods of time, that were not uncovered by our clinical drug development programs.

We are 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.

We are developing BIO89-100 for the treatment of NASH, an indication for which there are no approved products. Because there is no established regulatory approval process for NASH, the development of a novel product candidates such as BIO89-100 may 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. Certain of our competitors have recently experienced regulatory setbacks for NASH therapies following communications from the FDA. We currently do not know the impact, if any, that these setbacks could have on the path for regulatory approval for NASH therapies generally or for BIO89-100. 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.

We are also developing BIO89-100 for the treatment of SHTG. 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.

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 clinical development plans for 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.

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 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 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. In addition, we will require large quantities of BIO89-100 for large clinical trials and to commercialize BIO89-100. Our current manufacturer may not be able to scale production to the larger quantities and we may not be able to find another manufacturer who has the capacity to manufacture a commercial-scale quantity of BIO89-100.

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.

We have begun producing certain of the reagents required for the glycoPEGylation at BTPH using the know-how transferred to us from Teva Pharmaceutical Industries Ltd ("Teva") under our Reagent Supply and Technology Transfer Agreement. We have not completed the manufacturing process for these reagents and cannot guarantee that we will be able to produce them successfully, or scale up our production for the quantities needed for commercialization.

Teva continues to supply us with certain reagents and will continue to do so until December 31, 2022. We expect the manufacturing of such reagents will be transferred to a new supplier prior to the end of 2022. Any complications arising under our agreement with Teva 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 cGMP. We 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.

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. 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. The process of manufacturing BIO89-100, and in particular, the glycoPEGylation process, is complex, highly regulated, subject to several risks 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, including 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.

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 clinical trials of and seek regulatory approvals for BIO89-100. We believe that our existing cash, cash equivalents and short-term available-for-sale securities, together with the proceeds available from our line of credit pursuant to our Loan Agreement (as defined above), will fund our projected operating requirements for a period of at least one year from the date of this Quarterly Report on Form 10-Q is filed with the SEC.

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 other than the unused portion of the line of credit available to us pursuant to the Loan Agreement. 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 Note 5 of our accompanying condensed consolidated financial statements.

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. 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. Certain of these companies have recently published positive data regarding their clinical trials, which may further increase the competition we face. 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.

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 in NASH. 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. This may make it difficult for us to differentiate our products from currently approved therapies, which may adversely impact our business strategy. 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. Insurers and other third-party payors may also encourage the use of generic products or specific branded products prior to utilization of BIO89-100. 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 liver or 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.

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. 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. 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.

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. If another such disruption in credit and financial markets and deterioration of confidence in economic conditions occurs, 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.

Our Loan and Security Agreement with Silicon Valley Bank (as amended, the "Loan Agreement") contains certain covenants that could adversely affect our operations and, if an event of default were to occur, we could be forced to repay any outstanding indebtedness sooner than planned and possibly at a time when we do not have sufficient capital to meet this obligation.

Pursuant to the Loan Agreement, we have pledged substantially all of our assets, other than our intellectual property rights, and have agreed that we may not sell or assign rights to our patents and other intellectual property without the prior consent of Silicon Valley Bank ("SVB"). Additionally, the Loan Agreement contains certain affirmative and negative covenants that could prevent us from taking certain actions without the consent of our lenders. These covenants may limit our flexibility in operating our business and our ability to take actions that might be advantageous to us and our stockholders. The Loan Agreement also includes customary events of default, including, among other things, a change of control. Upon the occurrence and continuation of an event of default, all amounts due under the Loan Agreement become (in the case of a bankruptcy event), or may become (in the case of all other events of default and at the option of SVB), immediately due and payable. If an event of default under the Loan Agreement should occur, we could be required to immediately repay any outstanding indebtedness. If we are unable to repay such debt, the lenders would be able to foreclose on the secured collateral, including our cash accounts, and take other remedies permitted under the Loan Agreement. Even if we are able to repay any indebtedness on an event of default, the repayment of these sums may significantly reduce our working capital and impair our ability to operate as planned.

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

We are in the early stages of building the full team that we anticipate we will need to complete the development BIO89-100 and other future product candidates. 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 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. 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 experience difficulty in adjusting to our growth and strategic focus.

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 in the biotechnology and pharmaceutical industries. If we are not able to attract and retain necessary personnel and consultants to accomplish our business objectives, it may significantly impede the achievement of our development and commercial objectives and our ability to implement our business strategy. In addition, we are highly dependent on the development, regulatory, manufacturing, commercialization and financial 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.

We are developing 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 or obtain new drug product, which would require additional costs and cause delay.

We are developing 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 developed a new refrigerated liquid formulation and have engaged a formulation development company to also explore a freeze-dried, or lyophilized, formulation. We have commenced development of a pre-filled syringe for the new drug product formulation and we also plan to begin development of a pen-type autoinjector. There is no assurance that we will be successful in developing a new drug product formulation, a pre-filled syringe 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, pre-filled syringe 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 for certain aspects of our product candidate development process and 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 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. 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.

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.

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.

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. Collaborations are complex and time-consuming to negotiate and document. 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.

We may not be successful in our efforts to identify, in-license or acquire, discover, develop or commercialize additional product candidates.

We may seek to identify, in-license or acquire, discover, develop and commercialize additional product candidates. We cannot assure you that our effort to in-license or acquire additional product candidates will be successful. Even if we are successful in in-licensing or acquiring additional product candidates, their requisite development activities may require substantial resources, and we cannot assure you that these development activities will result in regulatory approvals.

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. Doing business internationally potentially involves a number of risks, any of which 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.

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. Our clinical trial liability insurance coverage may not adequately cover all liabilities that we may incur.

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. 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 laws.

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. While to our knowledge we have not experienced any material system failure, accident or security breach to date we have been subject to periodic phishing attempts. If a material system failure, accident or security breach 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.

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. 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.

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 quicker 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.

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 those referenced in Part I, Item 1. "Business—Government Regulation and Product Approval". 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 the product candidate.

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. 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.

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. 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.

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.

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. 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.

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. 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.

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.

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.

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. 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.

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.

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 product candidates. Thus, we cannot guarantee that our product candidates, or our commercialization thereof, do not and will not infringe any third party's intellectual property.

Risks Related to Ownership of Our Common Stock

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 price you paid for your shares. 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.

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, could depress the market price of our common stock. Certain holders of shares of our common stock 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, we have filed a registration statement registering under the Securities Act the shares of our common stock reserved for issuance under our 2019 Equity Incentive Plan, including shares issuable upon exercise of outstanding options. These shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates. Further, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt or equity securities.

Raising additional capital may cause dilution to existing stockholders, restrict our operations or require us to relinquish rights to our technologies.

Existing stockholders 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 or the Loan Agreement. 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.

General Risk Factors

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

As of March 31, 2021, our executive officers, directors and other holders of 5% or more of our common stock beneficially owned a majority of our outstanding common stock. As a result, 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.

We previously identified material weaknesses in our internal control over financial reporting, which have been remediated. If we identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, we may not be able to produce timely and accurate financial statements, and we or our independent registered public accounting firm may conclude that our internal control over financial reporting is not effective, which could adversely affect our investors' confidence and our stock price.

As an emerging growth company under the JOBS Act, our management is required to report upon the effectiveness of our internal control over financial reporting under Section 404 of the Sarbanes-Oxley Act. Our independent registered public accounting firm is not required to formally attest to the effectiveness of our internal control over financial reporting until the date we are no longer an emerging growth company and reach accelerated filer status. 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, 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. As previously disclosed, 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. While we have remediated such material weaknesses, 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 in the future.

Our amended and restated certificate of incorporation, amended and restated 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 and restated certificate of incorporation and our amended and restated 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. In addition, as a Delaware corporation, we are 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 and restated certificate of incorporation 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 and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for certain actions or proceedings under Delaware statutory or common law. Our amended and restated certificate of incorporation 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. 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 and restated certificate of incorporation to be inapplicable or unenforceable, we may incur additional costs associated with resolving such action in other jurisdictions.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

Use of Proceeds from our Initial Public Offering

On November 13, 2019, we completed our initial public offering ("IPO"), pursuant to which we issued and sold an aggregate of 6,100,390 shares of common stock at the IPO price of $16.00 per share. The aggregate gross proceeds from our IPO were $97.6 million, and the net proceeds were $87.7 million after deducting underwriting discounts and commissions of $6.8 million and other offering expenses of $3.1 million. The offer and sale of the shares of common stock in the IPO were registered pursuant to registration statements on Form S-1 (File Nos. 333-234174 and 333-234617), which the SEC declared effective on November 8, 2019. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning 10% or more of any class of our equity securities or to any other affiliates. The underwriters for our IPO were BofA Securities, Inc., SVB Leerink LLC, RBC Capital Markets, LLC, and Oppenheimer & Co. Inc.

The net proceeds from our IPO have been used and will be used, together with our cash and cash equivalents 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, fund our Phase 2 trial of BIO89-100 in patients with SHTG as well as evaluate potential new indications for BIO89-100, and BIO89-100 manufacturing and scale up, with the balance to be used to fund working capital and other general corporate purposes, which may include licensing, acquiring or investing in complementary businesses, technologies, products or assets, the acquisition or licensing of other products, businesses or technologies.

There has been no material change in the intended use of proceeds from our IPO as described in our final prospectus filed with the SEC pursuant to Rule 424(b)(4) on November 12, 2019.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Number	Description
2.1	Contribution and Exchange Agreement, dated as of September 17, 2019, by and among 89Bio Ltd., the Company and its shareholders (filed with the SEC as Exhibit 2.1 to the Company's Form S-1 filed on October 11, 2019).
3.1	Second Amended and Restated Certificate of Incorporation (filed with the SEC as Exhibit 3.1 to the Company's Form 8-K filed on November 15, 2019).
3.2	Second Amended and Restated Bylaws (filed with the SEC as Exhibit 3.2 to the Company's Form 8-K filed on November 15, 2019).
4.1	Specimen common stock certificate of the registrant (filed with the SEC as Exhibit 4.1 to the Company's Form S-1/A filed on October 28, 2019).
4.2	Investors' Rights Agreement, dated as of September 17, 2019, by and among the Company and certain of its shareholders (filed with the SEC as Exhibit 4.2 to the Company's Form S-1 filed on October 11, 2019).
4.3	Form of Warrant to Purchase Common Stock for Silicon Valley Bank (filed with SEC as Exhibit 4.1 to the Company's Form 8-K filed on April 13, 2020).
10.1*	First Amendment to Loan and Security Agreement, dated as of March 30, 2021, among Silicon Valley Bank, the Lenders party thereto, 89bio, Inc., 89bio Management, Inc. and 89Bio Ltd.
10.2*	Second Amendment to Loan and Security Agreement, dated as of April 30, 2021, among Silicon Valley Bank, the Lenders party thereto, 89bio, Inc., 89bio Management, Inc. and 89bio Ltd.
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934.
32#	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350.
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith.

\# Furnished herewith and not deemed to be "filed" for purposes of Section 18 of the Exchange Act, and shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

89bio, Inc.

Date: May 13, 2021

By: /s/ Rohan Palekar

Rohan Palekar

Chief Executive Officer

(principal executive officer)

Date: May 13, 2021

By: /s/ Ryan Martins

Ryan Martins

Chief Financial Officer

(principal financial and accounting officer)

Exhibit 10.1

FIRST AMENDMENT TO
LOAN AND SECURITY AGREEMENT

THIS **FIRST AMENDMENT** to Loan and Security Agreement (this "**Amendment**") is entered into as of March 30, 2021, by and between SILICON VALLEY BANK, a California corporation with an office located at 3003 Tasman Drive, Santa Clara, CA 95054 ("**Bank**" or "**SVB**"), as collateral agent (in such capacity, "**Collateral Agent**"), the Lenders listed on Schedule 1.1 of the Loan Agreement or otherwise a party hereto from time to time, including SVB in its capacity as a Lender (each a "**Lender**" and collectively, the "**Lenders**"), and 89BIO, INC., a Delaware corporation with offices located at 142 Sansome Street, 2nd Floor, San Francisco, CA 94104 ("**89Bio**"), 89BIO MANAGEMENT, INC., a Delaware corporation with offices located at 142 Sansome Street, 2nd Floor, San Francisco, CA 94104 ("**89Bio Management**"), and 89BIO LTD, an Israeli company with offices located at 6 Hamada Street, Herzliya, Israel 4673340 ("**89Bio Israel**" or "**ISR Borrower**") (89Bio, 89Bio Management, and 89Bio Israel, individually and collectively, jointly and severally, "**Borrower**").

RECITALS

A. Collateral Agent, Lenders and Borrower have entered into that certain Loan and Security Agreement dated as of April 7, 2020 (as amended or modified from time to time, the "**Loan Agreement**").

B. Lenders have extended credit to Borrower for the purposes permitted in the Loan Agreement.

C. Borrower has requested that Collateral Agent and Lenders (i) modify requirements related to the Draw Period and (ii) make certain other revisions to the Loan Agreement as more fully set forth herein.

D. Collateral Agent and Lenders have agreed to modify and to amend certain provisions of the Loan Agreement, but only to the extent, in accordance with the terms, subject to the conditions and in reliance upon the representations and warranties set forth below.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing recitals and other good and valuable consideration, the receipt and adequacy of which is hereby acknowledged, and intending to be legally bound, the parties hereto agree as follows:

1. Definitions. Capitalized terms used but not defined in this Amendment shall have the meanings given to them in the Loan Agreement.

2. Amendments to Loan Agreement.

2.1 Section 2.2(b) (Repayment). Section 2.2(b) of the Loan Agreement hereby is amended and restated in its entirety to read as follows:

"(b) Repayment. Borrower shall make monthly payments of interest only commencing on the first (1st) Payment Date following the Funding Date of each Term Loan, and continuing on the Payment Date of each successive month thereafter through and including the Payment Date immediately preceding the Amortization Date. Borrower agrees to pay, on the Funding Date of each Term Loan, any initial partial monthly interest payment otherwise due for the period between the Funding Date of such Term Loan and the first Payment Date thereof. Commencing on the Amortization Date, and continuing on the Payment Date of each month thereafter, Borrower shall make consecutive equal monthly payments of principal, together with applicable interest, in arrears, to each Lender, as calculated by Collateral Agent (which calculations shall be deemed correct absent manifest error) based upon: (1) the amount of such Lender's Term Loan, (2) the effective rate of interest, as determined in Section 2.3(a), and (3) a repayment schedule equal to (i) if the

Amortization Date is May 1, 2021, nineteen (19) months, and (ii) if the Amortization Date is October 1, 2021, twenty-four (24) months. All unpaid principal and accrued and unpaid interest with respect to each Term Loan is due and payable in full on the Maturity Date. Each Term Loan may only be prepaid in accordance with Sections 2.2(c) and 2.2(d)."

2.2 Section 13.1 (Definitions). The following terms and their respective definitions hereby are amended and restated, in Section 13.1 of the Loan Agreement as follows:

"**Amortization Date**" is May 1, 2021; provided, however, if the Term B Loan is funded, then the Amortization Date with respect to all Term Loans shall be extended to October 1, 2021.

"**Draw Period**" is the period commencing on the Effective Date and ending on the earlier of (i) April 30, 2021, and (ii) the occurrence of an Event of Default.

"**Term B Milestones**" means (i) the delivery by Borrower to Collateral Agent and the Lenders of evidence, in form and content acceptable to Collateral Agent and Lenders, of Borrower, prior to April 30, 2021, achieving positive Phase 1b/2a NASH data sufficient to initiate a Phase 2b trial and (ii) the funding of the Term A Loans in the full amount of the Term Loan Commitment for the Term A Loans.

3. Limitation of Amendment.

3.1 The amendments set forth in **Section 2**, are effective for the purposes set forth herein and shall be limited precisely as written and shall not be deemed to (a) be a consent to any amendment, waiver or modification of any other term or condition of any Loan Document, or (b) otherwise prejudice any right or remedy which Collateral Agent or any Lender may now have or may have in the future under or in connection with any Loan Document.

3.2 This Amendment shall be construed in connection with and as part of the Loan Documents and all terms, conditions, representations, warranties, covenants and agreements set forth in the Loan Documents, except as herein amended, are hereby ratified and confirmed and shall remain in full force and effect.

4. Representations and Warranties. To induce Collateral Agent and Lenders to enter into this Amendment, Borrower hereby represents and warrants to Collateral Agent and Lenders as follows:

4.1 Immediately after giving effect to this Amendment (a) the representations and warranties contained in the Loan Documents are true, accurate and complete in all material respects as of the date hereof (except to the extent such representations and warranties relate to an earlier date, in which case they are true and correct as of such date), and (b) no Event of Default has occurred and is continuing;

4.2 Borrower has the power and authority to execute and deliver this Amendment and to perform its obligations under the Loan Agreement, as amended by this Amendment;

4.3 The organizational documents of Borrower delivered to Collateral Agent and Lenders on the Effective Date, or subsequent thereto, remain true, accurate and complete and have not been amended, supplemented or restated and are and continue to be in full force and effect;

4.4 The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, have been duly authorized;

4.5 The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, do not and will not contravene (a) any law or regulation binding on or affecting Borrower, (b) any contractual restriction with a Person binding on Borrower, (c) any order, judgment or decree of any court or other governmental or public body or authority, or subdivision thereof, binding on Borrower, or (d) the organizational documents of Borrower;

4.6 The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, do not require any order, consent, approval, license, authorization or validation of, or filing, recording or registration with, or exemption by any governmental or public body or authority, or subdivision thereof, binding on Borrower; and

4.7 This Amendment has been duly executed and delivered by Borrower and is the binding obligation of Borrower, enforceable against Borrower in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, liquidation, moratorium or other similar laws of general application and equitable principles relating to or affecting creditors' rights.

5. Counterparts. This Amendment may be executed in any number of counterparts and all of such counterparts taken together shall be deemed to constitute one and the same instrument.

6. Effectiveness. This Amendment shall be deemed effective upon the due execution and delivery to Collateral Agent and Lenders of (i) this Amendment by each party hereto, and (ii) Borrower's payment of all Lenders' Expenses incurred through the date of this Amendment.

[*Balance of Page Intentionally Left Blank*]

In Witness Whereof, the parties hereto have caused this Amendment to be duly executed and delivered as of the date first written above.

BORROWER:

89BIO, INC.

By /s/ Rohan Palekar
Name: Rohan Palekar
Title: Chief Executive Officer

89BIO LTD

By /s/ Rohan Palekar
Name: Rohan Palekar
Title: Chief Executive Officer

89BIO MANAGEMENT, INC

By /s/ Rohan Palekar
Name: Rohan Palekar
Title: Chief Executive Officer

COLLATERAL AGENT AND LENDER:

SILICON VALLEY BANK

By /s/ Shawn Parry
Name: Shawn Parry
Title: Managing Director

Exhibit 10.2

SECOND AMENDMENT TO
LOAN AND SECURITY AGREEMENT

THIS **SECOND AMENDMENT** to Loan and Security Agreement (this "**Amendment**") is entered into as of April 30, 2021, by and between SILICON VALLEY BANK, a California corporation with an office located at 3003 Tasman Drive, Santa Clara, CA 95054 ("**Bank**" or "**SVB**"), as collateral agent (in such capacity, "**Collateral Agent**"), the Lenders listed on Schedule 1.1 of the Loan Agreement or otherwise a party hereto from time to time, including SVB in its capacity as a Lender (each a "**Lender**" and collectively, the "**Lenders**"), and 89BIO, INC., a Delaware corporation with offices located at 142 Sansome Street, 2nd Floor, San Francisco, CA 94104 ("**89Bio**"), 89BIO MANAGEMENT, INC., a Delaware corporation with offices located at 142 Sansome Street, 2nd Floor, San Francisco, CA 94104 ("**89Bio Management**"), and 89BIO LTD, an Israeli company with offices located at 6 Hamada Street, Herzliya, Israel 4673340 ("**89Bio Israel**" or "**ISR Borrower**") (89Bio, 89Bio Management, and 89Bio Israel, individually and collectively, jointly and severally, "**Borrower**").

RECITALS

A. Collateral Agent, Lenders and Borrower have entered into that certain Loan and Security Agreement dated as of April 7, 2020 (as amended by that certain First Amendment to Loan and Security Agreement dated March 30, 2021, and amended or modified from time to time, the "**Loan Agreement**").

B. Lenders have extended credit to Borrower for the purposes permitted in the Loan Agreement.

C. Borrower has requested that Collateral Agent and Lenders (i) modify requirements related to the Draw Period and (ii) make certain other revisions to the Loan Agreement as more fully set forth herein.

D. Collateral Agent and Lenders have agreed to modify and to amend certain provisions of the Loan Agreement, but only to the extent, in accordance with the terms, subject to the conditions and in reliance upon the representations and warranties set forth below.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing recitals and other good and valuable consideration, the receipt and adequacy of which is hereby acknowledged, and intending to be legally bound, the parties hereto agree as follows:

1. Definitions. Capitalized terms used but not defined in this Amendment shall have the meanings given to them in the Loan Agreement.

2. Amendments to Loan Agreement.

2.1 Section 2.2(b) (Repayment). Section 2.2(b) of the Loan Agreement hereby is amended and restated in its entirety to read as follows:

"(b) Repayment. Borrower shall make monthly payments of interest only commencing on the first (1st) Payment Date following the Funding Date of each Term Loan, and continuing on the Payment Date of each successive month thereafter through and including the Payment Date immediately preceding the Amortization Date. Borrower agrees to pay, on the Funding Date of each Term Loan, any initial partial monthly interest payment otherwise due for the period between the Funding Date of such Term Loan and the first Payment Date thereof. Commencing on the Amortization Date, and continuing on the Payment Date of each month thereafter, Borrower shall make consecutive equal monthly payments of principal, together with applicable interest, in arrears, to each Lender, as calculated by Collateral Agent (which calculations shall be deemed correct absent manifest error) based upon: (1) the amount of such Lender's Term Loan, (2) the effective rate of interest, as determined in Section 2.3(a), and (3) a repayment schedule equal to (i) if the

Amortization Date is June 1, 2021, eighteen (18) months, and (ii) if the Amortization Date is October 1, 2021, twenty-four (24) months. All unpaid principal and accrued and unpaid interest with respect to each Term Loan is due and payable in full on the Maturity Date. Each Term Loan may only be prepaid in accordance with Sections 2.2(c) and 2.2(d)."

2.2 Section 13.1 (Definitions). The following terms and their respective definitions hereby are amended and restated, in Section 13.1 of the Loan Agreement as follows:

"**Amortization Date**" is June 1, 2021; provided, however, if the Term B Loan is funded, then the Amortization Date with respect to all Term Loans shall be extended to October 1, 2021.

"**Draw Period**" is the period commencing on the Effective Date and ending on the earlier of (i) May 31, 2021, and (ii) the occurrence of an Event of Default.

"**Term B Milestones**" means (i) the delivery by Borrower to Collateral Agent and the Lenders of evidence, in form and content acceptable to Collateral Agent and Lenders, of Borrower, prior to May 31, 2021, achieving positive Phase 1b/2a NASH data sufficient to initiate a Phase 2b trial and (ii) the funding of the Term A Loans in the full amount of the Term Loan Commitment for the Term A Loans.

3. Limitation of Amendment.

3.1 The amendments set forth in **Section 2**, are effective for the purposes set forth herein and shall be limited precisely as written and shall not be deemed to (a) be a consent to any amendment, waiver or modification of any other term or condition of any Loan Document, or (b) otherwise prejudice any right or remedy which Collateral Agent or any Lender may now have or may have in the future under or in connection with any Loan Document.

3.2 This Amendment shall be construed in connection with and as part of the Loan Documents and all terms, conditions, representations, warranties, covenants and agreements set forth in the Loan Documents, except as herein amended, are hereby ratified and confirmed and shall remain in full force and effect.

4. Representations and Warranties. To induce Collateral Agent and Lenders to enter into this Amendment, Borrower hereby represents and warrants to Collateral Agent and Lenders as follows:

4.1 Immediately after giving effect to this Amendment (a) the representations and warranties contained in the Loan Documents are true, accurate and complete in all material respects as of the date hereof (except to the extent such representations and warranties relate to an earlier date, in which case they are true and correct as of such date), and (b) no Event of Default has occurred and is continuing;

4.2 Borrower has the power and authority to execute and deliver this Amendment and to perform its obligations under the Loan Agreement, as amended by this Amendment;

4.3 The organizational documents of Borrower delivered to Collateral Agent and Lenders on the Effective Date, or subsequent thereto, remain true, accurate and complete and have not been amended, supplemented or restated and are and continue to be in full force and effect;

4.4 The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, have been duly authorized;

4.5 The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, do not and will not contravene (a) any law or regulation binding on or affecting Borrower, (b) any contractual restriction with a Person binding on Borrower, (c) any order, judgment or decree of any court or other governmental or public body or authority, or subdivision thereof, binding on Borrower, or (d) the organizational documents of Borrower;

4.6 The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, do not require any order,

consent, approval, license, authorization or validation of, or filing, recording or registration with, or exemption by any governmental or public body or authority, or subdivision thereof, binding on Borrower; and

4.7 This Amendment has been duly executed and delivered by Borrower and is the binding obligation of Borrower, enforceable against Borrower in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, liquidation, moratorium or other similar laws of general application and equitable principles relating to or affecting creditors' rights.

5. Counterparts. This Amendment may be executed in any number of counterparts and all of such counterparts taken together shall be deemed to constitute one and the same instrument.

6. Effectiveness. This Amendment shall be deemed effective upon the due execution and delivery to Collateral Agent and Lenders of (i) this Amendment by each party hereto, (ii) Borrower's payment of all Lenders' Expenses incurred through the date of this Amendment, and (iii) Borrower's payment of an amendment fee in an amount equal to Eight Thousand Dollars ($8,000).

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In Witness Whereof, the parties hereto have caused this Amendment to be duly executed and delivered as of the date first written above.

BORROWER:

89BIO, INC.

By /s/ Rohan Palekar

Name: Rohan Palekar

Title: Chief Executive Officer

89BIO LTD

By /s/ Rohan Palekar

Name: Rohan Palekar

Title: Chief Executive Officer

89BIO MANAGEMENT, INC

By /s/ Rohan Palekar

Name: Rohan Palekar

Title: Chief Executive Officer

COLLATERAL AGENT AND LENDER:

SILICON VALLEY BANK

By /s/ Max Eberhart

Name: Max Eberhart

Title: SVP

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Rohan Palekar, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of 89bio, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 13, 2021

By: /s/ Rohan Palekar

Rohan Palekar
Chief Executive Officer
(principal executive officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Ryan Martins, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of 89bio, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 13, 2021

By: /s/ Ryan Martins

Ryan Martins
Chief Financial Officer
(principal financial and accounting officer)

Exhibit 32

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of 89bio, Inc. (the "Company") for the period ending March 31, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company hereby certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 13, 2021

By: /s/ Rohan Palekar

Rohan Palekar
Chief Executive Officer
(principal executive officer)

By: /s/ Ryan Martins

Ryan Martins
Chief Financial Officer
(principal financial and accounting officer)

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. §1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Note: A signed original of this written statement required by §906 has been provided to 89bio, Inc. and will be retained by 89bio, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.