REFINITIV

DELTA REPORT

10-Q

ETNB - 89BIO, INC.

10-Q - MARCH 31, 2024 COMPARED TO 10-Q - SEPTEMBER 30, 2023

The following comparison report has been automatically generated

TOTAL DELTAS	1552
CHANGES	95
DELETIONS	775
ADDITIONS	682

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 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 September 30, March 31, 2023 2024

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) 432-9270

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**

	Symbol(s)	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 ☒

As of November 6, 2023 May 6, 2024, the registrant had 75,638,516 98,383,998 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)

	September 30, 2023 (Unaudited)	December 31, 2022	March 31, 2024 (Unaudited)	December 31, 2023
Assets				
Current assets:				
Cash and cash equivalents	$ 26,251,925	$ 55,255	$ 217,573	$ 316,161
Short-term available-for-sale securities	6,378	2,905		
Marketable securities			344,715	262,709
Prepaid and other current assets	11,222	7,920	12,494	14,664
Total current assets	9,526	6,080	574,782	593,534
Operating lease right-of-use asset	238	363		
Operating lease right-of-use assets			2,118	2,293
Property and equipment, net	58	92	37	46
Other assets	9	9	385	396
Total assets	$ 110,460	$ 246,819	$ 577,322	$ 596,269
Liabilities and stockholders' equity				
Current liabilities:				
Accounts payable	$ 3,190	$ 2,250	$ 15,352	$ 8,585

Accrued expenses	14,133	11,944	20,295	20,530
Operating lease liability, current	176	168		
Operating lease liabilities, current			702	496
Term loan, current			1,892	—
Total current liabilities	25,212	24,614	38,241	29,611
Operating lease liability, non-current	536	186		
Term loan, non-current, net	24,637	20,192		
Operating lease liabilities, noncurrent			1,640	1,817
Term loan, noncurrent, net			23,065	24,795
Other noncurrent liabilities			3,837	3,740
Total liabilities	49,902	44,992	66,783	59,963
Commitments and contingencies (Note 5)				
Stockholders' equity:				
Common stock	75	51		
Common stock, $0.001 par value: 200,000,000 shares authorized; 95,199,724 and 93,269,377 shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively			95	93
Additional paid-in capital	827,878	467,374	1,020,076	993,455
Accumulated other comprehensive loss	(547)	(350)		
Accumulated other comprehensive (loss) income			(519)	190
Accumulated deficit	(417,197)	(315,243)	(509,113)	(457,432)

Total stockholders' equity	41 0,2 09	15 1,8 32	510,539	536,306
Total liabilities and stockholders' equity	46 0,1 $ 11	19 6,8 $ 24	$ 577,322	$ 596,269

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 September 30,		Nine Months Ended September 30,		Three Months Ended March 31,	
	2023	2022	2023	2022	2024	2023
Operating expenses:						
Research and development	31,4 17	22,1 97	88,6 38	61,7 32	$ 47,428	$ 22,306
General and administrative	7,92 8	4,84 4	21,3 60	15,1 55	9,849	6,218
Total operating expenses	39,3 45	27,0 41	109, 998	76,8 87	57,277	28,524
Loss from operations	(39,3 45)	(27,0 41)	(109, 998)	(76,8 87)	(57,277)	(28,524)
Interest expense	(959)	(535)	(3,92 8)	(1,37 7)	(863)	(2,075)

Interest income and other, net	5,579	773	11,972	843	6,556	1,763
Net loss before income tax	(34,725)	(26,803)	(101,954)	(77,421)	(51,584)	(28,836)
Income tax expense	—	(2)	—	(3)	(97)	—
Net loss	$ (34,725)	$ (26,805)	$ (101,954)	$ (77,424)	$ (51,681)	$ (28,836)
Other comprehensive income (loss):						
Unrealized gain (loss) on available-for-sale securities	41	(136)	(200)	(408)		
Other comprehensive (loss) income:						
Unrealized (loss) gain on marketable securities					(714)	114
Foreign currency translation adjustments	6	14	3	32	5	(4)
Total other comprehensive income (loss)	$ 47	$ (122)	$ (197)	$ (376)		
Total other comprehensive (loss) income					$ (709)	$ 110
Comprehensive loss	$ (34,678)	$ (26,927)	$ (102,151)	$ (77,800)	$ (52,390)	$ (28,726)
Net loss per share, basic and diluted	$ (0.45)	$ (0.57)	$ (1.50)	$ (2.63)	$ (0.54)	$ (0.54)
Weighted-average shares used to compute net loss per share, basic and diluted	76,336,050	47,253,527	67,962,848	29,413,621	95,846,740	53,171,370

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 and Nine Months Ended September 30, 2023 March 31, 2024 and 2023

(Unaudited)

(In thousands, except share amounts)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amounts				
Balance as of December 31, 2022	50,560,590	$ 51	$ 467,374	$ (350)	$ (315,243)	$ 151,832
Issuance of common stock in public offering, net of issuance costs	19,461,538	19	296,798	—	—	296,817
Issuance of common stock in at-the-market public offerings, net of issuance costs	968,000	1	13,421	—	—	13,422
Issuance of common stock upon exercise of warrants	1,682,500	2	8,958	—	—	8,960
Issuance of common stock upon exercise of stock options	61,408	—	185	—	—	185
Issuance of common stock upon vesting of restricted stock units, net of withholding taxes	133,669	—	(693)	—	—	(693)
Issuance of common stock warrants in connection with term loan	—	—	482	—	—	482
Stock-based compensation	—	—	3,551	—	—	3,551
Net loss	—	—	—	—	(28,836)	(28,836)
Other comprehensive income	—	—	—	110	—	110

Balance as of March 31, 2023	72,867,705	$ 73	$ 790,076	$ (240)	$ (344,079)	$ 445,830
Issuance of common stock in at-the-market public offerings, net of issuance costs	1,200,539	1	23,666	—	—	23,667
Issuance of common stock upon exercise of warrants	1,245,070	1	6,629	—	—	6,630
Issuance of common stock upon exercise of stock options	107,832	—	327	—	—	327
Issuance of common stock upon vesting of restricted stock units, net of withholding taxes	31,527	—	—	—	—	—
Issuance of common stock upon ESPP purchases	13,927	—	142	—	—	142
Stock-based compensation	—	—	4,137	—	—	4,137
Net loss	—	—	—	—	(38,393)	(38,393)
Other comprehensive loss	—	—	—	(354)	—	(354)
Balance as of June 30, 2023	75,466,600	$ 75	824,977	$ (594)	(382,472)	441,986
Issuance of common stock upon exercise of stock options	27,372	—	117	—	—	117
Issuance of common stock upon vesting of restricted stock units, net of withholding taxes	144,544	—	(1,597)	—	—	(1,597)
Stock-based compensation	—	—	4,381	—	—	4,381
Net loss	—	—	—	—	(34,725)	(34,725)
Other comprehensive income	—	—	—	47	—	47
Balance as of September 30, 2023	75,638,516	$ 75	$ 827,878	$ (547)	$ (417,197)	$ 410,209

	Common Stock		Additional	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amounts	Paid-in Capital	Income (Loss)	Deficit	Equity

Balance as of December 31, 2023	93,269,377	$ 93	$ 993,455	$ 190	$ (457,432)	$ 536,306
Issuance of common stock in at-the-market public offerings, net of issuance costs	1,396,888	2	21,047	—	—	21,049
Issuance of common stock upon exercise of common stock warrants	337,713	—	1,798	—	—	1,798
Issuance of common stock upon exercise of stock options	1,626	—	7	—	—	7
Issuance of common stock upon vesting of restricted stock units, net of tax withholding for net share settlement	194,120	—	(1,229)	—	—	(1,229)
Stock-based compensation	—	—	4,998	—	—	4,998
Net loss	—	—	—	—	(51,681)	(51,681)
Other comprehensive loss	—	—	—	(709)	—	(709)
Balance as of March 31, 2024	95,199,724	$ 95	1,020,076	$ (519)	(509,113)	$ 510,539

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89bio, Inc.

Condensed Consolidated Statements of Stockholders' Equity

For the Three and Nine Months Ended September 30, 2022

(Unaudited)

(In thousands, except share amounts)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amounts				
Balance as of December 31, 2021	20,317,204	$ 20	$ 8	$ (64)	$ (213,217)	$ 125,957
Issuance of common stock upon exercise of stock options	12,065	—	29	—	—	29

Issuance of common stock upon vesting of restricted stock units, net	22,115	—	—	—	—	—
Stock-based compensation	—	—	2,512	—	—	2,512
Net loss	—	—	—	—	(25,565)	(25,565)
Other comprehensive loss	—	—	—	(192)	—	(192)
Balance as of March 31, 2022	20,351,384	$ 20	$ 341,759	$ (256)	$ (238,782)	$ 102,741
Issuance of common stock upon ESPP purchases	15,979	—	43	—	—	43
Withholding taxes related to restricted stock units	—	—	(69)	—	—	(69)
Stock-based compensation	—	—	2,586	—	—	2,586
Net loss	—	—	—	—	(25,054)	(25,054)
Other comprehensive loss	—	—	—	(62)	—	(62)
Balance as of June 30, 2022	20,367,363	$ 20	$ 344,319	$ (318)	$ (263,836)	$ 80,185
Issuance of common stock and warrants in public offering, net of issuance costs	18,675,466	20	88,219	—	—	88,239
Issuance of common stock in at-the-market public offering, net of issuance costs	1,242,132	1	8,369	—	—	8,370
Issuance of common stock upon cashless exercise of warrants	3,143,682	3	(3)	—	—	—
Issuance of common stock upon exercise of warrants	10,000	—	53	—	—	53
Issuance of common stock upon exercise of stock options	114,203	—	208	—	—	208
Issuance of common stock upon vesting of restricted stock units, net of withholding taxes	71,779	—	(53)	—	—	(53)
Stock-based compensation	—	—	2,500	—	—	2,500
Net loss	—	—	—	—	(26,805)	(26,805)
Other comprehensive loss	—	—	—	(122)	—	(122)
Balance as of September 30, 2022	43,624,625	$ 44	$ 443,612	$ (440)	$ (290,641)	$ 152,575

	Common Stock		Additional	Accumulated Other		Total
	Shares	Amounts	Paid-in Capital	Comprehensive Loss	Accumulated Deficit	Stockholders' Equity
Balance as of December 31, 2022	50,560,590	$ 51	$ 467,374	$ (350)	$ (315,243)	$ 151,832
Issuance of common stock in public offerings, net of issuance costs	19,461,538	19	296,798			296,817
Issuance of common stock in at-the-market public offerings, net of issuance costs	968,000	1	13,421	—	—	13,422
Issuance of common stock upon exercise of common stock warrants	1,682,500	2	8,958	—	—	8,960
Issuance of common stock upon exercise of stock options	61,408	—	185	—	—	185
Issuance of common stock upon vesting of restricted stock units, net of tax withholding for net share settlement	133,669	—	(693)	—	—	(693)
Issuance of common stock warrants in connection with term loan	—	—	482	—	—	482
Stock-based compensation	—	—	3,551	—	—	3,551
Net loss	—	—	—	—	(28,836)	(28,836)
Other comprehensive income	—	—	—	110	—	110
Balance as of March 31, 2023	72,867,705	$ 73	$ 790,076	$ (240)	$ (344,079)	$ 445,830

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)

	Nine Months Ended September 30,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (101,954)	$ (77,424)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	12,069	7,598
Net accretion on available-for-sale securities	(4,297)	(183)
Accretion of final payment fee on term loan	285	365
Amortization of debt issuance costs	410	227
Loss on extinguishment of term loan facility	1,208	—
Noncash operating lease expense	125	135
Depreciation	34	50
Changes in operating assets and liabilities:		
Prepaid and other current assets	(3,238)	4,756
Other assets	—	72
Accounts payable	(1,599)	7,308
Accrued expenses	2,189	3,243
Operating lease liability	(125)	(141)
Net cash used in operating activities	(94,893)	(53,994)
Cash flows from investing activities:		
Proceeds from sales and maturities of available-for-sale securities	157,428	87,260
Purchases of available-for-sale securities	(216,804)	(110,137)
Purchases of property and equipment	—	(5)
Net cash used in investing activities	(59,376)	(22,882)
Cash flows from financing activities:		
Proceeds from issuance of common stock in public offering, net of issuance costs	296,817	88,239

Proceeds from issuance of common stock in at-the-market public offering, net of issuance costs	37,089	8,370
Proceeds from term loan facility, net of issuance costs	24,363	—
Proceeds from issuance of common stock upon exercise of warrants	15,590	53
Proceeds from issuance of common stock upon exercise of stock options	629	237
Proceeds from issuance of common stock upon ESPP purchases	142	43
Payment of withholding taxes related to restricted stock units	(2,290)	(122)
Repayment of term loan facility	(21,400)	—
Net cash provided by financing activities	350,940	96,820
Net change in cash and cash equivalents, and restricted cash	196,671	19,944
Cash and cash equivalents, and restricted cash at beginning of period	55,255	52,457
Cash and cash equivalents at end of period	$ 251,926	$ 72,401
Supplemental disclosures of cash information:		
Cash paid for interest	$ 1,913	$ 706
Cash paid for operating leases	$ 139	$ 187
Supplemental disclosures of noncash information:		
Issuance of common stock warrants in connection with term loan	$ 482	$ —
Remeasurement of lease liability and right of use asset in connection with lease modification	$ —	$ 338

	Three Months Ended March 31,	
	2024	2023
Cash flows from operating activities:		
Net loss	$ (51,681)	$ (28,836)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	4,998	3,551
Net accretion of discounts on investments in marketable securities	(2,822)	(1,040)
Amortization of debt discount and accretion of deferred debt costs	162	219
Loss on extinguishment of debt	—	1,208
Noncash operating lease expense	175	41
Depreciation	9	14
Changes in operating assets and liabilities:		
Prepaid and other assets	2,089	(4,599)
Accounts payable	6,767	4,225

Accrued expenses	457	(4,827)
Operating lease liabilities	29	(41)
Other noncurrent liabilities	97	—
Net cash used in operating activities	(39,720)	(30,085)
Cash flows from investing activities:		
Proceeds from sales and maturities of marketable securities	72,140	37,880
Purchases of marketable securities	(152,038)	(33,774)
Net cash (used in) provided by investing activities	(79,898)	4,106
Cash flows from financing activities:		
Proceeds from issuance of common stock in public offerings, net of issuance costs	—	296,817
Payments of deferred offering costs	(253)	—
Proceeds from issuance of common stock in at-the-market public offerings, net of issuance costs	21,067	13,422
Proceeds from term loan facility, net of issuance costs	—	24,363
Proceeds from issuance of common stock upon exercise of common stock warrants	1,798	8,960
Proceeds from issuance of common stock upon exercise of stock options	104	185
Payments for taxes related to net share settlement upon vesting of restricted stock units	(1,686)	(693)
Repayment of term loan	—	(21,400)
Net cash provided by financing activities	21,030	321,654
Net change in cash and cash equivalents	(98,588)	295,675
Cash and cash equivalents at beginning of period	316,161	55,255
Cash and cash equivalents at end of period	$ 217,573	$ 350,930
Supplemental disclosures of cash information:		
Cash paid for interest	$ 679	$ 542
Cash paid related to operating lease liabilities	$ 46	$ 47
Supplemental disclosures of noncash information:		
Issuance of common stock warrants in connection with term loan	$ —	$ 482
Unpaid offering costs included in accrued expenses	$ 18	$ —

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

89bio, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements

1. Organization and Basis of Presentation Liquidity

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, pegozafermin, a specifically engineered glycoPEGylated analog of fibroblast growth factor 21 ("FGF21"), is currently being developed for the treatment of metabolic dysfunction-associated steatohepatitis ("MASH"), previously known as nonalcoholic steatohepatitis, and for the treatment of severe hypertriglyceridemia. hypertriglyceridemia ("SHTG").

89bio was formed as a Delaware corporation in June 2019 to carry on the business of 89Bio Ltd., which was incorporated in Israel in January 2018.

Liquidity

The accompanying condensed consolidated financial statements Company has incurred significant losses and negative cash flows from operations since inception and had an accumulated deficit of $509.1 million as of March 31, 2024. The Company has historically financed its operations primarily through the sale of equity securities, including warrants, and from borrowings under term loan facilities. To date, none of the Company's product candidates have been prepared assuming the Company will continue as a going concern, which contemplates the realization of assets approved for sale, and liquidation of liabilities in the normal course of business. To date, the Company has not generated revenues any revenue from its activities and has incurred substantial commercial products. The Company expects operating losses. Management expects the Company losses to continue to generate substantial operating losses and increase for the foreseeable future until it completes as the Company progresses its clinical development of activities for its products and seeks regulatory approvals to market such products. product candidates.

The Company had believes its existing cash, and cash equivalents and short-term available-for-sale marketable securities of $448.3 562.3 million as of September 30, 2023.

The Company expects that its cash and cash equivalents and short-term available-for-sale securities as of September 30, 2023 March 31, 2024 will be sufficient to fund its planned operating expenses expense and capital expenditure

requirements for a period of at least one year from the date of the issuance of these unaudited condensed consolidated financial statements are filed with the Securities and Exchange Commission ("SEC"). statements.

2. Summary of Significant Accounting Policies

Unaudited Condensed Consolidated Financial Statements Basis of Presentation

The accompanying interim unaudited condensed consolidated financial statements have been prepared in accordance conformity with accounting principles generally accepted accounting principles in the United States ("U.S. GAAP"), the instructions to Form 10-Q and Rule 10-01 of Regulation S-X and applicable rules and regulations of the SEC Securities and Exchange Commission ("SEC") regarding interim financial reporting.

Unaudited Interim Condensed Consolidated Financial Statements

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, 2022 December 31, 2023 and in the opinion of management, reflect all adjustments, which include only normal recurring adjustments that are 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 and nine months ended September 30, 2023 interim periods presented. Interim results are not necessarily indicative of the results to be expected for the full year ending December 31, 2023 December 31, 2024 or for any other future annual or interim period. The condensed consolidated balance sheet as of December 31, 2022 December 31, 2023 was derived from the audited financial statements as of that date. date and, due to its summary nature, does not include all the disclosures required by U.S. GAAP in audited financial statements. 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, 2022 December 31, 2023, which was filed with the SEC on March 15, 2023 March 1, 2024.

Reclassification

Certain prior period amounts in the Company's condensed consolidated statements of operations and comprehensive loss have been reclassified to conform to the current period presentation. Specifically, interest expense is disclosed separately on the Company's condensed consolidated statements of operations and comprehensive loss, which had no impact on reported net loss, comprehensive loss, or loss per share.

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. For the Company and its subsidiary in Israel, the functional currency has been determined to be the U.S. Dollar.

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 accruals for uncertain tax positions, accrued research and development expenses and the fair value valuation of stock options and unrecognized tax benefits. options. 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.

There was no change in unrecognized tax benefits during the three months ended September 30, 2023. Unrecognized tax benefits increased by approximately $6.7 million during the nine months ended September 30, 2023. This change had no impact on the effective tax rate because of corresponding deductions from deferred tax assets.

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. The fair value of the Company's term loan approximates its carrying value, or amortized cost, due to the prevailing market rates of interest it bears. 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; and

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.

Assets Measured at Fair Value on a Recurring Basis

As of March 31, 2024 and December 31, 2023, cash equivalents and marketable securities were the only financial instruments measured and recorded at fair value on a recurring basis on the Company's condensed consolidated balance sheets.

Financial Instruments Not Carried at Fair Value

The Company's financial instruments, including cash, other current assets, accounts payable and accrued expenses are carried at cost which approximates their fair value because of the short-term nature of these financial instruments. The fair value of the Company's term loan approximates its carrying value, or amortized cost, due to the prevailing market rates of interest it bears.

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 primarily consist primarily of amounts invested in money market funds, and commercial paper that and U.S. government Treasury securities and are stated carried at fair value.

Investments Marketable Securities

Investments have been classified The Company invests its excess cash in marketable securities with high credit ratings including money market funds, commercial paper, securities issued by the U.S. government and its agencies and corporate debt securities. The Company accounts for all marketable securities as available-for-sale, and as the sale of such securities may be required prior to maturity. These marketable securities 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. Realized unrealized gains and losses if any, on available-for-sale reported as accumulated other comprehensive income (loss) until realized. The cost of debt securities is adjusted for accretion of premiums and amortization of discounts to maturity. Such amortization and accretion, as well as interest and dividends, are included in interest income and other, net. Realized gains and losses from the sale of marketable securities, if any, are determined on a specific identification basis and are also included in interest income and other, net. The cost Company's marketable securities are classified as current assets, which reflects management's intention to use the proceeds from sales of investments sold is based on these

securities to fund its operations, as necessary, even though the specific-identification method. The Company has not experienced any material realized gains stated maturity date may be one year or losses in more beyond the periods presented. current balance sheet date.

The Company periodically evaluates whether declines assesses its marketable securities for impairment. For marketable securities in fair values of its available-for-sale securities below amortized cost are due to credit-related factors or other factors. This evaluation consists of several qualitative and quantitative factors regarding the creditworthiness of the issuers of the security, the severity and duration of the an unrealized loss as well as position, this assessment first takes into account the Company's ability and intent to hold the available-for-sale security until a forecasted recovery occurs. Additionally, the Company assesses sell, or whether it has plans to sell the security or it is more likely than not that it will be required to sell any available-for-sale securities the security before recovery of its amortized cost basis. If either of these criteria are met, the marketable security's amortized cost basis is written down to fair value through interest income and other, net. For marketable securities in an unrealized loss position that do not meet the aforementioned criteria, the Company assesses whether the decline in fair value has resulted from credit losses or other factors. In making this assessment, the Company considers the extent to which fair value is less than amortized cost, any changes to the rating of the security by a rating agency, and any adverse conditions specifically related to the security, among other factors. If this assessment indicates that a credit loss may exist, the present value of cash flows expected to be collected from the security are compared to the amortized cost basis of the security. If the present value of cash flows expected to be collected is less than the amortized cost basis, a credit loss exists and an allowance for credit losses will be recorded in interest income and other, net, limited by the amount that the fair value is less than the amortized cost basis. Any additional impairment not recorded through an allowance for credit losses is recognized in other comprehensive loss. Changes in the allowance for credit losses are recorded as provision for (or reversal of) credit loss expense. Losses are charged against the allowance when management believes the uncollectability of a security is confirmed or when either of the criteria regarding intent or requirement to sell is met. These changes are recorded in interest income and other, net. To date, the Company has not recorded any impairment charges on its available-for-sale securities related to expected credit losses. Any remaining losses related to other factors are excluded from earnings and are reported as a component of comprehensive loss as an unrealized loss.

Comprehensive Loss 6

Income Taxes

The Company accounts for uncertain tax positions using a more-likely-than-not threshold for recognizing and resolving uncertain tax positions. This evaluation is based on factors including, but not limited to, changes in facts or circumstances, changes in tax law, effectively settled issues under audit, and new audit activity. Interest and penalties

related to unrecognized tax benefits are included within income tax expense. For the three months ended March 31, 2024, the Company recorded income tax expense of $0.1 million for the accrual of additional interest related to unrecognized tax benefits.

Basic and Diluted Net Loss per Share

Basic and diluted net loss per share is calculated based upon the weighted-average number of shares of common stock outstanding during the period. Shares of common stock that are potentially issuable for little or no cash consideration at issuance, such as the Company's comprehensive pre-funded warrants issued in July 2022 and December 2023 are included in the calculation of basic and diluted net loss per share, even if they are antidilutive. During periods of income, participating securities are allocated a proportional share of income determined by dividing total weighted-average participating securities by the sum of the total weighted-average common shares and participating securities (the "two-class method"). Shares of the Company's common stock warrants participate in any dividends that may be declared by the Company and are therefore considered to be participating securities. Participating securities have the effect of diluting both basic and diluted earnings per share during periods of income. During periods of loss, no loss is comprised allocated to participating securities since they have no contractual obligation to share in the losses of the Company. Diluted loss per share is computed after giving consideration to the dilutive effect of stock options, restricted stock units ("RSUs"), performance stock units ("PSUs") and common stock warrants, except where such non-participating securities would be anti-dilutive. As the Company incurred net losses for the periods presented, basic net loss and changes in unrealized gains or losses on available-for-sale per share is the same as diluted net loss per share since the effects of potentially dilutive securities and foreign currency translation adjustments. are antidilutive.

Recently Adopted Accounting Standards

In June 2016, The Company did not adopt any new standards or updates issued by the Financial Accounting Standards Board ("FASB") issued ASU 2016-13, *Financial Instruments—Credit Losses (Topic 326)*: *Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"), which replaces during 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 Company adopted this new guidance on January 1, 2023, using a modified retrospective approach and adoption did not have a material impact on the Company's consolidated financial statements and related disclosures.

In August 2020, the FASB issued ASU No. 2020-06*, Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40)—Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*, which simplifies the accounting for convertible instruments, amends the guidance on derivative scope exceptions for contracts in an entity's own equity, and modifies the guidance on diluted earnings per share calculations as a result of these changes. The Company early adopted ASU 2020-06 as of January 1,

2023, using a modified retrospective approach and adoption did not have three months ended March 31, 2024 that had a material impact on the Company's consolidated financial statements and related disclosures.

Accounting Pronouncements Not Yet Adopted

In November 2023, the FASB issued ASU No. 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures* ("ASU 2023-07"), which is intended to improve reportable segment disclosure requirements, primarily through enhanced disclosures about significant expenses. ASU 2023-07 requires disclosures to include significant segment expenses that are regularly provided to the chief operating decision maker ("CODM"), a description of other segment items by reportable segment, and any additional measures of a segment's profit or loss used by the CODM when deciding how to allocate resources. The ASU also requires all annual disclosures required by Topic 280 to be included in interim periods. All disclosure requirements under this ASU are also required for public entities with a single reportable segment. The ASU is effective for the Company's annual periods beginning on January 1, 2024 and interim periods beginning on January 1, 2025. Early adoption is permitted and requires retrospective application to all prior periods presented in the financial statements. The Company expects to adopt ASU 2023-07 in its Annual Report on Form 10-K for the year ending December 31, 2024 and in the interim periods thereafter. The Company is in the process of evaluating the requirements of this update, which is expected to result in expanded disclosures within the consolidated financial statements upon adoption.

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* ("ASU 2023-09"), which requires companies to disclose, on an annual basis, specific categories in the effective tax rate reconciliation and provide additional information for reconciling items that meet a quantitative threshold. In addition, ASU 2023-09 requires companies to disclose additional information about income taxes paid. The ASU is effective for the Company's annual periods beginning on January 1, 2025 and will be applied on a prospective basis with the option to apply the standard retrospectively. Early adoption is permitted. The Company expects to adopt ASU 2023-09 in its Annual Report on Form 10-K for the year ending December 31, 2025 and in annual periods thereafter. The Company is in the process of evaluating the requirements of this update, which is expected to result in expanded disclosures within the consolidated financial statements upon adoption.

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3. Fair Value Measurements

The following tables present the Company's financial assets measured at fair value on a recurring basis by level within the fair value hierarchy as of September 30, 2023 were as follows for the periods indicated (in thousands):

	March 31, 2024

	Valuation Hierarchy	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value	Valuation Hierarchy	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Money market funds	Level 1	$ 8,947	$ —	$ —	$ 8,947	Level 1	$ 4,073	$ —	$ —	$ 4,073
Commercial paper	Level 2	104,151	—	(50)	104,101	Level 2	124,016	—	(71)	123,945
U.S. treasury bills	Level 2	115,237	11	(12)	115,236					
U.S. government bonds	Level 2	89,910	1	(278)	89,633	Level 2	194,344	47	(377)	194,014
Agency bonds	Level 2	32,660	—	(197)	32,463	Level 2	53,252	10	(107)	53,155
Agency discount securities	Level 2	2,479	—	(3)	2,476					
Corporate debt securities	Level 2	3,159	—	(34)	3,125	Level 2	5,184	—	(22)	5,162
Total cash equivalents and available-for-sale securities		356,954	$ 12	$ (574)	355,981					
U.S. Treasury securities						Level 2	49,505	—	(8)	49,497
Total cash equivalents and marketable securities							$ 430,374	$ 57	$ (585)	$ 429,846
Classified as:										
Cash equivalents					159,603					$ 85,131
Short-term available-for-sale securities					196,378					

Total cash equivalents and available-for-sale securities	355,98 $ 1
Marketable securities	344,715
Total cash equivalents and marketable securities	$ 429,846

		December 31, 2023			
	Valuation Hierarchy	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Money market funds	Level 1	$ 493	$ —	$ —	$ 493
Commercial paper	Level 2	94,261	—	(55)	94,206
U.S. government bonds	Level 2	137,976	250	(142)	138,084
Agency bonds	Level 2	45,481	152	(44)	45,589
Corporate debt securities	Level 2	3,177	—	(12)	3,165
U.S. Treasury securities	Level 2	71,754	36	(1)	71,789
Agency discount securities	Level 2	7,975	1	—	7,976
Total cash equivalents and marketable securities		$ 361,117	$ 439	$ (254)	$ 361,302
Classified as:					
Cash equivalents					$ 98,593
Marketable securities					262,709
Total cash equivalents and marketable securities					$ 361,302

The valuation techniques used to measure the fair values of the Company's Level 2 financial assets measured at instruments, which generally have counterparties with high credit ratings, are based on quoted market prices when available. If quoted market prices are not available, the fair value for the security is estimated under the market or income approach using pricing models with market observable inputs.

The following table summarizes the estimated fair value of investments in marketable securities by effective contractual maturity dates as of September 30, 2023 were as follows March 31, 2024 (in thousands):

Within one year	$ 314,373

After one year through two years		115,473
Total cash equivalents and marketable securities	$	429,846

Within one year	$	316,468
After one year through two years		39,513
Total cash equivalents and available-for-sale securities	$	355,981

As of March 31, 2024, the Company's marketable securities in an unrealized loss position include primarily fixed-rate debt securities of varying maturities, which are sensitive to changes in the yield curve and other market conditions. Substantially all of the fixed-rate debt securities in a loss position are investment-grade debt securities. The Company has the intent and ability to hold such securities until recovery of the unrealized losses. Based on the Company's financial assets measured at fair value on a recurring basis by level within assessment, the fair value hierarchy unrealized losses as of December 31, 2022 March 31, 2024 were as follows (in thousands):

	Valuation Hierarchy	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Money market funds	Level 1	$ 18,224	$ —	$ —	$ 18,224
Commercial paper	Level 2	104,279	1	(84)	104,196
U.S. government bonds	Level 2	18,225	1	(109)	18,117
Agency bonds	Level 2	13,986	—	(78)	13,908
Corporate debt securities	Level 2	10,488	—	(62)	10,426
U.S. treasury bills	Level 2	7,414	1	(21)	7,394
Agency discount securities	Level 2	5,216	9	—	5,225
Non-U.S. debt securities	Level 2	3,975	—	(20)	3,955
Total cash equivalents and available-for-sale securities		$ 181,807	$ 12	$ (374)	$ 181,445
Classified as:					
Cash equivalents					$ 48,540
Short-term available-for-sale securities					132,905
Total cash equivalents and available-for-sale securities					$ 181,445

The Company's financial assets measured at fair value by contractual maturity primarily due to changes in interest rates and not due to increased credit risks associated with specific securities. No allowance for credit losses was recorded as of December 31, 2022 were as follows (in thousands): March 31, 2024 and December 31, 2023.

Within one year	$	175,243

After one year through two years	6,202
Total cash equivalents and available-for-sale securities	$ 181,445

4. Balance Sheet Components

Prepaid and other current assets consist of the following as of the periods indicated presented (in thousands):

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	September 30, 2023	December 31, 2022
Prepaid research and development	$ 9,193	$ 5,727
Prepaid taxes	611	646
Prepaid other	1,418	1,547
Total prepaid and other current assets	$ 11,222	$ 7,920

	March 31, 2024	December 31, 2023
Prepaid research and development	$ 9,009	$ 11,579
Prepaid taxes	615	614
Prepaid other	2,870	2,471
Total prepaid and other current assets	$ 12,494	$ 14,664

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

	September 30, 2023	December 31, 2022	March 31, 2024	December 31, 2023
Accrued research and development expenses	$ 8,684	$ 6,499	$ 15,881	$ 13,017
Accrued employee and related expenses	3,937	4,165	2,603	6,248
Accrued professional and legal fees	1,432	1,052	1,776	1,110
Accrued other expenses	80	228	35	155

Total accrued expenses	$ 14,133	$ 11,944	$ 20,295	$ 20,530

5. Commitments and Contingencies

Asset Transfer and License Agreement with Teva Pharmaceutical Industries Ltd

In April 2018, the Company concurrently entered into two Asset Transfer and License Agreements (the "Teva Agreements") with Teva Pharmaceutical Industries Ltd ("Teva") under which it acquired certain patents and intellectual property relating to two programs: (1) Teva's glycoPEGylated FGF21 program, including the compound TEV-47948 (pegozafermin), a glycoPEGylated long-acting FGF21 and (2) Teva's development program of small molecule inhibitors of fatty acid synthase. Fatty Acid Synthase. Pursuant to the Teva Agreements, the Company paid Teva an initial nonrefundable upfront payment of $6.0 million and million. Under each license agreement, the Company could be obligated is required to pay Teva up to $67.5 million under each program, for a total of $135.0 2.5 million upon the achievement of certain a specified clinical development milestone, and additional payments totaling up to $65.0 million upon achievement of certain commercial milestones. In addition, Each milestone payment shall be payable once, upon the first occurrence of the applicable milestone. The Company is also 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 upon 120 days' written notice to Teva, (ii) by either party, if the other party materially breaches any of its obligations under the Teva 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 their 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 In the three fourth quarter of 2023, the Company made a $2.5 million milestone payment to Teva following the achievement of a clinical development milestone under the FGF21 program in SHTG. As of March 31, 2024, the timing and nine months ended September 30, 2023 likelihood of achieving any remaining milestones are uncertain. Milestone payment obligations will be recognized when payment becomes probable and 2022, none reasonably estimable, which is generally upon achievement of the development and commercial milestones were met and accordingly, there were no milestone payments related to the Teva Agreements (see Note 10). applicable milestone.

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6. Term Loan Facility

2021 Loan Agreement

In April 2020, January 2023, the Company entered into a Loan and Security Agreement (the "Loan ("the Loan Agreement") with the lenders referred to therein, and Silicon Valley Bank ("SVB" lender parties thereto (the "Lenders"), as collateral agent. The Loan Agreement as amended in May 2021 (the "2021 Loan Agreement") provided for (i) a secured term A loan facility (the "Term A Loan Facility") of up to $20.0 million and (ii) a secured term B loan facility (the "Term B Loan Facility") of up to $5.0 million. The Term A Loan Facility of $20.0 million was fully drawn as of December 2022 and the Term B Loan Facility expired unused.

In January 2023, the Company executed a loan and security agreement with new lenders (the "2023 Loan Agreement") and from the proceeds repaid $21.4 million in outstanding principal, final payment fee, prepayment fee and interest due under the 2021 Loan Agreement. Repayment of the 2021 Loan Agreement was accounted for as an extinguishment as the 2023 Loan Agreement was with new lenders. The Company recorded a loss on extinguishment of $1.2 million, which was recognized as a component of interest expense on the Company's condensed consolidated statements of operations and comprehensive loss.

2023 Loan Agreement

In January 2023, the Company executed the 2023 Loan Agreement with the lenders referred to therein, K2 HealthVentures LLC ("K2HV") as administrative agent and Ankura Trust Company, LLC as collateral agent. The 2023 Loan Agreement provides for up to $100.0 million in aggregate principal in term loans, consisting of a first term loan an initial tranche of $25.0 million that was funded at closing, two subsequent term loans totaling second and third tranches of $25.0 15.0 million and $10.0 million, respectively, that may be funded upon the achievement of certain time-based, clinical and regulatory milestones, and a fourth term loan tranche of up to $50.0 million that may be funded upon discretionary approval by the lenders. Lenders. As of September 30, 2023March 31, 2024, the second term loan of $15.0 million tranche expired unused. undrawn. The third $10.0 million tranche is available through June 30, 2024 and the fourth $50.0 million tranche remains available, at the sole discretion of the Lenders.

The term loans Borrowings under the Loan Agreement are secured by substantially all of the assets of the Company, excluding the Company's intellectual property. The 2023 Loan Agreement contains customary representations and warranties, restricts certain activities and includes customary events of default, including payment default, breach of covenants, change of control, and material adverse effects. In addition, starting January 1, 2024, the Company is required to maintain minimum unrestricted cash and cash equivalents equal to 5.0 times the average change in cash and cash equivalents measured over the trailing three-month period. As of March 31, 2024, the Company was in compliance with all covenants under the Loan Agreement.

The term loans Borrowings under the Loan Agreement mature on January 1, 2027 and provide for interest-only payments until February 1, 2025. Consecutive equal payments of principal and interest are due once the interest-only period has elapsed. The term loans Borrowings under the Loan Agreement bear interest equal to the greater of (i) 8.45% and (ii) the sum of (a) the Prime Rate as reported in The Wall Street Journal plus (b) 2.25%. The interest rate on the term loan was 9.75% at inception and 10.75% as of September 30, 2023 March 31, 2024. In addition, a final payment fee of 5.95% of the principal amount of the term loans is due upon the earlier of prepayment or maturity of the term loans. The Company has the option to prepay the entire outstanding balance of borrowings under the term loans Loan Agreement, subject to a prepayment fee ranging from 3.0 1.0% to 1.0 3.0% depending on the timing of such prepayment. A commitment fee equal to 0.6% of the principal amount of the fourth term loan tranche is also payable should such loan be funded. if drawn.

At any time prior to full repayment of outstanding borrowings under the term loans, Loan Agreement, the lenders Lenders may elect to convert up to an aggregate of $7.5 million of the principal amount of the term loans then outstanding borrowings into shares of the Company's common stock at a conversion price of $12.6943 per share. The embedded conversion option qualifies for a scope exception from derivative accounting because it is both indexed to the Company’s own stock and meets met the conditions for equity classification.

Total debt issuance costs related to the first term loan were facility of $0.8 million, including which includes the fair value of warrants issued in connection with the warrant related to the first term loan (discussed below) facility, were recorded as a debt discount since the first term loan was funded at inception. discount. The debt discount, together with the final payment fee, are recognized as interest expense using the effective interest method over the term of the loan. loan facility.

The expected repayments of principal amount due on the term loans borrowings as of September 30, 2023 March 31, 2024 are as follows (in thousands):

Remainder of 2023	$	—
2024		—
2025		10,774
2026		13,036
2027		1,190
Total principal repayments		25,000
Final payment fee		285
Total principal repayments and final payment fee		25,285
Unamortized debt discount		(648)
Total term loan, non-current, net	$	24,637

2024 (remaining nine months)	$	—
2025		10,774

2026	13,036
2027	1,190
Total principal outstanding	25,000
Plus accumulated accretion of final payment fee	493
Less unamortized debt discount	(536)
Total net carrying value	24,957
Term loan, current	(1,892)
Term loan, noncurrent, net	$ 23,065

Warrants

In January 2023, in connection with the 2023 Loan Agreement, the Company issued the lenders Lenders a warrant to purchase up to an aggregate of 204,815 shares of the Company's common stock at an exercise price of $9.7649 per share (the "warrant shares") that expires in January 2033. The warrant shares become exercisable upon the funding of each term loan. tranche and have a 10-year term. In connection with the first term loan tranche that was funded at closing, 51,204 of the warrant shares became exercisable. The warrant shares cannot be settled for cash and include a cashless exercise feature allowing the holder to receive shares net of shares withheld in lieu of the exercise price. The warrant shares also provide for automatic cashless exercise under certain specific conditions and settlement is permitted in unregistered shares. The 51,204 warrant shares meet met the requirements for equity classification.

The Company determined the fair value of the 51,204 warrant shares issued using the Black-Scholes option-pricing model with the following assumptions: risk-free interest rate of 3.9%, no dividends, expected volatility of 93.8% and expected term of 10.0 years.

Of the remaining 153,611 warrant shares (the "contingent warrants"), 122,839 122,889 warrant shares are contingently exercisable upon the funding of each subsequent term loan and have the same exercise price and contractual term remain outstanding and 30,722 warrant shares associated with the second term loan tranche were forfeited as of September 30, 2023 March 31, 2024. The contingent warrants did not meet the derivative scope exception or equity classification criteria and were accounted for as a derivative liability. The initial fair value and the fair value as of September 30, 2023 March 31, 2024 of the contingent warrants was insignificant. The contingent warrants derivative liability is remeasured each reporting period until settled or extinguished with subsequent changes in fair value recorded as interest expense in the condensed consolidated statements of operations and comprehensive loss. The initial fair value of the contingent warrants derivative liability was determined using a probability weighted Black-Scholes option pricing model based on the same Black-Scholes input assumptions described above.

7. Stockholders' Equity

Common Stock Reserved for Issuance

As of September 30, 2023, The Company had the Company's following shares of common stock available reserved for future issuance, were on an as-if-converted basis, as follows: of the periods presented:

Shares available for future grant under the equity incentive plans	1,848,784
Shares available for future issuance under the employee stock purchase plan	1,220,897
Shares available for future issuance upon the exercise of warrants and pre-funded warrants	11,212,805
Total available for future issuance	14,282,486

	March 31, 2024	December 31, 2023
Stock options outstanding	6,891,349	4,686,577
RSUs and PSUs outstanding	1,508,546	987,550
Shares available for future grants under equity incentive plans	2,600,491	1,790,684
Shares available for future issuance under the employee stock purchase plan	1,207,607	1,207,607
Warrants to purchase common stock outstanding	10,075,092	10,412,806
Pre-funded warrants to purchase common stock outstanding	1,881,081	1,881,081
Conversion feature related to outstanding term loan	590,816	590,816
Total available for future issuance	24,754,982	21,557,121

Public Offerings

At-the-Market ("ATM") Offerings

In March 2021, the Company entered into a an ATM sales agreement (as amended, the "Sales Agreement") with SVB Securities Leerink Partners LLC and Cantor Fitzgerald & Co. (the "Sales Agents") pursuant to which it the Company may offer and sell shares up to $75.0 million of the Company's its common stock (the "2021 ATM Facility") from time to time in "at-the-market" offerings (the "ATM Facility"). pursuant to an effective registration statement. The Sales Agents are entitled to compensation at a commission equal to 3.0% of the aggregate gross sales price per share sold under the Sales Agreement.

During the three months ended March 31, 2023, the Company received aggregate proceeds of $13.4 million, net of commissions, from sales of 968,000 shares of its common stock pursuant to the ATM Facility.

On February 15, 2023, the Company entered into Amendment No. 1 to the Sales Agreement with the Sales Agents, pursuant to which the Company may offer and sell up to $150.0 million of its common stock, from time to time, through the ATM Facility at a commission of up to 3.0% of the aggregate gross sales price per share sold under the Sales Agreement.

During For the three months ended June 30, 2023 March 31, 2023, the Company received aggregate proceeds of $ sold 23.7 million, net of commissions, from sales of 1,200,539 968,000 shares of its common stock pursuant under the 2021 ATM Facility and received net proceeds of $13.4 million, after deducting commissions and offering costs of $0.4 million.

In February 2023, the Company entered into an amendment to the Sales Agreement, establishing a new ATM Facility.

July 2022 Public Offering

In July 2022, the Company completed facility with an underwritten public aggregate offering amount of up to $150.0 million of its common stock warrants (the "2023 ATM Facility") pursuant to purchase shares of its common stock and pre-funded warrants to purchase shares of its common stock. The an effective registration statement. For the three months ended March 31, 2024, the Company sold 18,675,466 1,396,888 shares of its common stock with accompanying warrants to purchase up to 9,337,733 shares of its common stock at a combined public offering price of $3.55 per share. The Company also sold 7,944,252 pre-funded warrants to purchase shares of its common stock with accompanying warrants to purchase up to 3,972,126 shares of its common stock at a combined public offering price of $3.549 per pre-funded warrant, which represents under the per share public offering price for the common stock less $0.001 per share, the exercise price for each pre-funded warrant. The Company raised aggregate 2023 ATM Facility resulting in net proceeds of $88.2 21.0 million, net of underwriting discounts after deducting commissions and commissions of $5.7 million and other offering costs of $0.6 0.5 million. As of March 31, 2024, there was $104.4 million remaining for future sales under the 2023 ATM Facility.

The exercise of the outstanding warrants is subject to a beneficial ownership limitation of 9.99%, or at the election of the holder prior to the issuance of the warrant, 4.99%. The exercise of the outstanding pre-funded warrants is subject to a beneficial ownership limitation of 9.99%, or at the election of the holder prior to the issuance of the pre-funded warrant, 4.99%, which a holder may increase or decrease from time to time but shall not exceed 19.99%. The exercise price and number of shares of common stock issuable upon the exercise of the warrants and pre-funded warrants are subject to adjustment in the event of any stock dividends, stock splits, reverse stock split, recapitalization, or reorganization or similar transaction, as described in the agreements. Under certain circumstances, the warrants and pre-funded warrants may be exercisable on a "cashless" basis. The warrants and pre-funded warrants were classified as a component of stockholders' equity and additional paid-in capital because such warrants and pre-funded warrants (i) are freestanding financial instruments that are legally detachable and separately exercisable from the equity instruments, (ii) are immediately exercisable, (iii) do not embody an obligation for the Company to repurchase its shares, (iv) permit the holders to receive a

fixed number of common shares upon exercise, (v) are indexed to the Company's common stock and (vi) meet the equity classification criteria. In addition, the warrants and pre-funded warrants do not provide any guarantee of value or return.

March 2023 Underwritten Public Offering Offerings

In March 2023, the Company completed an underwritten public offering of its common stock. The Company sold 19,461,538 shares of its common stock at a public offering price of $16.25 per share. The Company raised aggregate share and received net proceeds of $296.8 million, net of underwriting discounts and commissions of $19.0 million and other offering costs of $0.5 million.

Common Stock Warrants

As of September 30, 2023 March 31, 2024, the Company's outstanding warrants to purchase shares of its common stock were as follows:

	Shares of Common Stock Underlying Warrants	Exercise Price Per Share	Expiration Date
Warrant issued in connection with term loan (SVB)	25,000	$ 22.06	June 30, 2025
Warrant issued in connection with term loan (SVB)	33,923	19.12	May 28, 2031
Warrants issued in connection with term loan facility	174,093	9.76	January 27, 2033
Warrants issued in connection with public offering	9,842,076	5.325	July 1, 2024
Pre-funded warrants issued in connection with public offerings	1,881,081	0.001	Do not expire
Total outstanding	11,956,173		

	Shares of Common Stock Underlying Warrants	Exercise Price Per Share	Expiration Date
Warrant issued with term loan to SVB	25,000	$ 22.06	June 30, 2025
Warrant issued with term loan to SVB	33,923	19.12	May 28, 2031
Warrants issued with term loan to K2HV	174,093	9.76	January 27, 2033
Warrants issued in public offering	10,179,789	5.325	July 1, 2024
Pre-funded warrants issued in public offering	800,000	0.001	Do Not Expire
Total outstanding	11,212,805		

8. Stock-Based Compensation

Equity Incentive Plans

In September 2019, the Company's board of directors adopted the 2019 Equity Incentive Plan (the "2019 Plan"), which also became effective in September 2019. The Company initially reserved has issued stock-based awards from various equity incentive and stock purchase plans, as more fully described in Note 8—*2,844,193 Stock-Based Compensation* 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 in an amount equal to 4% of the total number of shares of the Company's capital stock outstanding Notes to Consolidated Financial Statements section in its Annual Report on Form 10-K for the immediately preceding December 31, or a lesser number of shares determined by the Company's board of directors. year ended December 31, 2023.

In February 2023, the Company's board of directors adopted the 2023 Inducement Plan (the "2023 Plan"), which also became effective in February 2023. The Company initially reserved 1,500,000 shares of common stock for issuance under the 2023 Plan. Under the 2023 Plan, new employees are eligible to receive equity awards as a material inducement to the commencement of employment with the Company. During the three and nine months ended September 30, 2023, options to purchase an aggregate of 279,600 and 417,700 shares, respectively, were granted to 14 and 20 new employees, respectively, under the 2023 Plan.

Employee Stock Purchase Plan

In October 2019, the Company's board of directors 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 are accomplished through the participation of discrete offering periods and each offering is expected to be six months in duration. 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. Equity Incentive Plans Activity

Stock Options

The following table summarizes stock option activity under the Company's equity incentive plans for the nine three months ended September 30, 2023 March 31, 2024:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (In years)	Aggregate Intrinsic Value (In thousands)	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, 2022	3,161,917	$ 80	7.9	$ 2				
Balance outstanding as of December 31, 2023					4,686,577	$ 14.11	7.9	$ 11,712
Granted	1,783,900	15.18			2,241,000	9.99		
Exercised	(196,612)	3.20			(1,626)	4.44		
Cancelled and forfeited	(70,178)	10.77			(34,602)	12.94		
Balance outstanding as of September 30, 2023	4,679,027	$ 14	8.0	$ 2				
Exercisable as of September 30, 2023	2,005,286	$ 22	6.8	$ 4				
Balance outstanding as of March 31, 2024					6,891,349	$ 12.78	8.3	$ 16,139

Exercisable as of March 31, 2024	2,617,844	$ 14.76	6.8	$ 9,011

The fair value of stock 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,	
	2024	2023
Expected term (years)	5.5–6.1	5.5–6.1
Expected volatility	89.4–90.4%	91.6–93.2%
Risk-free interest rate	3.8–4.1%	3.4–3.8%
Expected dividend	—	—

As of March 31, 2024, total unrecognized stock-based compensation expense related to unvested stock options was $

	Nine Months Ended September 30,	
	2023	2022
Expected term (years)	5.5-6.1	5.5-6.1
Expected volatility	91.6-99.2%	89.9-91.0%
Risk-free interest rate	3.4-4.6%	1.6-3.4%
Expected dividend	—	—

Restricted Stock Units (“RSUs”) 34.8 million, which is expected to be recognized over a weighted-average period of 3.0 years.

The Company has granted certain employees service-based RSU and PSUs

RSUs that generally vest annually over a two or three-year period. The restrictions lapse over time for these service-based RSUs. In the event of termination of the holder’s continuous service to the Company, any unvested portion of the service-based RSUs is cancelled. For the three months ended September 30, 2023 and 2022, the Company recognized $0.9 million and $0.3 million, respectively, in expense related to the service-based RSUs. For the nine months ended September 30, 2023 and 2022, the Company recognized $2.4 million and $0.7 million, respectively, in expense related to the service-based RSUs.

In February 2021, the Company granted performance-based RSUs that vest PSUs generally contain performance conditions associated with corporate goals, such as to one-third on each one-year anniversary date, subject to achievement of a development milestone and continued service to the Company. In each of February 2022 and 2023, a

portion of the performance-based RSUs vested upon achievement of the development milestone and satisfaction of the continued service condition.

In February and September 2022, the Company granted performance-based RSUs that vest during the applicable performance period, subject to the achievement of certain corporate or department targets and continued service to the Company. In September 2022, March 2023 and June 2023, a portion of the performance-based RSUs development milestones, that were granted in February 2022 vested vests upon achievement of specific targets and satisfaction of the continued service condition.

As of September 30, 2023, it was probable that the remaining performance conditions would be met for the Company's performance-based RSUs and expense was recognized using the accelerated attribution method. For the three months ended September 30, 2023 and 2022, the Company recognized expense of $ over a 0.2one million and $ to 0.3three-year million, respectively, related to performance-based RSUs. For the nine months ended September 30, 2023 and 2022, the Company recognized $0.8 million and $1.1 million, respectively, in expense related to the performance-based RSUs. period.

The following table summarizes RSU and PSU activity for the nine three months ended September 30, 2023 March 31, 2024:

	RSUs		PSUs	
	Number of Shares	Weighted-Average Grant Date Fair Value per Share	Number of Shares	Weighted-Average Grant Date Fair Value per Share
Balance outstanding as of December 31, 2023	688,382	$ 10.72	299,168	$ 5.96
Granted	651,950	9.98	192,000	9.98
Vested	(157,172)	13.43	(159,168)	7.00
Canceled	(6,614)	10.78	—	—
Balance outstanding as of March 31, 2024	1,176,546	$ 9.95	332,000	$ 7.79

As of March 31, 2024, total unrecognized stock-based compensation expense related to RSUs and PSUs was $12.3 million, which is expected to be recognized over a weighted-average period of 1.9 years.

Stock-Based Compensation

	Number of RSUs	Weighted Average Fair Value at Date of Grant per Unit
Balance outstanding as of December 31, 2022	1,095,738	$ 5.77
Granted	379,075	15.02
Vested / released	(309,740)	5.82
Cancelled / forfeited	(177,523)	$ 5.89
Balance outstanding as of September 30, 2023	987,550	$ 9.28

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

	Three Months Ended September 30,		Nine Months Ended September 30,		Three Months Ended March 31,	
	2023	2022	2023	2022	2024	2023
Research and development	$ 1,938	$ 1,019	$ 5,136	$ 2,917	$ 2,315	$ 1,486
General and administrative	2,443	1,481	6,933	4,681	2,683	2,065
Total stock-based compensation	$ 4,381	$ 2,500	$ 12,069	$ 7,598	$ 4,998	$ 3,551

9. Net Loss Per Share

The following table presents the weighted-average shares outstanding used to calculate basic and diluted net loss per share for the periods indicated:

	Three Months Ended March 31,	
	2024	2023
Common stock	93,965,659	52,371,370
Pre-funded warrants	1,881,081	800,000

Total	95,846,740	53,171,370

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

	Nine Months Ended September 30,	
	2023	2022
Stock options to purchase common stock	4,679,027	3,123,221
Unvested RSUs	987,550	1,118,735
Warrants to purchase common stock[1]	10,412,805	13,358,782
Conversion shares under the term loan with K2HV	590,816	—
ESPP	9,758	20,353
Total	16,679,956	17,621,091

[1] The table above excludes pre-funded warrants issued in connection with the July 2022 public offering (see Note 7).

	Three Months Ended March 31,	
	2024	2023
Stock options outstanding	6,891,349	4,463,459
RSUs and PSUs outstanding	1,508,546	1,218,377
Warrants to purchase common stock	10,075,092	11,688,597
Conversion feature related to outstanding term loan	590,816	590,816
ESPP	13,091	7,721
Total	19,078,894	17,968,970

10. Subsequent Events

Teva Agreements BiBo Collaboration Agreement

On April 4, 2024, the Company entered into a collaboration agreement (the "Collaboration Agreement") with BiBo Biopharma Engineering Co., Ltd., a company incorporated under the laws of the People's Republic of China ("BiBo"), pursuant to which BiBo will construct a production facility specifically designed to supply the Company with pegozafermin for commercialization, if approved (the "Production Facility").

In October 2023, Pursuant to the Collaboration Agreement, BiBo will build the Production Facility at BiBo's facility in the Lin-gang Special Area of China (Shanghai) Pilot Free Trade Zone to manufacture the bulk active ingredient (the "Drug Substance") required to produce pegozafermin for commercial supply. The platform is expected to provide the Company achieved a clinical development milestone related with manufacturing capacity to meet its commercial needs based on current projections. Under the enrollment Collaboration Agreement, the Company will pay BiBo an aggregate of patients pursuant to the Teva Agreements. As a result, a $2.5 135.0 million milestone payment became due and toward the construction of the Production Facility (collectively, the "Payment"), of which 45% of the Payment will be payable (see Note 5). in the third quarter of 2024. The remainder of the Payment will become payable upon achievement of certain specified milestones, of which up to an additional approximately 45% of the Payment could become payable within the next 12 months, depending on the timing of achievement of certain milestones. If the actual costs of the Production Facility are substantially greater than the estimated budget, the parties will negotiate a means of allocating such cost overruns.

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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, 2022 December 31, 2023. 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, pegozafermin, a specifically engineered glycoPEGylated analog of fibroblast growth factor 21 ("FGF21"), is currently being developed for the treatment of metabolic dysfunction-associated steatohepatitis ("MASH"), previously known as nonalcoholic steatohepatitis, ("NASH") and for the treatment of severe hypertriglyceridemia ("SHTG").

NASH MASH is a severe form of metabolic dysfunction-associated steatotic liver disease, previously known as nonalcoholic fatty liver disease, and is characterized by inflammation and fibrosis in the liver that can progress to cirrhosis, liver failure, hepatocellular carcinoma and death. There are currently no approved products for the treatment of NASH. In 2020 and 2022, we presented positive topline results from cohorts 1 through 6 and cohort 7, respectively, in our Phase 1b/2a trial of pegozafermin in NASH MASH patients, which has have informed the advancement of our subsequent clinical strategy in NASH. We initiated a MASH. In our Phase 2b ENLIVEN trial (ENLIVEN) evaluating of pegozafermin in fibrosis stage 2 or 3 NASH MASH patients, in June 2021. Patients patients received weekly doses (15 mg and 30 mg) or an every two-week every-two-week dose (44 mg) of pegozafermin or placebo for 24 weeks followed by a blinded extension phase of an additional 24 weeks for a total treatment period of 48 weeks, with some of the placebo patients re-randomized to receive pegozafermin in the extension phase. In August 2022, we reported the completion of enrollment in ENLIVEN with 219 patients. weeks. We reported topline 24 week data from ENLIVEN in March 2023. The 44 mg every-two-week and the 30 mg weekly dose groups both met, with high statistical significance, both of the primary histology endpoints per the U.S. Food and Drug Administration ("FDA") guidance definitions on endpoints for accelerated approval in non-cirrhotic NASH MASH patients. The 44 mg every two-week and the 30 mg weekly dose groups both demonstrated at least one-stage fibrosis improvement without worsening of NASH (27% and 26%, respectively) at 3.5 times the placebo rate (7%) and NASH resolution without worsening of fibrosis (26% and 23%, respectively), between 12 to 14 times the placebo rate (2%). These dose groups also demonstrated statistically significant and clinically meaningful improvements in liver fat, non-invasive markers of liver fibrosis and inflammation as well as meaningful improvements in other metabolic and lipid markers. Pegozafermin was generally well tolerated with a favorable safety profile consistent with prior studies. In September 2023, the FDA granted breakthrough therapy Breakthrough Therapy Designation to pegozafermin in patients with MASH. In addition, in March 2024, the EMA granted Priority Medicines ("PRIME") designation to pegozafermin in patients with NASH. MASH, based on clinical data from the Phase 2b ENLIVEN trial. In November 2023, we announced positive topline data from the blinded extension phase of our Phase 2b ENLIVEN trial at 48 weeks. Both the 44 mg every-two-week and 30 mg weekly dose groups demonstrated statistically significant improvements across Non-Invasive Tests ("NITs") representing key markers of liver health. The benefits observed at week 48 represented by NITs were consistent with the histology and NITs results observed at week 24, indicating sustained benefits over time.

The ENLIVEN study also included 14 biopsy-confirmed NASH patients with compensated cirrhosis (F4 patients) who were not part of the primary analysis but continued in the study. 12 of these 14 patients underwent a follow-up biopsy at week 24. In a descriptive analysis of these data, five out of 11 pegozafermin-treated patients experienced at least one-stage improvement in liver fibrosis with no worsening of NASH by week 24 compared with zero out of 1 patient on placebo. An additional two pegozafermin-treated patients experienced at least one-stage improvement in liver fibrosis with no worsening of ballooning or inflammation.

Results from the ENLIVEN trial were published in the New England Journal of Medicine and simultaneously presented in a late-breaking oral session at the European Association for the Study of the Liver Congress. Additional data included in these publications showed that treatment with pegozafermin resulted in significant benefit across several key sub populations of NASH patients, and adding pegozafermin to patients taking GLP-1 therapies improved key NASH measures.

We expect to receive feedback from the FDA regarding our clinical development in the fourth quarter of 2023, and to pursue EU scientific advice in parallel. Subject to regulatory approval, our proposed clinical development plans include we held successful end-of-Phase 2 meetings with the FDA, supporting the advancement of pegozafermin into a Phase 3 trial evaluating F2/F3 patients program and future biologics license application ("BLA") filing. We received scientific advice from the European Medicines Agency ("EMA"), which generally aligned with a histology endpoint for accelerated approval and a the feedback from the FDA.

The Phase 3 trial in parallel with an outcomes endpoint for full approval. The planned SHTG ENLIGHTEN program will include two Phase 3 trials are evaluating patients with MASH: (i) ENLIGHTEN-Fibrosis, which is enrolling patients with fibrosis stage F2-F3 (F2-F3) and (ii) ENLIGHTEN-Cirrhosis, which is expected to satisfy enroll patients with compensated cirrhosis (F4). During the safety database requirements for NASH. first quarter of 2024, we announced the initiation of the ENLIGHTEN-Fibrosis Phase 3 clinical trial. We expect to initiate our Phase 3 program for NASH the ENLIGHTEN-Cirrhosis clinical trial in the first half second quarter of 2024.

We are also developing pegozafermin for the treatment of SHTG. In June 2022, we announced positive topline results from the ENTRIGUE Phase 2 trial of pegozafermin in SHTG patients. SHTG is a condition identified by severely elevated levels of triglycerides (≥500 mg/dL), which is associated with an increased risk of NASH, MASH, cardiovascular events and acute pancreatitis. The trial met its primary endpoint demonstrating statistically significant and clinically meaningful reductions in triglycerides from baseline

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and key secondary endpoints. We have received feedback from the FDA supporting the advancement of pegozafermin into and initiated our Phase 3 and initiated ENTRUST trial, the first of two recommended Phase 3 trials, in the second quarter of 2023. We expect to report topline results from the first of the two our Phase 3 trials ENTRUST trial in 2025. Safety data from the ongoing SHTG Phase 3 program is expected to support the safety database requirements for MASH and vice versa.

In October 2023, April 2024, we achieved entered into a clinical development milestone related collaboration agreement (the "Collaboration Agreement") with BiBo Biopharma Engineering Co., Ltd., pursuant to which BiBo will construct a production facility specifically designed to supply us with pegozafermin for commercialization, if approved (the "Production Facility"). Pursuant to the enrollment Collaboration Agreement, BiBo will build the Production Facility at BiBo's facility in the Lin-gang Special Area of patients in China (Shanghai) Pilot Free Trade Zone to manufacture the bulk active

ingredient (the “Drug Substance”) required to produce pegozafermin for commercial supply. The platform is expected to provide us with manufacturing capacity to meet our Phase 3 trials and, as a result, a $2.5 million milestone payment became due pursuant to our Asset Transfer and License Agreements (the “Teva Agreements”) with Teva Pharmaceutical Industries Ltd (“Teva”). commercial needs based on current projections.

We commenced operations in 2018 and have devoted substantially all of our resources to raising capital, acquiring our initial product candidate, identifying and developing pegozafermin, licensing certain related technology, conducting research and development activities (including preclinical studies and clinical trials) and providing general and administrative support for these operations.

As of September 30, 2023, We currently have contractual relationships with Northway Biotechpharma (“BTPH”) and BiBo pursuant to which they supply us with pegozafermin for our cash and cash equivalents and short-term available-for-sale securities totaled $448.3 million. Based on our current operating plan, we believe that our cash and cash equivalents and short-term available-for-sale securities as of September 30, 2023 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”). clinical trials.

We have incurred net losses since our inception. Our net losses for the three months ended September 30, 2023 March 31, 2024 and 2022 2023 were $34.7 million $51.6 million and $26.8 million, respectively. Our net losses for the nine months ended September 30, 2023 and 2022 were $102.0 million and $77.4 million $28.8 million, respectively. As of September 30, 2023 March 31, 2024, we had an accumulated deficit of $417.2 million $509.1 million. We expect to continue to incur significant expenses and increasing operating losses as we advance pegozafermin and any future product candidates through clinical trials, seek regulatory approval for pegozafermin 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 pegozafermin 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.

Based on our current operating plan, we expect our existing cash, cash equivalents and marketable securities of $562.3 million as of March 31, 2024 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 Securities and Exchange Commission (“SEC”).

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, pegozafermin. 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 services are provided based on invoices and statements received from our external service providers and by monitoring the status of specific activities and invoices received from our external service providers. their activities. 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 payment becomes probable and reasonably estimable, which is generally upon achievement of milestones. the milestone.

We expect our research and development expenses to increase for the foreseeable future as we continue the development of pegozafermin 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, time-consuming, and the successful development of pegozafermin and any future product candidates is highly uncertain. To the extent that pegozafermin 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 pegozafermin 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 pegozafermin 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, employee benefits and stock-based compensation for personnel in executive, finance, commercial 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.

Interest Expense

Interest expense primarily consists of interest expense, accretion of final payment fees and amortization of deferred debt issuance costs related to our term loan facility. facility, and loss on extinguishment debt.

Interest Income and Other, Net

Interest income and other, net primarily consists of interest income including accretion of discount on available-for-sale marketable securities, offset by amortization of premium on available-for-sale marketable securities.

Results of Operations

Three Months Ended September 30, 2023 March 31, 2024 and 2022 2023

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

	Three months ended September 30,		
	2023	2022	Change
Operating expenses:			
Research and development	$ 31,417	$ 22,197	$ 9,220
General and administrative	7,928	4,844	3,084
Total operating expenses	39,345	27,041	12,304
Loss from operations	(39,345)	(27,041)	(12,304)
Interest expense	(959)	(535)	(424)
Interest income and other, net	5,579	773	4,806
Net loss before tax	$ (34,725)	$ (26,803)	$ (7,922)
	Three months ended March 31,		

	2024	2023	Change
Operating expenses:			
Research and development	$ 47,428	$ 22,306	$ 25,122
General and administrative	9,849	6,218	3,631
Total operating expenses	57,277	28,524	28,753
Loss from operations	(57,277)	(28,524)	(28,753)
Interest expense	(863)	(2,075)	1,212
Interest income and other, net	6,556	1,763	4,793
Net loss before tax	$ (51,584)	$ (28,836)	$ (22,748)

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 September 30,		
	2023	2022	Change
Contract manufacturing	$ 14,517	$ 6,373	$ 8,144
Clinical development	10,447	11,981	(1,534)
Personnel-related expenses	5,948	3,553	2,395
Other expenses	505	290	215
Total research and development expenses	$ 31,417	$ 22,197	$ 9,220

	Three months ended March 31,		
	2024	2023	Change
Contract manufacturing	$ 21,351	$ 7,906	$ 13,445
Clinical development	17,924	8,966	8,958
Personnel-related expenses	7,733	5,026	2,707
Other expenses	420	408	12
Total research and development expenses	$ 47,428	$ 22,306	$ 25,122

Research and development expenses increased by $9.2 million, or 42%, to $31.4 million for $25.1 million in the three months ended September 30, 2023 from $22.2 million for March 31, 2024 compared to the three months ended September

30, 2022. same period in 2023. The change in research and development expenses was due primarily attributable to an increase of $8.1 million in contract manufacturing costs related to manufacturing and for scale-up activities performed by our third-party contract manufacturing partner and the initiation of our ENLIGHTEN-Fibrosis Phase 3 clinical trial. Also contributing to the change was an increase of $2.4 million in personnel-related costs primarily due to higher headcount and expenses including stock-based compensation offset in part driven by a decrease of $1.5 million in clinical development costs, mainly as a result of approaching the end of one of our ongoing trials. higher headcount.

General and Administrative Expenses

General and administrative expenses increased by $3.1 million, or 64%, to $7.9 million for $3.6 million in the three months ended September 30, 2023 from $4.8 million for March 31, 2024 compared to the three months ended September 30, 2022. same period in 2023. The change in general and administrative expenses was mainly due primarily attributable to an a $2.0 million increase of $1.8 million in professional services to support our continued growth fees and an a $1.6 million increase of $1.5 million in personnel-related costs primarily due to higher expenses including stock-based compensation and driven by higher headcount. This increase was offset in part by a decrease of $0.3 million in insurance-related costs.

Interest Expense

Interest expense increased decreased by $0.4 million to $1.0 million for $1.2 million in the three months ended September 30, 2023 from $0.5 million for the three months ended September 30, 2022, primarily due to higher interest rates and term loan balance during the three months ended September 30, 2023 as March 31, 2024 compared to the three months ended September 30, 2022.
same period in 2023. The decrease was attributable to a $1.2 million loss on extinguishment of debt recognized in the prior year period.

Interest Income and Other, Net

Interest income and other, net increased by $4.8 million to $5.6 million for in the three months ended September 30, 2023 from $0.8 million for the three months ended September 30, 2022, primarily due to higher interest income from our cash equivalents and short-term available-for-sale securities as a result of higher investment balances and favorable interest rates during the three months ended September 30, 2023 as March 31, 2024 compared to the three months ended September 30, 2022.

Nine Months Ended September 30, 2023 and 2022

same period in 2023. The following table summarizes our results of operations for the periods presented (in thousands):

	Nine months ended September 30,		
	2023	2022	Change
Operating expenses:			
Research and development	$ 88,638	$ 61,732	$ 26,906
General and administrative	21,360	15,155	6,205
Total operating expenses	109,998	76,887	33,111
Loss from operations	(109,998)	(76,887)	(33,111)
Interest expense	(3,928)	(1,377)	(2,551)
Interest income and other, net	11,972	843	11,129
Net loss before tax	$ (101,954)	$ (77,421)	$ (24,533)

Research and Development Expenses

The following table summarizes the period-over-period changes increase was related to a change in research and development expenses for the periods presented (in thousands):

	Nine months ended September 30,		
	2023	2022	Change
Contract manufacturing	$ 37,652	$ 13,869	$ 23,783
Clinical development	33,501	36,039	(2,538)
Personnel-related expenses	16,263	10,891	5,372
Other expenses	1,222	933	289
Total research and development expenses	$ 88,638	$ 61,732	$ 26,906

Researchand development expenses increased by $26.9 million, or 44%, to $88.6 million for the nine months ended September 30, 2023 from $61.7 million for the nine months ended September 30, 2022. The change was due to market interest rates, as well as an increase of $23.8

million in contract manufacturing costs related to manufacturing and scale-up activities and an increase of $5.4 million in personnel-related costs primarily due to higher headcount and stock-based compensation, offset in part by a decrease of $2.5 million in clinical development costs, mainly as a result of approaching the end of one of our ongoing trials.

General and Administrative Expenses

General and administrative expenses increased by $6.2 million, or 41%, to $21.4 million for the nine months ended September 30, 2023 from $15.2 million for the nine months ended September 30, 2022. The change was primarily due to an increase of $3.9 million in costs related to professional services to support our continued growth and an increase of $3.0 million in personnel-related costs primarily due to higher stock-based compensation and headcount. This increase was offset in part by a decrease of $0.8 million in insurance-related costs.

Interest Expense

Interest expense increased by $2.6 million to $3.9 million for the nine months ended September 30, 2023 from $1.4 million for the nine months ended September 30, 2022, primarily due to a $1.2 million loss on extinguishment upon repayment of our prior term loan and due to higher interest rates and term loan balance during the nine months ended September 30, 2023 as average invested balances compared to the nine months ended September 30, 2022.

Interest Income and Other, Net

Interest income and other, net increased by $11.1 million to $12.0 million for the nine months ended September 30, 2023 from $0.8 million for the nine months ended September 30, 2022, primarily due to higher interest income from our cash equivalents and short-term available-for-sale securities as a result of higher investment balances and favorable interest rates during the nine months ended September 30, 2023 as compared to the nine months ended September 30, 2022. same period in 2023.

Liquidity and Capital Resources

To date, we have incurred significant net losses and negative cash flows from operations. As of September 30, 2023 March 31, 2024, we had available cash, and cash equivalents and short-term available-for-sale marketable securities of $448.3 million $562.3 million and an accumulated deficit of $417.2 million $509.1 million.

Sources of Liquidity

At-the-Market ("ATM") Offerings

In March 2021, we entered into a an ATM sales agreement (as amended, the "Sales Agreement") with SVB Securities Leerink Partners LLC and Cantor Fitzgerald & Co. (the "Sales Agents") pursuant to which we may offer and sell up to $75.0 million of shares of our common stock (the "2021 ATM Facility") from time to time in "at-the-market" offerings (the "ATM Facility"). pursuant to an effective registration statement. The Sales Agents are entitled to compensation at a commission equal of up to 3.0% of the aggregate gross sales price per share sold under the Sales Agreement. During For the three months ended March 31, 2023, pursuant to our ATM Facility, we received aggregate proceeds of $13.4 million, net of commissions from sales of sold 968,000 shares of our common stock. stock under the 2021 ATM Facility and received net proceeds of $13.4 million.

In February 2023, we entered into Amendment No. 1 an amendment to the Sales Agreement, establishing a new ATM facility with the Sales Agents, pursuant to which we may offer and sell an aggregate offering amount of up to $150.0 million of shares of our common stock from time (the "2023 ATM Facility") pursuant to time, through the ATM Facility. During an effective registration statement. For the three months ended June 30, 2023 March 31, 2024, pursuant to our ATM Facility, we received aggregate proceeds of $23.7 million, net of commissions from sales of 1,200,539 sold 1,396,888 shares of our common stock. stock under the 2023 ATM Facility resulting in net proceeds of $21.0 million. As of March 31, 2024, there was $104.4 million remaining for future sales under the 2023 ATM Facility.

Underwritten Public Offerings

In July 2022, we completed an underwritten public offering (the "July 2022 Offering") of our common stock, warrants to purchase shares of our common stock and pre-funded warrants to purchase shares of our common stock and raised aggregate net proceeds of $88.2 million, net of after deducting underwriting discounts and commissions of $5.7 million and other offering costs of $0.6 million. As of September 30, 2023 March 31, 2024, warrants to purchase 10,179,789 9,842,076 shares of our common stock at an exercise price of $5.325 per share remain outstanding. Our pre-funded These warrants to purchase shares of our common stock are exercisable for a nominal amount. will expire on July 1, 2024.

In March 2023, we completed an underwritten public offering (the "March 2023 Offering") of our common stock and sold 19,461,538 shares of our common stock at a public offering price of $16.25 per share. We raised aggregate net proceeds of $296.8 million, net of after deducting underwriting discounts and commissions of $19.0 million and other offering costs of $0.5 million.

In December 2023, we completed an underwritten public offering of our common stock and pre-funded warrants to purchase shares of our common stock and raised net proceeds of $161.8 million, after deducting underwriting discounts and commissions of $10.4 million and other offering costs of $0.4 million.

Term Loan Facility

In January 2023, we entered into a loan Loan and security agreement Security Agreement (the "2023 Loan "Loan Agreement") with the lenders named therein lender parties thereto (the "Lenders"). , K2 HealthVentures LLC as administrative agent and Ankura Trust Company, LLC as collateral agent. The 2023 Loan Agreement provides for up to $100.0 million in aggregate principal in term loans, consisting of a first term loan an initial tranche of $25.0 million that was funded at closing, two subsequent term loans totaling $25.0 million second and third tranches of $15.0 million and $10.0 million, respectively, that may be funded upon the achievement of certain time-based, clinical and regulatory milestones, and a fourth term loan tranche of up to $50.0 million that may be funded upon discretionary approval by the Lenders. The proceeds of the first term loan were primarily used to repay our obligations under our prior term loan facility. As of September 30, 2023 March 31, 2024, the second term loan $15.0 million tranche expired undrawn. The third $10.0 million tranche is available through June 30, 2024 and the fourth $50.0 million tranche remains available, at the sole discretion of $15.0 million expired unused. the Lenders.

Funding Requirements

Our primary use of cash is to fund operating expenses, which consist primarily of research and development expenditures related to our lead product candidate, pegozafermin. pegozafermin, as well as the funding of a portion of the construction of the Production Facility. We plan to increase our research and development expenses 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, current operating plan, we expect that our existing cash, and cash equivalents and short-term available-for-sale marketable securities of $562.3 million as of September 30, 2023 March 31, 2024 will be sufficient to fund our anticipated cash requirements 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 pegozafermin and preclinical studies or clinica 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 pegozafermin 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 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):

	Nine months ended September 30,	Three months ended March 31,

	2023	2022	2024	2023
Net cash (used in) provided by				
Operating activities	$ (94,893)	$ (53,994)	$ (39,720)	$ (30,085)
Investing activities	(59,376)	(22,882)	(79,898)	4,106
Financing activities	350,940	96,820	21,030	321,654
Net change in cash and cash equivalents	$ 196,671	$ 19,944	$ (98,588)	$ 295,675

Operating Activities

During For the nine three months ended September 30, 2023 March 31, 2024, net cash used in operating activities was $94.9 million, which consisted of $39.7 million reflects a net loss of $102.0 million $51.6 million, partially offset by a net change of $9.4 million in operating assets and liabilities and aggregate noncash charges of $2.5 million. Noncash charges primarily included stock-based compensation expense of $5.0 million, net accretion of discounts on investments in marketable securities of $2.8 million, amortization of debt discount and accretion of deferred debt costs of $0.2 million and noncash operating lease expense of $0.2 million. The net change in operating assets and liabilities was mainly due to an increase in accounts payable and accrued expenses of $7.2 million and a decrease in prepaid and other assets of $2.1 million, primarily driven by timing of payments made and an increase in services rendered by contract research organizations and contract manufacturing organizations in connection with our clinical trials.

For the three months ended March 31, 2023, net cash used in operating activities of $30.1 million reflects a net loss of $28.8 million and a net change of $2.8 million $5.2 million in our net operating assets and liabilities, partially offset by aggregate noncash charges of $4.0 million. Noncash charges primarily included stock-based compensation expense of $3.6 million, a loss on debt extinguishment of $1.2 million related to our prior term loan, amortization of debt discount and accretion of the final payment fee related to our new term loan facility of $0.2 million, offset in part by non-cash charges net accretion of $9.8 million discounts on investments in marketable securities of $1.0 million. The change in our operating assets and liabilities was primarily due attributable to a $3.2 million $4.6 million increase in prepaid and other current assets due to higher contract manufacturing costs related to manufacturing and scale-up related spend offset in part by an increase and a net decrease of $0.6 million in accounts payable and accrued expenses due to the timing of payments. The non-cash charges are primarily comprised of $12.1 million in stock-based compensation, $1.2 million in loss recognized on extinguishment of our prior term loan, $0.4 million in amortization of debt issuance costs, and $0.3 million in accretion of the final payment fee related to our new term loan facility, offset in part by $4.3 million of net accretion on available-for-sale securities.

During the nine months ended September 30, 2022, net cash used in operating activities was $54.0 million, which consisted of a net loss of $77.4 million, offset in part by non-cash charges of $8.2 million and a net change of $15.2 million in our net operating assets and liabilities. The non-cash charges are primarily comprised of $7.6 million in stock-based compensation, $0.4 million in accretion of the final payment fee related to our term loan facility and $0.2 million in amortization of debt issuance costs, offset in part by $0.2 million in amortization of premium on available-for-sale securities. The change in our operating assets and liabilities was primarily due to a $10.5 million increase in accounts payable and

accrued expenses due to the timing of payments and a $4.8 million decrease in prepaid and other current assets due to timing of payments.

Investing Activities

During For the nine three months ended September 30, 2023 March 31, 2024, net cash used in investing activities was $59.4 million $79.9 million, which consisted of $216.8 million $152.0 million in purchases of available-for-sale marketable securities, offset in part by $157.4 million $72.1 million in proceeds from sales and maturities of available-for-sale marketable securities.

During For the nine three months ended September 30, 2022 March 31, 2023, net cash used in provided by investing activities was $22.9 million $4.1 million, which primarily consisted of $110.1 million $37.9 million in purchases proceeds from sales and maturities of available-for-sale marketable securities, offset in part by $87.3 million $33.8 million in proceeds from maturities purchases of available-for-sale marketable securities.

Financing Activities

During For the nine three months ended September 30, 2023 March 31, 2024, net cash provided by financing activities was $350.9 million $21.0 million, which primarily consisted of net proceeds of $21.1 million pursuant to the sale of our common stock under our 2023 ATM Facility and proceeds of $1.8 million from the exercise of warrants. This was offset in part by payments for taxes of $1.7 million related to net share settlement upon vesting of restricted stock units.

For the three months ended March 31, 2023, net cash provided by financing activities was $321.7 million, which primarily consisted of net proceeds of $296.8 million from the March 2023 Offering, sale of common stock in public offerings, net proceeds of $37.1 million $24.4 million from our term loan facility pursuant to our Loan Agreement, net proceeds of $13.4 million pursuant to the sale of our common stock under our 2021 ATM Facility, net proceeds of $24.4 million from our new term loan facility pursuant to our 2023 Loan Agreement, and proceeds of $15.6 million $9.0 million from the exercise of warrants. This was offset in part primarily by the repayment in full of $21.4 million on our prior term loan, including the final payment and prepayment fees and payment of $2.3 million for withholding taxes related to restricted stock units. fees.

During the nine months ended September 30, 2022, net cash provided by financing activities was $96.8 million, which primarily consisted of net proceeds of $88.2 million from the sale of common stock Contractual Obligations and warrants from the July 2022 Offering and net proceeds of $8.4 million pursuant to the sale of common stock from our ATM Facility. Commitments

Debt Obligations

Our 2023 As of March 31, 2024, the outstanding debt balance of $25.0 million under our Loan Agreement provides for term loans up is scheduled to $100.0 million. As of September 30, 2023, we had drawn the first term loan of $25.0 million and the second term loan of $15.0 million expired unused. The term loans mature on January 1, 2027, and

provide provides for interest-only payments until February 1, 2025. Consecutive equal payments For additional information regarding the terms of principal the

debt and interest rates are due once payable, see Note 6 to our unaudited condensed consolidated financial statements under Part I, Item 1 of this Quarterly Report on Form 10-Q.

Production Facility Funding Commitments

On April 4, 2024, we entered into the interest-only period has elapsed. The term loans bear interest equal Collaboration Agreement. Pursuant to the greater Collaboration Agreement, BiBo will build the Production Facility at BiBo's facility in the Lin-gang Special Area of (i) 8.45% and (ii) China (Shanghai) Pilot Free Trade Zone to manufacture the sum Drug Substance required to produce pegozafermin for commercial supply. The platform is expected to provide us with manufacturing capacity to meet our commercial needs based on current projections. Under the Collaboration Agreement, we will pay BiBo an aggregate of (a) $135.0 million toward the Prime Rate as reported in The Wall Street Journal plus (b) 2.25%. The interest rate on the term loan was 10.75% as of September 30, 2023. In addition, a final payment fee of 5.95% construction of the principal amount Production Facility (collectively, the "Payment"), of which 45% of the term loans is due upon Payment will be payable in the earlier third quarter of prepayment or maturity 2024. The remainder of the term loans. We have the option Payment will become payable upon achievement of certain specified milestones, of which up to prepay not less than all an additional approximately 45% of the outstanding term loans subject to a prepayment fee ranging from 3.0% to 1.0% Payment could become payable within the next 12 months, depending on the timing of achievement of certain milestones. If the actual costs of the Production Facility are substantially greater than the estimated budget, the parties will negotiate a means of allocating such prepayment. A 0.6% commitment fee is also payable should the fourth term loan be funded. cost overruns.

Other Contractual Obligations Asset Transfer and Commitments

See Note 5 to our condensed consolidated financial statements for additional disclosures. License Agreement with Teva Pharmaceutical Industries Ltd

In October April 2018, we concurrently entered into two Asset Transfer and License Agreements (the "Teva Agreements") with Teva Pharmaceutical Industries Ltd ("Teva") under which we acquired certain patents and intellectual property relating to two programs: (1) Teva's glycoPEGylated FGF21 program, including the compound TEV-47948

(pegozafermin), a glycoPEGylated long-acting FGF21 and (2) Teva's development program of small molecule inhibitors of Fatty Acid Synthase. Pursuant to the Teva Agreements, we paid Teva an initial nonrefundable upfront payment of $6.0 million. Under each license agreement, we are required to pay Teva $2.5 million upon the achievement of a specified clinical development milestone, and additional payments totaling up to $65.0 million upon achievement of certain commercial milestones. Each milestone payment shall be payable once, upon the first occurrence of the applicable milestone. We are also 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 us without cause upon 120 days' written notice to Teva, (ii) by either party, if the other party materially breaches any of its obligations under the Teva 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 their glycoPEGylated FGF21 program in the event we, or any of our affiliates or sublicensees, challenges any of the Teva patents licensed to us, and the challenge is not withdrawn within 30 days of written notice from Teva.

In the fourth quarter of 2023, the we achieved made a $2.5 million milestone payment to Teva following the achievement of a clinical development milestone related to under the enrollment FGF21 program in SHTG. As of patients pursuant to March 31, 2024, the Teva Agreements. As a result, a $2.5 million milestone timing and likelihood of achieving any remaining milestones are uncertain. Milestone payment became due. There have been no other material changes from obligations will be recognized when payment becomes probable and reasonably estimable, which is generally upon achievement of the contractual obligations disclosed in our Annual Report on Form 10-K for the year ended December 31, 2022. applicable milestone.

Critical Accounting Estimates

There have been no significant changes in our critical accounting estimates as compared to the critical accounting estimates disclosed in our Annual Report on Form 10-K for the year ended December 31, 2022 December 31, 2023.

Recent Accounting Pronouncements

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

JOBS Act Accounting Election

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 (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.

Based on the aggregate market value of our common stock held by non-affiliates as of June 30, 2023, we believe we will become a “large accelerated filer” and no longer qualify as an emerging growth company or smaller reporting company as of December 31, 2023. Because we believe our emerging growth company and non-accelerated filer status will expire on December 31, 2023, we expect to be required, pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002, to include in our Annual Report on Form 10-K for the year ending December 31, 2023 an attestation report as to the effectiveness of our internal control over financial reporting that is issued by our independent registered public accounting firm. In addition, beginning with our Quarterly Report on Form 10-Q for the quarter ending March 31, 2024, we expect to no longer be permitted to take advantage of the reduced reporting requirements applicable to smaller reporting companies.

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 There have been no material changes in Item 10(f)(1) of Regulation S-K, and are not required to provide market risk from the information under this item.

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provided in Part II, Item 7A “Quantitative and Qualitative Disclosures About Market Risk,” in our Annual Report on Form 10-K for the year ended December 31, 2023.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

As of September 30, 2023 March 31, 2024, 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 Securities Exchange Act) Act of 1934, as amended (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

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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 our management, including our 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 September 30, 2023 March 31, 2024 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 September 30, 2023 March 31, 2024 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.
- Our business depends on the success of pegozafermin, our only product candidate under clinical development, wh has not completed a pivotal trial. If we are unable to obtain regulatory approval for and successfully commercialize pegozafermin or other future product candidates, or we experience significant delays in doing so, our business will materially harmed.
- Clinical drug development involves a lengthy and expensive process with uncertain timelines and uncertain outcor and the results of prior preclinical or clinical trials are not necessarily predictive of our future results.
- We will require substantial additional capital to finance our operations, which may not be available to us on accept terms, or at all. As a result, we may not complete the development and commercialization of pegozafermin or deve new product candidates.
- 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 dela or otherwise adversely affected.
- We have relied on, and expect to continue to rely on, third-party manufacturers and vendors to produce and releas pegozafermin or any future product candidates. Any failure by a third-party to produce and release acceptable pro candidates for us pursuant to our specifications and regulatory standards may delay or impair our ability to initiate complete our clinical trials, obtain and maintain regulatory approvals or commercialize approved products.
- Pegozafermin 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.

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- We are developing pegozafermin for the treatment of NASH, an indication for which there are no approved products, MASH and the treatment of SHTG. The requirements for approval of pegozafermin by the FDA and comparable foreign regulatory authorities may be difficult to predict and may change over time, which makes it diff to predict the timing and costs of the clinical development.

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- 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 cha as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.
- The manufacture of biologic products is complex and we are subject to many manufacturing risks, any of which co substantially increase our costs and limit supply of our products.
- We face substantial competition, which may result in others discovering, developing or commercializing competing products before or more successfully than us.
- The ongoing COVID-19 pandemic has resulted and may in the future result in significant disruptions to our clinical trials o other business operations, which could have a material adverse effect on our business. we do.
- Unstable market and economic conditions, inflation, increases in interest rates, natural disasters, public health cris political crises, geopolitical events, such as the crisis in Ukraine and Israel, or other macroeconomic conditions, m have serious adverse consequences on our business and financial condition.
- Our 2023 Loan Agreement contains certain covenants that could adversely affect our operations and, if an event o default were to occur, we could be forced to repay any outstanding indebtedness sooner than planned and possibl a time when we do not have sufficient capital to meet this obligation.
- Pegozafermin has not received regulatory approval. If we are unable to obtain regulatory approvals to market pegozafermin 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 pegozaferm Any termination or loss of significant rights, including the right to glycoPEGylation technology, or breach, under the agreements or any future license agreement related to our product candidates, would materially and adversely aff 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, pegozafermin 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.

Pegozafermin is in development and, to date, we have not generated any revenue from the licensing or commercialization of pegozafermin. We will not be able to generate product revenue unless and until pegozafermin or any future product candidate, alone or with future partners, successfully completes clinical trials, receives regulatory approval and is successfully commercialized. As pegozafermin 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, pegozafermin and any future product candidates. We expect to incur substantial and increasing operating losses over the next several years as our research and development, clinical trials 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 or may take longer than expected to advance through development or may not 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.

Our business depends on the success of pegozafermin, 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 pegozafermin or other future product candidates, or we experience significant delays in doing so, our business will be materially harmed.

The primary focus of our product development is pegozafermin for the treatment of patients with NASH MASH and the treatment of patients with SHTG. Currently, pegozafermin 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 pegozafermin for the treatment of NASH MASH or 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 pegozafermin. If we cannot successfully develop, obtain regulatory approval for and commercialize pegozafermin, we may not be able to continue our operations. The future regulatory and commercial success of pegozafermin is subject to a number of risks, including that, if approved for NASH MASH or SHTG, pegozafermin will likely compete with products that may reach approval for the treatment of NASH MASH prior to pegozafermin, products that are currently approved for the treatment of SHTG and the off-label use of currently marketed products for NASH MASH 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.

Pegozafermin 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 pegozafermin, may not prove to be safe and effective in clinical trials. We have no limited direct experience as a company in conducting pivotal trials required to obtain regulatory approval and we expect that the Phase 3 trials we are conducting and plan to conduct will be more expansive and complex than the trials we have conducted to date. We may be unable to conduct clinical trials at preferred sites, enlist clinical investigators, enroll sufficient numbers of participants,, procure sufficient drug supply 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 an ongoing clinical trial is successful, it may be insufficient to demonstrate that pegozafermin 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 pegozafermin 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 pegozafermin 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, pegozafermin 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, Phase 1b/2a and Phase 2 clinical trials have involved small patient populations and, because of the small sample size in such trials, the results of these those clinical trials may be subject to substantial variability, including the inherent variability associated with biopsies in NASH MASH patients, 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 pegozafermin or other future product candidates and receive the necessary regulatory approvals, our business will be materially harmed.

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 pegozafermin 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 in connection with our ongoing activities, particularly as we conduct Phase 3 clinical trials of, and seek regulatory approvals approval for pegozafermin and prepare for commercialization of pegozafermin. We believe that our existing cash, and cash equivalents and short-term available-for-sale marketable securities will be sufficient to fund our projected operating requirements for a period of at least one year from the date 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 pegozafermin and any future product candidates. Our ability to complete new and ongoing clinical trials for pegozafermin may be subject to our ability to raise additional capital. We do not have any committed external source of funds other than as a result of any sales that we may make

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pursuant to the Sales Agreement for our ATM Facility (defined above) and proceeds from our 2023 Loan Agreement, which are subject to the achievement of certain milestones and/or consent of the lenders. We may also receive additional funds from the exercise of outstanding warrants. 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. The current market environment for small biotechnology companies, like 89bio, and broader macroeconomic factors may preclude us from successfully raising additional capital.

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 pegozafermin 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 rights relating to pegozafermin, and from whom we licensed patents and know-how related to glycoPEGylation technology that is used in the manufacture of pegozafermin. For additional information regarding this license agreement, please see Note 5 of our to accompanying unaudited condensed consolidated financial statements.

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 pegozafermin or any future product candidates. We currently have two active investigational new drug (“IND”) applications with the FDA in the United States for pegozafermin. 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 pegozafermin 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 pegozafermin 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 pegozafermin 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 pegozafermin 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, there are inherent difficulties in diagnosing NASH, MASH, which can currently only be definitively diagnosed through a liver biopsy, and identifying SHTG patients. Specifically, identifying patients most likely to meet NASH MASH enrollment criteria on biopsy is an ongoing challenge, with existing clinical indicators lacking both sensitivity and specificity. As a result, NASH MASH trials often suffer from high levels of screen failure following central review of the baseline liver biopsy, which can lead to lower enrollment. In addition, we do not have experience enrolling patients with cirrhosis and such enrollment make take longer than we expect. As a result of such difficulties and the significant competition for recruiting NASH MASH 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. Further, in the event one of our competitors receives regulatory approval for their product candidate before we do, we may have difficulty enrolling patients if they choose to take an approved drug, rather than enroll in a clinical trial. 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 pegozafermin and any future product candidates. We plan to leverage the safety database from the SHTG Phase 3 program across both the SHTG and NASH MASH indications. If we are not able enroll enough patients in our trials sufficient to support the safety database, our ability to advance the development of pegozafermin may be adversely affected.

We have relied on, and expect to continue to rely on, third-party manufacturers and vendors to produce and release pegozafermin or any future product candidates. Any failure by a third-party to produce and release 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 pegozafermin and any future product candidates. We currently have a sole source relationship contractual relationships with BTPH and BiBo pursuant to which they supply us with pegozafermin. pegozafermin for our clinical trials. If there should be any disruption in our supply arrangement with BTPH or BiBo, including any adverse events affecting BTPH or BiBo, it could have a negative effect on the clinical development of pegozafermin and other operations while we work to identify and qualify an alternate supply source. In addition, we will require large quantities of pegozafermin for our large Phase 3 clinical trials and to commercialize pegozafermin. Our current manufacturer may not be able Accordingly, in April 2024, we entered into the Collaboration Agreement with BiBo, pursuant to which BiBo will construct the Production Facility in China specifically designed to produce the larger quantities required pegozafermin for Phase 3 studies. We have identified a manufacturing partner for commercial-scale manufacturing, commercial supply, however, we cannot guarantee that such partner BiBo will be able to complete construction of the Production Facility and scale up and produce the quantities we would require to commercialize pegozafermin.

Pursuant to the Collaboration Agreement, BiBo will build the Production Facility at BiBo's facility in the Lin-gang Special Area of China (Shanghai) Pilot Free Trade Zone to manufacture the Drug Substance required to produce pegozafermin for commercial supply. The platform is expected to provide us with manufacturing capacity to meet our commercial needs based on current projections. Under the Collaboration Agreement, we will pay BiBo an aggregate of $135.0 million toward the construction of the Production Facility, of which 45% of the Payment will be payable in the third quarter of 2024. The remainder of the Payment will become payable upon achievement of certain specified milestones, of which up to an additional approximately 45% of the Payment could become payable within the next 12 months, depending on the timing of

achievement of certain milestones. If the actual costs of the Production Facility are substantially greater than the estimated budget, the parties will negotiate a means of allocating such cost overruns. We do may be ultimately responsible for a substantial portion of such overruns and it could negatively impact our financial condition and results of operations. We cannot guarantee that BiBo will complete or make operational the Production Facility in a timely manner or at all.

We expect to continue to rely on third-party manufacturers and suppliers, including BiBo, if we receive regulatory approval for pegozafermin or any other product candidates. The terms of our commercial supply of pegozafermin may not be favorable to us and could have a long-term supply agreement with any third-party manufacturer material impact on our results of operations.

Under the terms of the Collaboration Agreement, we may be ultimately responsible for a substantial portion of cost overruns and there it could negatively impact our financial condition and results of operations. See further discussion in Part I, Item 2 “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Contractual Obligations and Commitments.” We cannot guarantee that BiBo will complete or make operational the Production Facility in a timely manner or at all.

There is no guarantee that our third-party manufacturers will be able to fulfill our supply needs. 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 any of our third-party manufacturers or vendors, including our fill-finish vendor, are not able to fulfill their supply or manufacturing obligations in a timely manner, our clinical trials may be delayed. In addition, 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 under our Reagent Supply and Technology Transfer Agreement. We have not completed the manufacturing process for all 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 supplied us with certain reagents until December 31, 2022. We transferred the manufacturing of such reagents to new suppliers prior to the end of 2022. Any significant delay in the acquisition or decrease in the availability of these raw materials from suppliers could considerably delay the manufacture of pegozafermin, which could adversely impact the timing of any planned trials or the regulatory approvals of pegozafermin.

We rely on third-party vendors for our assay development and testing. If such third-party vendors are unable to successfully produce or test such assays, it may substantially increase our cost or could adversely impact the timing of any planned trials or the regulatory approvals of pegozafermin.

The FDA and other comparable foreign regulatory authorities require manufacturers to register manufacturing facilities. The FDA and other comparable foreign regulatory authorities also inspect these facilities to confirm compliance with current good manufacturing practices (“cGMP”). 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 pegozafermin 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

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approval on a timely basis. Supply chain issues, including those resulting from the COVID-19 pandemic and the ongoing war in Ukraine and the acts of piracy and military unrest in the Red Sea, may affect our third-party vendors and cause delays. Furthermore, since we have engaged a manufacturer located in China, we are exposed to the possibility of product supply disruption and increased costs in the event of changes in the legislation or policies of the United States, including the proposed BIOSECURE bill, or Chinese governments, political unrest or unstable economic conditions in China. These and other risks associated with our collaboration with BiBo, based in China, may materially adversely affect our ability to attain or maintain quantities of pegozafermin needed for commercialization, if approved. In addition, we have agreed to arbitrate claims related to the Collaboration Agreement with BiBo in Shanghai under the laws of the People's Republic of China, which may limit our ability to enforce our contractual rights against BiBo. 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 pegozafermin from BTPH or BiBo, which is are our sole primary manufacturing source sources for pegozafermin, we anticipate that the

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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.

Pegozafermin 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 pegozafermin 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 pegozafermin 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 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 pegozafermin 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 pegozafermin or any future product candidates or approved products. Further, we expect that pegozafermin 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 pegozafermin 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 pegozafermin for the treatment of NASH, an indication for which there are no approved products, MASH and the treatment of SHTG. The requirements for approval of pegozafermin by the FDA and comparable foreign regulatory authorities may be difficult to predict and may change over time, which makes it difficult to predict the timing and costs of the clinical development.

We are developing pegozafermin for the treatment of NASH, an indication for which there are no approved products. MASH. Although there are guidelines issued by the FDA for the development of drugs for the treatment of NASH, MASH, the development of a novel product candidates such as pegozafermin 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 MASH therapies, we expect that the path for regulatory approval for NASH MASH 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. In particular, regulatory authority expectations about liver biopsy data may evolve especially as more information is published about the inherent variability in liver biopsy data. Certain of our competitors have experienced regulatory setbacks for NASH MASH 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 MASH therapies generally or for pegozafermin. Furthermore, In addition, if one of the histology endpoints from other companies receives regulatory approval for its MASH therapy before we do, such approval could impact our development of pegozafermin. We may have difficulty enrolling patients in our Phase 2b ENLIVEN trial may not be accepted as primary endpoints 3 program for patients with MASH if patients choose to take an approved drug, rather than enroll in a pivotal Phase 3 trial or clinical trial. In addition, we expect that the first therapy that is approved for FDA the treatment of MASH will establish initial pricing and labelling expectations, which could impact our pricing and labelling if pegozafermin receives marketing approval.

We are also developing pegozafermin for the treatment of SHTG. Clinical trials for the treatment of SHTG may be relatively costly and time-consuming. In addition, the requirements for approval by the FDA and comparable foreign regulatory authorities may change over time. If the FDA requires additional evidence in addition to our ongoing Phase 3 program in

SHTG to support a successful submission for approval, we may be required to make changes to our program design that could impact timelines and cost.

Our anticipated development costs would likely increase if development of pegozafermin 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, or make changes to ongoing or future clinical trial designs. In addition, if we are unable to leverage our safety database for both SHTG and NASH MASH indications, we may be required to perform additional trials, which would result in increased costs and may affect the timing or outcome of our clinical trials.

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, Novo Nordisk, Akero Therapeutics, Inc. and Boston Pharmaceuticals are also developing

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FGF21 product candidates for the treatment of NASH. MASH. 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 pegozafermin or even the viability or prospects of pegozafermin 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.

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, pegozafermin has been manufactured by a single third-party manufacturer, BTPH, solely manufacturers for preclinical studies and clinical trials. The process of manufacturing pegozafermin, and in particular, the glycoPEGylation process, is complex, highly regulated and subject to several risks and requires significant expertise and capital investment, including for 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 pegozafermin 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 face substantial competition, which may result in others discovering, developing or commercializing competing products before or more successfully than us. we do.

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 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 MASH 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 MASH and SHTG, will increase. We may also face competition indirectly from companies seeking to develop developing therapies like the incretins to treat obesity. obesity and/or Type 2 diabetes. Some incretin-based therapies are also being developed for the treatment of MASH.

There are numerous currently approved therapies for treating diseases other than NASH MASH and some of these currently approved therapies may exert effects that could be similar to pegozafermin in NASH. MASH. 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 pegozafermin 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 pegozafermin. In addition, many companies are developing new therapeutics, and we cannot predict what the standard of care will be as pegozafermin or any future product candidates progress through clinical development. In addition, to the extent pegozafermin 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 pegozafermin 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

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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.

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, have been adversely affected by health epidemics in regions where we have business operations, and such health epidemics have caused and could continue to cause significant disruption in the operations of third parties upon whom we rely. In response to COVID-19, we have implemented a hybrid work policy, the effects of which may negatively impact our growth, including our ability to recruit and onboard new employees, and productivity.

The COVID-19 pandemic has impacted execution and enrollment of our trials. Given the surges in cases of COVID-19 experienced previously and uncertainty regarding other variants, we cannot predict how our ongoing or future trials may be impacted.

In addition, COVID-19 has 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.

The COVID-19 pandemic continues to evolve. 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 pegozafermin.

Unstable market and economic conditions, inflation, increases in interest rates, natural disasters, public health crises, such as the COVID-19 pandemic, political crises, geopolitical events, such as the crisis in Ukraine and Israel, or other macroeconomic conditions, may have serious adverse consequences on our business and financial condition.

The global economy, including credit and financial markets, have experienced extreme volatility and disruptions at various points over the last few decades, including, among other things, diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, supply chain shortages, increases in inflation rates, higher interest rates, and uncertainty about economic stability. For example, the COVID-19 pandemic public health crises have resulted in widespread unemployment, economic slowdown and extreme volatility in the capital markets. The Federal Reserve has raised interest rates multiple times in response to concerns about inflation and it may raise them again. Higher interest rates, coupled with reduced government spending and volatility in financial markets, may increase economic uncertainty and affect consumer spending. Similarly, the ongoing military conflicts between Russia and Ukraine and between Israel and surrounding areas and the rising tensions between China and Taiwan have created extreme volatility in the global capital markets and may have further global economic consequences, including disruptions of the global supply chain. Any such volatility and disruptions may adversely affect our business or the third parties on whom we rely. If the equity and credit markets deteriorate, including as a result of political unrest or war, it may make any necessary debt or equity financing more difficult to complete, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and share price and could require us to delay or abandon development or commercialization plans. In addition, there is a risk that one or more

of our service providers, manufacturers or other partners would not survive or be able to meet their commitments to us under such circumstances, which could directly affect our ability to attain our operating goals on schedule and on budget.

We have experienced and may in the future experience disruptions as a result of such macroeconomic conditions, including delays or difficulties in initiating or expanding clinical trials and manufacturing sufficient quantities of materials. Any one or a combination of these events could have a material and adverse effect on our results of operations and financial condition.

The 2023 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 2023 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 our lenders. Additionally, the 2023 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 2023 Loan Agreement also includes customary events of default, including, among other things, an event of default upon a change of control. Upon the occurrence and continuation of an event of default, all amounts due under the 2023 Loan Agreement become automatically (in the case of a bankruptcy event of default) or may become (in the case of all other events of default and at the option of the administrative agent), immediately due and payable. If an event of default under the 2023 Loan Agreement should occur and be continuing, 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 2023 Loan Agreement. Even if we are able to repay such accelerated debt amount under the 2023 Loan Agreement upon 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 pegozafermin 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 new presentations for the liquid formulation of pegozafermin 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 pre-filled syringe and plan to begin development of a pen-type autoinjector to deliver the liquid formulation of pegozafermin. Any formulation and presentation intended for commercialization is subject to regulatory approval. While the FDA has approved our new drug product formulation, there is no assurance that we will be successful in developing and receiving approval of a pre-filled syringe or an autoinjector on a timely basis or at all, any of which could impede our development and commercialization strategy for pegozafermin. In addition, there is no assurance comparable foreign regulatory authorities will approve our new drug product formulation. 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 pegozafermin and jeopardize our ability to commence product sales and generate revenue from pegozafermin, 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. If these third parties do not successfully perform and comply with

regulatory requirements, we may not be able to successfully complete clinical development, obtain regulatory approval, or commercialize our product candidates and our business could be substantially harmed.

We expect to depend on collaborators, partners, licensees, clinical investigators, contract research organizations, 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 and to manufacture clinical and commercial scale quantities of our drug substance and drug product and expect to depend on these third parties 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 pegozafermin or any future product candidates, producing additional losses and depriving us of potential revenue.

In addition, we have relied upon and plan to continue to rely upon third party contract research organizations ("CROs") to conduct, monitor, and manage preclinical and clinical programs. We rely on these parties for execution of clinical trials, and we manage and control only some aspects of their activities. We remain responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs and other vendors are required to comply with all applicable laws, regulations, and guidelines, including those required by the FDA, EMA and comparable foreign regulatory authorities for all of our product candidates in clinical development. If we or any of our CROs or vendors fail to comply with applicable and evolving laws, regulations, and guidelines, the results generated in our clinical trials may be deemed insufficient or unreliable, and the FDA, EMA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our contract research organizations, CMO, suppliers, and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, acts of war, medical pandemics or epidemics, such as the novel coronavirus, and other natural or man-made disasters or business interruptions. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

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

Although the development and commercialization of pegozafermin 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 MASH 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 subjects us to U.S. and foreign governmental trade, import and export, and customs regulations and laws including various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls and the U.S. Export Administration Regulations. 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. From time to time, we are subject to periodic phishing attempts. In the third quarter of 2021, we discovered a business email compromise caused by phishing. The phishing attack did not result in the misappropriation of any funds and we do not believe that it had a material adverse effect on our business. We implemented remedial measures promptly following this incident, however, we cannot guarantee that our implemented remedial measures will prevent additional related, as well as unrelated, incidents. 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

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

We do not expect pegozafermin or any future product candidate to be commercially available for several years, if at all. Pegozafermin 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 pegozafermin 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, MASH, and while there are guidelines issued by the FDA for the development of drugs for the treatment of NASH, MASH, it is unclear whether the requirements for approval will change in the future or whether the FDA will rely on regulatory precedent for future regulatory approvals. Any such changes may require us to conduct new trials that could delay our timeframe and increase the costs of our programs related to pegozafermin or any future product candidate for the treatment of NASH MASH or SHTG. In addition, we cannot be certain which efficacy endpoints or presentation thereof clinical or regulatory agencies may require in a Phase 3 clinical trial of NASH or for approval of our product candidates.

Even if we are able to obtain regulatory approvals for pegozafermin 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 pegozafermin 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 Based on guidelines issued by the FDA for the development of drugs for the treatment of NASH, MASH, if pegozafermin 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. MASH. Under the Food and Drug Omnibus Reform Act of 2022, the FDA may require, as appropriate, that such studies be underway prior to approval or within a specific time period after the date of approval for a product granted accelerated approval. If pegozafermin 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 pegozafermin 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 pegozafermin 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 pegozafermin or any future product candidates will ever obtain regulatory approval. Pegozafermin or any future product candidate could fail to receive

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regulatory approval from the FDA or comparable foreign regulatory authorities for many reasons, including those referenced in Part I, Item 1. "Business— "Business–Government Regulation and Product Approval" in our Annual Report on Form 10-K. 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.

We have received breakthrough therapy Breakthrough Therapy designation for pegozafermin in NASH MASH from the FDA and PRIME designation for pegozafermin in MASH from the EMA, but such designation may not actually lead to a faster development or regulatory review or approval process. process, and does not increase the likelihood that pegozafermin will receive marketing approval. In addition, we may seek breakthrough therapy Breakthrough Therapy, Fast Track or PRIME designation for other indications or future product candidates, but we might not receive such designation.

In September 2023, we received breakthrough therapy Breakthrough Therapy designation for pegozafermin in NASH MASH from the FDA. However, the receipt of breakthrough therapy Breakthrough Therapy designation for pegozafermin in NASH MASH may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA.

In March 2024, the EMA granted PRIME status to pegozafermin in patients with MASH, and, in the future, we may seek Fast Track designation or PRIME designation for our other product candidates. If a drug or biologic is intended for the treatment of a serious or life-threatening condition and the drug or biologic demonstrates the potential to address unmet medical needs for this condition, the sponsor may apply for Fast Track designation. The sponsor of a Fast Track product candidate has opportunities for more frequent interactions with the applicable FDA review team during product development and, once a BLA is submitted, the application may be eligible for priority review. A Fast Track product candidate may also be eligible for rolling review, where the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA. The FDA has broad discretion whether or not to grant this designation.

PRIME is a program launched by the EMA to enhance support for research on and development of medicines that have demonstrated preliminary safety and efficacy and thus the potential to target a significant unmet medical need and bring a major therapeutic advantage to patients. This regulatory program offers developers of promising medicines enhanced interaction and early dialogue with the EMA and is designed to optimize development plans and speed evaluation ensuring these medicines reach patients as early as possible. The EMA has broad discretion whether or not to grant this designation.

In addition, we may seek breakthrough therapy Breakthrough Therapy designation, Fast Track designation or PRIME designation for other indications or future product candidates. Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even Even if we believe that a current or future particular product candidate meets the criteria is eligible for designation as a breakthrough therapy, these designations, we cannot assure you that the FDA, EMA or similar regulatory agency would decide to grant them. Breakthrough Therapy, Fast Track and PRIME designations may disagree and instead determine not result in a faster development process, review or approval compared to make such designation. conventional FDA or EMA procedures, respectively. In addition, even though pegozafermin is designated as a breakthrough therapy Breakthrough Therapy in NASH, MASH, the FDA may later decide that the product candidate no longer meets the conditions for designation and the designation may be rescinded. The Breakthrough Therapy, Fast Track and PRIME designations do not assure ultimate regulatory approval by the FDA or the EMA. Many drugs and biologics that have received Breakthrough Therapy, Fast Track or PRIME designation have failed to obtain approval. See Part I, Item 1. “Business—Expedited Programs for Serious Conditions” in our Annual Report on Form 10-K.

We plan to conduct clinical trials for pegozafermin at sites outside the United States, and the FDA may not accept data from trials conducted in such locations.

We have conducted and expect in the future to conduct one or more of our clinical trials outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of this data is subject to conditions imposed by the FDA. For example, the clinical trial must be well designed and conducted and performed by qualified investigators in accordance with ethical principles. The trial population must also adequately represent the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. In addition, while these clinical trials are subject to the applicable local laws, FDA acceptance of the data will depend on its determination that the trials also complied with all applicable U.S. laws and regulations. If the FDA does not accept the data from any trial that we conduct outside the United States, it would likely result in the need for additional trials, which would be costly and time-consuming and would delay or permanently halt our development of the applicable product candidates. Even if the FDA accepted such data, it could require us to modify our planned clinical trials to receive clearance to initiate such trials in the United States or to continue such trials once initiated.

Further, conducting international clinical trials presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs that could restrict or limit our ability to conduct our clinical trials, the administrative burdens of conducting clinical trials under multiple sets of foreign regulations, foreign exchange fluctuations, diminished protection of intellectual property in some countries, as well as political and economic risks relevant to foreign countries.

Even if pegozafermin 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

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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.

We expect the product candidates we develop will be regulated as biologics, and therefore they may be subject to competition sooner than anticipated.

The BPCIA was enacted as part of the Affordable Care Act to establish an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as “interchangeable” based on its similarity to an approved biologic. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the reference product was approved under a BLA. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when processes intended to implement BPCIA may be fully adopted by the FDA, any of these processes could have a material adverse effect on the future commercial prospects for our biological products.

We believe that any of the product candidates we develop that is approved in the United States as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider the subject product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of the reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

In addition, the first biologic product submitted under the abbreviated approval pathway that is determined to be interchangeable with the reference product has exclusivity against other biologics submitted under the abbreviated approval pathway for the lesser of (i) one year after the first commercial marketing, (ii) 18 months after approval if there is no legal challenge, (iii) 18 months after the resolution in the applicant’s favor of a lawsuit challenging the biologics’ patents if an application has been submitted, or (iv) 42 months after the application has been approved if a lawsuit is ongoing within the 42-month period. The approval of a biologic product biosimilar to one of our product candidates could have a material adverse impact on our business as it may be significantly less costly to bring to market and may be priced significantly lower than our product candidates.

Current and future legislation may increase the difficulty and cost for us, and any collaborators, to obtain marketing approval of and commercialize our drug candidates and affect the prices we, or they, may obtain.

Heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products has resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare therapies, which could result in reduced demand for our product candidates or additional pricing pressures. On August 16, 2022, President Biden signed into law the Inflation Reduction Act of 2022 ("IRA"), which, among other provisions, included several measures intended to lower the cost of prescription drugs and related healthcare reforms. We cannot be sure whether additional legislation or rulemaking related to the IRA will be issued or enacted, or what impact, if any, such changes will have on the profitability of any of our drug candidates, if approved for commercial use, in the future.

Healthcare insurance coverage and reimbursement may be limited or unavailable for our product candidate, if approved, which could make it difficult for us to sell our product candidate or other therapies profitably.

The success of pegozafermin, if approved, depends on the availability of coverage and adequate reimbursement from third-party payors including governmental healthcare programs, such as Medicare and Medicaid, commercial payors, and health maintenance organizations. We cannot be sure that coverage and reimbursement will be available for, or accurately estimate the potential revenue from, our product candidates or assure that coverage and reimbursement will be available for any product that we may develop.

Governments outside the United States tend to impose strict price controls, which may adversely affect our revenue, if any.

In some countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a drug. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations. To obtain coverage and reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our drug

candidate to other available procedures. If reimbursement of our drugs is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially.

Risks Related 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 pegozafermin 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 pegozafermin 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

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that in the United States. These products may compete with pegozafermin 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 pegozafermin. 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 the FGF21 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 pegozafermin. Under this agreement, we were granted a perpetual, non-exclusive (but exclusive as to pegozafermin), non-transferable, worldwide license to patents and know-how related to glycoPEGylation technology used in the development, manufacture and commercialization of pegozafermin and products containing pegozafermin. The FGF21 Agreement also contains numerous covenants with which we must comply, including the utilization of commercially reasonable efforts to develop and ultimately commercialize pegozafermin, as well as certain reporting covenants and the obligation to make royalty payments, if and when pegozafermin 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 pegozafermin and products containing pegozafermin. 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 pegozafermin 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 pegozafermin. 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 pegozafermin 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 pegozafermin 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 fluctuate significantly and results announced by us and our collaborators or competitors could cause our stock price to decline, 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. Our stock price could fluctuate significantly due to various factors in addition to those otherwise described in this Quarterly Report on Form 10-Q, including those described in these "Risk Factors," including business developments announced by us and by our collaborators and competitors, or as a result of market trends and daily trading volume. The business developments that could affect our stock price include announcements or disclosures from competitors in the same class or category, new collaborations, clinical advancement, commercial launch or discontinuation of product candidates in the same class or category and regulatory approvals for our product candidates or product candidates in the same class or category. Our stock price could also fluctuate significantly with the level of overall investment interest in small-cap biotechnology stocks or for other reasons unrelated to our business. 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, or issuance of shares of our common stock upon exercise of warrants 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 Plan and 2023 Inducement 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.

In addition, we must settle exercises of our outstanding warrants in shares of our common stock. The issuance of shares of our common stock upon exercise of the warrants will dilute the ownership interests of our stockholders, which could depress the trading price of our common stock. In addition, the market's expectation that exercises may occur could depress the trading price of our common stock even in the absence of actual exercises. Moreover, the expectation of exercises could encourage the short selling of our common stock, which could place further downward pressure on the trading price of our common stock.

Certain of our executive officers and directors have entered or may enter into Rule 10b5-1 plans providing for sales of shares of our common stock from time to time. Under a Rule 10b5-1 plan, a broker executes trades pursuant to parameters established by the executive officer or director when entering into the plan, without further direction from the executive officer or director. A Rule 10b5-1 plan may be amended or terminated in some circumstances. Our executive officers and directors also may buy or sell additional shares outside of a Rule 10b5-1 plan when they are not in possession of material nonpublic information.

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, including under the ATM Facility (defined above), or debt. 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.

Hedging activity by investors in the warrants could depress the trading price of our common stock.

We expect that many investors in our warrants will seek to employ an arbitrage strategy. Under this strategy, investors typically short sell a certain number of shares of our common stock and adjust their short position over time while they continue to hold the warrants. Investors may also implement this type of strategy by entering into swaps on our common

stock in lieu of, or in addition to, short selling shares of our common stock. This market activity, or the market's perception that it will occur, could depress the trading price of our common stock.

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 September 30, 2023 March 31, 2024, 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.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud. If we are unable to maintain effective internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our stock may decrease.

We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

Based The Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act") requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. In particular, we are required to perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report on the aggregate market value effectiveness of our common stock held internal controls

over financial reporting, as required by non-affiliates as Section 404(a) of June 30, 2023, we believe we will become a "large accelerated filer" and no longer qualify as an emerging growth company or smaller reporting company as of December 31, 2023. Because we believe our emerging growth company and non-accelerated filer status will expire on December 31, 2023, we expect to be required, pursuant to the Sarbanes-Oxley Act. Section 404(b) of the Sarbanes-Oxley Act of 2002 ("Section 404"), also requires our independent auditors to include in our Annual Report express an opinion on Form 10-K for the year ending December 31, 2023 an attestation report as to the effectiveness of our internal control over financial reporting reporting. Ensuring that we have adequate internal controls in place so that we can produce accurate financial statements on a timely basis is issued by our independent registered public accounting firm. a costly and time-consuming effort that will need to be evaluated frequently. If we are unable to maintain effective internal control over financial reporting, we may not have adequate, accurate or timely financial information, our independent registered public accounting firm may issue a report that is adverse, and we may be unable to meet our reporting obligations as a public company or comply with the requirements of the SEC or Section 404. This could result in a restatement of our financial statements, the imposition of sanctions, including the inability of registered broker dealers to make a market in our common stock, or investigation by regulatory authorities. Any such action or other negative results caused by our inability to meet our reporting requirements or comply with legal and regulatory requirements or by disclosure of an accounting, reporting or control issue could adversely affect the trading price of our securities and our business. Material weaknesses in our internal control over financial reporting could also reduce our ability to obtain financing or could increase the cost of any financing we obtain. This could result in If we are not able to comply with the requirements of Section 404 or if we or our independent registered public accounting firm are unable to express an adverse reaction in opinion as to the effectiveness of our internal control over financial markets due to a loss of reporting, investors may lose confidence in the reliability accuracy and completeness of our financial statements. reports, the market price of our stock could decline and we could be subject to sanctions or investigations by Nasdaq, the SEC, or other regulatory authorities, which would require additional financial and management resources.

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.

Our ability to use our net operating loss carryforwards and other tax attributes may be limited. If we are required to pay any tax assessment, it could impact our net operating loss carryforwards, as well as our results of operations and financial condition.

As of December 31, 2022 December 31, 2023, we had U.S. federal and state net operating loss ("NOL") carryforwards of $160.9 million $195.0 million and $169.8 million $302.8 million, respectively, which may be available to offset future taxable income. As of December 31, 2022 December 31, 2023, we also had gross federal tax credits of $4.3 million $7.5 million, which may be used to offset future tax liabilities. These Certain NOLs and tax credit carryforwards will begin to expire in 2040. 2039. Use of our NOL carryforwards and tax credit carryforwards depends on many factors, including having current or future taxable income, which cannot be assured.

In addition, the Company is currently under examination by in December 2023, the Israeli Tax Authorities issued a tax authorities for 2018 assessment claiming our 2019 reorganization and 2019, which intercompany transaction to license the intellectual property rights from our subsidiary in Israel should be treated as a sale of intellectual property rights. If this matter is litigated and the Israeli Tax Authorities are able to successfully sustain their position and we are required to pay a tax assessment, it could impact our NOL carryforwards as well as and our results of operations and financial condition if could be materially and adversely affected. See further discussion in Part II, Item 7 "Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Estimates—Income Taxes" and in Note 9 to

our consolidated financial statements appearing under Part II, Item 8 of our Annual Report on Form 10-K for the year ended December 31, 2023.

Litigation costs and the outcome of litigation could have a material adverse effect on our business.

From time to time we are required may be subject to make litigation claims through the ordinary course of our business operations regarding, but not limited to, securities litigation, employment matters, security of patient and employee personal information, contractual relations with collaborators and licensors and intellectual property rights. Litigation to defend ourselves against claims by third parties, or to enforce

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any payments at the conclusion rights that we may have against third parties, could result in substantial costs and diversion of the examination. our resources, causing a material adverse effect on our business, financial condition, results of operations or cash flows.

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

None.

Item 3. Defaults upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None. ***Trading Plans***

During the fiscal quarter ended March 31, 2024, no director or Section 16 officer adopted or terminated any Rule 10b5-1 trading arrangement or non-Rule 10b5-1 trading arrangement (in each case as defined in Item 408(a) of Regulation S-K).

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	Certificate of Amendment to the Second Amended and Restated Certificate of Incorporation of 89bio, Inc. (filed with the SEC as Exhibit 3.1 to the Company's Form 8-K filed on June 9, 2023).
3.3	Second Third Amended and Restated Bylaws of the Company (filed with the SEC as Exhibit 3.2 3.1 to the Company's Current Report on Form 8-K filed on November 15, 2019) November 14, 2023)..
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	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).

4.3	Form of Warrant to Purchase Common Stock for Silicon Valley Bank (filed with the SEC as Exhibit 4.1 to the Company's Current Report on Form 8-K filed on June 4, 2021).
4.4	Form of Warrant (filed with the SEC as Exhibit 4.1 to the Company's Form 8-K filed on July 1, 2022).
4.4 4.5	Form of Pre-Funded Warrant (filed with the SEC as Exhibit 4.2 to the Company's Form 8-K filed on July 1, 2022).
4.5 4.6	Form of Warrant to Purchase Common Stock for K2 HealthVentures LLC (filed with the SEC as Exhibit 4.1 to the Company's Form 8-K/A filed on February 2, 2023).
4.7	Form of Pre-Funded Warrant (filed with the SEC as Exhibit 4.1 to the Company's Current Report on Form 8-K filed on December 8, 2023).
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*	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File as its XBRL tags are embedded within the Inline XBRL document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document With Embedded Linkbase Documents
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	The cover page for the Company's Quarterly Report on Form 10-Q has been formatted in Inline XBRL and contained in Exhibit 101

* 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: November 9, 2023 May 9, 2024

By: /s/ Rohan Palekar

Rohan Palekar

Chief Executive Officer

(principal executive officer)

Date: November 9, 2023 May 9, 2024

By: /s/ Ryan Martins

Ryan Martins

Chief Financial Officer

(principal financial and accounting officer)

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 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 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 consolid subsidiaries, is made known to us by others within those entities, particularly during the period in which this report being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to b 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 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 t 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 reportin and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control ove 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 th registrant's internal control over financial reporting.

Date: November 9, 2023 May 9, 2024

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 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 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 consolid subsidiaries, is made known to us by others within those entities, particularly during the period in which this report being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to b 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

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 t 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 reportin and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control ove 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 th registrant's internal control over financial reporting.

Date: November 9, 2023 May 9, 2024

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 September 30, 2023 March 31, 2024, 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; a

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

operations of the Company.

Date: November 9, 2023 May 9, 2024

By: /s/ Rohan Palekar

Rohan Palekar

Chief Executive Officer

(principal executive officer)

Date: November 9, 2023 May 9, 2024

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.

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