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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2023

OR

o 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: 001-36183

Eiger BioPharmaceuticals, Inc.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**33-0971591**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
2155 Park Boulevard Palo Alto, CA	**94306**
(Address of Principal Executive Offices)	**(Zip Code)**

(650) 272-6138
(Registrant's Telephone Number, Including Area Code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock (par value $0.001 per share)	EIGR	The Nasdaq Stock Market LLC

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 x No o

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 x No o

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

Large accelerated filer	o	Accelerated filer	o
Non-accelerated filer	x	Smaller reporting company	x
Emerging growth company	o		

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. o

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

As of November 6, 2023, the number of outstanding shares of the registrant's common stock, par value $0.001 per share, was 44,384,684.

Our independent registered public accounting firm is KPMG LLP, San Francisco, CA, Auditor ID: 185

EIGER BIOPHARMACEUTICALS, INC.
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In this Quarterly Report on Form 10-Q, "we," "our," "us," "Eiger," and "the Company" refer to Eiger BioPharmaceuticals, Inc. Eiger, Eiger BioPharmaceuticals, the Eiger logo and other trade names, trademarks or service marks of Eiger are the property of Eiger BioPharmaceuticals, Inc. This Quarterly Report on Form 10-Q contains references to our trademarks and to trademarks belonging to other entities. Trade names, trademarks and service marks of other companies appearing in this Quarterly Report on Form 10-Q are the property of their respective holders. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by any other companies.

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Eiger BioPharmaceuticals, Inc.
Condensed Consolidated Balance Sheets
(In thousands)

	September 30, 2023 (Unaudited)	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 27,501	$ 25,798
Short-term debt securities	11,920	73,150
Accounts receivable, net	1,321	1,749
Inventories, net	1,105	2,853
Prepaid expenses and other current assets	12,777	13,985
Total current assets	54,624	117,535
Property and equipment, net	677	696
Operating lease right-of-use assets	209	561
Other assets	144	1,347
Total assets	$ 55,654	$ 120,139
Liabilities and Stockholders' (Deficit) Equity		
Current liabilities:		
Accounts payable	$ 4,858	$ 8,975
Accrued liabilities	11,461	15,655
Current portion of operating lease liabilities	205	491
Total current liabilities	16,524	25,121
Debt	40,734	39,625
Operating lease liabilities	—	83
Total liabilities	57,258	64,829
Stockholders' (deficit) equity:		
Common stock	44	44
Additional paid-in capital	497,140	492,759
Accumulated other comprehensive loss	(86)	(300)
Accumulated deficit	(498,702)	(437,193)
Total stockholders' (deficit) equity	(1,604)	55,310
Total liabilities and stockholders' (deficit) equity	$ 55,654	$ 120,139

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

Eiger BioPharmaceuticals, Inc.
Condensed Consolidated Statements of Operations
(Unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Product revenue, net	$ 3,209	$ 4,024	$ 11,720	$ 10,038
Other revenue	—	—	250	750
Total revenue	3,209	4,024	11,970	10,788
Costs and operating expenses:				
Cost of sales	115	1,231	(77)	1,492
Research and development	14,568	22,198	50,717	56,761
Selling, general and administrative	5,454	6,964	20,502	20,804
Total costs and operating expenses	20,137	30,393	71,142	79,057
Loss from operations	(16,928)	(26,369)	(59,172)	(68,269)
Interest expense	(1,412)	(1,092)	(4,040)	(2,912)
Interest income	485	347	1,856	613
Other (expense) income, net	(175)	3	(149)	(1,044)
Loss before provision for income taxes	(18,030)	(27,111)	(61,505)	(71,612)
Provision for income taxes	—	—	4	26
Net loss	$ (18,030)	$ (27,111)	$ (61,509)	$ (71,638)
Net loss per common share:				
Basic and diluted	$ (0.41)	$ (0.62)	$ (1.39)	$ (1.76)
Weighted-average common shares outstanding:				
Basic and diluted	44,320,164	44,010,553	44,254,711	40,806,581

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

Eiger BioPharmaceuticals, Inc.
Condensed Consolidated Statements of Comprehensive Loss
(Unaudited)
(In thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Net loss	$ (18,030)	$ (27,111)	$ (61,509)	$ (71,638)
Other comprehensive loss:				
Unrealized gain (loss) on available-for-sale debt securities, net	26	141	186	(471)
Foreign currency translation adjustment	52	—	27	—
Comprehensive loss	$ (17,952)	$ (26,970)	$ (61,296)	$ (72,109)

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

Eiger BioPharmaceuticals, Inc.
Condensed Consolidated Statements of Stockholders' (Deficit) Equity
(Unaudited)
(In thousands, except share amounts)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' (Deficit) Equity
	Shares	Amount				
Balance at December 31, 2022	44,074,284	$ 44	$ 492,759	$ (300)	$ (437,193)	$ 55,310
Issuance of common stock upon ESPP purchase	29,986	—	41	—	—	41
Issuance of common stock upon release of restricted stock units and performance stock units	192,147	—	—	—	—	—
Stock-based compensation expense	—	—	2,542	—	—	2,542
Unrealized gain on available-for-sale debt securities, net	—	—	—	167	—	167
Cumulative translation adjustment	—	—	—	(37)	—	(37)
Net loss	—	—	—	—	(22,784)	(22,784)
Balance at March 31, 2023	44,296,417	44	495,342	(170)	(459,977)	35,239
Stock-based compensation expense	—	—	745	—	—	745
Unrealized loss on available-for-sale debt securities, net	—	—	—	(7)	—	(7)
Cumulative translation adjustment	—	—	—	13	—	13
Net loss	—	—	—	—	(20,695)	(20,695)
Balance at June 30, 2023	44,296,417	44	496,087	(164)	(480,672)	15,295
Issuance of common stock upon ESPP purchase	21,700	—	15	—	—	15
Issuance of common stock upon release of restricted stock units and performance stock units	66,567	—	—	—	—	—
Stock-based compensation expense	—	—	1,038	—	—	1,038
Unrealized gain on available-for-sale debt securities, net	—	—	—	26	—	26
Cumulative translation adjustment	—	—	—	52	—	52
Net loss	—	—	—	—	(18,030)	(18,030)
Balance at September 30, 2023	44,384,684	$ 44	$ 497,140	$ (86)	$ (498,702)	$ (1,604)

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

Eiger BioPharmaceuticals, Inc.
Condensed Consolidated Statements of Stockholders' (Deficit) Equity
(Unaudited)
(In thousands, except share amounts)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2021	34,568,821	$ 35	$ 412,930	$ (149)	$ (340,417)	$ 72,399
Issuance of common stock upon offering at-the-market, net of $1,288 of commissions	5,841,786	6	45,604	—	—	45,610
Issuance of common stock upon exercise of stock options	15,995	—	144	—	—	144
Vesting of common stock issued under Product Development Agreement	—	—	19	—	—	19
Issuance of common stock upon ESPP purchase	18,130	—	64	—	—	64
Issuance of common stock upon release of restricted stock units	85,106	—	—	—	—	—
Stock-based compensation expense	—	—	2,047	—	—	2,047
Unrealized loss on available-for-sale debt securities, net	—	—	—	(373)	—	(373)
Net loss	—	—	—	—	(22,643)	(22,643)
Balance at March 31, 2022	40,529,838	41	460,808	(522)	(363,060)	97,267
Issuance of common stock upon offering at-the-market, net of $716 of commissions and issuance costs	2,686,288	2	20,562	—	—	20,564
Issuance of common stock to lender	749,053	1	4,999	—	—	5,000
Issuance of common stock upon exercise of stock options	1,604	—	9	—	—	9
Stock-based compensation expense	—	—	2,208	—	—	2,208
Unrealized loss on available-for-sale debt securities, net	—	—	—	(239)	—	(239)
Net loss	—	—	—	—	(21,884)	(21,884)
Balance at June 30, 2022	43,966,783	44	488,586	(761)	(384,944)	102,925
Issuance of common stock upon exercise of stock options	3,512	—	27	—	—	27
Issuance of common stock upon ESPP purchase	29,985	—	104	—	—	104
Issuance of common stock upon release of restricted stock units	47,748	—	—	—	—	—
Stock-based compensation expense	—	—	2,222	—	—	2,222
Unrealized gain on available-for-sale debt securities, net	—	—	—	141	—	141
Net loss	—	—	—	—	(27,111)	(27,111)
Balance at September 30, 2022	44,048,028	$ 44	$ 490,939	$ (620)	$ (412,055)	$ 78,308

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

Eiger BioPharmaceuticals, Inc.
Condensed Consolidated Statements of Cash Flow
(Unaudited)
(In thousands)

	Nine Months Ended September 30,	
	2023	2022
Operating activities		
Net loss	$ (61,509)	$ (71,638)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	218	219
Inventory write down	11	1,043
Amortization of debt securities premiums and discounts	(1,046)	698
Loss on extinguishment of debt	—	1,144
Non-cash interest expense	1,109	867
Reduction in the carrying amount of right-of-use assets	352	407
Common stock issued under Product Development Agreement	—	19
Stock-based compensation	4,325	6,477
Change in operating assets and liabilities:		
Accounts receivable	421	118
Inventories	2,263	(892)
Prepaid expenses and other current assets	424	(2,181)
Other assets	1,987	(616)
Accounts payable	(4,157)	2,722
Accrued liabilities	(4,623)	1,315
Operating lease liabilities	(369)	(465)
Net cash used in operating activities	(60,594)	(60,763)
Investing activities		
Purchase of debt securities available-for-sale	(19,388)	(55,538)
Proceeds from maturities of debt securities available-for-sale	81,850	43,489
Purchase of property and equipment	(233)	(116)
Net cash provided by (used in) investing activities	62,229	(12,165)
Financing activities		
Issuance of common stock upon offering at-the-market, net of commissions	—	66,402
Proceeds from issuance of common stock to lender	—	5,000
Proceeds from issuance of common stock upon stock option exercises	—	180
Proceeds from issuance of common stock upon ESPP purchase	56	168
Proceeds from debt	—	39,840
Repayment of debt	—	(33,277)
Payment of debt issuance costs	—	(1,054)
Common stock offering costs	(22)	(244)
Net cash provided by financing activities	34	77,015
Effect of foreign exchange on cash and cash equivalents	34	—
Net increase in cash and cash equivalents	1,703	4,087
Cash and cash equivalents at beginning of period	25,798	22,221
Cash and cash equivalents at end of period	$ 27,501	$ 26,308
Supplemental disclosure of cash flow information:		
Interest paid	$ 2,931	$ 2,038
Income taxes paid	$ 188	$ 43

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

Eiger BioPharmaceuticals, Inc.
Notes to the Condensed Consolidated Financial Statements
(Unaudited)

1. Description of Business

Eiger BioPharmaceuticals, Inc. (the Company or Eiger) was incorporated in the State of Delaware on November 6, 2008. Eiger is a commercial-stage biopharmaceutical company focused on the development of innovative therapies for rare metabolic diseases.

Eiger's lead product candidate, avexitide, is a well-characterized, first-in-class glucagon-like peptide-1 (GLP-1) antagonist and is in development for the treatment of post-bariatric hypoglycemia (PBH) and other forms of hyperinsulinemic hypoglycemia (HH) arising after gastrointestinal surgeries. These disorders are characterized by exaggerated secretion of GLP-1 after meals, dysregulated secretion of insulin, followed by a rapid drop in blood sugar. Avexitide is the only drug in development for PBH with Breakthrough Therapy designation by the U.S. Food and Drug Administration (FDA). Avexitide is also in development for congenital hyperinsulinism (HI), an ultra-rare, life-threatening, pediatric disorder of persistent hypoglycemia that results in irreversible brain damage in up to 50% of children with the condition. Avexitide has completed Phase 2 for both PBH and HI, and Phase 3 study start-up activities for PBH have been initiated.

The FDA approved the Company's first commercial product, Zokinvy® (lonafarnib), to reduce risk of mortality of Hutchinson-Gilford progeria syndrome (HGPS) and for treatment of processing-deficient progeroid laminopathies (PL), with either heterozygous LMNA mutation with progerin-like protein accumulation, or homozygous or compound heterozygous ZMPSTE24 mutations, on November 20, 2020. Collectively known as progeria, HGPS and PL are ultra-rare, fatal, genetic premature aging diseases that accelerate mortality in young patients. In July 2022, the Company announced that the European Commission (EC) granted marketing authorization (MA) under exceptional circumstances for Zokinvy through the centralized procedure. The EC's MA is valid in all 27 European Union (EU) member states plus Iceland, Liechtenstein, and Norway. In May 2022, the Pharmaceutical Division at the Ministry of Health of Israel granted regulatory approval for Zokinvy in Israel. In August 2022, the Medicine and Healthcare products Regulatory Agency (MHRA) granted approval in the UK.

The Company commercially launched Zokinvy in the U.S. in January 2021 and started to recognize product revenue in the first quarter of 2021. The first European sales were recognized in the fourth quarter of 2022.

In June 2023, the Company announced that it is focusing its clinical development efforts on advancing avexitide in HH indications, including PBH. The Company will continue to commercialize Zokinvy (lonafarnib) for the treatment of HGPS and processing-deficient PL. In addition, Eiger is evaluating strategic partnering options for its virology assets, lonafarnib and peginterferon lambda. In June 2023, the Company also announced that it has appointed David Apelian, MD, PhD, MBA, who has served as interim Chief Executive Officer (CEO) since December 2022, as the Company's next CEO.

The Company's principal operations are based in Palo Alto, California, with subsidiaries in Delaware, Ireland, England and Wales. The Company operates in one segment.

Liquidity

As of September 30, 2023, the Company had $39.4 million of cash, cash equivalents and short-term securities, comprised of $27.5 million of cash and cash equivalents and $11.9 million of short-term debt securities available-for-sale. The Company had an accumulated deficit of $498.7 million as of September 30, 2023 and negative cash flows of $60.6 million from operating activities during the nine months ended September 30, 2023. As the Company continues to incur losses, its transition to profitability will depend on the successful development, approval, and commercialization of product candidates and on the achievement of sufficient revenues to support its cost structure. The Company may never achieve profitability, and until it does, the Company will need to continue to raise additional capital. Based on its recurring losses from operations incurred since inception, expectation of continuing operating losses and negative cash flows for the foreseeable future, need to raise additional capital to finance its future operations, and given the current cash, cash equivalents and short-term securities balance, the Company has concluded that there is substantial doubt regarding the Company's ability to continue as a going concern beyond twelve months after the date that these condensed consolidated financial statements are issued.

The Company is evaluating potential options including the ability to raise additional capital and continues to evaluate potential strategic partnering options for its antiviral assets of lonafarnib for HDV and peginterferon lambda; however, there can be no assurance that any strategic transactions will occur or that the Company will be successful in raising additional capital. The Company has sources of liquidity available under an "at-the-market" equity financing facility with Jefferies LLC (the 2022 ATM Facility) and Tranche B of the Innovatus Loan as discussed in Note 6. The Company has no plans to draw upon Tranche B of the Innovatus Loan. The registration statement registering the offer and sale of shares pursuant to the 2022 ATM Facility is set to expire in December 2023, and there can be no assurance that we will be able to register future offers or sales under the 2022 ATM Facility. To the extent that the Company raises additional capital through the sale of equity, including pursuant to the 2022 ATM Facility and offerings of debt or other securities convertible into equity, stockholder ownership interest will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect the rights of holders of our common stock. The Company has not raised any proceeds under the 2022 ATM Facility during 2023 and presently has no plans to raise any proceeds under the facility. As a result, the Company has concluded that management’s plans do not alleviate substantial doubt about the Company’s ability to continue as a going concern. The consolidated financial statements have been prepared assuming the Company will continue as a going concern, which contemplates the continuity of operations, the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. The financial statements do not include any adjustments relating to the recovery of the recorded assets or the classification of the liabilities that might be necessary should the Company be unable to continue as a going concern.

2. Summary of Significant Accounting Policies

Basis of Presentation

The condensed consolidated financial statements include the accounts of Eiger BioPharmaceuticals, Inc. and its wholly owned subsidiaries, EBPI Merger Inc., EB Pharma LLC, Eiger BioPharmaceuticals Europe Limited, and EigerBio Europe Limited, have been prepared in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP) and follow the requirements of the Securities and Exchange Commission (SEC) regarding interim financial reporting. All intercompany balances and transactions have been eliminated in consolidation. Certain information and note disclosures normally included in the financial statements prepared in accordance with U.S. GAAP have been condensed or omitted pursuant to such rules and regulations. As such, the information included in this Quarterly Report on Form 10-Q should be read in conjunction with the consolidated financial statements and accompanying notes included in the Annual Report on Form 10-K for the year ended December 31, 2022 filed with the SEC on March 17, 2023.

Significant Accounting Policies

Other than impacted accounting policies related to the Company's adoption of current expected credit loss (CECL) as disclosed below, there have been no new or material changes to the significant accounting policies discussed in the Company’s Annual Report on Form 10-K for the year ended December 31, 2022.

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 at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. On an ongoing basis, the Company evaluates its estimates. The Company bases its estimates on historical experience and on various other market-specific and relevant assumptions that the Company believes to be reasonable under the circumstances. Actual results could differ from those estimates.

Concentrations of Risk

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash, cash equivalents and investments. The Company’s cash is held by financial institutions in the United States and Ireland. Amounts on deposit may at times exceed federally insured limits. The Company is exposed to credit risk in the event of default by the financial institutions holding its cash, cash equivalents and investments and issuers of investments. The Company manages its credit risk by holding its cash, cash equivalents and investments in large financial institutions within the U.S and Ireland. In addition, the Company’s investment policy limits investments to certain types of instruments such as money market funds, debt securities issued by the U.S. government and its agencies, corporate debt securities, commercial paper as well as asset-backed securities, and places restrictions on the credit ratings, maturities and concentration by type and issuer. The Company has not experienced any losses on its deposits of cash, cash equivalents and

investments. The Company relies on one supply chain for each of its product candidates. If any of the single source suppliers in any of the supply chains fail to satisfy the Company's requirements on a timely basis, the Company could suffer delays in its clinical development programs and activities which could adversely affect its operating results.

Two customers accounted for approximately 58 percent and 39 percent of the Company's accounts receivable as of September 30, 2023. Two customers accounted for approximately 58 percent and 42 percent of the Company's accounts receivable as of December 31, 2022. Two customers accounted for approximately 74 percent and 26 percent of product revenue during the three months ended September 30, 2023. Two customers accounted for approximately 76 percent and 23 percent of product revenue during the nine months ended September 30, 2023. One customer accounted for approximately 99 percent of product revenue during the three months ended September 30, 2022. One customer accounted for approximately 100 percent of product revenue during the nine months ended September 30, 2022.

Foreign Currency Exchange

Foreign Currency Transaction Risk

The foreign currency transaction risk relates to changes in exchange rates on monetary assets, liabilities, revenues and expenses held at Eiger BioPharmaceuticals Europe Limited. Gains and losses on foreign currency transactions result primarily from monetary assets, liabilities, revenues and expenses denominated in Euro. Aggregated transaction losses for the three and nine months ended September 30, 2023 were $0.2 million and $0.1 million, respectively. The Company expects the foreign currency gain/loss to continue to fluctuate as long as the Company continue to hold monetary assets and liabilities at its subsidiaries in Ireland and England and Wales. Market uncertainty could potentially lead to significant volatility with foreign currency exchange rates, which could result in additional foreign currency gain/loss.

Foreign Currency Translation Risk

The foreign currency translation risk relates to the translation of the foreign consolidated subsidiaries' assets, liabilities, revenues and expenses from the subsidiaries' functional currency to the U.S. dollar at each reporting date. Fluctuations in exchange rates may impact the amount of assets, liabilities, revenues and expenses reported on the consolidated balance sheets and consolidated statements of operations. The financial statements of the Company's foreign subsidiaries, which have a functional currency other than the U.S. dollar, are translated into U.S. dollars using a current exchange rate. Gains and losses resulting from this translation are recognized as a foreign currency translation adjustment within accumulated other comprehensive loss, which is a component of stockholders' (deficit) equity and comprehensive income (loss). Aggregate translation gain, net of tax, was $52,000 and $27,000 for the three months and nine months ended September 30, 2023, respectively. There were no translation gains or losses for the three and nine months ended September 30, 2022.

Debt Securities

All securities are short-term in nature and consist of debt securities classified as available-for-sale and have maturities greater than 90 days, but less than 365 days from the date of acquisition. The Company's debt securities consist of available-for-sale securities that are classified as Level 2 because their value is based on valuations using significant inputs derived from, or corroborated by, observable market data. The Company evaluates, on a quarterly basis, its available-for-sale debt securities for potential impairment. For available-for-sale debt securities in an unrealized loss position, the Company assesses whether such declines are due to credit related factors such as changes to the rating of the security by a ratings agency, market conditions and supportable forecasts of economic and market conditions, among others. If the fair value of available-for-sale debt securities is less than the amortized cost basis, the Company assesses whether it has plans to sell the security or it is more likely than not it will be required to sell any available-for-sale debt security before recovery of its amortized cost basis. If either condition is met, the security's amortized cost basis is written down to fair value and is recognized through other (expense) income, net. If neither condition is met, declines as a result of credit losses, if any, are recognized as an allowance for credit loss, limited to the amount of unrealized loss, through other (expense) income, net. Any portion of the unrealized loss that is not a result of a credit loss, is recognized in other comprehensive loss. The cost of available-for-sale securities sold is based on the specific-identification method. Realized gains and losses on the sale of debt securities are determined using the specific-identification method and recorded in other (expense) income, net.

Accounts Receivable

Accounts receivable represent amounts billed to the Company's customers, net of an allowance for credit losses. Trade accounts receivable are recorded at invoiced amounts and do not bear interest. The allowance for credit losses reflects the Company's best estimate of probable losses inherent in the receivable portfolio determined based on various factors,

including age of the outstanding invoice, credit quality of the customer, historical experience, current economic conditions, and management's expectations of future economic conditions. The Company regularly reviews the adequacy of the allowance for credit losses by considering the age of each outstanding invoice and the collection history of each customer to determine the appropriate amount of allowance for credit losses.

The Company had no allowance for credit losses as of September 30, 2023 and December 31, 2022. The Company had no credit losses for the periods presented.

Recent Adopted Accounting Pronouncements

In June 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Updates (ASU) No. 2016-13, *Financial Instruments—Credit Losses (Topic 326)*. ASU 2016-13 requires an entity to utilize a new impairment model that requires measurement and recognition of expected credit losses for most financial assets and certain other instruments, including but not limited to available-for-sale debt securities. Credit losses relating to available-for-sale debt securities will be recorded through an allowance for credit losses rather than as a direct write-down to the security. The new guidance requires the use of forward-looking expected credit loss models based on historical experience, current conditions, and reasonable and supportable forecasts that affect the collectability of the reported amount, which may result in earlier recognition of credit losses under the new guidance. In April 2019, the FASB issued ASU No. 2019-04, *Codification Improvements to Topic 326, Financial Instruments – Credit Losses, Topic 815, Derivatives and Hedging, and Topic 825, Financial Instruments,* which clarifies and corrects certain unintended applications of the guidance contained in each of the amended Topics. Additionally, in May 2019, the FASB issued ASU No. 2019-05, *Financial Instruments – Credit Losses (Topic 326),* which provides an option to irrevocably elect to measure certain individual financial assets at fair value instead of amortized cost. In November 2019, the FASB issued ASU No. 2019-10, *Financial Instruments – Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842),* which deferred the effective date for ASU No. 2016-13 for smaller reporting companies to fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. The Company adopted this guidance on a modified-retrospective basis effective January 1, 2023 and noted no material impact to the Company's condensed consolidated financial statements.

3. Fair Value Measurements

Fair value accounting is applied for all financial assets and liabilities that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually). As of September 30, 2023 and December 31, 2022, the carrying amount of cash equivalents, accounts receivable, prepaid expenses and other current assets, accounts payable and accrued liabilities approximated their estimated fair value due to their relatively short maturities. Management believes the terms of its long-term debt reflect current market conditions for an instrument with similar terms and maturity, therefore the carrying value of the Company's debt approximated its fair value.

There were no transfers into or out of Level 3 of the fair value hierarchy during the periods presented.

The following tables present the fair value hierarchy for assets and liabilities measured at fair value, and summarize the estimated value of the Company's cash equivalents and debt securities and the gross unrealized holding gains and losses (in thousands):

	September 30, 2023				
	Level	Amortized cost	Unrealized gain	Unrealized loss	Estimated Fair Value
Cash equivalents:					
Money market funds	1	$ 9,553	$ —	$ —	$ 9,553
Total cash equivalents		$ 9,553	$ —	$ —	$ 9,553
Debt securities:					
U.S. government bonds	2	$ 11,934	$ —	$ (14)	$ 11,920
Total debt securities		$ 11,934	$ —	$ (14)	$ 11,920
Classified as:					
Cash equivalents	1				$ 9,553
Short-term debt securities	2				11,920
					$ 21,473

	December 31, 2022				
	Level	Amortized cost	Unrealized gain	Unrealized loss	Estimated Fair Value
Cash equivalents:					
Money market funds	1	$ 11,546	$ —	$ —	$ 11,546
Commercial paper	2	3,968	—	—	3,968
Total cash equivalents		$ 15,514	$ —	$ —	$ 15,514
Debt securities:					
U.S. government bonds	2	$ 39,646	$ 3	$ (86)	$ 39,563
Corporate debt securities	2	28,759	—	(117)	28,642
Commercial paper	2	4,945	—	—	4,945
Total debt securities		$ 73,350	$ 3	$ (203)	$ 73,150
Classified as:					
Cash equivalents	1 & 2				$ 15,514
Short-term debt securities	2				73,150
					$ 88,664

Other than the debt balance as discussed in Note 6, there were no financial liabilities as of September 30, 2023 and December 31, 2022.

During the three and nine months ended September 30, 2023, the Company did not recognize any credit losses. The Company determined that the decline in fair value of debt securities was not due to credit-related factors, and no allowance for expected credit losses was recorded as of September 30, 2023. There were unrealized losses of $14,000 as of September 30, 2023, and no unrealized losses have been in the loss position for more than 12 months. However, the Company is planning to hold these securities until maturity and expects to recover the amortized cost basis.

4. Balance Sheet Components

Inventories

Inventories consist of the following (in thousands):

	September 30, 2023	December 31, 2022
Raw materials	$ 517	$ 1,703
Work-in-progress	494	884
Finished goods	94	266
Total inventories, net	$ 1,105	$ 2,853

The write downs of inventory were immaterial for the three and nine months ended September 30, 2023. The Company wrote down $1.0 million of inventory for the three and nine months ended September 30, 2022.

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following (in thousands):

	September 30, 2023	December 31, 2022
Short term deposits	$ 5,006	$ 4,542
Prepaid research costs	3,751	2,822
Prepaid contract manufacturing costs	1,659	3,542
Prepaid insurance	604	586
Prepaid marketing	122	753
Other	1,635	1,740
Total prepaid expenses and other current assets	$ 12,777	$ 13,985

Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	September 30, 2023	December 31, 2022
Compensation and related benefits	$ 3,600	$ 6,167
Contract research costs	3,688	4,188
Product revenue reserves	2,334	1,373
Contract manufacturing costs	922	2,101
Legal fees	187	562
Other	730	1,264
Total accrued liabilities	$ 11,461	$ 15,655

5. Bristol-Meyers Squibb License Agreement

On April 20, 2016, the Company and Bristol-Myers Squibb Company (BMS) entered into a License Agreement (the BMS License Agreement) and a Common Stock Purchase Agreement (the BMS Purchase Agreement).

Under the BMS License Agreement, BMS granted the Company an exclusive, worldwide, license to research, develop, manufacture, and sell products containing PEG-interferon Lambda-1a (peginterferon lambda or the Licensed Product) for all therapeutic and diagnostic uses in humans and animals. The Company is responsible for the development and commercialization of the Licensed Product at its sole cost and expense. The Company paid BMS $2.0 million and issued 157,587 shares of its common stock at an aggregate fair value of $3.2 million in April 2016. The BMS License Agreement

also includes development and regulatory milestone payments totaling $61.0 million and commercial sales milestones of up to $128.0 million. The Company is obligated to pay BMS annual net sales royalties in the range of mid-single to mid-teens, depending on net sales levels. In fourth quarter of 2020, the Company recorded a $3.0 million milestone in research and development expense, triggered on successful demonstration of proof of concept, as defined by the BMS License Agreement, in a Phase 2 clinical trial. In March 2022, the Company recorded a $5.0 million milestone expense in research and development, which was related to the initiation of a Phase 3 clinical trial, as defined under the BMS License Agreement.

6. Debt

Innovatus Term Loan

On June 1, 2022 (Closing Date), the Company entered into a term loan and security agreement (Innovatus Loan) with Innovatus Life Sciences Lending Fund I, LP (Innovatus), providing for up to $75.0 million funded in three tranches with a maturity date of August 31, 2027. The floating per annum interest rate of the Innovatus Loan is equal to the sum of (a) the greater of (i) the Prime Rate published in the Money Rates section of the Wall Street Journal (or any successor thereto) and (ii) 3.5%, plus (b) 3.75%; provided that, at the election of the Borrower, up to 2.25% of such rate shall be payable in-kind until the third anniversary of the closing date. The Company is required to make monthly interest-only payments through July 1, 2027, after which the Company is required to make monthly amortizing payments, with the remaining balance of the principal plus accrued and unpaid interest due at maturity. 2.25% of the interest is payable in-kind for the first three years of the term by increasing the principal balance. Prepayments of the loan, in whole or in part, will be subject to an early prepayment fee which ranges between 3% and 0% and declines each year until the third anniversary date of the Closing Date, after which no prepayment fee is required. The Company is also required to pay an exit fee upon any payment or prepayment equal to 6.5% of the aggregate principal amount of the tranches funded under the Innovatus Loan. The Innovatus Loan contains customary representations, warranties, events of default, including failure to pay amounts due, breaches of covenants and warranties, material adverse change events, certain cross defaults and judgements, and insolvency, and covenants of the Company and its subsidiaries, including a requirement to maintain a cash balance of not less than 5% of the aggregate principal amount of funded and outstanding loan terms at all times. Should the Company be unable to comply with these covenants or if the Company defaults on any portion of its outstanding borrowings, the lender can also impose a 5% penalty, restrict access to additional borrowings under the loan and security agreement, and accelerate the maturity of the debt to be immediately due and payable. The Company believes it is in compliance with the terms included with the Innovatus Loan. The Innovatus Loan is secured by perfected first priority liens on the Company's assets, including a commitment by the Company to not allow any liens to be placed upon the Company's intellectual property.

The Company was funded $40.0 million in June 2022 on the Closing Date under Tranche A. The remaining $35.0 million is divided into two tranches (Tranche B and Tranche C). The $17.5 million under each of Tranche B and Tranche C will be available for a period commencing on the later of (a) the first date that the Company achieves certain development and regulatory milestones applicable to each Tranche and (b) November 1, 2022. Both Tranche B and Tranche C draw periods end on the earlier of (a) June 30, 2024 or (b) an event of default. The Company is currently eligible to draw the $17.5 million under Tranche B, but has not done so as of September 30, 2023.

The Company identified a number of embedded derivatives that require bifurcation from the Innovatus Loan. These embedded features include mandatory prepayment upon an event of default or change in control and contingent rate increases. However, the fair value of these embedded features was deemed to be immaterial on the date of issuance. At each subsequent reporting period, the Company will reassess the fair value of the embedded features and will record a liability if the fair value of the features becomes material.

In connection with the issuance of the Innovatus Loan, the Company recorded a debt discount of $0.2 million and capitalized debt issuance costs of $1.1 million. The discount and issuance costs will be amortized over the life of the loan. Interest expense for the Innovatus Loan for the three and nine months ended September 30, 2023 was $1.4 million and $4.0 million, respectively, and is inclusive of non-cash amortization of the debt discount and debt issuance costs and accretion of final payment. The carrying amount of the Innovatus Loan approximates fair value. The effective interest rate for the Innovatus Loan was 13.84% as of September 30, 2023.

Additionally, in connection with entering into the Innovatus Loan, the Company entered into a Stock Purchase Agreement with Innovatus for the sale of common stock with an aggregate value of $5.0 million. On June 1, 2022, the Company issued

749,053 shares of common stock to Innovatus at a per share purchase price of $6.6751, the preceding five-day volume weighted average price per share.

A portion of the loan proceeds was used to repay in full the approximately $33.5 million of aggregate principal amount, unpaid interest, and exit fees in connection with loans outstanding owed to Oxford Finance LLC (the Oxford Loan) by the Company.

Oxford Term Loan

On June 1, 2022, upon entering into the Innovatus Loan, the Company repaid the Oxford Loan, including (i) the $30.0 million outstanding principal balances, (ii) $0.2 million in accrued and unpaid interest, and (iii) other final payments consisting of $3.3 million, for a total payment of $33.5 million. The Company recorded a loss of $1.1 million on early extinguishment of the debt related to the unamortized debt premium, discount, and cost of issuance, which was recognized as a component of other (expense) income, net in the condensed consolidated statement of operations.

The Company accounts for the amortization of the debt discount utilizing the effective interest method. Debt and unamortized discount balances are as follows (in thousands):

	September 30, 2023	December 31, 2022
Face value of debt	$ 41,218	$ 40,531
Exit fee	2,600	2,600
Unamortized debt discount associated with exit fee, debt issuance costs and loan origination fees	(3,084)	(3,506)
Total debt, net	$ 40,734	$ 39,625

7. Common Stock

The Company had reserved shares of common stock for issuance as follows:

	September 30, 2023	December 31, 2022
Options issued and outstanding	7,335,274	6,143,183
Options available for future grants	3,359,214	1,976,460
Restricted and performance stock units outstanding	219,562	641,407
Shares available for issuance under ESPP	736,371	788,057
Shares available for issuance under 2021 Inducement Plan	702,600	380,000
Total	12,353,021	9,929,107

8. Stock-Based Compensation

In June 2016, the Company’s Board of Directors adopted and in August 2016 the Company’s stockholders approved the Amended and Restated 2013 Equity Incentive Plan (Restated 2013 Plan). As of September 30, 2023, there were 3,359,214 shares available for grant under the Restated 2013 Plan.

During the second quarter of 2021, the Company approved the 2021 Inducement Plan to be used exclusively for grants of awards to individuals that were not previously employees or directors of the Company as a material inducement to such individuals’ entry into employment with the Company within the meaning of Rule 5635(c)(4) of the Nasdaq Listing Rules. As of September 30, 2023, there were 702,600 shares remaining and available to be issued under the 2021 Inducement Plan.

Awards Modification

On February 6, 2023, the Company entered into a separation agreement and general release with David Cory, the Company's former President and CEO. Pursuant to the separation agreement, 50% of Mr. Cory's unvested equity awards were accelerated to vest on the date the separation agreement was executed. Additionally, the exercise period for Mr.

Cory's vested awards was extended, including his accelerated awards. The stock compensation recognized related to these modifications was $0 and $0.9 million for the three and nine months ended September 30, 2023, which is reflected in selling, general and administrative expenses.

Stock-Based Compensation Expense

Total stock-based compensation expense recognized was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Research and development	$ 650	$ 856	$ 2,001	$ 2,301
Selling, general and administrative	388	1,366	2,324	4,176
Total	$ 1,038	$ 2,222	$ 4,325	$ 6,477

As of September 30, 2023, the total unrecognized compensation expense related to unvested options was $6.2 million, which the Company expects to recognize over an estimated weighted average period of 2.7 years.

9. Income Taxes

The Company’s provision for income taxes was approximately $0 and $4,000 for the three and nine months ended September 30, 2023, respectively, with an effective tax rate of (0.01)% for the nine months ended September 30, 2023. The Company’s provision for income taxes was approximately $0 and $26,000 for the three and nine months ended September 30, 2022, respectively, with an effective tax rate of (0.04)% for the nine months ended September 30, 2022. The effective tax rate in each period differs from the U.S. statutory tax rate primarily due to the valuation allowances on the Company’s deferred tax assets as it is more likely than not that some or all of the Company’s deferred tax assets will not be realized. The tax expense recorded for the three and nine months ended September 30, 2023 relates to state taxes.

10. Commitments and Contingencies

Lease Agreements

In October 2017, the Company entered into a non-cancelable operating facility lease agreement for 8,029 square feet of office space located at 2155 Park Boulevard in Palo Alto, California. The lease commenced on March 1, 2018 and was to expire in February 2023. The lease had a three-year renewal option prior to expiration. The lease included rent escalation clauses throughout the lease term. In October 2017, the Company provided a security deposit of $0.3 million. In February 2023, the Company amended the lease to extend the lease by one year with a one year renewal option. The extended lease commenced on March 1, 2023 and expires on February 28, 2024. The Company accounted for the amendment as a lease modification in accordance with ASC Topic 842. The Company also has additional operating leases that are included in its lease accounting but are not considered material for disclosure.

The maturities of the Company’s operating lease liabilities as of September 30, 2023 were as follows (in thousands):

Undiscounted lease payments	September 30, 2023
Remaining in 2023	$ 124
2024	84
2025	1
Total undiscounted payments	209
Less: imputed interest	4
Present value of future lease payments	205
Less: current portion of operating lease liabilities	205
Operating lease liabilities	$ —

Rent expense recognized for the Company’s operating leases was $0.1 million for the three months ended September 30, 2023 and 2022, and $0.4 million for the nine months ended September 30, 2023 and 2022. Under the terms of the lease

agreements, the Company is also responsible for certain variable lease payments that are not included in the measurement of the lease liability. Variable lease payments for the operating leases were $23,000 for the three months ended September 30, 2023 and 2022, and $0.1 million for the nine months ended September 30, 2023 and 2022.

The operating cash outflows for the operating lease liabilities were $0.4 million and $0.5 million for the nine months ended September 30, 2023 and 2022, respectively. As of September 30, 2023 and December 31, 2022, the weighted-average remaining lease terms were 0.4 years and 1.2 years, and weighted-average discount rates were 12.81% and 12.82%, respectively.

Legal Matters

Schoen v. Eiger BioPharmaceuticals, Inc., et al., Case No. 22-cv-06985

On November 8, 2022 a putative securities class action complaint was filed in the United States District Court for the Northern District of California alleging that the company and two former executives violated Sections 10(b) and 20(a) of the Securities Exchange Act and SEC Rule 10b-5. The complaint alleged generally that between March 2021 and October 2022, material misstatements and omissions were made to shareholders regarding the TOGETHER study of peginterferon lambda for the treatment of COVID-19 as well as the likelihood of FDA approval of an Emergency Use Authorization for peginterferon lambda. The Court appointed a lead plaintiff on March 2, 2023. On April 10, 2023, the lead plaintiff filed a notice of voluntary dismissal without prejudice.

The Progeria Research Foundation, Inc. v. Eiger BioPharmaceuticals, Inc. Arbitration

On November 15, 2022, the Company received a demand for arbitration (Demand) from claimant The Progeria Research Foundation, Inc. (PRF) asserting two claims under a May 15, 2018 Collaboration and Supply Agreement (the PRF Collaboration Agreement) between the parties. PRF has alleged that the Company breached an obligation to supply quantities of a drug as requested by PRF. PRF also has a claim for declaratory relief regarding the grant of licenses under the PRF Collaboration Agreement. On January 18, 2023, the Company filed a response to the Demand denying PRF's claims, contesting the arbitrability of PRF's claim for declaratory relief, and asserting a counterclaim for declaratory relief related to the contractual provision underlying PRF's original drug supply claim. To give the parties an opportunity to discuss a potential negotiated resolution of their dispute, the arbitration has been suspended through the end of 2023. As a result, all arbitration activities are now on hold, and the final hearing, originally scheduled for May 9 – 12, 2023, in Boston, Massachusetts, was cancelled.

11. Net Loss Per Share

Basic net loss per share of common stock is calculated by dividing the net loss by the weighted average number of shares of common stock outstanding during the period, without consideration for potentially dilutive securities. Since the Company was in a loss position for the three and nine months ended September 30, 2023 and 2022, diluted net loss per share is the same as basic net loss per share as the inclusion of all potential common shares outstanding would have been anti-dilutive. Dilutive potential common stock equivalents include the assumed exercise, vesting and issuance of employee stock awards using the treasury stock method.

The following table sets forth the outstanding potentially dilutive securities which have been excluded in the calculation of diluted net loss per share because including such securities would be anti-dilutive (in common stock equivalent shares):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Options to purchase common stock	7,335,274	6,876,679	7,335,274	6,876,679
Restricted and Performance stock units (unvested)	219,562	753,356	219,562	753,356
ESPP	252,922	85,110	252,922	85,110
Total	7,807,758	7,715,145	7,807,758	7,715,145

12. Subsequent Events

In preparing the condensed consolidated financial statements as of September 30, 2023, the Company evaluated subsequent events for recognition and measurement purposes through the filing date of this Quarterly Report on Form 10-Q. The

Company concluded that no events or transactions have occurred that require disclosure in the accompanying condensed consolidated financial statements.

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

You should read the following discussion and analysis of Eiger BioPharmaceuticals, Inc.'s (Eiger) financial condition and results of operations together with our unaudited condensed consolidated financial statements and related notes thereto included in Part I, Item 1 of this Quarterly Report on Form 10-Q, and our consolidated financial statements and related notes thereto for the year ended December 31, 2022, included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on March 17, 2023. This discussion and other parts of this report contain forward-looking statements that involve risks and uncertainties, such as our plans, objectives, expectations, intentions and beliefs. Our actual results could differ materially from those discussed in 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 entitled "Risk Factors" included elsewhere in this report.

Forward-Looking Statements

This Quarterly Report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements In some cases, forward-looking statements are identified by words such as "believe," "will," "may," "estimate," "continue," "anticipate," "intend," "should," "plan," "expect," "predict," "could," "potentially" or the negative of these terms or similar expressions. You should read these statements carefully because they discuss future expectations, contain projections of future results of operations or financial condition, or state other "forward-looking" information. These statements relate to, among other things, our future plans, objectives, strategic partnering options for our virology assets, expectations, intentions, the potential for our programs, the timing of our clinical trials and financial performance and our ability to fund our planned operations, and the assumptions that underlie these statements. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements. Factors that might cause such a difference include, but are not limited to, those discussed in this Quarterly Report on Form 10-Q in Part II, Item 1A — "Risk Factors," and elsewhere in this Quarterly Report on Form 10-Q. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. These statements, like all statements in this Quarterly Report on Form 10-Q, speak only as of their date, and we undertake no obligation to update or revise these statements in light of future developments. We caution investors that our business and financial performance are subject to substantial risks and uncertainties.

Overview

In June 2023, in connection with an extensive portfolio prioritization review, we announced that the Company is focusing its clinical development efforts on advancing avexitide in hyperinsulinemic hypoglycemia (HH) indications. We will continue to commercialize Zokinvy for the treatment of Hutchinson-Gilford progeria syndrome (HGPS) and processing-deficient progeroid laminopathies (PL). In addition, we are evaluating strategic partnering options for our virology assets, lonafarnib and peginterferon lambda. During 2023, we have also undertaken certain cost savings initiatives, including a 43% reduction in workforce to date and efforts to reduce out-of-pocket spending related to our hepatitis delta (HDV) development program. In June 2023, we also announced that we had appointed David Apelian, MD, PhD, MBA, who had served as interim CEO since December 2022, as our next CEO.

Our lead product candidate, avexitide, is a well characterized, first-in-class glucagon-like peptide-1 (GLP-1) antagonist and is in development for the treatment of post-bariatric hypoglycemia (PBH) and other form of hyperinsulinemic hypoglycemia (HH) arising after gastrointestinal surgeries. These disorders are characterized by exaggerated secretion of GLP-1 after meals, dysregulated secretion of insulin, and a rapid drop in blood sugar. Avexitide is the only drug in development for PBH with Breakthrough Therapy designation by the U.S. Food and Drug Administration (FDA). Avexitide is also in development for congenital hyperinsulinism (HI), an ultra-rare, life-threatening, pediatric disorder of persistent hypoglycemia that results in irreversible brain damage in up to 50% of children with the condition. Avexitide has completed Phase 2 for both PBH and HI, and Phase 3 study start-up activities for PBH have been initiated. In connection with our Phase 3 start-up activities, we have observed low levels of product-related impurities in the finished drug product. Although not unusual for this class of compounds, we are working with our Contract Manufacturing Organizations (CMOs) to control these materials to ensure that an adequate supply of materials with a sufficient shelf-life can be released for Phase 3 studies.

On November 20, 2020, the FDA approved our first commercial product, Zokinvy, to reduce the risk of mortality of HGPS and for treatment of processing-deficient PL with either heterozygous LMNA mutation with progerin-like protein accumulation, or homozygous or compound heterozygous ZMPSTE24 mutations. Collectively known as progeria, these are ultra-rare and rapidly fatal genetic conditions of accelerated aging in children. On July 20, 2022, we announced that the EC granted MA under exceptional circumstances for Zokinvy for the treatment of progeria through the centralized procedure. The MA is valid for 5 years from date of authorization in all 27 EU member states plus Iceland, Liechtenstein, and Norway and is subject to annual reassessment of the benefit/risk profile based on the requirements set forth in the MA under exceptional circumstances. In May 2022, the Pharmaceutical Division at The Ministry of Health of Israel granted regulatory approval for Zokinvy in Israel. In August 2022, marketing authorization of Zokinvy was granted by the UK's Medicine and Healthcare products Regulatory Agency (MHRA) as part of the UK's European Commission Decision Reliance Procedure.

We commercially launched Zokinvy in the U.S. in January 2021 and in Europe in November 2022 and started to record product revenue in the first quarter of 2021. Our first European sales were recognized in the fourth quarter of 2022.

We continue to evaluate strategic partnering options for our virology assets: lonafarnib, a first-in-class, oral prenylation inhibitor, and peginterferon lambda, a potential first-in-class interferon.

For lonafarnib, in June 2023, we completed and reported end of study data from the single, pivotal Phase 3 D-LIVR study in patients with chronic HDV. The end of treatment Week 48 data demonstrated that the primary endpoint was achieved in both the oral and combination lonafarnib treatment arms. 24-week post-treatment data demonstrated that both lonafarnib arms showed a statistically significant difference in composite response rate compared to placebo. Our pre-New Drug Application (pre-NDA) meeting with FDA was supportive of a potential path to an NDA approval for both oral and combination lonafarnib regimens as finite therapies.

For peginterferon lambda, in September 2023, we announced our decision to discontinue the Phase 3 *LIMT-2* study of peginterferon lambda in patients with chronic HDV. The decision was based on the recommendation of the Data Safety Monitoring Board (DSMB) for the study following its quarterly safety review. In a communication dated September 7, 2023, the DSMB recommended the discontinuation of the *LIMT-2* study due to observations of four patients with hepatobiliary events that resulted in liver decompensation. Potential remains for peginterferon lambda for development in hepatitis B virus (HBV), respiratory diseases such as COVID-19 and influenza, as well as other virology indications.

We have historically incurred operating losses in each year since inception, and we expect to incur losses for the foreseeable future. We had a net loss of $18.0 million and $27.1 million for the three months ended September 30, 2023 and 2022, respectively. We had a net loss of $61.5 million and $71.6 million for the nine months ended September 30, 2023 and 2022, respectively. As of September 30, 2023, we had an accumulated deficit of $498.7 million. Substantially all of our operating losses have resulted from expenses incurred in connection with our research and development programs and from selling, general and administrative costs associated with our operations.

We expect to incur significant expenses and increasing operating losses for at least the next several years as we initiate and continue the clinical development of, and seek regulatory approval for, and potentially commercialize our product candidates, which will require the addition of new personnel and upgrades to our information technology systems. We expect that our operating losses will fluctuate significantly from quarter to quarter and year to year due to timing of clinical development programs and efforts to achieve additional regulatory approvals. We have completed a program prioritization assessment and are executing on a strategy with a focus on enhancing long-term shareholder value.

Financial Operations Overview

Product Revenue, Net

Our product revenue, net consists of sales of Zokinvy for HGPS and processing-deficient PL in the United States and under a reimbursed early access program, or cohort ATU program, in France. In November 2022, sales of Zokinvy launched commercially in Europe through our wholly owned subsidiary in Ireland.

Cost of Sales

Cost of sales consists primarily of direct and indirect costs related to the manufacturing of Zokinvy for commercial sale, including third-party manufacturing costs, third party logistics costs, write down of inventories, and other period costs.

Research and Development Expenses

Research and development expenses represent costs incurred to conduct research and development, such as the development of our product candidates. We recognize all research and development costs as they are incurred. Research and development expenses consist primarily of the following:

- expenses incurred under agreements with consultants, contract research organizations and clinical trial sites that conduct research and development activities on our behalf;
- laboratory and vendor expenses related to the execution of clinical trials;
- contract manufacturing expenses, primarily for the production of clinical trial supplies;
- license fees associated with our license agreements; and
- internal costs that are associated with activities performed by our research and development organization and generally benefit multiple programs. These costs are not separately allocated by product candidate. Unallocated internal research and development costs consist primarily of:
    - personnel costs, which include salaries, benefits and stock-based compensation expense;
    - allocated facilities and other expenses, which include expenses for rent and maintenance of facilities and depreciation expense; and
    - regulatory expenses and technology license fees related to development activities.

The largest component of our operating expenses has historically been the investment in clinical trials, including contract manufacturing arrangements, clinical trial material related costs and other research and development activities. However, we do not allocate internal research and development costs, such as salaries, benefits, stock-based compensation expense and indirect costs to product candidates on a program-specific basis. The following table shows our research and development expenses for the three and nine months ended September 30, 2023 and 2022 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Product candidates:				
Avexitide	$ 1,726	$ 3,254	$ 4,522	$ 6,976
Lonafarnib	4,826	6,877	18,968	19,385
Peginterferon lambda	4,080	6,964	12,835	17,359
Internal research and development costs	3,936	5,103	14,392	13,041
Total research and development expense	$ 14,568	$ 22,198	$ 50,717	$ 56,761

We expect research and development expenses will continue to be significant and may increase in the future as we attempt to advance our product candidates into and through later stage clinical trials and pursue regulatory approvals, which will require a significant investment in regulatory support and contract manufacturing and clinical trial material related costs. In addition, in the future we may evaluate opportunities to acquire or in-license other product candidates and technologies, which may result in higher research and development expenses due to license fees and/or milestone payments.

The process of conducting clinical trials necessary to obtain regulatory approval is costly and time consuming. We may never succeed in timely developing and achieving regulatory approval for our product candidates. The probability of success of our product candidates may be affected by numerous factors, including clinical data, competition, intellectual property rights, manufacturing capability and commercial viability. As a result, we are unable to determine the duration and completion costs of our development projects or when and to what extent we will generate revenue from the commercialization and sale of any of our product candidates.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist of personnel costs, allocated expenses, expenses for outside professional services, including legal, audit, accounting services, insurance costs and costs associated with being a public company, and commercial related expenses. Personnel costs consist of salaries, benefits and stock-based compensation. Allocated expenses consist of facilities and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, depreciation expense and other supplies. Our expenses include costs related to compliance with the rules and regulations of the SEC and Nasdaq, insurance, investor relations, banking fees and other administrative expenses and professional services. We expect our selling, general and administrative expenses to fluctuate in the future due to sales and marketing activities from the commercialization of our product candidates.

Interest Expense

Interest expense consists of interest on our long-term borrowings.

Interest Income

Interest income consists of interest earned on our investments in debt securities and cash equivalents.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our unaudited condensed consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of these unaudited condensed consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities revenues, and expenses. On an ongoing basis, we evaluate these estimates and judgments. We base our estimates on historical experience and on various assumptions that we believe to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities and the recording of revenues and expenses that are not readily apparent from other sources. Actual results may differ materially from these estimates. There were no material changes to our critical accounting policies and estimates as disclosed in our 2022 Annual Report on Form 10-K filed with SEC on March 17, 2023.

Results of Operations

Comparison of the Three Months Ended September 30, 2023 and 2022

The following table summarizes results of operations for the three months ended September 30, 2023 and 2022 (in thousands):

	Three Months Ended September 30,		$ Change	% Change
	2023	2022		
Product revenue, net	$ 3,209	$ 4,024	$ (815)	(20)%
Total revenue	3,209	4,024	(815)	(20)%
Costs and operating expenses:				
Cost of sales	115	1,231	(1,116)	(91)%
Research and development	14,568	22,198	(7,630)	(34)%
Selling, general and administrative	5,454	6,964	(1,510)	(22)%
Total costs and operating expenses	20,137	30,393	(10,256)	(34)%
Loss from operations	(16,928)	(26,369)	9,441	(36)%
Interest expense	(1,412)	(1,092)	(320)	29 %
Interest income	485	347	138	40 %
Other (expense) income, net	(175)	3	(178)	*
Net loss	$ (18,030)	$ (27,111)	$ 9,081	(33)%

*Percentage not meaningful.

Product revenue, net

Product revenue, net decreased by $0.8 million for the three months ended September 30, 2023 compared to the same period in 2022. The decrease was primarily due to a $1.6 million decrease in U.S. sales. It was partially offset by an increase of $0.8 million in France ATU sales compared to no such sales for the same period in 2022.

Cost of sales

Cost of sales decreased by $1.1 million for the three months ended September 30, 2023 compared to the same period in 2022. The decrease was primarily due to a non-conforming batch of inventory that was written off during the three months ended September 30, 2022.

Research and development expenses

Research and development expenses decreased by $7.6 million for the three months ended September 30, 2023 compared to the same period in 2022. The decrease was primarily due to a decrease of $6.0 million in clinical and contract manufacturing expenditures consisting of a $5.5 million decline in manufacturing costs for peginterferon lambda and avexitide and a $0.5 million decrease in clinical costs related to the LNF-011 study, a $1.1 million decrease in compensation and personnel related expense due to a decrease in headcount, and a $0.3 million decrease in outside services across programs including consulting and advisory services due to a decline in spending on peginterferon lambda programs.

Selling, general and administrative expenses

Selling, general and administrative expenses decreased by $1.5 million for the three months ended September 30, 2023 compared to the same period in 2022. The decrease was primarily due to a $1.0 million decrease in compensation and personnel related expense, including stock-based compensation, due to a decrease in headcount, and a $0.4 million decrease in outside services, including consulting, advisory and accounting services.

Interest expenses

Interest expense increased by $0.3 million for the three months ended September 30, 2023 compared to the same period in 2022. The increase was primarily due to an increase in the outstanding principal balance and increase in the effective interest rate of our Innovatus Loan entered into in June 2022.

Interest income

Interest income increased by $0.1 million for the three months ended September 30, 2023 compared to the same period in 2022. The increase was primarily due to an increase in interest rates.

Other (expense) income, net

Other (expense) income, net decreased by $0.2 million for the three months ended September 30, 2023 compared to the same period in 2022. The decrease was primarily due to foreign currency transaction loss from the significant volatility of the foreign currency exchange rates.

Comparison of the Nine Months Ended September 30, 2023 and 2022

The following table summarizes results of operations for the nine months ended September 30, 2023 and 2022 (in thousands):

	Nine Months Ended September 30,		$ Change	% Change
	2023	2022		
Product revenue, net	$ 11,720	$ 10,038	$ 1,682	17 %
Other revenue	250	750	(500)	(67)%
Total revenue	11,970	10,788	1,182	11 %
Costs and operating expenses:				
Cost of sales	(77)	1,492	(1,569)	(105)%
Research and development	50,717	56,761	(6,044)	(11)%
Selling, general and administrative	20,502	20,804	(302)	(1)%
Total costs and operating expenses	71,142	79,057	(7,915)	(10)%
Loss from operations	(59,172)	(68,269)	9,097	(13)%
Interest expense	(4,040)	(2,912)	(1,128)	39 %
Interest income	1,856	613	1,243	203 %
Other (expense) income, net	(149)	(1,044)	895	(86)%
Loss before provision for income taxes	(61,505)	(71,612)	10,107	(14)%
Provision for income taxes	4	26	(22)	(85)%
Net loss	$ (61,509)	$ (71,638)	$ 10,129	(14)%

Product revenue, net

Product revenue, net increased by $1.7 million for the nine months ended September 30, 2023 compared to the same period in 2022. The increase was primarily due to $1.3 million from product sales in Germany compared to no such sales for the same period in 2022 and an increase of $1.4 million in sales under the ATU program in France during the period. It was partially offset by a decrease of $1.1 million in U.S. sales.

Other revenue

Other revenue decreased by $0.5 million for the nine months ended September 30, 2023 compared to the same period in 2022. The decrease was primarily due to the timing of certain upfront payments received under the terms of the MDA with AnGes.

Cost of sales

Cost of sales decreased by $1.6 million for the nine months ended September 30, 2023 compared to the same period in 2022. The decrease was primarily due to a non-conforming batch of inventory that was written off during the nine months ended September 2022 and a reversal of an inventory accrual related to a non-conforming batch of product where we were notified in June 2023 that we were no longer obligated to pay for such product.

Research and development expenses

Research and development expenses decreased by $6.0 million for the nine months ended September 30, 2023 compared to the same period in 2022. The decrease was primarily due to a $5.0 million decrease in milestone expenses related to the Phase 3 LIMT-2 study of peginterferon lambda for HDV under our License Agreement with Bristol-Myers Squibb Company, which occurred in March 2022, a $1.8 million decrease in outside services across programs including consulting and advisory services due to a decline in spending on peginterferon lambda programs and a $0.3 million decrease in clinical and contract manufacturing expenditures. It was partially offset by a $0.7 million increase in compensation and personnel related expenses, including severance payouts for terminated employees, and a $0.3 million increase in regulatory expenses.

Selling, general and administrative expenses

Selling, general and administrative expenses decreased by $0.3 million for the nine months ended September 30, 2023 compared to the same period in 2022. The decrease was primarily due to a $0.9 million decrease in compensation and personnel related expense including stock-based compensation, due to a decrease in headcount and a $0.2 million decrease in sales and marketing. It was partially offset by a $0.8 million increase in outside services, including consulting, advisory and technical accounting services, as well as legal fees due to ongoing litigation and outsourced legal activities.

Interest expenses

Interest expense increased by $1.1 million for the nine months ended September 30, 2023 compared to the same period in 2022. The increase was primarily due to an increase in the outstanding principal balance and increase in the effective interest rate of our long-term borrowings related to the Innovatus Loan.

Interest income

Interest income increased by $1.2 million for the nine months ended September 30, 2023 compared to the same period in 2022. The increase was primarily due to an increase in interest rates.

Other (expense) income, net

Other (expense) income, net change of $0.9 million for the nine months ended September 30, 2023 compared to the same period in 2022. The decrease was primarily due to a loss on early extinguishment of the Oxford Loan in June 2022.

Provision for income taxes

Provision for income taxes decreased by $22,000 compared to the same period in 2022. The change was primarily due to tax expense related to state taxes.

Liquidity and Capital Resources

Sources of Liquidity

As of September 30, 2023, we had $39.4 million of cash, cash equivalents and short-term debt securities, comprised of $27.5 million of cash and cash equivalents and $11.9 million of short-term debt securities available-for-sale, and an accumulated deficit of $498.7 million.

On June 1, 2022, we entered into the Innovatus Loan with Innovatus, providing for up to $75.0 million funded in three tranches with a maturity date of August 31, 2027. We were funded $40.0 million in June 2022 at the closing, of which approximately $33.5 million was used to pay off loans outstanding under the Oxford Loan. We recorded a loss of $1.1 million on early extinguishment of the debt which was recognized as a component of Other (expense) income, net in the consolidated statement of operations and comprehensive loss. As part of the agreement with Innovatus, we are required to maintain a cash balance of not less than 5% of the aggregate principal amount of funded and outstanding term loans at all times. We are currently eligible to draw the $17.5 million under Tranche B, and have not done so as of September 30, 2023.

Additionally, in connection with entering into the Innovatus Loan, we entered into a Stock Purchase Agreement with Innovatus for the sale of common stock with an aggregate value of $5.0 million. On June 1, 2022, we issued 749,053 shares of common stock to Innovatus at a per share purchase price of $6.6751. Refer to Note 6 of our unaudited condensed consolidated financial statements included within Item 1 of this Quarterly Report on Form 10-Q for additional details.

On March 25, 2022, we entered into an Open Market Sale Agreement[SM] with Jefferies, pursuant to which we can sell up to a maximum of $50.0 million of our common stock in offerings that are deemed “at the market” offerings as defined in Rule 415 under the Securities Act, under Eiger’s currently effective shelf registration statement (the 2022 ATM Facility). In April 2022, we completed offerings from the 2022 ATM facility for a total of 2,686,288 shares of our common stock resulting in net proceeds of $20.8 million, after deducting commissions costs. No additional offerings have been completed since April 2022. As of September 30, 2023, there was approximately $28.7 million remaining under the 2022 ATM Facility for future issuance. We have not sold shares under the 2022 ATM Facility during 2023. The registration statement registering the offer and sale of shares pursuant to the 2022 ATM Facility is set to expire in December 2023, and there can be no assurance that we will be able to register future offers or sales under the 2022 ATM Facility. To the extent that the Company raises additional capital through the sale of equity, including pursuant to the 2022 ATM Facility and offerings of

debt or other securities convertible into equity, stockholder ownership interest will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect the rights of holders of our common stock. In addition, based on our public float as of the filing of this Quarterly Report on Form 10-Q, we are only permitted to file a shelf registration statement subject to Instruction I.B.6 to Form S-3, which is referred to as the "baby shelf" rule. For so long as our public float is less than $75.0 million, we may not sell more than the equivalent of one-third of our public float during any 12 consecutive months pursuant to the baby shelf rules.

Based on our recurring losses from operations incurred since inception, expectation of continuing operating losses and negative cash flows for the foreseeable future, and need to raise additional capital to finance our future operations, management has concluded that there is substantial doubt regarding Eiger's ability to continue as a going concern beyond twelve months after the date that our condensed consolidated financial statements are issued.

Our primary uses of cash are to fund operating expenses, including research and development expenditures and selling, general and administrative expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in outstanding accounts payable and accrued expenses.

Future Funding Requirements

Prior to 2021, we had not generated any product revenue. We launched our first commercial product, Zokinvy, in January 2021. We expect our expenses to increase in connection with our ongoing development and manufacturing activities, particularly as we continue the research, development, manufacture and clinical trials of, and seek regulatory approval for our product candidates.

Our primary uses of capital are, and we expect will continue to be, funding the development of our avexitide product candidates, sales and marketing costs for commercialization of Zokinvy, compensation and related expenses, operational, manufacturing, financial, and management personnel, and costs associated with operating as a public company. We expect to incur substantial expenditures in the foreseeable future for the development and potential commercialization of our product candidates. We have reduced our workforce by 43% to date and have reduced out-of-pocket spending related to our HDV development program in an effort to extend our cash runway. We are actively seeking additional capital to fund losses from operations and capital funding needs through public or private equity offerings and/or debt financings, including through potential additional collaborations or strategic partnerships with other companies, or through a combination of the foregoing. As a result of economic conditions, general global economic uncertainty, political change and other factors, we do not know whether additional capital will be available when needed, or that, if available, we will be able to obtain additional capital on reasonable terms. If we are unable to raise additional capital due to the volatile global financial markets, general economic uncertainty or other factors, we may need to curtail planned development or commercialization activities. The sale of additional equity, including pursuant to the 2022 ATM Facility, or convertible debt could result in additional dilution to our stockholders. The incurrence of indebtedness would result in debt service obligations and could result in operating and financing covenants that would restrict our operations. We can provide no assurance that financing will be available in the amounts we need or on terms acceptable to us, if at all. If we are not able to secure adequate additional funding we may be forced to delay, make reductions in spending, extend payment terms with suppliers, liquidate assets where possible, and/or suspend or curtail planned programs. Any of these actions could materially harm our business.

Cash Flows

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

	Nine Months Ended September 30,	
	2023	2022
Net cash used in operating activities	$ (60,594)	$ (60,763)
Net cash provided by (used in) investing activities	62,229	(12,165)
Net cash provided by financing activities	34	77,015
Effect of foreign exchange on cash and cash equivalents	34	—
Net increase in cash and cash equivalents	$ 1,703	$ 4,087

Cash flows from operating activities

Cash used in operating activities for the nine months ended September 30, 2023 was $60.6 million, which primarily consisted of a net loss of $61.5 million, stock-based compensation expense of $4.3 million, non-cash interest expense of $1.1 million, amortization of debt securities discount of $1.0 million, reduction in the carrying amount of right-of-use assets of $0.4 million and depreciation and amortization of $0.2 million. Additionally, cash used in operating activities reflected changes in net operating assets due to a decrease of $8.8 million in accounts payable and accrued liabilities primarily due to the timing of payments, a decrease of $0.4 million in operating lease liabilities, partially offset by a decrease of $2.3 million in inventories, a decrease of $2.0 million in other assets, a decrease of $0.4 million in prepaid expenses and other current assets and a decrease of $0.4 million in accounts receivable.

Cash used in operating activities for the nine months ended September 30, 2022 was $60.8 million, which primarily consisted of a net loss of $71.6 million, stock-based compensation expense of $6.5 million, loss on extinguishment of long-term debt of $1.1 million, inventory write down of $1.0 million, non-cash interest expense of $0.9 million, amortization of debt securities discount of $0.7 million, amortization of operating lease right-of-use assets of $0.4 million and depreciation and amortization of $0.2 million. Additionally, cash used in operating activities reflected changes in net operating assets due to an increase of $4.1 million in accounts payable and accrued liabilities, primarily due to the timing of payments, and a decrease of $0.1 million in accounts receivable, partially offset by an increase of $2.2 million in prepaid expenses and other current assets, an increase of $0.9 million in inventories, an increase of $0.6 million in other assets, and a decrease of $0.5 million in operating lease liabilities.

Cash flows from investing activities

Cash provided by investing activities for the nine months ended September 30, 2023 was $62.2 million, primarily consisting of $81.9 million of proceeds from maturities of debt securities, which were partially offset by $19.4 million of purchases of debt securities and $0.2 million of purchases of property and equipment.

Cash used in investing activities for the nine months ended September 30, 2022 was $12.2 million, primarily consisting of $55.5 million of purchases of debt securities, which were partially offset by $43.5 million of proceeds from maturities of debt securities.

Cash flows from financing activities

Cash provided by financing activities for the nine months ended September 30, 2023 was $34,000, primarily consisting of $56,000 proceeds from issuance of common stock upon ESPP purchases, which were partially offset by $22,000 payment of common stock offering costs.

Cash provided by financing activities for the nine months ended September 30, 2022 was $77.0 million, which primarily consisted of $66.4 million of proceeds net of commissions from the issuance of common stock under the 2020 and 2022 ATM Facilities, $39.8 million of proceeds from debt, $5.0 million of proceeds from issuance of common stock to lender, $0.3 million proceeds from issuance of common stock upon stock option exercises and ESPP purchases, which were partially offset by the $33.3 million repayment of debt, $1.1 million payment of debt issuance costs and $0.2 million of common stock offering costs.

Contractual Obligations and Other Commitments

Our contractual obligations as of September 30, 2023 have not materially changed from what we presented in our Annual Report on Form 10-K for the year ended December 31, 2022 filed with the SEC on March 17, 2023.

ITEM 3. Quantitative and Qualitative Disclosures about Market Risk

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934 and are not required to provide the information under this item.

ITEM 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We are responsible for maintaining disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Disclosure controls and procedures are controls and other procedures designed to ensure that the information required to be disclosed by us in the reports that we file or submit 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 us in the reports that we file or submit under the Exchange Act 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.

Based on our management's evaluation (with the participation of our principal executive officer and our principal financial officer) of our disclosure controls and procedures as required by Rule 13a-15 under the Exchange Act, our principal executive officer and our principal financial officer have concluded that our disclosure controls and procedures were effective to achieve their stated purpose as of September 30, 2023, the end of the period covered by this report.

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) that occurred during the nine months ended September 30, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

None.

ITEM 1A. RISK FACTORS

You should carefully consider the following risk factors, as well as the other information in this Quarterly Report on Form 10-Q, and in our other public filings. The occurrence of any of the following risks could harm our business, financial condition, results of operations and/or growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this Quarterly Report on Form 10-Q and those we may make from time to time. You should consider all of the risk factors described when evaluating our business.

Risk Factor Summary

Below is a summary of material factors that make an investment in our common stock speculative or risky. Importantly, this summary does not address all of the risks and uncertainties that we face. Additional discussion of the risks and uncertainties summarized in this risk factor summary, as well as other risks and uncertainties that we face, can be found under "Risk Factors" in Part II, Item 1A of this Quarterly Report. The below summary is qualified in its entirety by that more complete discussion of such risks and uncertainties. You should carefully consider the risks and uncertainties described under "Risk Factors" in Part II, Item 1A of this Quarterly Report as part of your evaluation of an investment in our common stock.

- We are a commercial-stage biopharmaceutical company with multiple product candidates in clinical development and a limited operating history. We have incurred net losses each year since our inception. We have one U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA)-approved product for commercial sale, Zokinvy, and prior to 2021, have never generated any product revenue and may never be profitable.
- We cannot give any assurance that we will generate data for our current lead product candidate avexitide or any other candidate sufficient to receive regulatory approval, and without regulatory approval we will not be able to market such products.
- Prior to the approval of our NDA for Zokinvy to reduce the risk of mortality in HGPS, and for treatment of processing-deficient PL with either heterozygous LMNA mutation with progerin-like protein accumulation, or homozygous or compound heterozygous ZMPSTE24 mutations, we had not submitted an application for approval or obtained FDA approval for any product. We may not be able to obtain FDA approval of any future NDA or Biologics License Application (BLA) for our product candidates, which would prohibit commercialization.
- Our business strategy is based upon obtaining and maintaining Orphan Drug designation for our product candidates. If we are unable to obtain or maintain Orphan Drug designation or regulatory approval, our business would be substantially harmed.
- Our future success depends in part on our ability to attract, retain, and motivate qualified personnel**.**
- Product development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies may not be predictive of future study results.
- We rely on clinical studies of our product candidates in order to obtain regulatory approval. We may find it difficult to enroll patients in our clinical studies given the limited number of patients who have the diseases for which our product candidates are being studied.
- If clinical studies of our product candidates fail to demonstrate safety, efficacy, purity and/or potency to the satisfaction of the FDA or similar regulatory authorities outside the United States or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.
- We rely on third parties to conduct our clinical studies, manufacture our product candidates and perform other services. Our ability to obtain regulatory approval or commercialize our product candidates and our business could be impaired if these collaborations are unsuccessful.
- If the market opportunities for our product candidates are smaller than we believe they are, we may not meet our revenue expectations. Because the patient populations in the market for our product candidates may be small, we

must be able to successfully identify patients and acquire a significant market share to achieve profitability and growth.

- We face intense competition and rapid technological change and the possibility that our competitors may develop therapies that are similar, more advanced or more effective than ours.
- We currently have limited marketing and sales capabilities for the commercialization of our product candidates.
- Zokinvy sales reflect utilization of the product in the ultra-rare conditions of Hutchinson-Gilford progeria syndrome (HGPS) and processing-deficient progeroid laminopathies (PL) among a small number of patients, and thus sales volume may fluctuate over time due to the inherent mortality in these serious diseases.
- The commercial success of any of our current or future product candidates will depend upon the degree of market acceptance by physicians, patients, third-party payors and others in the medical community. Sales of our products depend substantially on the extent to which the costs of our product candidates will be paid for or reimbursed by healthcare management organizations or government authorities or third-party payors.
- We are currently conducting and will continue to conduct clinical trials for our product candidates outside the United States, which could expose us to risks that could have a material adverse effect on our business, including conflicts in the Middle East and risks in connection with the actions taken by the Russian Federation in Ukraine and surrounding areas.
- We intend to rely on a combination of exclusivity from Orphan Drug designation and our patent rights for our product candidates. If we are unable to maintain exclusivity from the combination of these approaches, then our ability to compete effectively in our markets may be harmed.
- The annual reassessment by the EMA of the risk-benefit balance for Zokinvy including information on the safe and effective use may not be positive, which could lead to a variation, suspension, revocation of our marketing authorization or requirement to fulfil additional specific obligations.
- If we are unable to maintain effective proprietary rights for our product candidates, or if the scope of the intellectual property protection is not sufficiently broad, our competitors could develop and commercialize product candidates similar or identical to ours.
- We may be unsuccessful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in-licenses. If we fail to comply with obligations in the agreements under which we license intellectual property and other rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.
- We may not be successful in any efforts to identify, license, discover, develop or commercialize additional product candidates.
- Healthcare legislative reform measures may have a material adverse effect on our business and results of operations. If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs.
- The proposals to revise the European legislation on pharmaceuticals lead to uncertainties over the regulatory framework that will be applicable to medicinal products in the EU, including orphan medicinal products.
- We face potential product liability, and, if successful claims are brought against us, we may incur substantial liability and costs.
- We are dependent upon information technology systems and any failure or security breach of such systems could result in a material disruption in the development of our product candidates or other business operations as well as result in statutory or contractual obligations or otherwise expose us to liability.
- COVID-19 has and may continue to adversely affect our financial condition and our business as well as those of third parties on which we rely on significant manufacturing, clinical or other business operations.
- If we fail to maintain or regain compliance with the listing standards of Nasdaq, our common stock may be delisted, which could have a material adverse effect on the liquidity of our common stock and our ability to raise additional capital.

Risks Related to our Financial Condition, Integration and Capital Requirements

We have incurred losses since our inception, have a limited operating history on which to assess our business, and anticipate that we will continue to incur significant losses for the foreseeable future. We will require substantial additional capital to achieve our goals.

We are a commercial-stage biopharmaceutical company with a limited operating history. We have incurred net losses in each year since our inception. For the three months ended September 30, 2023 and 2022, we reported a net loss of $18.0 million and $27.1 million, respectively. For the nine months ended September 30, 2023 and 2022, we reported a net loss of $61.5 million and $71.6 million, respectively. As of September 30, 2023, we had an accumulated deficit of $498.7 million. Our prior losses, combined with expected future losses, have had and may continue to have an adverse effect on our stockholders' (deficit) equity and working capital.

Based on our recurring losses from operations incurred since inception, expectation of continuing operating losses and negative cash flows for the foreseeable future, and need to raise additional capital to finance our future operations, management has concluded that there is substantial doubt regarding Eiger's ability to continue as a going concern for beyond twelve months after the date that our condensed consolidated financial statements are issued. In addition, we may not be able to access a portion of our existing cash, cash equivalents and short-term securities due to market and other conditions. For example, on March 10, 2023, the Federal Deposit Insurance Corporation (FDIC) was appointed receiver of Silicon Valley Bank (SVB), where we maintain an operating account with a balance that exceeded the FDIC insurance limit. On March 12, 2023, the U.S. Treasury Department, the Federal Reserve and the FDIC jointly announced enabling actions that fully protect all depositors of SVB and that such depositors would have access to all of their funds starting March 13, 2023. On March 26, 2023, the FDIC announced that First Citizens BancShares would acquire the commercial banking business of SVB. Although the cash in our accounts at Silicon Valley Bank did not impact our operations, we cannot be certain that future market corrections or other conditions will not impact our ability to access our cash, cash equivalents and short-term securities. We continue to maintain an operating account at SVB and have begun measures to reduce our deposit concentration risk. If other banks and financial institutions enter receivership or become insolvent in the future in response to financial conditions affecting the banking system and financial markets, our ability to access our existing cash, cash equivalents and short-term securities may be threatened.

In addition, we will continue to require substantial additional capital to continue our clinical development, manufacturing and regulatory approval efforts and potential commercialization activities. Accordingly, we will need to raise substantial additional capital to continue to fund our operations. The amounts and timing of our future funding requirements will depend on many factors, including our ability to achieve regulatory approval and the pace and results of our clinical development efforts. While we are actively seeking additional capital to fund losses from operations and capital funding needs through public or private equity offerings and/or debt financings, through potential additional collaborations or strategic partnerships with other companies, or through a combination of the foregoing, additional funds may not be available when we need them on terms that are favorable to us, or at all. Failure to raise capital as and when needed, on favorable terms or at all, would have a negative impact on our financial condition and our ability to develop our product candidates.

We have devoted substantially all of our financial resources to identify, acquire, and develop our product candidates, including manufacturing of clinical supplies, conducting clinical studies and providing selling, general and administrative support for our operations. To date, we have financed our operations primarily through the sale of equity securities and debt facilities. The amount of our future net losses will depend, in part, on the rate of our future expenditures and our ability to obtain funding through equity or debt financings, strategic collaborations, or grants. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We expect losses to increase as we advance our clinical development programs in various clinical studies. We may need significant additional resources in order to aggressively move avexitide forward successfully based on the discussions with the FDA. It may be several years, if ever, before we complete pivotal clinical studies and have additional product candidates approved for commercialization. We expect to invest significant funds into our clinical candidates to advance these compounds to potential regulatory approval.

If we obtain regulatory approval to market one or more additional product candidates, our future revenue will depend upon the size of any markets in which our product candidates may receive approval, and our ability to achieve sufficient market acceptance, pricing, reimbursement from third-party payors, and adequate market share for our product candidates in those markets. Even if we obtain adequate market share for our product candidates, because the potential markets in which our product candidates may ultimately receive regulatory approval could be very small, we may never become profitable despite obtaining such market share and acceptance of our products. We have also agreed with The Progeria Research

Foundation to make Zokinvy available to progeria (HGPS and processing-deficient PL) patients under an expanded access program that may not result in payment to us. Future clinical trials of new therapies for progeria conducted by third parties may also result in patients converting from commercially reimbursed Zokinvy to product provided through clinical trials and result in lower revenues received by us.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future and our expenses will increase substantially if and as we:

- continue the clinical development of our product candidate;
- in-license or acquire additional product candidates;
- undertake the scale up and commercial manufacturing or have manufactured our product candidate;
- advance our programs into larger, more expensive clinical studies;
- initiate additional nonclinical, clinical, or other studies for our product candidate;
- commercialize and provide expanded access to Zokinvy for the treatment of HGPS and processing-deficient PL
- identify and develop potential commercial opportunities, such as avexitide for PBH and HI;
- seek regulatory and marketing approvals and reimbursement for our product candidate;
- establish a sales, marketing, and distribution infrastructure to commercialize any products for which we may obtain marketing approval and market ourselves;
- seek to identify, assess, acquire, and/or develop other product candidates;
- make milestone, royalty or other payments under third-party license agreements;
- develop and educate PBH and HI markets;
- seek to maintain, protect, and expand our intellectual property portfolio;
- seek to attract and retain skilled personnel;
- create additional infrastructure to support our operations as a public company and our product development and planned future commercialization efforts; and experience any delays or encounter issues with the development and potential for regulatory approval of our clinical candidates such as safety issues, clinical trial accrual delays, longer follow-up for planned studies, additional major studies, or supportive studies necessary to support marketing approval.

Further, the net losses we incur may fluctuate significantly from quarter to quarter and year to year, such that a period-to-period comparison of our results of operations may not be a representative indication of our future performance.

Prior to 2021, we never generated any product revenue and may never be profitable.

We have one product approved for commercialization in the U.S. and EU for two ultra-rare diseases. Zokinvy works to (i) reduce the risk of mortality in HGPS, and (ii) treat processing-deficient PL with either heterozygous LMNA mutation with progerin-like protein accumulation, or homozygous or compound heterozygous ZMPSTE24 mutations. Zokinvy was approved by the FDA in November 2020 and launched commercially in the U.S. in January 2021. In July 2022, our MAA for Zokinvy was approved by the EC, under the exceptional circumstances procedure. The MA is subject to the EMA's continued review on an annual basis of new efficacy and safety information which may become available. Our ability to generate substantial revenue and achieve profitability depends on our ability to (i) obtain the regulatory and marketing approvals necessary to commercialize Zokinvy in foreign jurisdictions, alone or with strategic collaboration partners, and (ii) to successfully complete the development of, and obtain the regulatory and marketing approvals necessary to commercialize, more of our product candidates in the U.S. or foreign jurisdictions. We do not anticipate generating significant product revenue for the foreseeable future. Our ability to generate future product revenue depends heavily on our success in many areas, including, but not limited to:

- completing research and development of our product candidates;
- obtaining additional and maintaining current regulatory and marketing approvals for our product candidates;

- manufacturing product candidates and establishing and maintaining supply and manufacturing relationships with third parties that meet regulatory requirements and our supply needs in sufficient quantities to meet market demand for our product candidates, if approved;
- marketing, launching and commercializing product candidates for which we obtain regulatory and marketing approval, either directly or with a collaborator or distributor;
- gaining market acceptance of our product candidates as treatment options;
- addressing any competing products;
- protecting and enforcing our intellectual property rights, including patents, trade secrets, and know-how;
- negotiating favorable terms in and maintaining any collaboration, licensing, or other arrangements into which we may enter;
- obtaining reimbursement or pricing for our product candidates that supports profitability; and
- attracting, hiring, and retaining qualified personnel.

Even if we obtain additional product approvals for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. Our current pipeline of product candidates has been in-licensed from third parties and we will have to develop or acquire manufacturing capabilities in order to continue development and potential commercialization of our product candidates. Additionally, if we are not able to generate sufficient revenue from the sale of any approved products, we may never become profitable.

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

To the extent that we raise additional capital through the sale of equity, including pursuant to the 2022 ATM Facility, debt or other securities convertible into equity, stockholder ownership interest will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect your rights as a common stockholder such as the Loan and Security Agreement we entered into with Innovatus Life Sciences Lending Fund I, LP (Innovatus) in June 2022 (the Innovatus Loan). The Innovatus Loan was a $75.0 million debt financing arrangement with Innovatus wherein we borrowed the first tranche of $40.0 million upon closing of the debt financing in June 2022. The Innovatus Loan is secured by perfected first priority liens on our assets. The Innovatus Loan includes customary events of default, including failure to pay amounts due, breaches of covenants and warranties, material adverse change events, certain cross defaults and judgments, and insolvency.

If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates or future revenue streams or grant licenses on terms that are not favorable to us. In addition, while we are seeking strategic partners for our virology assets, lonafarnib and peginterferon lambda, we may not be able to identify strategic partners, or enter into agreements on terms favorable to us, or at all. In addition, such transactions may require consents from third parties, which we may be unable to obtain. Further, our ability to raise additional capital may be adversely impacted by worsening global economic conditions and continuing disruptions to and volatility in the credit and financial markets in the U.S. and worldwide, including as a result of COVID-19. We cannot assure you that we will be able to obtain additional funding if and when necessary to fund our entire portfolio of product candidates to meet our projected plans. If we are unable to obtain funding on a timely basis, we may be required to delay or discontinue one or more of our development programs or the commercialization of any product candidates or be unable to expand our operations or otherwise capitalize on potential business opportunities, which could materially affect our business, financial condition, and results of operations.

Covenants in the Innovatus Loan restrict our business and operations in many ways, and if we do not effectively comply with our covenants, our financial conditions and results of operations could be adversely affected.

The Innovatus Loan provides for up to $75.0 million in term loans due on August 31, 2027, of which $40.7 million in principal is outstanding as of September 30, 2023. All of our current and future assets, secure our borrowings under the Innovatus Loan. The Innovatus Loan requires that we comply with certain covenants applicable to us, including among other things, covenants restricting dispositions, changes in business, management, ownership or business locations, mergers or acquisitions, indebtedness, encumbrances, distributions, investments, transactions with affiliates and subordinated debt, any of which could restrict our business and operations, particularly our ability to respond to changes in our business or to take specified actions to take advantage of certain business opportunities that may be presented to us.

Our failure to comply with any of the covenants could result in a default under the Innovatus Loan, which could permit the lenders to declare all or part of any outstanding borrowings to be immediately due and payable. If we are unable to repay those amounts, the lenders under the Innovatus Loan could proceed against the collateral granted to them to secure that debt, and our inability to use or dispose of those assets would seriously harm our business. In addition, should we be unable to comply with these covenants or if we default on any portion of our outstanding borrowings, the lenders can also impose a 5.0% penalty, restrict access to additional borrowings under the loan and security agreement, and accelerate the maturity of the debt. Any default under the Innovatus Loan would materially affect our liquidity and ability to fund our operations and complete our planned clinical trials and regulatory filings would be substantially impaired.

Risks Related to the Development of our Product Candidates

We are dependent on the success of our product candidates, which are in various stages of clinical development. Certain of our product candidates have produced results in academic settings to date or for other indications than those that we contemplate, and we cannot give any assurance that we will generate data for any of our product candidates sufficient to receive regulatory approval in our planned indications, which will be required before they can be commercialized.

To date, we have invested substantially all of our efforts and financial resources to identify, acquire, and develop our portfolio of product candidates. Our future success is dependent on our ability to further develop, obtain regulatory approvals for, and commercialize one or more of these product candidates. Our NDA for Zokinvy to reduce the risk of mortality in HGPS, and for treatment of processing-deficient progeroid laminopathies (PL) with either heterozygous LMNA mutation with progerin-like protein accumulation, or homozygous or compound heterozygous ZMPSTE24 mutations, was approved in November 2020. Prior to the U.S. Zokinvy commercial launch in 2021, we had not generated revenue from sales of any products and may never be able to develop or commercialize additional product candidates. In addition, we have a commitment to provide access to Zokinvy for patients with HGPS and PL with either heterozygous LMNA mutation with progerin-like protein accumulation, or homozygous or compound heterozygous ZMPSTE24 mutations, for no or minimal cost to those patients.

With respect to potential commercial products, we currently have one product candidate, avexitide, that has completed Phase 2 for PBH and HI. Phase 3 study start-up activities for avexitide in PBH have been initiated. It may be years before our studies are completed, and new studies are initiated, if at all.

We provide our geographically diverse clinical sites with good clinical practice protocols. We review and monitor the execution of our protocols at our various sites in an effort to understand those protocols are being followed. There can be no assurance that the data we develop for our product candidates in our planned indications will be sufficient or complete enough to obtain regulatory approval. Likewise, there can be no assurance that the data obtained from foreign clinical trial sites in studies not conducted under an investigational new drug, or IND, application will be accepted in support of an application for regulatory approval or authorization for use in the U.S. Similarly, data obtained from foreign clinical trial sites may not be accepted by other foreign regulatory authorities in support of an application for regulatory approval or authorization for use in these jurisdictions.We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our current product candidates. We cannot be certain that any of our product candidates will be successful in clinical studies or receive regulatory approval. Further, our product candidates may not receive regulatory approval even if they are successful in clinical studies. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations.

We may not be able to obtain FDA approval of any future NDA or BLA for our product candidates.

The clinical development, manufacturing, labeling, packaging, storage, recordkeeping, advertising, promotion, export, import, marketing and distribution and other possible activities relating to lonafarnib, avexitide and any other product candidate that we may develop in the future are subject to extensive regulation in the United States. Prior to the approval of our NDA for Zokinvy to reduce the risk of mortality in HGPS, and for treatment of PL with either heterozygous LMNA mutation with progerin-like protein accumulation, or homozygous or compound heterozygous ZMPSTE24 mutations, we had not submitted an application for approval or obtained FDA approval for any product.

Approval of an NDA or a BLA is not guaranteed, and the approval process is an expensive and uncertain process that may take several years. The FDA and foreign regulatory entities also have substantial discretion in the approval process. The number and types of preclinical studies and clinical trials that will be required for approval varies depending on the product candidate, the disease or the condition that the product candidate is designed to target and the regulations applicable to any particular product candidate. Data are subject to varying interpretation and the FDA may not agree that our clinical data

support that any of our product candidates are safe and effective for the proposed therapeutic use. Despite the time and expense associated with preclinical studies and clinical trials, failure can occur at any stage, and we could encounter problems that require us to repeat or perform additional preclinical studies or clinical trials or generate additional chemistry, manufacturing and controls data, including product stability data. In previous studies, ECG abnormalities were observed in our lonafarnib program. In addition, our Phase 3 *LIMT-2* study of peginterferon lambda in patients with chronic HDV was terminated due to observations of hepatobiliary events that resulted in liver decompensation. The decision was based on the recommendation of the study's Data Safety Monitoring Board and FDA following a safety review. The FDA and similar foreign authorities could delay, limit or deny approval of a product candidate, and may ultimately approve the product for narrower indications or with unfavorable labeling that would impede our commercialization of the product.

Approval procedures vary among countries and can involve additional product testing and additional administrative review periods, including obtaining reimbursement and pricing approval in select markets. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks associated with FDA approval as well as additional, presently unanticipated, risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others, including the risk that our product candidates may not be approved for all indications requested and that such approval may be subject to limitations on the indicated uses for which the product may be marketed.

Our business strategy is based upon obtaining and maintaining Orphan Drug designation for our products candidates, which is an uncertain process. The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming, and inherently unpredictable. If we are unable to obtain or maintain Orphan Drug designation or regulatory approval for our product candidates, our business would be substantially harmed.

Our approach to identifying and developing product candidates depends, in large part, on our ability to obtain and maintain Orphan Drug designation from regulatory authorities in major markets. Without the potential protection of this regulatory exclusivity upon approval, many of our product candidates would otherwise not justify investment. While we assess the potential for obtaining Orphan Drug designation at the time that we contemplate the acquisition of product candidates and we intend to timely file for such designation, there can be no assurance that we will obtain Orphan Drug designation or be able to successfully meet the regulatory requirements to maintain that designation with the planned clinical trials for our product candidates. Failure to obtain and maintain Orphan Drug designation would make our product candidates significantly less competitive and potentially not viable investments for further development. Although we currently have Orphan Drug designation for some of our product candidates in multiple targeted indications, failure to demonstrate significant benefit over existing approved products in pivotal clinical trials may lead to marketing approval but without qualifying for Orphan Drug protection in some regions, such as in Europe.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable, typically takes many years following the commencement of clinical studies and depends upon numerous factors. 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 clinical development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application. We have obtained U.S. and EMA regulatory approval for one product, Zokinvy, and it is possible that none of our current product candidates or any future product candidates we may seek to develop will ever obtain regulatory approval.

Future applications for our product candidates could fail to receive regulatory approval for many reasons, including but not limited to the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design, size or implementation of our clinical studies;
- the population studied in the clinical program may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from our development efforts;
- the data collected from clinical studies of our product candidates may not be sufficient or complete or meet the regulatory requirements to support the submission of an NDA, BLA, or other submission or to obtain regulatory approval in the United States or foreign jurisdictions;

- the FDA or comparable foreign regulatory authorities may find failures in our manufacturing processes, validation procedures and specifications, or facilities of our third-party manufacturers with which we contract for clinical and commercial supplies that may delay or limit our ability to obtain regulatory approval for our product candidates; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our NDA, BLA or other submission insufficient for approval.

The lengthy and uncertain regulatory approval process, as well as the unpredictability of the results of clinical studies, may result in our failing to obtain additional regulatory approval to market any of our product candidates or to be significantly delayed from our expectations for potential approval, which would significantly harm our business, results of operations, and prospects. In addition, although we have obtained Orphan Drug designation for five of our development programs to date, there can be no assurance that the FDA or comparable foreign regulatory authorities will grant our similar status for our other proposed development indications or other product candidates in the future.

Although the FDA has granted Rare Pediatric Disease designation to avexitide for the treatment of congenital hyperinsulinism, NDA approval for this program may not meet the eligibility criteria for a priority review voucher.

Our avexitide compound has received Rare Pediatric Disease (RPD) designation from the FDA for the treatment of congenital hyperinsulinism (HI). The FDA defines a “rare pediatric disease” as a serious or life-threatening disease in which the serious or life-threatening manifestations primarily affect patients under the age of 18 years, that is, a disease or condition that affects fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 in the United States when there is no reasonable expectation that the cost of developing and making available the product in the United States will be recovered from sales in the United States for that drug or biological product. Specifically, under this program, a sponsor who receives an approval for a drug or biologic for a “rare pediatric disease” may qualify for a voucher that can be redeemed to receive a priority review of a subsequent marketing application for a different product. The sponsor of a rare pediatric disease product receiving a priority review voucher may transfer (including by sale) the voucher to another sponsor. The voucher may be further transferred any number of times before the voucher is used, as long as the sponsor making the transfer has not yet submitted the application. The FDA may also revoke any priority review voucher if the rare pediatric disease product for which the voucher was awarded is not marketed in the U.S. for at least 12 months following the date of approval. In addition, the priority review voucher is only awarded to an NCE, thus if a compound is approved first for an indication that is not a rare pediatric disease the compound may not be eligible to receive the voucher. While we obtained and sold the priority review voucher issued upon approval of Zokinvy to reduce the risk of mortality in HGPS, and for treatment of PL with either heterozygous LMNA mutation with progerin-like protein accumulation, or homozygous or compound heterozygous ZMPSTE24 mutations, there can be no assurance that we will be successful in obtaining approval for avexitide for the treatment of HI, or that a priority review voucher will be issued at the time of any such approval.

Congress has only authorized the Rare Pediatric Disease Priority Review Voucher Program until September 30, 2024. However, if a product candidate receives RPD designation before September 30, 2024, it is eligible to receive a voucher if it is approved before September 30, 2026. Avexitide may not be approved by that date, or at all, and, therefore, we may not be in a position to obtain a priority review voucher prior to expiration of the program, unless Congress further reauthorizes the program.

There is no assurance we will receive a rare pediatric disease priority review voucher. Also, although priority review vouchers may be sold or transferred to third parties, there is no guarantee that we will be able to realize any value if we were to sell a priority review voucher.

Although we have received Breakthrough Therapy designations, this may not lead to a faster development, regulatory review or approval process, and it does not increase the likelihood of receiving marketing approval in the United States.

We have received Breakthrough Therapy designation for avexitide for the treatment of PBH and HI. A Breakthrough Therapy is defined as a therapy that is intended, alone or in combination with one or more other therapies, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the therapy may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For therapies that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Therapies designated as breakthrough therapies by the FDA may also be eligible for priority review and accelerated approval.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. The Breakthrough Therapy designations we have obtained may not result in faster development processes, reviews or approvals compared to therapies considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, the FDA may later decide that any of our development programs no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the product no longer meets the conditions for qualification. Thus, even though we intend to seek Breakthrough Therapy designation for some or all of our future product candidates for the treatment of various conditions, there can be no assurance that we will receive any such Breakthrough Therapy designation.

We may submit an application for our product candidates under the Accelerated Approval Pathway. If we are unable to obtain approval or licensure of our product candidates through the Accelerated Approval Program in the United States, we may be required to conduct additional nonclinical and clinical studies and trials beyond those that we currently contemplate, which could increase the expense of obtaining, reduce the likelihood of obtaining and/or delay the timing of obtaining, necessary marketing approval. Even if we receive approval from the FDA through the Accelerated Approval Program, if any required confirmatory post-marketing trial does not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA may seek to withdraw the approval.

We may submit an NDA or BLA for our product candidates under the Accelerated Approval Pathway. If we are unable to obtain approval of our product candidates through the Accelerated Approval Program in the United States, we may be required to conduct additional nonclinical and clinical studies and trials beyond those that we currently contemplate, which could increase the expense of obtaining, reduce the likelihood of obtaining and/or delay the timing of obtaining, necessary marketing approval. Even if we receive approval from the FDA through the Accelerated Approval Program, if any required confirmatory post-marketing trial does not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA may seek to withdraw the approval.

For any approval to market a product, we must provide the FDA and foreign regulatory agencies with clinical data that adequately demonstrate the safety, efficacy, purity and/or potency of the product for the indication applied for in the NDA, BLA, or other respective regulatory filings. The Accelerated Approval Program is one of several approaches used by the FDA to make prescription drugs and biologics more rapidly available for the treatment of serious or life-threatening diseases. Section 506(c) of the Federal Food, Drug and Cosmetic Act (FDCA) provides that the FDA may grant accelerated approval to "a product for a serious or life-threatening condition upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments." Approval through the Accelerated Approval Program is typically subject, however, to the requirement that the applicant conduct additional post-marketing clinical trials to verify and describe the product's clinical benefit. Typically, clinical benefit is verified when post-marketing clinical trials show that the product provides a clinically meaningful positive therapeutic effect, that is, an effect on how a patient feels, functions, or survives. The FDA may require that these studies be underway prior to Accelerated Approval pursuant to the Food and Drug Omnibus Reform Act of 2022 (FDORA). If such confirmatory post-marketing trial fails to confirm the product's clinical profile or risks and benefits, the FDA may withdraw its approval of the product. The FDA has broad discretion with regard to approval through the Accelerated Approval Program, and even if we believe that the Accelerated Approval Program is appropriate for our product candidates, we cannot assure you that the FDA will ultimately agree. The FDA may also change its policies with respect over Accelerated Approval over time. For example, in March 2023, the FDA announced the availability of draft guidance on "Clinical Trial Considerations to Support Accelerated Approval of Oncology Therapeutics," in which the agency outlined, and invited public comment on, its "preferred approach" of randomized controlled trials, including those that provide for longer term follow-up that could fulfill a post-marketing requirement to verify clinical benefit. In that draft guidance, the FDA acknowledged that historically, single-arm trial designs and response endpoints have most commonly been used in oncology, but noted that such trials have limitations. Furthermore, even if we do obtain approval through the Accelerated Approval Program, we may not experience a faster development process, review or approval compared to conventional FDA procedures.

Our lonafarnib-based regimens for the treatment of HDV has completed Phase 3 studies with endpoints intended to support accelerated approval. The primary endpoint for the D-LIVR study, the Phase 3 study of lonafarnib-based regimens, is a composite of a > 2 log reduction in HDV RNA and ALT normalization at end of 48 weeks of treatment and is intended to support accelerated approval. The study endpoints were previously achieved in Phase 2 studies and are consistent with

FDA guidance on the development of treatments for HDV. While these proposed endpoints are designed to be consistent with FDA guidance, there is no assurance that approval will be granted on a timely basis, or at all. FDA may disagree that the design of, or results from, our studies support accelerated approval. Additionally, the FDA could require us to conduct further studies or trials prior to granting approval of any type, including by determining that approval through the Accelerated Approval Program is not appropriate and that our clinical trials may not be used to support approval through the conventional pathway. We might not be able to fulfill the FDA's requirements in a timely manner, which would cause delays, or approval might not be granted because our submission is deemed incomplete by the FDA. There also can be no assurance that after subsequent FDA feedback we will continue to pursue approval through the Accelerated Approval Program. A failure to obtain approval through the Accelerated Approval Program could result in a longer time period to obtain approval of our product candidates, could increase the cost of their development, could delay our ability to commercialize our products and could significantly harm our financial position and competitive position in the marketplace.

Even if we receive approval for one or more of our product candidates through the Accelerated Approval Program, we will be subject to rigorous post-marketing requirements, possibly including the completion of one or more confirmatory post-marketing trials as the FDA may require, to verify the clinical benefit of the product, and submission to the FDA of all promotional materials prior to their dissemination. The FDA could seek to withdraw the approval for multiple reasons, including if we fail to conduct any required confirmatory post-marketing trial with due diligence, our confirmatory post-marketing trial does not confirm the predicted clinical benefit, other evidence shows that the product is not safe or effective under the conditions of use, or we disseminate promotional materials that are found by the FDA to be false and misleading.

Moreover, Congress has recently enacted potential changes to the Accelerated Approval Program that could impact our ability to obtain an Accelerated Approval, or increase the burdens associated with post marketing requirements in the event we do obtain an Accelerated Approval. In particular, FDA must specify certain conditions for required post approval studies for products that receive Accelerated Approval, which may include enrollment targets and milestones, including the target date for study completion, by the time the product is approved. FDA may also require post approval studies to be underway at the time of Accelerated Approval or within a specified time period following Accelerated Approval for such products.

Any delay in obtaining, or inability to obtain, approval through the Accelerated Approval Program, or any issues in maintaining approval granted under the Accelerated Approval Program, would delay or prevent commercialization of our products, and would materially adversely affect our business, financial condition, results of operations, cash flows and prospects

Product development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies may not be predictive of future study results.

Clinical testing is expensive and generally takes many years to complete, and the outcome is inherently uncertain. Failure can occur at any time during the clinical study process. The results of preclinical studies and early clinical studies of our product candidates may not be predictive of the results of larger, later-stage controlled clinical studies. Product candidates that have shown promising results in early-stage clinical studies may still suffer significant setbacks in subsequent clinical studies. Our clinical studies to date have been conducted on a small number of patients in limited numbers of clinical sites and in academic settings or for other indications. We will have to conduct larger, well-controlled studies in our proposed indications to verify the results obtained to date and to support any regulatory submissions for further clinical development. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical studies due to lack of efficacy or adverse safety profiles despite promising results in earlier, smaller clinical studies. Moreover, clinical data are often susceptible to varying interpretations and analyses. We do not know whether any Phase 2, Phase 3, or other clinical studies we have conducted or may conduct will demonstrate consistent or adequate safety, efficacy, purity and/or potency with respect to the proposed indication for use sufficient to obtain regulatory approval to receive regulatory approval or market our product candidates. For example, in September 2023, we announced our decision to discontinue the Phase 3 *LIMT-2* study of peginterferon lambda in patients with chronic HDV. The decision was based on the recommendation of the Data Safety Monitoring Board (DSMB) for the study following its quarterly safety review. In a communication dated September 7, 2023, the DSMB recommended, and FDA agreed, to the discontinuation of the *LIMT-2* study due to observations of four patients with hepatobiliary events that resulted in liver decompensation.

We may find it difficult to enroll patients in our clinical studies given the limited number of patients who have the diseases for which our product candidates are being studied. Difficulty in enrolling patients could delay or prevent clinical studies of our product candidates.

Identifying and qualifying patients to participate in clinical studies of our product candidates is essential to our success. The timing of our clinical studies depends in part on the rate at which we can recruit patients to participate in clinical trials of our product candidates, and we may experience delays in our clinical studies if we encounter difficulties in enrollment.

The eligibility criteria of our planned clinical studies may further limit the available eligible study participants as we expect to require that patients have specific characteristics that we can measure or meet the criteria to assure their conditions are appropriate for inclusion in our clinical studies. We may not be able to identify, recruit, and enroll a sufficient number of patients to complete our clinical studies in a timely manner because of the perceived risks and benefits of the product candidate under study, the availability and efficacy of competing therapies and clinical studies, and the willingness of physicians to participate in our planned clinical studies. For example, early in the COVID-19 pandemic, certain clinical study sites that were scheduled to open were delayed in activating and other sites suspended randomization of subjects for a period of time. Future restrictions could result in delays of our clinical trials. If patients are unwilling to participate in our clinical studies for any reason, the timeline for conducting studies and obtaining regulatory approval of our product candidates may be delayed.

FDA may also modify or enhance trial requirements which may affect enrollment. In August 2023, FDA published a guidance document, Informed Consent, Guidance for IRBs, Clinical Investigators, and Sponsors, which supersedes past guidance and finalizes draft guidance on informed consent. FDA's new guidance presents evolving requirements for informed consent which may effect recruitment and retention of patients in clinical trials. Effects on recruitment and retention of patients may hinder or delay a clinical trial and could cause a significant setback to an applicable program.

If we experience delays in the completion of, or termination of, any clinical study of our product candidates, the commercial prospects of our product candidates could be harmed, and our ability to generate product revenue from any of these product candidates could be delayed or prevented. In addition, any delays in completing our clinical studies would likely increase our overall costs, impair product candidate development and jeopardize our ability to obtain regulatory approval relative to our current plans. Any of these occurrences may harm our business, financial condition, and prospects significantly.

Clinical studies are costly, time consuming and inherently risky, and we may fail to demonstrate safety, efficacy, purity and/or potency to the satisfaction of applicable regulatory authorities.

Clinical development is expensive, time consuming and involves significant risk. We cannot guarantee that any clinical studies will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical studies can occur at any stage of development. Events that may prevent successful or timely completion of clinical development include but are not limited to:

- inability to generate satisfactory preclinical, toxicology, or other in vivo or in vitro data or diagnostics to support the initiation or continuation of clinical studies necessary for product approval;
- delays in reaching agreement on acceptable terms with contract research organizations (CROs) and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical study sites;
- delays in obtaining required Institutional Review Board (IRB) approval at each clinical study site;
- failure to permit the conduct of a study by regulatory authorities, after review of an investigational new drug (IND) or equivalent foreign application or amendment;
- delays in recruiting qualified patients, or patients dropping out of, in our clinical studies;
- feasibility of continuous trial execution in countries impacted by war, geopolitical conflict and other humanitarian crises, including conflicts in the Middle East;
- failure by clinical sites or our CROs or other third parties to adhere to clinical study requirements or report complete findings;
- failure to perform the clinical studies in accordance with the FDA's good clinical practice (GCP) requirements, or applicable foreign regulatory guidelines;

- occurrence of adverse events associated with our product candidates;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- the cost of clinical studies of our product candidates;
- negative or inconclusive results from our clinical trials which may result in our deciding, or regulators requiring us, to conduct additional clinical studies or abandon development programs in other ongoing or planned indications for a product candidate; and
- delays in reaching agreement on acceptable terms with third-party manufacturers and the time for manufacture of sufficient quantities of our product candidates for use in clinical studies.

Any inability to successfully complete clinical development and obtain regulatory approval could result in additional costs to us or impair our ability to generate revenue. Clinical study delays could also shorten any periods during which our products have patent protection and may allow competitors to develop and bring products to market before we do, which could impair our ability to obtain or maintain Orphan Drug designation exclusivity and to successfully commercialize our product candidates and may harm our business and results of operations.

The COVID-19 Public Health Emergency (PHE) expired in the U.S. and, while we intend to pursue similar temporary use authorizations in non-U.S. jurisdictions, we may not be able to receive such authorizations from foreign regulatory agencies. If we do receive a similar temporary use authorization, absent a full marketing authorization for that indication, our ability to sell our products may be limited.

Various regulatory pathways are available in jurisdictions outside the United States to make products available for emergency use. For example, regulatory authorities in certain EU Member States may temporarily authorize the distribution of an unauthorized drug in response to the suspected or confirmed spread of pathogenic agents such as the virus which is causing COVID-19. Obtaining such a temporary authorization is dependent upon a number of factors, which are not under our control. If such authorizations would be granted, they would only apply for a limited period of time. We might thus no longer be authorized to distribute our product under these authorizations if that time limit expired. The regulatory authorities in the EU or in other jurisdictions outside the U.S. may grant a conditional marketing authorization for medicinal products intended for the treatment of seriously debilitating or life-threatening diseases prior to the submission of comprehensive clinical data if that treatment is of major therapeutic advantage to the patients concerned or no other authorized treatment is available. In emergency situations, such a conditional marketing authorization may also be granted for these medicinal products where comprehensive preclinical or pharmaceutical data have not been supplied. These conditional marketing authorizations are subject to specific conditions (e.g., completing on-going studies or conducting new studies) which must be fulfilled within a timeline specified in the marketing authorization. These marketing authorizations are valid for a short period of time (*e.g.*, one year) which can usually be renewed. If we would apply for such a conditional marketing authorization the regulatory authority concerned may reject our application because it considers that the benefit-risk balance of our product is not favorable or it judges it unlikely that we would be able to provide comprehensive data. If we would obtain such a conditional marketing authorization we may not be able to complete (timely) the studies which the regulatory authority imposed as a condition for the marketing authorization or the data collected in the course of these studies may indicate that our product does not have a favorable benefit-risk profile. As a result, we may not be able to continue distributing our product because the conditional marketing authorization has been revoked or not renewed, or the regulatory authority refused finally to grant a regular marketing authorization.

Regulatory authorities in the EU or other jurisdictions outside the EU may make a product available for compassionate reasons to a group of patients with a chronically or seriously debilitating disease or whose disease is considered to be life-threatening, and who cannot be treated satisfactorily with an authorized medicinal product provided that the product is subject of an application for marketing authorization or is undergoing clinical trials. If we would request a regulatory authority to make our product available to patient under these conditions the regulatory authority may reject our request if, for example, it considers that the patients concerned can be treated satisfactorily with other products that are already authorized.

Programs which make products available under the conditions mentioned above are usually authorized for a limited period of time (*e.g.*, one year). Regulatory authorities may not renew expiring authorizations for these programs if we terminate prematurely a clinical trial with our product or decide not to submit or to withdraw an application for marketing authorization in the jurisdiction concerned. That may, for example, happen because pharmacovigilance data or other data collected during our clinical trials indicate that our product does not have the appropriate benefit-risk balance.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

Our avexitide product candidate has been studied in over 70 PBH patients and 39 HI patients, and the most common adverse events are injection site bruising/reaction, headache, diarrhea, nausea and dizziness. There is no guarantee that additional or more severe side effects will not be identified through other clinical studies of avexitide.

Our lonafarnib product candidate has been studied in thousands of oncology patients, and the most common non-hematologic adverse events of any grade were gastrointestinal system disorders (nausea, anorexia, diarrhea and vomiting), weight loss, fatigue and rash. Use of Zokinvy to reduce the risk of mortality in HGPS, and for treatment of processing-deficient progeroid laminopathies with either heterozygous LMNA mutation with progerin-like protein accumulation, or homozygous or compound heterozygous ZMPSTE24 mutations, has been reported to cause ECG abnormalities, but these ECG abnormalities have not resulted in a risk of mortality for these patients. There is no guarantee that additional or more severe side effects or other properties will not be identified through other clinical studies of lonafarnib.

For example, in September 2023, we announced our decision to discontinue the Phase 3 *LIMT-2* study of peginterferon lambda in patients with HDV. The decision was based on the recommendation of the Data Safety Monitoring Board (DSMB) for the study following its quarterly safety review. In a communication dated September 7, 2023, the DSMB recommended, and FDA agreed, to the discontinuation of the *LIMT-2* study due to observations of four patients with hepatobiliary events that resulted in liver decompensation. There is no guarantee that additional or more severe side effects will not be identified through future clinical studies for other uses of peginterferon lambda. Undesirable side effects, other properties, and negative results for other indications may negatively impact the development and potential for approval of our product candidates for our proposed indications.

Additionally, even if one or more of our current product candidates receives marketing approval, and we or others later may identify undesirable side effects caused by such products, potentially significant negative consequences could result, including but not limited to:

- regulatory authorities may withdraw approvals of such products;
- regulatory authorities may require additional warnings on the label;
- we may be required to create a Risk Evaluation and Mitigation Strategy (REMS) plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers, and/or other elements to assure safe use;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of a product candidate, even if approved, and could significantly harm our business, results of operations, and prospects.

We are subject to ongoing regulatory requirements related to the U.S. and EU approvals of Zokinvy, and if we obtain additional regulatory approvals for a product candidate, we will be subject to additional ongoing regulatory requirements.

If our product candidates are approved, they will be subject to ongoing regulatory requirements with respect to manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies, and submission of safety, efficacy and other post-approval information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities.

Manufacturers and manufacturers' facilities are required to continuously comply with FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to current Good Manufacturing Practices (cGMP) regulations and corresponding foreign regulatory manufacturing requirements. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any NDA, BLA, or MAA.

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product candidate may be marketed or to the conditions of approval, or contain requirements

for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety, efficacy, purity and/or potency of the product candidate. We will be required to report certain adverse reactions and production problems, if any, to the FDA and comparable foreign regulatory authorities.

Any new legislation addressing product safety issues could result in delays in product development or commercialization, or increased costs to assure compliance. If our original marketing approval for a product candidate was obtained through an accelerated approval pathway, we could be required to conduct a successful post-marketing clinical study to confirm the clinical benefit for our products. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of marketing approval.

If a regulatory agency discovers 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, or disagrees with the promotion, marketing, or labeling of a product, the regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

- issue warning letters;
- impose civil or criminal penalties;
- suspend or withdraw regulatory approval;
- suspend any of our ongoing clinical studies;
- refuse to approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our contract manufacturers' facilities; or
- require a product recall.

In addition, prescription drugs and biologics may be promoted only for the approved indications in accordance with the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label may be subject to significant liability. However, physicians may, in their independent medical judgment, prescribe legally available products for off-label uses. The FDA does not regulate the behavior of physicians in their choice of treatments, but the FDA does restrict manufacturer's communications on the subject of off-label use of their products.

Any government investigation of alleged violations of law would be expected to require us to expend significant time and resources in response and could generate adverse publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to develop and commercialize our products and the value of us and our operating results would be adversely affected.

We rely on third parties to conduct our clinical studies, manufacture our product candidates and perform other services. 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 have relied upon and plan to continue to rely upon investigators and third-party CROs to conduct, monitor and manage our ongoing clinical programs. We rely on these parties for execution of clinical studies and manage and control only certain aspects of their activities. We remain responsible for ensuring that each of our studies 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, our investigators, and our CROs and other vendors are required to comply with all applicable laws, regulations and guidelines, including those required by the FDA and comparable foreign regulatory authorities for all of our product candidates in clinical development. If we or any of our investigators, CROs or vendors fail to comply with applicable laws, regulations and guidelines, the results generated in our clinical studies may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional studies before approving our marketing applications. We cannot assure you that our CROs and other vendors will meet these requirements, or that upon inspection by any regulatory authority, such regulatory authority will determine that efforts, including any of our clinical studies, comply with applicable requirements. Our failure to comply with these laws, regulations and guidelines may require us to repeat clinical studies or conduct larger additional studies, which would be costly and delay the regulatory approval process.

If any of our relationships with investigators or third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs in a timely manner or do so on commercially reasonable terms. In addition, our CROs may not prioritize our clinical studies relative to those of other customers and any turnover in personnel or delays in the allocation of CRO employees by the CRO may negatively affect our clinical studies. If investigators or CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, our clinical studies may be delayed or terminated, and we may not be able to meet our current plans with respect to our product candidates. CROs may also involve higher costs than anticipated, which could negatively affect our financial condition and operations. In addition, we do not currently have, nor do we plan to establish, the capability to manufacture product candidates for use in the conduct of our clinical studies or in support of our commercialization of potential products, and we lack the resources and the capability to manufacture any of our product candidates on a clinical or commercial scale without the use of third-party manufacturers. We plan to rely on third-party manufacturers and their responsibilities will include purchasing from third-party suppliers the materials necessary to produce our product candidates for our clinical studies and regulatory approval. There are expected to be a limited number of suppliers for the active ingredients and other materials that we expect to use to manufacture our product candidates, and we may not be able to identify alternative suppliers to prevent a possible disruption of the manufacture of our product candidates for our clinical studies, and, if approved, ultimately for commercial sale. Although we generally do not expect to begin a clinical study unless we believe we have a sufficient supply of a product candidate to complete the study, any significant delay or discontinuity in the supply of a product candidate, or the active ingredient or other material components in the manufacture of the product candidate, could delay completion of our clinical studies and potential timing for regulatory approval of our product candidates, which would harm our business and results of operations. For example, in connection with Phase 3 start-up activities for avexitide, we observed low levels of product-related impurities in the finished drug product. Although not unusual for this class of compounds, we are working with our CMOs to control these impurities to a level agreed by FDA, and to ensure that an adequate supply of materials with a sufficient shelf-life can be released for Phase 3 studies. In the longer term, the impurities will be fully tox qualified to a higher level, and the product specifications will be updated to allow for a suitable commercial shelf-life.

With respect to our lonafarnib program, we procured an inventory of product from Merck to supply our initial clinical study needs. In 2016, we transferred the manufacturing of drug substance and drug product to our third-party contractors. The material used for ongoing progeria clinical studies, expanded access program, and commercial Zokinvy supply are sourced from CMOs. These same vendors are currently under development for commercial qualification. Materials used for our avexitide clinical trials are also sourced from CMOs. Our vendors have successfully made GMP batches for our clinical studies, however, our trials could be delayed if quality, stability, or other issues occur in relation to the manufacture of any unique batch. If these CMOs are not able to provide us with sufficient quantities of product for our clinical trials or in support of our commercialization of potential products on a timely basis, or at all, whether due to production shortages or other supply interruptions resulting from any delay, our clinical trials or regulatory approval may be delayed, or could impair our ability to generate revenue from the sale of such product candidate.

We rely and expect to continue to rely on third parties to manufacture our clinical product supplies, and if those third parties fail to obtain approval of government regulators, fail to provide us with sufficient quantities of product, or fail to do so at acceptable quality levels or prices our product candidates could be stopped, delayed, or made less profitable.

We do not currently have nor do we plan to acquire the infrastructure or capability internally to manufacture our clinical supplies for use in the conduct of our clinical trials, and we lack the resources and the capability to manufacture any of our product candidates on a clinical or commercial scale. We currently rely on outside vendors to source raw materials and manufacture our clinical supplies of our product candidates and plan to continue relying on third parties to manufacture our product candidates on a commercial scale, if approved.

The facilities used by our contract manufacturers to manufacture our product candidates will be subject to pre-approval inspection by the FDA that will be conducted after we submit our marketing applications to the FDA or comparable foreign regulatory authorities. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements, known as cGMPs, for manufacture of our product candidates. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, EMA or others, our future applications may not be approved by regulatory authorities, which would significantly delay our commercialization plans and increase our costs. We have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel, and in the past, we have experienced quality control issues with product manufactured by our contract manufacturers. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities,

which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

We do not yet have sufficient information to reliably estimate the cost of the commercial manufacturing of our product candidates, and the actual cost to manufacture our product candidates could materially and adversely affect the commercial viability of our product candidates. As a result, we may not be able to develop additional commercially viable products.

In addition, our reliance on third-party manufacturers exposes us to the following additional risks:

- We may be unable to identify manufacturers on acceptable terms or at all;
- Our third-party manufacturers might be unable to timely formulate and manufacture our product or produce the quantity and quality required to meet our clinical and commercial needs, if any;
- Contract manufacturers may not be able to execute our manufacturing procedures appropriately;
- Our future contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products;
- Manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMP and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards;
- We may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our product candidates; and
- Our third-party manufacturers could breach or terminate their agreement with us.

Each of these risks could delay our clinical trials, the approval of any of our product candidates by the FDA or comparable foreign regulatory authorities or the commercialization of our product candidates or result in higher costs or deprive us of potential product revenue. In addition, we rely on third parties to perform release testing on our product candidates prior to delivery to patients. If these tests are not conducted appropriately and test data is not reliable, patients could be put at risk of serious harm and could result in product liability suits.

The manufacturing of medical products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of biologic products often encounter difficulties in production, particularly in scaling up and validating initial production and absence of contamination. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, operator error, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Furthermore, if contaminants are discovered in our supply of our product candidates or in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot assure you that any stability or other issues relating to the manufacture of our product candidates will not occur in the future. Additionally, our manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to provide our product candidates to patients in clinical trials would be jeopardized. Any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely.

If the market opportunities for our product candidates are smaller than we believe they are, we may not meet our revenue expectations and, even assuming approval of a product candidate, our business may suffer. Because the patient populations in the market for our product candidates may be small, we must be able to successfully identify patients and acquire a significant market share to achieve profitability and growth.

We focus our product development principally on treatments for rare and ultra-rare diseases. Given the small number of patients who have the diseases that we are targeting, our eligible patient population and pricing estimates may differ significantly from the actual market addressable by our product candidate. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a

variety of sources, including the scientific literature, patient foundations, or market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. The number of patients may turn out to be lower than expected. For example, although we believe that data associated with avexitide are supportive of activity in PBH, there can be no assurance that our clinical trials will successfully address this condition. Likewise, the potentially addressable patient population for each of our product candidates may be limited or may not be amenable to treatment with our product candidates, and new patients may become increasingly difficult to identify or gain access to, which would adversely affect our results of operations and our business. Moreover, we expect that the sales of Zokinvy to patients with progeria will have limited profits given the ultra-rare nature of these diseases.

We face intense competition and rapid technological change and the possibility that our competitors may develop therapies that are similar, more advanced, or more effective than ours, which may adversely affect our financial condition and our ability to successfully commercialize our product candidates.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. We are currently aware of various existing therapies that may compete with our product candidates. For example, we have competitors both in the United States and internationally, including multinational pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies. Some of the pharmaceutical and biotechnology companies we expect to compete with include Recordati, MBX Bioscience, Vogenx, Zealand Pharmaceuticals, Rezolute, Hanmi Pharmaceutical, and Crinetics Pharmaceuticals as well as other smaller companies or biotechnology start-ups and large multinational pharmaceutical companies. Many of our competitors have substantially greater financial, technical, and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations. Additional mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. As a result, these companies may obtain regulatory approval more rapidly than we are able to and may be more effective in selling and marketing their products as well. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring, or licensing on an exclusive basis, products that are more effective or less costly than any product candidate that we may develop, or achieve earlier patent protection, regulatory approval, product commercialization, and market penetration than we do. Additionally, technologies developed by our competitors may render our potential product candidates uneconomical or obsolete, and we may not be successful in marketing our product candidates against competitors.

Although we commercially launched Zokinvy following its FDA approval, we have limited marketing and sales experience outside the U.S. If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate any revenue.

Although certain of our employees may have marketed, launched and sold other pharmaceutical products in the U.S. in the past while employed at other companies, we have limited experience selling and marketing our product candidates outside the U.S.. To successfully commercialize Zokinvy and additional products that may result from our development programs, we will need to invest in and expand these capabilities, either on our own or with others, which would be expensive, difficult and time consuming. Any failure or delay in the timely development of our internal commercialization capabilities could adversely impact the potential for success of our products.

Further, given our, limited experience in marketing and selling biopharmaceutical products outside the U.S., we may rely on future collaborators to commercialize our products. If collaborators do not commit sufficient resources to commercialize our future products and we are unable to develop the necessary marketing and sales capabilities on our own, we will be unable to generate sufficient product revenue to sustain or grow our business. We may be competing with companies that currently have extensive and well-funded marketing and sales operations, in particular in the markets our product candidates are intended to address. Without appropriate capabilities, whether directly or through third-party collaborators, we may be unable to compete successfully against these more established companies. In addition, we have established an expanded access program in order to make Zokinvy available for patients with progeria, which requires additional resources and costs to support.

The commercial success of any of our current or future product candidates will depend upon the degree of market acceptance by physicians, patients, third-party payors, and others in the medical community.

Even with the approvals from the FDA and comparable foreign regulatory authorities, the commercial success of our products will depend in part on the health care providers, patients, and third-party payors accepting our product candidates as medically useful, cost-effective, and safe. Any product that we bring to the market may not gain market acceptance by physicians, patients, third-party payors and other health care providers. The degree of market acceptance of any of our products will depend on a number of factors, including without limitation:

- the timing of our receipt of any marketing and commercialization licensures;
- the terms of any licensures and the countries in which licensures are obtained;
- the safety, efficacy, purity and/or potency of the product as demonstrated in clinical studies and potential advantages over competing treatments;
- the prevalence and severity of the disease and any side effects;
- the clinical indications for which approval is granted, including any limitations or warnings contained in a product's approved labeling;
- the convenience and ease of administration;
- the cost of treatment;
- the willingness of the patients and physicians to accept these therapies or any new methods of administration;
- the marketing, sales and distribution support for the product;
- the publicity concerning our products or competing products and treatments;
- the success of our physician education programs;
- availability of alternative effective treatments for the disease indications our product candidates are intended to treat and the relative risks, benefits and costs of those treatments; and
- the pricing and availability of third-party insurance coverage and reimbursement.

Even if a product displays a favorable safety, efficacy, purity and/or potency profile upon approval, market acceptance of the product remains uncertain. Efforts to educate the medical community and third-party payors on the benefits of the products may require significant investment and resources and may never be successful. If our products fail to achieve an adequate level of acceptance by physicians, patients, third-party payors, and other health care providers, we will not be able to generate sufficient revenue to become or remain profitable.

Failure to obtain or maintain adequate reimbursement or insurance coverage for new or current products could limit our ability to market those products and decrease our ability to generate revenue.

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

The pricing, coverage and reimbursement of our products must be sufficient to support our commercial efforts and other development programs and the availability and adequacy of coverage and reimbursement by governmental and private payors are essential for most patients to be able to afford expensive treatments, particularly in Orphan Drug designated indications where the eligible patient population is small. Sales of our products will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid for or reimbursed by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or government authorities, private health insurers, and other third-party payors. If coverage and reimbursement are not available, or are available only in limited amounts, we may have to subsidize or provide products for free or we may not be able to successfully commercialize our products. For example, Zokinvy for patients with HGPS and processing-deficient PL is provided under an expanded access program may not result in reimbursement.

In addition, there is significant uncertainty related to the insurance coverage and reimbursement for newly approved products. In the United States, the principal decisions about coverage and reimbursement for new drugs are typically made

by the Centers for Medicare & Medicaid Services (CMS), an agency within the U.S. Department of Health and Human Services (HHS), as CMS decides whether and to what extent a new drug will be covered and reimbursed under Medicare. Private payors often follow the coverage reimbursement policies established by CMS to a substantial degree. It is difficult to predict what CMS and other payors will decide with respect to coverage for products such as ours and what reimbursement our products may receive.

The process for determining whether a third-party payor will provide coverage for a drug product typically is separate from the process for setting the price of a drug product or for establishing the reimbursement rate that the payor will pay for the drug product once coverage is approved. Third-party payors may limit coverage to specific drug products on an approved list, also known as a formulary, which might not include all of the FDA-approved drugs for a particular indication. A decision by a third-party payor not to cover Zokinvy or any of our product candidates once approved could reduce utilization of such products and have a material adverse effect on our sales, results of operations and financial condition. Moreover, a third-party payor's decision to provide coverage for a drug product does not imply that adequate reimbursement will be available. Adequate third-party payor reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. Additionally, coverage and reimbursement for drug products can differ significantly from payor to payor. One third-party payor's decision to cover a particular medical product or service does not ensure that other payors will also provide coverage for the medical product or service or will provide coverage at an adequate reimbursement rate. As a result, the coverage determination process will require us to provide scientific and clinical support for the use of our products to each payor separately and will be a time-consuming process.

Third-party payors are increasingly challenging the prices charged for medical products and services, examining the medical necessity and reviewing the cost-effectiveness of drug products and medical services, in addition to questioning safety and efficacy. If third-party payors do not consider our products to be cost-effective compared to other available therapies, they may not cover our products after FDA approval or, if they do, the level of payment may not be sufficient to allow us to sell our products at a profit. Additionally, coverage policies and third-party reimbursement rates may change at any time. Therefore, even if favorable coverage and reimbursement status is attained for one or more of our products, less favorable coverage policies and reimbursement rates may be implemented in the future. If we are unable to obtain and maintain sufficient third-party coverage and adequate reimbursement, the commercial success of our products may be greatly hindered and our financial condition and results of operations may be materially and adversely affected.

Outside the United States, international operations are generally subject to extensive governmental price controls and other price-restrictive regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, Canada, and other countries has and will continue to put pressure on the pricing and usage of products. In many countries, the prices of products are subject to varying price control mechanisms as part of national health systems. Price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our products. Accordingly, in markets outside the United States, the potential revenue may be insufficient to generate commercially reasonable revenue and profits.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to limit or reduce healthcare costs may result in restrictions on coverage and the level of reimbursement for new products and, as a result, inadequate coverage or payment for our products.

In the EU, coverage and reimbursement status of our products, if approved, are provided for by the national laws of the EU Member States. In the EU, pricing and reimbursement schemes vary widely from Member State to Member State. Some Member States provide that products can only be effectively marketed after a reimbursement price has been agreed. Some Member States may require the completion of additional studies in order to compare the cost-effectiveness of a particular drug candidate to currently available therapies (so called health technology assessment, or HTA) in order to obtain reimbursement or pricing approval. EU Member States may approve a specific price for a product or it may instead adopt a system of direct or indirect controls on the profitability of the Company placing the product on the market. Other Member States may allow companies to fix their own prices for products, but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. Recently, many countries in the EU have increased the amount of discounts required on pharmaceuticals and these efforts could continue as countries attempt to manage healthcare expenditures, especially in light of the severe fiscal and debt crises experienced by many countries in the EU. The downward pressure on healthcare costs in general, particularly prescription drugs, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU Member States, and parallel trade (arbitrage between low-priced and high-priced Member States), can further reduce prices. There can be no assurance that any country that has price controls or reimbursement limitations for

drug products will allow favorable reimbursement and pricing arrangements for any of our products, if approved in those countries.

We expect to experience pricing pressures in connection with products due to increased and continued efforts to limit or reduce healthcare spending. The downward pressure on healthcare costs in general, particularly prescription drugs, has and is expected to continue to increase in the future. As a result, profitability of our products may be more difficult to achieve even if they receive regulatory approval.

We intend to rely on a combination of exclusivity from Orphan Drug designation as well as patent rights for our product candidates and any future product candidates. If we are unable to obtain or maintain exclusivity from the combination of these approaches, we may not be able to compete effectively in our markets.

Our business strategy is to focus on product candidates for which Orphan Drug designation may be obtained in the major markets of the world. In addition, we rely or will rely upon a combination of patents, trade secret protection, and confidentiality agreements to protect the intellectual property related to our technologies and product candidates. Our success depends in large part on our and our licensors' ability to obtain regulatory exclusivity and maintain patent and other intellectual property protection in the United States and in other countries with respect to our proprietary technology and products.

Under the Orphan Drug Act, the FDA may designate a product as an Orphan Drug if it is intended to treat a rare disease or condition, defined as a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the product will be recovered from sales in the United States. In the EU, the EMA's Committee for Orphan Medicinal Products (COMP) grants Orphan Drug designation to promote the development of products that are intended for the diagnosis, prevention, or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the EU. Additionally, designation is granted for products intended for the diagnosis, prevention, or treatment of a life-threatening, seriously debilitating or serious and chronic condition when, without incentives, it is unlikely that sales of the drug in the EU would be sufficient to justify the necessary investment in developing the drug or biological product or where there is no satisfactory method of diagnosis, prevention, or treatment, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition. In the United States, Orphan Drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. In addition, if a product receives the first FDA approval for the indication for which it has Orphan Drug designation, the product is entitled to Orphan Drug exclusivity, which means the FDA may not approve any other application to market the same product for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity or where the manufacturer is unable to assure sufficient product quantity.

Congress is considering updates to the Orphan Drug provisions of the FDCA in response to a recent decision by the U.S. Court of Appeals for the 11th Circuit. Any changes to the Orphan Drug provisions could change our opportunities for, or likelihood of success in obtaining, Orphan Drug exclusivity and would materially adversely affect our business, financial condition, results of operations, cash flows and prospects.

In the EU, Orphan Drug designation entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity following drug or biological product approval. This period may be reduced to six years if the Orphan Drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity.

Because the extent and scope of patent protection for our products may in some cases be limited, Orphan Drug designation is especially important for our products for which Orphan Drug designation may be available. For eligible products, we plan to rely on the exclusivity period under the Orphan Drug Act to maintain a competitive position. If we do not obtain or maintain Orphan Drug exclusivity for our drug and biological products that do not have broad patent protection, our competitors may then sell the same drug to treat the same condition sooner than if we had obtained Orphan Drug exclusivity and our revenue will be reduced.

Even though we have Orphan Drug designations for each of our development programs in the United States and the EU, we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing pharmaceutical products. Further, even if we obtain Orphan Drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different products with different active

moieties can be approved for the same condition. Even after an Orphan Drug is approved, the FDA or EMA can subsequently approve the same product with the same active moiety for the same condition if the FDA or EMA concludes that the later product is safer, more effective, or makes a major contribution to patient care. Orphan Drug designation neither shortens the development time or regulatory review time of a product candidate nor gives the product candidate any advantage in the regulatory review or approval process.

We have sought to protect our proprietary position by filing patent applications in the United States and abroad related to our product candidates that are important to our business. This process is expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain and involves complex legal and factual questions for which legal principles remain unsolved. The patent applications that we own or in-licensed may fail to result in issued patents with claims that cover our product candidates in the United States or in other foreign countries. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue, and even if such patents cover our product candidates, third parties may challenge their validity, enforceability, or scope, which may result in such patents being narrowed, found unenforceable or invalidated. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our product candidates, or prevent others from designing around our claims. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

We, independently or together with our licensors, have filed several patent applications covering various aspects of our product candidates. We cannot offer any assurances about which, if any, patents will issue, the breadth of any such patent or whether any issued patents will be found invalid and unenforceable or will be threatened by third parties. Any successful opposition to these patents or any other patents owned by or licensed to us after patent issuance could deprive us of rights necessary for the successful commercialization of any product candidates that we may develop. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced. Although we have licensed a number of patents covering methods of use and certain compositions of matter, we do not have complete patent protection for our product candidates. For example, in connection with our arbitration with The Progeria Research Foundation, Inc. (PRF) asserting two claims under a May 15, 2018 Collaboration and Supply Agreement with PRF, PRF is indirectly challenging the validity of our in-license of certain patents covering the methods of treating HGPS and progeroid laminopathies. Likewise, most of the patents or applications covering products that we have licensed in from Stanford have limited protection outside of the United States. Therefore, a competitor could develop the same or similar product that may compete with our product candidate.

Certain of our product licenses are limited to specified indications or therapeutic areas which may result in the same compound being developed and commercialized by a third party whom we have no control over or rights against. This may result in safety data, pricing or off-label uses from that third party’s product that may negatively affect the development and commercialization of our product candidates. If we cannot obtain and maintain effective protection of exclusivity from our regulatory efforts and intellectual property rights, including patent protection, for our product candidates, we may not be able to compete effectively, and our business and results of operations would be harmed.

The annual reassessment by the EMA of the risk-benefit balance, including information on the safe and effective use, for Zokinvy may not be positive, leading to a variation, suspension, revocation of our MA or fulfillment of additional specific obligations.

On July 20, 2022, we announced that the EC granted an MA under the exceptional circumstances procedure for Zokinvy to treat patients aged 12 months and older with HGPS and PL. The EC authorization follows the positive opinion granted by the Committee for Medicinal Products for Human Use (CHMP) in May 2022 which found that the risk-benefit balance for Zokinvy is favorable to recommend the granting of a MA although the rarity of the disease means that it was not possible to obtain complete information on Zokinvy during the assessment process. As a result, the MA was issued under the

exceptional circumstances procedure and subject to the EMA's continued review on an annual basis of new efficacy and safety information which may become available.

Under Article 14(8) Regulation (EC) No 726/2004, products for which the applicant can demonstrate that comprehensive data (in line with the requirements laid down in Annex I of Directive 2001/83/EC, as amended) cannot be provided (due to specific reasons foreseen in the legislation) might be eligible for marketing authorization under exceptional circumstances. This type of authorization is reviewed annually to reassess the risk-benefit balance. The fulfillment of any specific procedures/obligations imposed as part of the marketing authorization under exceptional circumstances is aimed at the provision of information on the safe and effective use of the product.

It is possible that the annual reassessment by the EMA of the risk-benefit balance including information on the safe and effective use for Zokinvy may not be positive. This could lead to the variation, suspension, revocation of our MA for Zokinvy in the EU, or lead to additional specific commitments or conditions being fulfilled.

We may not have sufficient patent term protections for our products to effectively protect our business.

Patents have a limited term. In the United States, the statutory expiration of a patent is generally 20 years after it is filed. Although various extensions may be available, the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from generic medications. In addition, upon issuance in the United States any patent term can be adjusted based on certain delays caused by the applicant(s) or the United States Patent and Trademark Office (USPTO). For example, a patent term can be reduced based on certain delays caused by the patent applicant during patent prosecution.

Patent term extensions under the Hatch-Waxman Act in the United States and under supplementary protection certificates in the EU may be available to extend the patent or data exclusivity terms of products. With respect to lonafarnib-based regimens, peginterferon lambda and avexitide, a substantial portion of the potential commercial opportunity will likely rely on patent term extensions, and we cannot provide any assurances that any such patent term extensions will be obtained and, if so, for how long. As a result, we may not be able to maintain exclusivity for our products for an extended period after regulatory approval, which would negatively impact our business and results of operations. If we do not have sufficient patent terms or regulatory exclusivity to protect our products, our business and results of operations will be adversely affected.

Patent laws and rule changes could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. We therefore cannot be certain that it or our licensors were the first to make the invention claimed in our owned and licensed patents or pending applications, or that we or our licensor were the first to file for patent protection of such inventions. Assuming the other requirements for patentability are met, in the United States prior to March 15, 2013, the first to make the claimed invention is entitled to the patent, while outside the United States, the first to file a patent application is entitled to the patent. After March 15, 2013, under the Leahy-Smith America Invents Act (the Leahy-Smith Act) enacted on September 16, 2011, the United States has moved to a first to file system. The Leahy-Smith Act also includes a number of significant changes that affect the way patent applications will be prosecuted and may also affect patent litigation. The effects of these changes are currently unclear as the USPTO must still implement various regulations, the courts have yet to address any of these provisions and the applicability of the act and new regulations on specific patents discussed herein have not been determined and would need to be reviewed. In general, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

If we are unable to maintain effective proprietary rights for our product candidates or any future product candidates, we may not be able to compete effectively in our markets.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult

to enforce and any other elements of our product candidates' discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. However, trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, scientific advisors, and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors.

Although we expect all of our employees and consultants to assign their inventions to us, and all of our employees, consultants, advisors, and any third parties who have access to our proprietary know-how, information, or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed or that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Misappropriation or unauthorized disclosure of our trade secrets could impair our competitive position and may have a material adverse effect on our business. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret.

Third-party claims of intellectual property infringement may prevent or delay our development and commercialization efforts.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There have been many lawsuits and other proceedings involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions, and reexamination proceedings before the USPTO and corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.
Third parties may assert that we are using or exploiting their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture, or methods for treatment related to the use or manufacture of our product candidates. Even if we conduct freedom to operate analyses, we would expect to do so only with respect to certain of our product candidates as they move through development. Accordingly, there may be third-party patents that would impair our ability to commercialize product candidates and we cannot assure you that we could obtain a license, or even if available, whether such license might be obtained on commercially reasonable terms. Even in those situations where we conduct a freedom to operate analysis, there can be no assurance that we would identify all relevant or necessary patents and patent applications that may apply to the manufacture and commercialization of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe, and if patents issue with respect to any such application and we become aware of such issuance, we would have to determine its impact on our efforts to develop and commercialize our product candidates and the strategy for obtaining a license or contesting any such issued patent.

If any third-party patents were held by a court of competent jurisdiction to cover aspects of our formulations, the manufacturing process of any of our product candidates, methods of use, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire or are finally determined to be invalid or unenforceable. Such a license may not be available on commercially reasonable terms, or at all.

If we fail to obtain a license, then parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys’ fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

We may not be successful in meeting our diligence obligations under our existing license agreements necessary to maintain our product candidates' licenses in effect. In addition, if required in order to commercialize our product candidates, we may be unsuccessful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in-licenses.

We currently have rights to the intellectual property, through licenses from third parties and under patents that we do not own, to develop and commercialize our product candidates. Because our programs may require the use of proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to maintain in effect these proprietary rights. For example, we have certain specified diligence obligations under our license agreement for lonafarnib. We may not be able to achieve the required diligence milestones in a timely manner, which may result in the license agreement being terminated, and we may be unable to successfully negotiate an extension or waiver of those termination rights. Any termination of license agreements with third parties with respect to our product candidates would be expected to negatively impact our business prospects.

We may be unable to acquire or in-license any compositions, methods of use, processes, or other third-party intellectual property rights from third parties that we identify as necessary for our product candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources, and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. Even if we are able to license or acquire third-party intellectual property rights that are necessary for our product candidates, there can be no assurance that they will be available on favorable terms.

We collaborate with U.S. and foreign academic institutions to identify product candidates, accelerate our research and conduct development. Typically, these institutions have provided us with an option to negotiate an exclusive license to any of the institution’s rights in the patents or other intellectual property resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue a program of interest to us.

If we are unable to successfully obtain and maintain rights to required third-party intellectual property, we may have to abandon development of that product candidate or pay additional amounts to the third party, and our business and financial condition could suffer.

Our product candidates marketed under NDAs may be subject to generic competition.

Under the Hatch-Waxman Act, a pharmaceutical manufacturer may file an abbreviated new drug application (ANDA) seeking approval of a generic copy of an approved innovator product marketed under an NDA. Generally, in place of clinical studies intended to demonstrate safety or effectiveness, an ANDA applicant usually needs only to submit data demonstrating that its product has the same active ingredient(s), strength, dosage form, route of administration and that it is bioequivalent to the branded product. Under the Hatch-Waxman Act, a manufacturer may also submit an NDA under section 505(b)(2) that references the FDA’s finding of safety and effectiveness of a previously approved drug. A 505(b)(2) NDA product may be for a new or improved version of the original innovator product.

Innovative small molecule drugs may be eligible for certain periods of regulatory exclusivity. The FDCA provides a period of five years of non-patent exclusivity for a new drug containing a new chemical entity (NCE). During the exclusivity period, the FDA may not accept for review an ANDA or a 505(b)(2) NDA submitted by another company for another version of such product candidate where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an approved NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, for new indications, dosages or strengths of an existing product candidate. This three-year exclusivity covers only the conditions associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for product candidates containing the original active agent for other conditions of use. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the nonclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Manufacturers may seek to launch these generic drugs following the expiration of the marketing exclusivity period, even if we still have patent protection for our drug. Competition that our drug candidates may face from generic versions of our drug candidates could materially and adversely impact our future revenue, profitability and cash flows and substantially limit our ability to obtain a return on the investments we have made in those drug candidates. Our future revenues, profitability and cash flows could also be materially and adversely affected and our ability to obtain a return on the investments we have made in those drug candidates may be substantially limited if our drug candidates, if and when approved, are not afforded the appropriate periods of non-patent exclusivity.

In addition to the benefits of regulatory exclusivity, an innovator NDA holder may have patents claiming the active ingredient, product formulation or an approved use of the drug, which would be listed with the product in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," known as the "Orange Book." If there are patents listed in the Orange Book, a generic applicant that seeks to market its product before expiration of the patents must include in the ANDA or 505(b)(2) what is known as a "Paragraph IV certification," challenging the validity or enforceability of, or claiming non-infringement of, the listed patent or patents. Notice of the certification must be given to the innovator, too, and if within 45 days of receiving notice the innovator sues to protect its patents, approval of the ANDA is stayed for 30 months, or as lengthened or shortened by the court.

If there are patents listed for our products in the Orange Book after approval by the FDA, ANDAs and 505(b)(2) NDAs with respect to those products would be required to include a certification as to each listed patent indicating whether the ANDA applicant does or does not intend to challenge the patent. We cannot predict whether any patents issuing from our pending patent applications will be eligible for listing in the Orange Book, how any generic competitor would address such patents, whether we would sue on any such patents, or the outcome of any such suit.

We may not be successful in securing or maintaining proprietary patent protection in the United States and/or in other countries for products and technologies we develop or license. Moreover, if any patents that are granted and listed in the Orange Book are successfully challenged by way of a Paragraph IV certification and subsequent litigation, the affected product could more immediately face generic competition and its sales would likely decline materially. Should sales decline, we may have to write off a portion or all of the intangible assets associated with the affected product and our results of operations and cash flows could be materially and adversely affected.

Our biological product candidates for which we intend to seek licensure may face competition from biosimilars.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively the ACA, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated licensure pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the licensure of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. 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 such processes intended to implement BPCIA may be fully adopted by the FDA, any such processes could have an adverse effect on the future commercial prospects for our product candidates.

There is a risk that any product candidates we may develop that are licensed as a biological product under a BLA would not qualify for the 12-year period of exclusivity or that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider any product candidates we may develop to be reference products for competing products, potentially creating the opportunity for competition sooner than anticipated. In addition, the approval of a biologic product biosimilar to one of our products 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 products. 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.

Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation, including litigation challenging the constitutionality of the ACA. For example, in December 2018, a

federal district court ruled that the ACA, without the "individual mandate" penalty (which was repealed by Congress as part of the Tax Cuts and Jobs Act), is unconstitutional in its entirety. In December 2019, the U.S. Court of Appeals for the 5th Circuit upheld the district court ruling that the individual mandate provisions are unconstitutional and remanded the case back to the district court for further analysis of whether such provisions could be severed from the remainder of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the case without specifically ruling on the constitutionality of the ACA. There may, however, be other efforts to challenge, repeal, or replace the ACA in the future. We continue to evaluate the effect that the ACA and its possible repeal and replacement has (or may have) on our business and exclusivity under the BPCIA. It is uncertain the extent to which any such changes may impact our business or financial condition.

The patent protection and patent prosecution for some of our product candidates is dependent on third parties.

While we normally seek and gain the right to fully prosecute the patents relating to our product candidates, there may be times when patents relating to our product candidates are controlled by our licensors. This is the case with our agreements with Stanford, of whom is primarily responsible for the prosecution of patents and patent applications licensed to us under the applicable collaboration agreements. If they or any of our future licensors fail to appropriately and broadly prosecute and maintain patent protection for patents covering any of our product candidates, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using, importing, and selling competing products. In addition, even where we now have the right to control patent prosecution of patents and patent applications, we have licensed from third parties, we may still be adversely affected or prejudiced by actions or inactions of our licensors in effect from actions prior to us assuming control over patent prosecution.

If we fail to comply with obligations in the agreements under which we license intellectual property and other rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

We are a party to a number of intellectual property license and supply agreements that are important to our business and expects to enter into additional license agreements in the future. Our existing agreements impose, and we expect that future license agreements will impose, various diligence, milestone payment, royalty, purchasing, supply and other obligations on us. If we fail to comply with our obligations under these agreements, or we are subject to a bankruptcy, our agreements may be subject to termination by the licensor, in which event we would not be able to develop, manufacture or market products covered by the license or subject to supply commitments.

Although we are not currently involved in any intellectual property litigation, we may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming, and unsuccessful.

Competitors may infringe our patents or the patents of our licensors. Although we are not currently involved in any intellectual property litigation, if we or one of our licensing partners were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidates is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable.

Interference proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into development partnerships that would help us bring our product candidates to market.

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. 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 our common stock.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

We employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we have written agreements and make every effort to ensure that our employees, consultants and independent contractors do not use the proprietary information or intellectual property rights of others in their work forums, and we are not currently subject to any claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties, we may in the future be subject to such claims. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

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

Filing, prosecuting, 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 can be 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 state laws in the United States. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may also export infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

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

Risks Related to our Business Operations

Our future success depends in part on our ability to attract, retain, and motivate qualified personnel.

On December 14, 2022, David Cory resigned as our President and CEO and a member of our Board, and on January 3, 2023, Sriram Ryali notified the Company of his resignation as the Company’s CFO, effective January 20, 2023, and on February 17, 2023, Erik Atkisson resigned as our General Counsel, Corporate Secretary and Chief Compliance Officer. The Company has also experienced recent turnover in its financial reporting function.

In June 2023, the Board appointed Dr. David Apelian as the Company’s CEO, and Dr. Apelian will remain a member of the Board. We are highly dependent on Dr. Apelian. On April 13, 2023, Eiger announced the appointments of William G. Kachioff as Chief Financial Officer, and James A. Vollins as General Counsel, Chief Compliance Officer and Corporate Secretary, to the Company's management team.

Recruiting and retaining other qualified employees, consultants, and advisors for our business, including scientific and technical personnel, will also be critical to our success. There is currently a shortage of highly qualified personnel in our industry, which is likely to continue. As a result, competition for personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical

and biotechnology companies for individuals with similar skill sets. In addition, failure to succeed in development and commercialization of our product candidates may make it more challenging to recruit and retain qualified personnel. The inability to recruit and retain qualified personnel, the loss of the services of Dr. Apelian or other members of our management team, or the failure to hire other qualified management personnel, may impede the progress of our research, development, and commercialization objectives and would negatively impact our ability to succeed.

Failure to comply with existing or future laws and regulations related to privacy or data security could lead to government enforcement actions (which could include civil or criminal fines or penalties), private litigation, other liabilities, and/or adverse publicity. Compliance or the failure to comply with such laws could increase the costs of our products and services, could limit their use or adoption, and could otherwise negatively affect our operating results and business.

Regulation of data processing is evolving as federal, state, and foreign governments continue to adopt new, or modify existing, laws and regulations addressing data privacy and security, and the collection, processing, storage, transfer, and use of data. We and our partners may be subject to current, new, or modified federal, state, and foreign data protection laws and regulations (e.g., laws and regulations that address data privacy and data security including, without limitation, health data). These new or proposed laws and regulations are subject to differing interpretations and may be inconsistent among jurisdictions, and guidance on implementation and compliance practices are often updated or otherwise revised, which adds to the complexity of processing personal data. These and other requirements could require us or our partners to incur additional costs to achieve compliance, limit our competitiveness, necessitate the acceptance of more onerous obligations in our contracts, restrict our ability to use, store, transfer, and process data, impact our or our partners' ability to process or use data in order to support the provision of our products or services, affect our or our partners' ability to offer our products and services in certain locations, or cause regulators to reject, limit or disrupt our clinical trial activities.

In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act) that govern the collection, use, disclosure, and protection of health-related and other personal information apply to our operations or the operations of our partners. In addition, we may receive unintended health information in error from third parties (including research institutions from which we may obtain clinical trial data) that are subject to privacy and security requirements under the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH). Depending on the facts and circumstances, we could be subject to significant penalties if we obtain, use, or disclose individually identifiable health information in a manner that is not authorized or permitted by HIPAA. On December 10, 2020, the Office of Civil Rights within the Department of Health and Human Services issued proposed revisions to the HIPAA Privacy Rule aimed at reducing regulatory burdens that may exist in discouraging coordination of care and patient access to their health information, among other changes. While a final rule has not yet been issued, if adopted, these proposed changes may require us to update our policies and procedures to comply with the new requirements. In particular, several state laws have recently been passed or amended to significantly expand privacy rights and obligations of businesses that process personal information, including identifiable sensitive health information. For example, in June 2018, California enacted the California Consumer Privacy Act (CCPA), which went into effect on January 1, 2020. The CCPA gives California residents expanded rights to access and require deletion of their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that may increase data breach litigation. The California Privacy Rights Act of 2020 (CPRA), which expands the CCPA, was passed in the election on November 3, 2020. The CPRA will, among other things, give consumers the ability to limit use of information deemed to be sensitive, increase the maximum penalties for violations concerning consumers under age 16, and establish the California Privacy Protection Agency to implement and enforce the new law and impose administrative fines. Following the CPRA, Virginia and Colorado have enacted similar, but not completely consistent, comprehensive privacy legislation that will also go into effect in January and July 2023, respectively. Many other states are considering similar legislation.

Aspects of these new state privacy laws, and their interpretation and enforcement, remain uncertain. The potential effects of these new and evolving state privacy laws are far-reaching and may require us to modify our data processing practices and policies and to incur substantial costs and expenses in an effort to comply. Although the California, Virginia and Colorado laws include exemptions for certain clinical trials data and HIPAA protected health information, the law may increase our compliance costs and potential liability with respect to other personal information we collect about California residents, and those health-data related exceptions may evolve through amendment or regulatory interpretation. The state privacy law developments, moreover, have prompted a number of additional proposals for new federal and state privacy legislation that, if passed, could increase our potential liability, increase our compliance costs and adversely affect our business.

Foreign data protection laws, including, without limitation, the EU GDPR that took effect in May 2018, and EU Member State data protection legislation, may also apply to health-related and other personal information obtained from individuals. The EU GDPR has been transposed into the national laws of the United Kingdom by virtue of section 3 of the EU (Withdrawal) Act 2018 as the UK GDPR (together, the EU GDPR and the UK GDPR, the GDPR). The EU GDPR has direct effect in all EU Member States and has extraterritorial effect where organizations outside of the EU process personal information of individuals in the EU in relation to the offering of goods or services to those individuals (targeting test) or the monitoring of their behavior (monitoring test). The UK GDPR has a similar extraterritorial test for organizations outside of the UK processing personal information of individuals in the UK in relation to the offering of goods or services to those individuals or the monitoring of their behavior. As such, the GDPR applies to us to the extent we are established in an EU Member State or the UK or we meet the requirements of either the targeting test or the monitoring test. These laws impose strict obligations on businesses, including to: (i) implement administrative, physical, technical, and organizational safeguards to protect personal information; (ii) establish an appropriate and valid legal basis for processing personal information; (iii) comply with accountability transparency requirements regarding the processing of personal information, which require controllers to demonstrate and record compliance with the GDPR and to provide more detailed information to data subjects regarding processing; (iv) comply with data protection rights of data subjects including a right of access to and rectification of personal information, a right to obtain restriction of processing or to object to processing of personal information, a right to ask for a copy of personal information to be provided to a third party in a useable format and erasing personal information in certain circumstances; (v) report certain personal data breaches to the relevant supervisory authority without undue delay (and no later than 72 hours, where feasible); (vi) obtain explicit consent for collection of sensitive personal information such as health data; and (vii) consider data protection as any new products or services are developed and to limit the amount of personal information processed.

The EU GDPR restricts the transfer of personal information from the European Economic Area (EEA) to the United States and other countries that the European Commission does not recognize as having “adequate” data protection laws unless the parties to the transfer have implemented an appropriate data transfer mechanism in accordance with the EU GDPR. The UK GDPR has similar restrictions on transfers of personal information from the United Kingdom to countries that the UK does not recognize as having “adequate” data protection laws in the United Kingdom (as discussed below) and Switzerland impose similar restrictions. One of the primary mechanisms allowing United States companies to import personal information from Europe had been certification to the EU-U.S. Privacy Shield and Swiss-U.S. Privacy Shield frameworks administered by the United States Department of Commerce. However, in July 2020, the Court of Justice of the EU (CJEU) invalidated the EU-U.S. Privacy Shield, and subsequent regulatory guidance required additional compliance efforts to analyze international data flows and take steps to ensure adequate protections for personal data transferred to the United States and other certain jurisdictions, including by implementing supplementary measures that provide privacy protections in addition to those provided under the Standard Contractual Clauses (SCCs). Moreover, new versions of the European Commission’s Standard Contractual Clauses, now the primary mechanism for the lawful transfer of personal information transfers from Europe and/or the United Kingdom to the United States or other countries, have been released requiring additional compliance and implementation efforts. The United Kingdom is also expected to publish its own set of SCCs in early 2022 for transfers of personal data outside of the United Kingdom. Similarly, the Swiss Federal Data Protection and Information Commissioner announced that the Swiss-U.S. Privacy Shield Framework is inadequate for personal information transfers from Switzerland to the United States in light of the CJEU’s July 2020 decision, and also raised questions about the viability of the older version of the Standard Contractual Clauses. As such, any transfers by us or our vendors of personal information from Europe may not comply with European data protection law, may increase our exposure to the EU GDPR’s heightened sanctions for violations of its cross-border data transfer restrictions and may reduce demand from companies subject to European data protection laws.

Moreover, where we rely on SCCs, we must now evaluate and implement supplementary measures that provide privacy protections additional to those provided under SCCs. This evaluation will, in particular, include an assessment as to whether the types of personal data transferred pursuant to SCCs may be subject to government surveillance in the data importer’s country and an assessment as to whether the data importer can meet its contractual obligations under the SCCs. This may have implications for our cross-border data flows and may result in compliance costs. Inability to import personal information from the EEA, United Kingdom or Switzerland may also restrict our clinical trial activities in Europe; limit our ability to collaborate with CROs, service providers, contractors and other companies subject to European data protection laws; and require us to increase our data processing capabilities in Europe at significant expense.

Additionally, other countries outside of Europe continue to enact or are considering enacting similar cross-border data transfer restrictions and laws requiring local data residency, which could increase the cost and complexity of delivering our services and operating our business. For example, Brazil enacted the General Data Protection Law (Lei Geral de Proteção

de Dados Pessoais or LGPD) (Law No. 13,709/2018), which broadly regulates the processing of personal information and imposes compliance obligations and penalties comparable to those of the EU GDPR.

Under the EU GDPR, regulators may impose substantial fines and penalties for non-compliance. Companies that violate the EU GDPR can face fines of up to the greater of 20 million Euros or 4% of their consolidated worldwide annual turnover (revenue) and restrictions or prohibitions on data processing. The EU also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies and obtain compensation for damages resulting from violations of the EU GDPR. The EU GDPR has increased our responsibility and liability in relation to personal information that we process, requiring us to put in place additional mechanisms to ensure compliance with the EU GDPR and other EU and international data protection rules. There may also be a risk that the measures will not be implemented correctly or that individuals within the business will not be fully compliant with the required procedures. Similarly, the UK GDPR introduces fines of up to the greater of £17.5 million or up to 4% of their consolidated worldwide annual turnover (revenue).

Failure to comply with U.S. and international data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties, fines or sanctions), private litigation, and/or adverse publicity and could negatively affect our operating results and business. Moreover, patients about whom we or our partners obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations related to security or privacy, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business. Compliance with data protection laws may be time-consuming, require additional resources and could result in increased expenses, reduce overall demand for our products and services and make it more difficult to meet expectations of or commitments to customers or partners.

Any of these matters could materially adversely affect our business, financial condition, or operational results.

Failure in our information technology and storage systems or our security measures, including without limitation, data breaches, or inadequacy of our business continuity and disaster recovery plans and procedures, could significantly disrupt the operation of our business.

Our ability to execute our business plan and maintain operations depends on the continued and uninterrupted performance of our, and our third-party vendors', information technology (IT) systems, and the availability of data related to our products, services and operations. IT systems and data are vulnerable to risks and damages from a variety of sources, including catastrophe or natural disaster, telecommunications or network failures, malicious human acts, breaches of security, cyber-attacks, loss of power or other natural or man-made events. Moreover, despite network security and back-up measures, we and our vendors frequently defend against and respond to data security attacks and incidents, and vendors' servers are potentially vulnerable to physical or electronic break-ins, computer viruses, software vulnerabilities, ransomware attacks and similar disruptive problems. If our business continuity and disaster recovery plans and procedures were disrupted, inadequate or unsuccessful in the event of a problem, we could experience a material adverse interruption of our operations.

Specifically, data security breaches, whether inadvertent or intentional, by employees or others, may expose proprietary information, trade secrets, personal information, clinical trial data or other sensitive data to unauthorized persons, impact the integrity, availability or confidentiality of our IT systems or data (including, but not limited to, data loss), or disrupt or interrupt our IT systems or operations. Our partners and vendors face similar risks and any security breach of their systems could adversely affect our security posture. Malicious attacks by third parties are of ever-increasing sophistication and can be made by groups and individuals with a wide range of motives (including, but not limited to, industrial espionage and financial motivation prompted by the enormous growth in ransomware over the past several years) and expertise, including organized criminal groups, "hacktivists," nation states and others. Foreign, federal, and state laws or regulations allows for the imposition of civil liability, fines and/or corrective action on entities that improperly use or disclose the personal information of individuals, including through a data security breach. Accordingly, data security breaches experienced by us, our collaborators or contractors could lead to significant fines, required corrective action, loss of trade secrets or other intellectual property, or could lead to the public exposure of personally identifiable information (including sensitive personal information) of our employees, collaborators, clinical trial patients, and others. A data security breach or privacy violation that leads to disclosure or modification of or prevents access to personal information, including personally identifiable information, patient information or protected health information, could result in civil liability, harm our reputation, compel us to comply with federal and/or state breach notification laws, subject us to mandatory corrective

action, require us to verify the correctness of database contents and otherwise subject us to liability under laws and regulations that protect personal data, resulting in increased costs or loss of revenue. If we are unable to adequately prevent, detect or respond to data security breaches or privacy violations, or implement satisfactory remedial measures in the wake of a data security incident, our operations could be disrupted, and we may suffer civil liability to our customers or individuals, loss of reputation, financial loss and other regulatory penalties because of lost or misappropriated information, including sensitive patient data, or our clinical trials may be adversely impacted from data loss resulting in delayed regulatory approvals or other operational impacts. In addition, these breaches and other inappropriate access events can be difficult to detect, and any delay in identifying and responding to them may lead to increased harm of the type described above. Moreover, the prevalent use of mobile devices or other remote working activity that access and process confidential information remotely increases the risk of data security breaches, which could lead to the loss of confidential information, trade secrets or other intellectual property. While we have implemented security measures designed to protect our data security and information technology systems, no set of security measures is infallible, and these measures may not prevent such events.

For example, in March 2021, we learned we were the victim of a business email compromise during which an unauthorized party gained access to the email account of an employee in our finance department. The incident resulted in a net loss of approximately $0.3 million. Based on our investigation, the incident was financially motivated and impacted a single email account. In response to the incident, we conducted a review of our corporate information technology and email policies and have implemented additional security measures.

Despite precautionary measures to prevent anticipated and unanticipated problems, including data breaches, there can be no assurance that our efforts to protect our data and information technology systems will prevent breakdowns or breaches in our systems (or that of our third-party providers). Such events could affect our IT systems, sustained or repeated system failures that interrupt our ability to generate, use and maintain data or our IT systems could adversely affect our ability to operate our business and result in increased costs or loss of revenue, other financial and reputational harm to us, theft of trade secrets and other proprietary information, legal claims or proceedings, liability under laws that protect the privacy of personal information and regulatory penalties.

The financial exposure from the events referenced above could either not be insured against or not be fully covered through any insurance that we maintain. There can be no assurance that the limitations of liability in our contracts would be enforceable or adequate or would otherwise protect us from liabilities or damages as a result of the events referenced above.

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

Although a substantial amount of our effort will focus on the continued clinical testing, potential approval, and commercialization of our existing product candidates, the success of our business is also expected to depend in part upon our ability to identify, license, discover, develop, or commercialize additional product candidates. Research programs to identify new product candidates require substantial technical, financial, and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful. Our research programs or licensing efforts may fail to yield additional product candidates for clinical development and commercialization for a number of reasons, including but not limited to the following:

- our research or business development methodology or search criteria and process may be unsuccessful in identifying potential product candidates;
- we may not be able or willing to assemble sufficient resources to acquire or discover additional product candidates;
- our product candidates may not succeed in preclinical or clinical testing;
- our potential product candidates may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- product candidates we develop may be covered by third parties' patents or other exclusive rights;
- the market for a product candidate may change during our program so that such a product may become unreasonable to continue to develop;

- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by patients, the medical community, or third-party payors.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs, or we may not be able to identify, license, discover, develop, or commercialize additional product candidates, which would have a material adverse effect on our business and could potentially cause us to cease operations.

Healthcare legislative reform measures may have a material adverse effect on our business and results of operations.

In the United States and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative initiatives and regulatory changes to reform the delivery and payment for healthcare items and services, which could affect our ability to profitably sell our products. For example, in March 2010, the Patient Protection and Affordable Care Act (ACA) was passed, which substantially changed the way health care is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. This law was designed to expand access to health insurance coverage for uninsured and underinsured individuals while at the same time containing overall healthcare costs. The framework of the ACA and other healthcare reforms continues to evolve as a result of executive, legislative, regulatory, and administrative developments. For example, for calendar years 2021 and 2022, the American Rescue Plan Act of 2021 temporarily increased premium tax credit assistance established under the ACA to help eligible individuals cover premiums for health insurance purchased through the health insurance marketplace and removed the 400% federal poverty level limit that otherwise applies for purposes of eligibility to receive premium tax credits. The Inflation Reduction Act of 2022 (IRA) extended this increased tax credit assistance and removal of the 400% federal poverty limit through 2025. There have also been legal challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed a judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. It is unclear how the healthcare reform measures of the Biden administration or other efforts, if any, to challenge, repeal, amend or replace the ACA will impact the ACA and our business.

Also, there has been heightened governmental scrutiny over pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in Congressional and federal agency inquiries regarding pricing and related practices, as well as proposed and enacted federal and state legislation and regulation 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. For example, the American Rescue Plan Act of 2021 included among its provisions a sunset of the ACA's cap on pharmaceutical manufacturers' rebate liability under the Medicaid Drug Rebate Program. Previously, under the ACA, manufacturers' rebate liability was capped at 100% of the average manufacturer price for a covered outpatient drug. Effective January 1, 2024, manufacturers' Medicaid Drug Rebate Program rebate liability will no longer be capped, potentially resulting in a manufacturer paying more in Medicaid Drug Rebate Program rebates than it receives on the sale of certain covered outpatient drugs.

The Biden Administration has continued to support legislative reforms to lower prescription drug prices in other ways. In August 2022, for instance, President Biden signed into law the IRA, which implements substantial changes to the Medicare program, including drug pricing reforms and changes to the Medicare Part D benefit design. Among other reforms, the IRA of 2022 imposes inflation rebates on drug manufacturers for products reimbursed under Medicare Parts B and D if the prices of those products increase faster than inflation; implements changes to the Medicare Part D benefit that, beginning in 2025, will cap patient annual out-of-pocket spending at $2,000, while imposing new discount obligations for pharmaceutical manufacturers and payors; and, beginning in 2026, establishes a "maximum fair price" for a fixed number of pharmaceutical and biological products covered under Medicare Parts B and D following a price negotiation process with the CMS. The IRA explicitly excludes from price negotiation orphan drugs designated for only one rare disease or condition and for which the only active approved indication is for such disease or condition. Those drugs with multiple orphan designations are not explicitly excluded from drug price negotiation.

Since the IRA was enacted, CMS has taken various steps to implement the drug pricing provisions of the law. This includes releasing a list of 43 Medicare Part B products that had an adjusted coinsurance rate based on the inflationary rebate provisions of the IRA for the time period of July 1, 2023 to September 30, 2023 on June 9, 2023; on June 30, 2023, issuing guidance detailing the requirements and parameters of the first round of price negotiations, to take place during 2023 and 2024, for products subject to the "maximum fair price" provision that would become effective in 2026; and, on August 29, 2023, releasing the initial list of 10 drugs subject to price negotiations. While it remains to be seen how the drug

pricing provisions imposed by the IRA will affect the broader pharmaceutical industry (including orphan drug development), several pharmaceutical manufacturers and other industry stakeholders have challenged the law, including through lawsuits brought against the HHS, the Secretary of HHS, CMS, and the CMS Administrator challenging the constitutionality and administrative implementation of the IRA's drug price negotiation provisions. We cannot predict the likelihood, nature or extent of other healthcare or drug pricing reforms that may arise from future legislation or other administration action nor can we predict how, or to what extent, the drug pricing policies or future healthcare reforms will affect our products. However, we expect these initiatives to increase pressure on drug pricing.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Any legislation at the state or federal level aimed at further healthcare reform may have the effect of limiting the amounts that government agencies will pay for healthcare products and services. For example, an emerging trend at the state level is the establishment of prescription drug affordability boards, some of which will prospectively permit certain states to establish upper payment limits for drugs that the state has determined to be "high-cost". In addition, policy changes, including potential modification or repeal of all or parts of the ACA or the implementation of new health care legislation, could result in significant changes to the health care system, which may prevent us from being able to generate revenue, attain profitability or commercialize our drugs. 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 products and services, which could result in reduced demand or lower pricing for our product candidates, or additional pricing pressures.

In the United States, the EU and other potentially significant markets for our product candidates, government authorities and third-party payors are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which has resulted in lower average selling prices. The increased emphasis on managed healthcare in the United States and on country and regional pricing and reimbursement controls in the EU will put additional pressure on product pricing, reimbursement and usage, which may adversely affect our future product sales and results of operations. These pressures can arise from rules and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and healthcare reform, pharmaceutical reimbursement policies and pricing in general.

The proposed revision of the European legislation on pharmaceuticals could lead to uncertainties over the regulatory framework that will be applicable to medicinal products in the EU, including orphan medicinal products.

In April 2023, the European Commission published proposals to revise the existing European legislation on medicinal products ("EU Pharma Law Review"). The revision consists of two proposals, a new directive and a new regulation ("EU Pharma Law Proposal"), that would amend and/or repeal and replace the relevant legislation concerning medicinal products for human use, including legislation concerning orphan medicinal products and medicinal products for paediatric use. The EU Pharma Law Review could have a significant impact on the designation of and incentives offered to orphan medicinal products in the EU. If adopted in current form, the EU Pharma Law Proposal would introduce the possibility for the Commission, by way of delegated acts, to derogate from the current prevalence criterion, and introduce specific criteria for certain conditions, due to the characteristics of such conditions or other scientific reasons. The EU Pharma Law Proposal also proposes changes to the current orphan market exclusivity ("OME") approach. If adopted in the current form, the EU Pharma Law Proposal would in most cases reduce the duration of the OME, and replace the current system with separate OME periods for each new indication, to a system with a single OME period for each active substance.

We may be subject, directly or indirectly, to foreign, federal and state healthcare fraud and abuse laws, false claims laws, and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties, sanctions or other liability.

Our operations may be subject to various foreign, federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, the federal False Claims Act, physician sunshine laws, the EU GDPR and/or the UK GDPR and other regulations. These laws may impact, among other things, our research, sales, marketing, education and patient assistance programs. In addition, we may be subject to patient privacy regulation by foreign, federal, and state governments in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying anything of value as remuneration, directly or indirectly, to induce, or in

return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;

- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;
- HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;
- HIPAA and its implementing regulations impose certain requirements on certain covered entity healthcare providers, health plans, and healthcare clearinghouse and their business associates that perform certain services involving the use or disclosure of individually identifiable health information as well as their covered subcontractors, relating to the privacy, security, and transmission of individually identifiable health information;
- The Physician Payments Sunshine Act, which requires manufacturers of certain drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to CMS information related to payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), teaching hospitals, physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists, and certified nurse midwives, as well as ownership and investment interests held by physicians and their immediate family members and applicable group purchasing organizations;
- the Federal Food, Drug, and Cosmetic Act (FDCA), which, among other things, prohibits the adulteration and misbranding of drugs and biological products;
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payors, including commercial insurers, state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; state and local laws requiring the registration of pharmaceutical sales representatives; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts; and federal and state laws requiring the disclosure of certain drug pricing information; and
- the EU GDPR and/or the UK GDPR (together, GDPR) and other EU Member State or English data protection legislation, which require data controllers and processors to (i) implement administrative, physical, technical, and organizational safeguards to protect personal information; (ii) establish an appropriate and valid legal basis for processing personal information (iii) comply with accountability transparency requirements regarding the processing of personal information, which require controllers to demonstrate and record compliance with the GDPR and to provide more detailed information to data subjects regarding processing; (iv) comply with data protection rights of data subjects including a right of access to and rectification of personal information, a right to obtain restriction of processing or to object to processing of personal information, a right to ask for a copy of personal information to be provided to a third party in a useable format and erasing personal information in certain circumstances; (v) report certain personal data breaches to the relevant supervisory authority without undue delay (and no later than 72 hours, where feasible); (vi) obtain explicit consent for collection of sensitive personal information such as health data; and (vii) consider data protection as any new products or services are developed and to limit the amount of personal information processed. In addition, the GDPR prohibits the international transfer of personal information outside of the EU and/or the UK including to the U.S., unless made to a country deemed to have adequate data privacy laws by the European Commission and/or the UK or a data transfer mechanism in accordance with the GDPR (as applicable) has been put in place.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent health care reform legislation has strengthened these laws.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply, we may be subject to penalties, including significant civil, criminal and administrative penalties, damages, disgorgement, fines, sanctions, exclusion from participation in government health care programs, such as Medicare and Medicaid, imprisonment, corporate integrity oversight and reporting obligations, contractual damages, reputational harm,

diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs in the US, we could be subject to additional rebate or discount requirements, fines, sanctions and exposure under other laws which could have an adverse effect on our business, results of operations and financial condition.

The Company's product is subject to government mandated rebates under the Medicaid Drug Rebate Program and other government health care programs in the United States. These programs generally require us to pay rebates or otherwise provide discounts to government payors in connection with drugs that are dispensed to beneficiaries of these programs. In some cases, such as with the Medicaid Drug Rebate Program, rebates are calculated based on pricing metrics we are required to report on a monthly and quarterly basis to the government agencies that administer the programs. These pricing metrics are complex and may vary across products and programs. Additionally, the requirements of government health care programs change frequently and are often subject to interpretation by regulatory agencies and the courts. Tracking these updates and maintaining compliance will be costly and time consuming. Further, errors in the submission of our pricing data, failure to make necessary pricing disclosures, and/or overcharging government payors (or failing to identify overpayments) could result in allegations against us under the federal False Claims Act and other laws and regulations, as well as subject us to potential termination of our rebate agreement with CMS. Responding to government investigations or enforcement actions and/or making necessary refunds to government payors would be expensive and time consuming and could have an adverse effect on our business, results of operations and financial condition.

Following Brexit, legal, political and economic uncertainty surrounding the exit of the U.K. from the EU may be a source of instability in international markets, create significant currency fluctuations, adversely affect our operations in the U.K. and pose additional risks to our business, revenue, financial condition and results of operations.

In June 2016, the electorate in the UK voted in favor of leaving the EU (commonly referred to as "Brexit"). Thereafter, in March 2017, the country formally notified the EU of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty and the UK formally left the EU on January 31, 2020. A transition period began on February 1, 2020, during which EU pharmaceutical law remained applicable to the UK. This transition period ended on December 31, 2020. The EU-UK Trade and Cooperation Agreement (TCA) was agreed on December 24, 2020. The UK and EU agreed that the TCA would apply provisionally from January 1, 2021, the TCA was ratified on April 30, 2021 and came into force on May 1, 2021.

Since the regulatory framework in the UK covering the quality, safety and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales and distribution of pharmaceutical products is derived from EU Directives and Regulations, Brexit could materially impact the future regulatory regime which applies to products and the approval of product candidates in the UK, as UK legislation now has the potential to diverge from EU legislation. It remains to be seen how Brexit will fully impact regulatory requirements for product candidates and products in the UK in the long-term.

At present, the regulatory framework for medicines that existed before the end of the transition period has effectively been preserved in UK domestic legislation as 'retained EU law' which has prevented substantial divergence to the regulation of medicines so far. However, the Retained EU Law (Revocation and Reform) Bill 2022 which intends to end the "special status" of retained EU law under UK law was enacted into law on June 29, 2023. It facilitates the departure from retained EU law, and may lead to greater regulatory divergence between the EU and UK in the future. In comparison, as matters currently stand, under the terms of the Northern Ireland Protocol (the NIP), implemented by the EU (Withdrawal Agreement) Act 2020, Northern Ireland is treated for the same purposes as if it were still an EU Member State, and must remain aligned to the EU single market and customs rules. The UK government has also introduced a bill 'Northern Ireland Protocol Bill' which if enacted into law would enable the government to unilaterally disapply parts of the NIP which may lead to changes to the regulatory environment in Northern Ireland, and may trigger retaliatory measures against the UK by the EU. However, on February 27, 2023, the UK government and the EU Commission reached political agreement on a package of proposed amendments to the NIP (Windsor Framework). These proposals were adopted on March 24, 2023 and include, amongst other measures a "carve-out from EU rules". Indeed, the UK medicines regulator (MHRA) will be responsible for approving medicines for the whole UK market, meaning that medicinal products available in Northern Ireland will not have to comply with EU law but rather with UK law, so medicinal products would be able to freely circulate between Northern Ireland and Great Britain. It is expected that these new measures put in place by the Windsor Framework will take effect from January 1, 2025. The EU-UK Trade and Cooperation Agreement allows for future deviation from the current regulatory framework and it is not known if and/or when any deviations may occur, which may have an impact on Eiger's business.

Companies now need to comply with a separate UK regulatory legal framework in order to commercialize medicinal products in Great Britain (namely, England, Wales and Scotland, as EU law currently applies in Northern Ireland). For instance, Great Britain will no longer be covered by centralized marketing authorizations (as matters stand, under the Northern Irish Protocol, centralized marketing authorizations will continue to be recognized in Northern Ireland). All medicinal products with a current centralized marketing authorization were automatically converted to Great Britain marketing authorizations on January 1, 2021. For a period of three years from January 1, 2021, the MHRA may rely on a decision taken by the European Commission on the approval of a new marketing authorization in the centralized procedure, in order to more quickly grant a new Great Britain marketing authorization. A separate application will, however, still be required. The MHRA has also introduced new procedures aimed at accelerating regulatory approvals and time to market, including 'rolling reviews' and the Innovative Licensing and Access Pathway (ILAP) although eligibility requirements apply.

The TCA and the proposed Bills allow for future deviation from the current regulatory framework and it is not known if and/or when any deviations may occur, which may have an impact on development, manufacture, marketing authorization, commercial sales and distribution of pharmaceutical products.

Our employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraudulent conduct or other illegal activity by our employees, independent contractors, principal investigators, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to: comply with the regulations of the FDA and non-U.S. regulators, provide accurate information to the FDA and non-U.S. regulators, comply with healthcare fraud and abuse laws in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, promotion, sales, marketing and certain business arrangements in the healthcare industry are subject to extensive laws intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct could also involve the improper use of information obtained in the course of patient recruitment or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of business conduct and ethics applicable to all of our employees, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

We face potential product liability, and, if successful claims are brought against us, we may incur substantial liability and costs. If the use or misuse of our product candidates harm patients or is perceived to harm patients even when such harm is unrelated to our product candidates, our regulatory approvals could be revoked or otherwise negatively impacted, and we could be subject to costly and damaging product liability claims.

The use or misuse of our product candidates in clinical trials and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. There is a risk that our product candidates may induce adverse events. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation;
- initiation of investigations by regulators;
- withdrawal of clinical trial participants;
- costs due to related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- the inability to commercialize our product candidates;

- product recalls, withdrawals or labeling, marketing or promotional restrictions; and
- decreased demand for our product candidates, if approved for commercial sale.

We believe our current product liability insurance coverage is appropriate in light of our clinical programs; however, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If and when we obtain marketing approval for product candidates, we intend to increase our insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. On occasion, large judgments have been awarded in class action lawsuits based on drugs or medical treatments that had unanticipated adverse effects. A successful product liability claims or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.

Patients with the diseases targeted by our product candidates are often already in severe and advanced stages of disease and have both known and unknown significant pre-existing and potentially life-threatening health risks. During the course of treatment, patients may suffer adverse events, including death, for reasons that may or may not be related to our product candidates. Such events could subject us to costly litigation, require us to pay substantial amounts of money to injured patients, delay, negatively impact or end our opportunity to receive or maintain regulatory approval to market our products, or require us to suspend or abandon our commercialization efforts. Even in a circumstance in which we do not believe that an adverse event is related to our products, the investigation into the circumstance may be time-consuming or inconclusive. These investigations may interrupt our sales efforts, delay our regulatory approval process in other countries, or impact and limit the type of regulatory approvals our product candidates receive or maintain. As a result of these factors, a product liability claim, even if successfully defended, could have a material adverse effect on our business, financial condition or results of operations.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

Our research and development activities and our third-party manufacturers' and suppliers' activities involve the controlled storage, use, and disposal of hazardous materials, including the components of our product candidates and other hazardous compounds. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling, and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' facilities pending their use and disposal. We cannot eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling, and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our licensors and our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently, and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. We do not currently carry biological or hazardous waste insurance coverage.

We are currently conducting and will continue to conduct clinical trials in foreign countries, which could expose us to risks that could have a material adverse effect on the success of our business and the delivery of clinical trial data.

We have conducted in the past clinical trials in the United States, Canada, Australia, Turkey, Germany, Pakistan, New Zealand, Mongolia, Spain, France, Bulgaria, Romania, Taiwan, Sweden, Italy, Belgium, Switzerland, United Kingdom, Greece, Moldova, Ukraine, Russia, and Israel, and accordingly, we are subject to risks associated with doing business globally, including commercial, political, and financial risks. Emerging regions, such as Eastern Europe, Latin America, Asia, and Africa, as well as more developed markets, such as the United Kingdom, France, Germany, and Australia, provide clinical study opportunities for us. In addition, we are subject to potential disruption caused by military conflicts; potentially unstable governments or legal systems; civil or political upheaval or unrest; local labor policies and conditions; possible expropriation, nationalization, or confiscation of assets; problems with repatriation of foreign earnings; economic or trade sanctions; closure of markets to imports; anti-American sentiment; terrorism or other types of violence in or outside the United States; health pandemics; and a significant reduction in global travel. Certain countries previously closed their borders due to COVID-19 preventing activation of clinical sites. Actions taken by the Russian Federation in

Ukraine and surrounding areas have destabilized the region and caused the adoption of comprehensive sanctions by, among others, the EU, the United States and the UK, which restrict a wide range of trade and financial dealings with Russia and Russian persons, as well as certain regions in Ukraine, including by imposing stricter export controls, prohibiting dealings with major Russian banks and credit institutions, and prohibiting trade with the Donetsk, Luhansk, Kherson and Zaporizhzhia regions of Ukraine. In addition, clinical site initiation and patient enrollment may be delayed, and we may not be able to access sites for initiation, monitoring and data collection in regions affected by conflict in the Middle East and the Russian invasion of Ukraine, including due to the prioritization of hospital resources away from clinical trials or as a result of government-imposed curfews, warfare, violence or other governmental action or events that restrict movement. Some patients may not be able to comply with clinical trial protocols if the conflict impedes patient movement or interrupts healthcare services. We could also experience disruptions in our supply chain or limits to our ability to obtain sufficient materials for our products in certain regions. Our success will depend, in part, on our ability to overcome the challenges we encounter with respect to these risks and other factors affecting U.S. companies with global operations. If our global clinical trials were to experience significant disruption due to these risks or for other reasons, it could have a material adverse effect on our operations and prospects.

We or the third parties upon whom we depend may be adversely affected by earthquakes, natural epidemics or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Earthquakes, health epidemics or other natural disasters could severely disrupt our operations and have a material adverse effect on our business. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, damaged critical infrastructure, such as the manufacturing facilities of our third-party CMOs, or otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. For example, in December 2019, an outbreak of a novel strain of coronavirus (COVID-19) originated in Wuhan, China. Since certain starting materials of certain of our products obtained from third-party chemical suppliers are manufactured in China and Japan, an outbreak of communicable diseases in the region, or the perception that such an outbreak could occur, and the measures taken by the governments of countries affected, could adversely affect our business, financial condition or results of operations by limiting our ability to manufacture product within or outside certain countries, forcing temporary closure of facilities that we rely upon or increasing the costs associated with obtaining starting materials and then clinical supplies of our product candidates. The extent to which the coronavirus or another PHE impacts our results will depend on future developments, which are highly uncertain and cannot be accurately predicted, including new information which may emerge concerning the severity of the coronavirus or other PHEs and the actions to contain the coronavirus or treat its impact, among others. In addition, our corporate headquarters is located in the San Francisco Bay Area, which has in the past experienced severe earthquakes, other natural disasters, and an outbreak of COVID-19. We do not carry earthquake insurance. We have limited disaster recovery and business continuity plans in place currently and our business would be impaired in the event of a serious disaster or similar event. We may incur substantial expenses to develop and implement any disaster recovery and business continuity plans, which could have a material adverse effect on our business.

Our business is currently adversely affected by and could be materially adversely affected in the future by the effects of disease outbreaks, epidemics and pandemics including the evolving effects of the COVID-19 outbreak. We had a significant number of clinical trial sites, and continue to depend on manufacturing operations for various stages of our supply chain, in countries that were directly affected by COVID-19.

Our business has been adversely affected by COVID-19 and could be materially and adversely impacted by COVID-19 or other health epidemics in regions where we have significant manufacturing facilities, concentrations of clinical trial sites or other business operations. The effects of COVID-19 and government and other responses thereto, including any resumption of shelter-in-place orders or work-from-home policies, may continue to negatively impact productivity, disrupt our business and delay our clinical programs and timelines, the magnitude of which would depend, in part, on the length and severity of any restrictions and other limitations on our ability to conduct our business in the ordinary course. These and similar, and perhaps more severe, disruptions in our operations could negatively impact our business, operating results and financial condition.

Further, as a result of other PHEs, including any resurgence of the COVID-19 pandemic, we may be required to develop and implement additional clinical study policies and procedures designed to help protect study participants from illness, which may include using telemedicine visits, remote monitoring of patients and clinical sites, and measures to ensure that data from clinical studies that may be disrupted as result of the pandemic are collected pursuant to the study protocol and consistent with GCPs, with any material protocol deviation reviewed and approved by the site IRB.

The FDA and EMA have in the past suspended, may continue to suspend, prioritize or delay certain foreign inspections, and if suspensions or delays in inspections occur, our product application reviews and potential approvals could be impacted or delayed. Further, prior surges in COVID-19 case numbers have contributed to interruptions in FDA's surveillance capabilities, and such disruptions may persist in the future as a result of future surges or other PHEs. We cannot predict whether, and when, FDA will decide to pause or resume inspections due to a pandemic.

Regulatory authorities outside the United States may adopt additional restrictions or other policy measures in response to PHEs, including providing guidance regarding the conduct of clinical trials. If global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, or impact reviews or other regulatory activities, it could significantly impact the ability of the FDA or other foreign regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

COVID-19 may continue to adversely affect our business operations, and the extent of the impact on our clinical development and regulatory efforts and the value of and market for our common stock will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time. In addition, to the extent COVID-19 adversely affects our business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties described elsewhere in this ''Risk Factors'' section.

Risks Related to Ownership of our Common Stock

The market price of our common stock has been and may continue to be highly volatile, and you may not be able to resell some or all of your shares at a desired market price.

The market price of our common stock has been and is likely to continue to be volatile. Our stock price could be subject to wide fluctuations in response to a variety of factors, including the following:

- results or delays in preclinical studies or clinical trials;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- unanticipated serious safety concerns related to the use of any of our product candidates;
- reports of adverse events in other gene therapy products or clinical trials of such products;
- inability to obtain additional funding;
- any delay in filing an IND, NDA, BLA, or MAA for any of our product candidates and any adverse development or perceived adverse development with respect to the FDA's review of that IND, NDA, or BLA (or the EMA's review of that MAA);
- our ability to obtain regulatory approvals for our product candidates, and delays or failures to obtain such approvals;
- failure of any of our product candidates, if approved, to achieve commercial success;
- failure to obtain or maintain Orphan Drug designation;
- failure to maintain our existing third-party license and supply agreements;
- failure by our licensors to prosecute, maintain, or enforce our intellectual property rights;
- changes in laws or regulations applicable to our product candidates;
- any inability to obtain adequate supply of our product candidates or the inability to do so at acceptable prices;
- adverse regulatory authority decisions;
- introduction of new products, services, or technologies by our competitors;
- failure to meet or exceed financial and development projections we may provide to the public;
- failure to meet or exceed the financial and development projections of the investment community;
- the perception of the pharmaceutical industry by the public, legislatures, regulators, and the investment community;
- announcements of significant acquisitions, strategic partnerships, joint ventures, or capital commitments by us or our competitors;

- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- additions or departures of key personnel;
- significant lawsuits, including patent or stockholder litigation;
- if securities or industry analysts do not publish research or reports about our business, or if they issue adverse or misleading opinions regarding our business and stock;
- changes in the market valuations of similar companies;
- general market or macroeconomic conditions;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- announcements by commercial partners or competitors of new commercial products, clinical progress or the lack thereof, significant contracts, commercial relationships or capital commitments;
- adverse publicity relating to the hepatitis market generally, including with respect to other products and potential products in such markets;
- the introduction of technological innovations or new therapies that compete with potential products of ours;
- changes in the structure of health care payment systems;
- period-to-period fluctuations in our financial results; and
- failure to maintain or regain compliance with listing standards of Nasdaq.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies, including very recently in connection with global macroeconomic and geopolitical conditions, including COVID-19, which volatility has resulted in decreased stock prices for many companies notwithstanding the lack of a fundamental change in their underlying business models or prospects. These broad market and industry factors, including potentially worsening economic conditions and other adverse effects or developments, may also adversely affect the 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 class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our profitability and reputation.

We will incur costs and demands upon management as a result of complying with the laws and regulations affecting public companies.

We have incurred and will continue to incur significant legal, accounting and other expenses associated with public company reporting requirements. We also incur costs associated with corporate governance requirements, including requirements under the Sarbanes-Oxley Act, as well as rules implemented by the SEC and The Nasdaq Stock Market LLC. These rules and regulations impose significant legal and financial compliance costs and make some activities more time-consuming and costly. For example, our management team consists of certain executive officers who have not previously managed and operated a public company. These executive officers and other personnel will need to devote substantial time to gaining expertise regarding operations as a public company and compliance with applicable laws and regulations. In addition, it may be more difficult for us to attract and retain qualified individuals to serve on our board of directors or as executive officers, which may adversely affect investor confidence and could cause our business or stock price to suffer.

If we fail to maintain or regain compliance with the listing standards of Nasdaq, our common stock may be delisted, which could have a material adverse effect on the liquidity of our common stock and our ability to raise additional capital.

Our common stock is currently listed on the Nasdaq Global Market. The Nasdaq Stock Market LLC has requirements that a company must meet in order to remain listed on the Nasdaq Global Market, including, among others, (i) a minimum closing bid price of $1.00 per share (the "Bid Price Requirement"), (ii) a market value of publicly held shares (excluding shares held by our executive officers, directors and 10% or more stockholders) of at least $1 million and (iii) either: (x) stockholders' equity of at least $10 million; or (y) a total market value of listed securities of at least $50 million.

On July 26, 2023, we received a deficiency letter from the Listing Qualifications Department of the Nasdaq Stock Market LLC notifying us that, for the prior 30 consecutive business days, the bid price for our common stock closed below the Bid Price Requirement.

We were provided a period of 180 calendar days, or until January 22, 2024 (the "Compliance Date"), to regain compliance with the Bid Price Requirement. If, at any time before the Compliance Date, the bid price for the Common Stock closes at $1.00 or more for a minimum of 10 consecutive business days, as required under the Compliance Period Rule, the Staff will provide written notification to us that it has regained compliance with the Bid Price Requirement. If Eiger does not regain compliance with the Bid Price Requirement by the Compliance Date, Eiger may be eligible for an additional 180 calendar day compliance period. To qualify, Eiger will be required to meet the continued listing requirement for market value of its publicly held shares of at least $1 million and all other initial listing standards for the Nasdaq Capital Market (with the exception of the Bid Price Requirement), including either: (x) stockholders' equity of at least $5 million; or (y) a total market value of listed securities of at least $50 million with stockholders' equity of at least $4 million, and will need to provide written notice of its intention to cure the deficiency during the second 180 calendar day compliance period, by effecting a reverse stock split, if necessary. In addition, Eiger had stockholders' deficit of $498.7 million at September 30, 2023, and there can be no assurance that Eiger will be able to satisfy the Nasdaq requirements for eligibility for an additional 180 calendar day compliance period to regain compliance with the Bid Price Requirement. In addition, Eiger may receive additional delisting notices from Nasdaq related to its stockholders' deficit at September 30, 2023 and the market value of its listed securities.

If Eiger does not regain compliance with the Bid Price Requirement by the Compliance Date and is not eligible for an additional compliance period at that time, or the Staff concludes that Eiger will not be able to cure the deficiency during the additional compliance period, the Staff will provide written notification to Eiger that its Common Stock will be subject to delisting. At that time, Eiger may appeal the Staff's delisting determination to a Nasdaq Hearings Panel. However, there can be no assurance that such appeal would be successful.

Eiger continues to monitor the closing bid price of the Common Stock and may, if appropriate, consider available options to regain compliance with the Bid Price Requirement, which could include seeking to effect a reverse stock split. However, there can be no assurance that Eiger will be able to regain compliance with the Bid Price Requirement.

The delisting of our common stock from the Nasdaq could impair the liquidity and market price of our common stock. It could also materially and adversely affect our access to the capital markets, and any limitation on market liquidity or reduction in the price of the common stock as a result of a delisting could adversely affect our ability to raise additional capital on terms acceptable to us, or at all.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us more difficult and may prevent attempts by our stockholders to replace or remove our management.

Provisions in our certificate of incorporation and bylaws may delay or prevent an acquisition or a change in management. These provisions include a classified board of directors, a prohibition on actions by written consent of our stockholders and the ability of the board of directors to issue preferred stock without stockholder approval. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits stockholders owning in excess of 15% of our voting stock from merging or combining with us. Although we believe these provisions collectively will provide for an opportunity to receive higher bids by requiring potential acquirers to negotiate with our board of directors, they would apply even if the offer may be considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove then current management by making it more difficult for stockholders to replace members of the board of directors, which is responsible for appointing the members of management.

We do not anticipate that we will pay any cash dividends in the foreseeable future.

We expect to retain our future earnings to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for our stockholders, if any, for the foreseeable future.

Future sales of shares by existing stockholders could cause our stock price to decline.

If existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after legal restrictions on resale lapse, the trading price of our common stock could decline. Certain of our existing stockholders, including Columbia Threadneedle Investments, Arkin, 683 Capital Management, The Vanguard Group, Telemetry Investments, and their respective affiliated entities, own substantial ownership interest in our common stock and any decision to sell a significant number of shares may negatively impact the price of our common stock.

The ownership of our common stock is highly concentrated, and it may prevent stockholders from influencing significant corporate decisions and may result in conflicts of interest that could cause our stock price to decline.

Our executive officers, directors and 5% stockholders and their affiliates beneficially own or control a significant portion of the outstanding shares of our common stock. Accordingly, these executive officers, directors, 5% stockholders and their affiliates, acting as a group, have substantial influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of our assets or any other significant corporate transactions. These stockholders may also delay or prevent a change of control of us, even if such a change of control would benefit our other stockholders. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.

Our net operating loss carryforwards and certain other tax attributes are now subject to limitations.

Our federal and state net operating loss (NOL) carry-forwards will begin to expire, if not utilized, beginning in 2030 for federal income tax purposes and 2028 for California state income tax purposes. These NOL carry-forwards could expire unused and be unavailable to offset future income tax liabilities. Under legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act, as modified by the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), U.S. federal net operating loss carryforwards generated in tax years beginning after December 31, 2017 may be carried forward indefinitely but, in the case of tax years beginning after December 31, 2020, may only be used to offset 80% of taxable income annually. In addition, California has enacted A.B. 85 which imposed limits on the usability of California state net operating losses and certain tax credits in tax years beginning after 2019 and before 2023. Such limitations could result in the expiration of portions of our net operating loss and tax credit carryforwards before utilization. On February 9, 2022, Senate Bill No. 113 was signed into California law and reinstates the net operating loss deduction, and removes the above-described temporary limitation on allowable credits, for taxable years beginning on or after January 1, 2022. Moreover, if a corporation undergoes an ownership change within the meaning of Section 382 of the Code (Section 382) the corporation's NOL carryforwards and certain other tax attributes arising from before the ownership change are subject to limitations on use after the "ownership change." In general, an ownership change occurs if there is a cumulative change in the corporation's equity ownership by certain stockholders that exceeds fifty percentage points over a rolling three-year period. Similar rules may apply under state tax laws. Our merger with Celladon resulted in such an ownership change and, accordingly, Celladon's NOL carryforwards and certain other tax attributes will be subject to further limitations on their use. In addition, we assessed whether Eiger had an ownership change, as defined by Section 382 of the Code, as a result of the Merger and other stock issuances that occurred from our formation through December 31, 2020. Based upon this assessment, we have experienced ownership changes on April 20, 2016, October 18, 2018 and December 31, 2020. Due to these ownership changes, reductions were made to our NOL and tax credit carryforwards under these rules. Additional ownership changes in the future could result in additional limitations on our net operating loss and tax credit carryforwards. Consequently, even if we achieve profitability, we may not be able to utilize a material portion of our NOL carryforwards and other tax attributes, which could have a material adverse effect on cash flow and results of operations. A full valuation allowance has been provided for the entire amount of our remaining net operating loss.

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.

ITEM 6. EXHIBITS

Exhibit Number	Description of Document
3.1	Amended and Restated Certificate of Incorporation of Celladon Corporation (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K of Celladon Corporation, filed with the SEC on February 10, 2014).
3.2	Amended and Restated Bylaws of Celladon Corporation (incorporated by reference to Exhibit 3.2 to the Current Report on Form 8-K, filed with the SEC on February 10, 2014).
3.3	Agreement and Plan of Merger and Reorganization, dated as of November 18, 2015, by and among Celladon Corporation, Celladon Merger Sub, Inc., and Eiger BioPharmaceuticals, Inc. (incorporated by reference to Exhibit 2.1 to the Current Report on Form 8-K filed with the SEC on November 19, 2015).
3.4	Certificate of Amendment of Amended and Restated Certificate of Incorporation of Celladon Corporation (incorporated by reference to Annex D to the Registration Statement on Form S-4, as amended (File No. 333-208521), originally filed with the SEC on December 14, 2015).
3.5	Certificate of Amendment of Amended and Restated Certificate of Incorporation of Celladon Corporation (incorporated by reference to Annex E to the Registration Statement on Form S-4, as amended (File No. 333-208521), originally filed with the SEC on December 14, 2015).
10.1**†	Offer Letter Agreement/Employment Agreement, dated as of November 25, 2019, by and between Eiger BioPharmaceuticals, Inc. and Ingrid Choong.
10.2**†	Promotion Letter Agreement, dated as of September 21, 2023, by and between Eiger BioPharmaceuticals, Inc. and Ingrid Choong.
31.1**	Certification of Principal Executive Officer required by Rule 13a-14(a) or Rule 15d-14(a).
31.2**	Certification of Principal Financial Officer required by Rule 13a-14(a) or Rule 15d-14(a).
32.1+	Certifications of Principal Executive Officer and Principal Financial Officer required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350).
99.1^#	Press release, dated August 14, 2023, titled "Eiger BioPharmaceuticals Reports Second Quarter 2023 Financial Results and Provides Business Update".
101.INS**	Inline XBRL Instance Document- the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH**	Inline XBRL Taxonomy Extension Schema Document
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 from the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2023, has been formatted in Inline XBRL.

+ This certification accompanies the Quarterly Report pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not be deemed "filed" by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

** Filed herewith.

† Management contract or compensatory plan.

^ Included herein solely to correct an incorrect hyperlink in the Exhibit Index to the Company's Current Report on Form 8-K filed with the SEC on August 14, 2023.

Furnished herewith.

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.

Eiger BioPharmaceuticals, Inc.

Date: November 9, 2023

By: /s/ David Apelian
David Apelian
Director, Chief Executive Officer
(Principal Executive Officer)

Eiger BioPharmaceuticals, Inc.

Date: November 9, 2023

By: /s/ William G. Kachioff
William G. Kachioff
Chief Financial Officer
(Principal Financial Officer)

25 November 2019

Eiger BioPharmaceuticals, Inc.
2155 Park Boulevard
Palo Alto, CA 94306

Ingrid Choong, Ph.D.

Re: Employment Terms

Dear Dr. Choong,

Eiger BioPharmaceuticals, Inc. ("Eiger" or the "Company") is pleased to offer the following terms to govern your continued employment in this Letter Agreement ("Agreement").

Duties, Compensation and Benefits

You will continue to serve as the Senior Vice President, Clinical Development, reporting to the Chief Executive Officer. You will work at our facility located at 2155 Park Boulevard in Palo Alto, California.

Your salary will be $300,000 per year, less payroll deductions and withholdings. You will be paid semimonthly, or in accordance with Company's compensation practices for other employees in place at the time.

In addition, you will be eligible for an annual bonus, targeted at 30% of your base salary, subject to applicable payroll deductions and withholdings ("Bonus"). Whether you receive this Bonus, and the amount of any such Bonus, will be determined by the Company in its sole discretion based upon your performance, the Company's performance and such other criteria that the Company deems relevant. Any Bonus shall be paid within thirty (30) days after the Company's determination that a Bonus shall be awarded. You will be eligible to earn a Bonus for any full calendar year provided that you remain employed by the Company as of December 31 of that year.

As an exempt salaried employee, you will be expected to be available and working during the Company's regular business hours, and without additional compensation, for such extended hours or additional time as appropriate to manage your responsibilities. The Company reserves the right to reasonably require you to perform your duties at places other than its Palo Alto facility from time to time, and to require reasonable business travel, including international travel, at the Company's expense.

You will be eligible for the following standard Company benefits: medical insurance, paid time off (PTO), 401(K), Employee Stock Purchase Plan (ESPP) and holidays. Details about these benefits are provided in the Employee Handbook and Summary Plan Descriptions, available for your review. Eiger may change compensation and benefits from time to time in its discretion.

The Company's Board of Directors (the "Board"), has previously, under the Eiger Equity Incentive Plan (the "Plan"), granted you options to purchase shares (the "Option") of the Company's Common Stock at fair market value as determined by the Board as of the date of grant. In addition, you will be eligible for future equity awards granted in accordance with the Company's plans as in effect from time to time at levels commensurate with your position and

responsibilities and subject to such terms as shall be determined by the Board or one of its committees in its or their sole discretion.

As an Eiger employee, you will be expected to abide by Company rules and policies, and acknowledge in writing that you have read the Company's Employee Handbook. As a condition of employment, you must sign and comply with the attached Employee Confidential Information and Inventions Assignment Agreement, which prohibits unauthorized use or disclosure of Eiger proprietary information, among other obligations.

In your work for the Company, you will be expected not to use or disclose any confidential information, including trade secrets, of any former employer or other person to whom you have an obligation of confidentiality. Rather, you will be expected to use only that information which is generally known and used by persons with training and experience comparable to your own, which is common knowledge in the industry or otherwise legally in the public domain, or which is otherwise provided or developed by the Company. You agree that you will not bring onto Company premises any unpublished documents or property belonging to any former employer or other person to whom you have an obligation of confidentiality. You hereby represent that you have disclosed to the Company any contract you have signed that may restrict your activities on behalf of the Company.

At Will Employment

Your employment with the Company will be "at-will." You may terminate your employment with Eiger at any time and for any reason whatsoever simply by notifying Eiger. Likewise, Eiger may terminate your employment at any time, with or without cause or advance notice. Your employment at-will status can only be modified in a written agreement signed by you and by an officer of Eiger.

Payments upon Termination other than without Cause or with Good Reason

Upon termination of your employment for any reason other than by the Company without Cause or by you with Good Reason, you shall be paid all accrued but unpaid Base Salary, any earned but unpaid Bonus, reimbursement for business expenses incurred by you but not yet paid to you as of the date your employment terminates, and all accrued but unused vacation (collectively, the "Accrued Payments"). Any unvested Company equity awards that you hold, including any unvested options and restricted stock units (collectively, "Outstanding Equity"), shall terminate as of your termination date.

Termination without Cause or with Good Reason

If, after you complete nine (9) months of employment with the Company, the Company terminates your employment without Cause (as defined below) or you resign for Good Reason (as defined below), and other than as a result of your death or disability, and provided such termination constitutes a "separation from service" (as defined under Treasury Regulation Section 1.409A-1(h)), then subject to your obligations below, you shall be entitled to receive the following severance benefits:

(i) an amount equal to nine (9) months of your then current base salary and pro-rata target bonus, less all applicable withholdings and deductions, paid over such nine (9) month period, on the schedule described below (the "Salary Continuation"); and

(ii) if you timely elect continued coverage under COBRA for yourself and your covered dependents, then the Company shall pay the COBRA premiums

necessary to continue your health insurance coverage in effect for yourself and your eligible dependents on the termination date until the earliest of (A) the close of the nine (9) month period following the termination of your employment, (B) the expiration of your eligibility for the continuation coverage under COBRA, or (C) the date when you become eligible for substantially equivalent health insurance coverage in connection with new employment or self-employment. If you become eligible for coverage under another employer's group health plan or otherwise cease to be eligible for COBRA during the period provided in this clause, you must immediately notify the Company of such event, and all payments and obligations under this clause shall cease.

Change in Control

If there is a Change in Control (as defined below), and within the date ninety (90) days before the closing of a Change in Control and ending on the date one (1) year after the effective date of that Change in Control, the Company terminates your employment without Cause (as defined below), and other than as a result of your death or disability, or you resign for Good Reason (as defined below), and provided such termination constitutes a Separation from Service, then subject to your obligations below, you shall be entitled to receive the following benefits:

(iii) acceleration of the vesting of the Outstanding Equity as of the date of termination as to 100% of the then-unvested Outstanding Equity, any Outstanding Equity that is subject to performance-based vesting conditions will be deemed to have been achieved at target, and you shall have 12 months from the date of termination in which to exercise your shares subject to any option the Accelerated Vesting;

(iv) an amount equal to twelve (12) months of your then current base salary and pro-rata target bonus, less all applicable withholdings and deductions, paid in lump sum on the date your employment terminates;

(v) if you timely elect continued coverage under COBRA for yourself and your covered dependents, then the Company shall pay the COBRA premiums necessary to continue your health insurance coverage in effect for yourself and your eligible dependents on the termination date until the earliest of (A) the close of the twelve (12) month period following the termination of your employment, (B) the expiration of your eligibility for the continuation coverage under COBRA, or (C) the date when you become eligible for substantially equivalent health insurance coverage in connection with new employment or self-employment. If you become eligible for coverage under another employer's group health plan or otherwise cease to be eligible for COBRA during the period provided in this clause, you must immediately notify the Company of such event, and all payments and obligations under this clause shall cease.

Your receipt of any of the severance benefits set forth above is conditional upon your continuing to comply with your legal and contractual obligations to the Company and your delivering to the Company an effective, general release of claims in favor of the Company in a form acceptable to the Company within 60 days following your termination date. The Salary Continuation will be paid in equal installments on the Company's regular payroll schedule and will be subject to applicable tax withholdings over the period outlined above following the date of your termination date; provided, however, that no payments will be made prior to the 60th day following your Separation from Service. On the 60th day following your Separation from Service, the Company will pay you in a lump sum the Salary Continuation that you would have received on or prior to such date under the original schedule but for the delay while waiting for

the 60th day in compliance with Code Section 409A and the effectiveness of the release, with the balance of the Salary Continuation being paid as originally scheduled.

Definitions

A "Change in Control" shall mean any consolidation or merger of the Company with or into any other corporation or other entity or person, or any other corporate reorganization, in which the capital stock of the Company immediately prior to such consolidation, merger or reorganization, represents less than 50% of the voting power of the surviving entity (or, if the surviving entity is a wholly owned subsidiary, its parent) immediately after such consolidation, merger or reorganization; any transaction or series of related transactions to which the Company is a party in which in excess of fifty percent (50%) of the Company's voting power is transferred; or the sale of 50% of the gross value or more of the assets of Company to an unrelated party; *provided* that a Change in Control shall not include (x) any consolidation or merger effected exclusively to change the domicile of the Company, or (y) any transaction or series of transactions principally for bona fide equity financing purposes in which cash is received by the Company or indebtedness of the Company is cancelled or converted or a combination thereof approved by two-thirds of the outstanding shares of preferred stock of the Company.

For purposes of this Agreement, "Good Reason" shall mean the occurrence of any of the following without your prior written consent: (i) relocation of your principal place of employment of over 35 miles from your then-current principal place of employment immediately prior to such relocation; (ii) a material and adverse change in your authority, duties, or responsibilities, or (iii) a reduction in your Base Salary or Bonus target percentage of Base Salary, unless the salaries or bonus target percentages of all other vice presidents of the Company are correspondingly and proportionately reduced. You cannot terminate your employment for Good Reason unless you have provided written notice to the Company of the existence of the circumstances providing grounds for termination for Good Reason within thirty (30) days after the existence of such event, and the Company has had at least thirty (30) days from the date on which such notice is provided to cure such circumstances, and you resign his employment within thirty (30) days after the end of such cure period.

For purposes of this Agreement, "Cause" shall mean that in the reasonable determination of the Board, you commit any felony or crime involving moral turpitude, participate in any fraud against the Company, willfully breach your duties to the Company, wrongfully disclose any trade secrets or other confidential information of the Company, or materially breach any material provision of the Agreement, the Employee

Confidential Information and Inventions Assignment Agreement or any other agreement entered into with the Company.

Section 280G of the Code

If any payment or benefit (including payments and benefits pursuant to this Agreement) that you would receive in connection with a Change in Control from the Company or otherwise ("Transaction Payment") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Internal Revenue Code (the "Code"), and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "Excise Tax"), then the Company shall cause to be determined, before any amounts of the Transaction Payment are paid to you, which of the following two alternative forms of payment would result in your receipt, on an after-tax basis, of the greater amount of the Transaction Payment notwithstanding that all or some portion of the Transaction Payment may be subject to the Excise Tax: (1) payment in full of the entire amount of the Transaction Payment (a "Full Payment"), or (2) payment of only a part of the Transaction Payment so that you receive the largest payment possible without the

imposition of the Excise Tax (a "Reduced Payment"). For purposes of determining whether to make a Full Payment or a Reduced Payment, the Company shall cause to be taken into account all applicable federal, state and local income and employment taxes and the Excise Tax (all computed at the highest applicable marginal rate, net of the maximum reduction in federal income taxes which could be obtained from a deduction of such state and local taxes). If a Reduced Payment is made, (x) you shall have no rights to any additional payments and/or benefits constituting the Transaction Payment, and (y) reduction in payments and/or benefits shall occur in the manner that results in the greatest economic benefit to you as determined in this paragraph. If more than one method of reduction will result in the same economic benefit, the portions of the Transaction Payment shall be reduced pro rata. Unless you and the Company otherwise agree in writing, any determination required under this paragraph shall be made in writing by the Company's independent public accountants (the "Accountants"), whose determination shall be conclusive and binding upon you and the Company for all purposes. For purposes of making the calculations required by this paragraph, the Accountants may make reasonable assumptions and approximations concerning applicable taxes and may rely on reasonable, good faith interpretations concerning the application of Sections 280G and 4999 of the Code. You and the Company shall furnish to the Accountants such information and documents as the Accountants may reasonably request in order to make a determination under this paragraph. The Company shall bear all costs the Accountants may reasonably incur in connection with any calculations contemplated by this paragraph as well as any costs incurred by you with the Accountants for tax planning under Sections 280G and 4999 of the Code.

Section 409A

It is intended that all of the severance benefits and other payments payable under this letter satisfy, to the greatest extent possible, the exemptions from the application of Code Section 409A provided under Treasury Regulations 1.409A 1(b)(4), 1.409A 1(b)(5) and 1.409A 1(b)(9), and this letter will be construed to the greatest extent possible as consistent with those provisions. For purposes of Code Section 409A (including, without limitation, for purposes of Treasury Regulation Section 1.409A 2(b)(2)(iii)), your right to receive any installment payments under this letter (whether severance payments, reimbursements or otherwise) shall be treated as a right to receive a series of separate payments and, accordingly, each installment payment hereunder shall at all times be considered a separate and distinct payment.

Notwithstanding any provision to the contrary in this letter, if you are deemed by the Company at the time of your Separation from Service to be a "specified employee" for purposes of Code Section 409A(a)(2)(B)(i), and if any of the payments upon Separation from Service set forth herein and/or under any other agreement with the Company are deemed to be "deferred compensation", then to the extent delayed commencement of any portion of such payments is required in order to avoid a prohibited distribution under Code Section 409A(a)(2)(B)(i) and the related adverse taxation under Section 409A, such payments shall not be provided to you prior to the earliest of (i) the expiration of the six-month period measured from the date of your Separation from Service with the Company, (ii) the date of your death or (iii) such earlier date as permitted under Section 409A without the imposition of adverse taxation. Upon the first business day following the expiration of such applicable Code Section 409A(a)(2)(B)(i) period, all payments deferred pursuant to this paragraph shall be paid in a lump sum to you, and any remaining payments due shall be paid as otherwise provided herein or in the applicable agreement. No interest shall be due on any amounts so deferred.

Arbitration

You and the Company agree that any and all disputes, claims, or causes of action, in law or equity, including but not limited to statutory claims, arising from or relating to the enforcement, breach, performance, or interpretation of this Agreement, your employment with the Company,

or the termination of your employment, shall be resolved, to the fullest extent permitted by law, by final, binding and confidential arbitration conducted by JAMS or its successor, under JAMS' then applicable rules and procedures for employment disputes before a single arbitrator (available upon request and also currently available at http://www.jamsadr.com/rules-employment-arbitration/). You acknowledge that by agreeing to this arbitration procedure, both you and the Company waive the right to resolve any such dispute through a trial by jury or judge or administrative proceeding. In addition, all claims, disputes, or causes of action under this section, whether by you or the Company, must be brought in an individual capacity, and shall not be brought as a plaintiff (or claimant) or class member in any purported class or representative proceeding, nor joined or consolidated with the claims of any other person or entity. The arbitrator may not consolidate the claims of more than one person or entity, and may not preside over any form of representative or class proceeding. To the extent that the preceding sentences regarding class claims or proceedings are found to violate applicable law or are otherwise found unenforceable, any claim(s) alleged or brought on behalf of a class shall proceed in a court of law rather than by arbitration. This paragraph shall not apply to any action or claim that cannot be subject to mandatory arbitration as a matter of law, including, without limitation, claims brought pursuant to the California Private Attorneys General Act of 2004, as amended. In the event you intend to bring multiple claims, including one of the Excluded Claims listed above, the Excluded Claims may be publicly filed with a court, while any other claims will remain subject to mandatory arbitration. You will have the right to be represented by legal counsel at any arbitration proceeding. The arbitrator shall: (a) have the authority to compel adequate discovery for the resolution of the dispute and to award such relief as would otherwise be permitted by law; and (b) issue a written statement signed by the arbitrator regarding the disposition of each claim and the relief, if any, awarded as to each claim, the reasons for the award, and the arbitrator's essential findings and conclusions on which the award is based. The arbitrator shall be authorized to award all relief that you or the Company would be entitled to seek in a court of law. The Company shall pay all JAMS arbitration fees in excess of the administrative fees that you would be required to pay if the dispute were decided in a court of law. Nothing in this Agreement is intended to prevent either you or the Company from obtaining injunctive relief in court to prevent irreparable harm pending the conclusion of any such arbitration. Any awards or orders in such arbitrations may be entered and enforced as judgments in the federal and state courts of any competent jurisdiction.

Miscellaneous

This offer is contingent upon a background check clearance, reference check, and satisfactory proof of your right to work in the United States. You agree to assist as needed and to complete any documentation at the Company's request to meet these conditions.

This letter, together with your Employee Proprietary Information and Inventions Agreement, forms the complete and exclusive statement of your employment agreement with Eiger. It supersedes any other agreements or promises made to you by anyone, whether oral or written. Changes in your employment terms, other than those changes expressly reserved to the Company's discretion in this letter, require a written modification signed by an officer of Eiger.

Please sign and date this letter if you wish to accept these terms to govern your employment at Eiger.

We look forward to your favorable reply and to a productive and enjoyable work relationship.

Sincerely,

/s/ David Cory
David Cory

President and Chief Executive Officer

Accepted:
/s/ Ingrid-Choong
Ingrid-Choong
11/25/2019
Date

CONFIDENTIAL

September 21, 2023

Ingrid Choong
Senior Vice President, Clinical Development

Dear Ingrid,

Eiger is very pleased to offer you a promotion to **Chief Business Officer** reporting directly to David Apelian, Chief Executive Officer. Your new responsibilities are outlined in the attached job description. Your remote position will continue to be headquartered at 2155 Park Blvd, Palo Alto, CA 94306.

The following are the details:

Your new annual base salary is **$440,000** which includes a promotion increase of 5.1% or $21,300.

Your FY23 STI target bonus eligibility is **40%** of your base salary.

You have also been granted a stock option to purchase **54,000** shares, which will become available in your E*TRADE account soon after the grant. The shares will vest monthly in 48 equal installments. The shares will be priced on the last trading day of the month.

Should you accept this offer, your new salary, STI target eligibility and options grant will be effective as of Thursday, September 21, 2023.

Thank you and congratulations! We look forward to your success in your new role!

Sincerely,

/s/ David Apelian
David Apelian
Chief Executive Officer

Acceptance:

I hereby accept this promotion at Eiger Biopharmaceuticals, Inc. I understand and agree that my employment with the company continues to be voluntarily and that I may resign at any time. Similarly, my employment may be terminated for any reason and at any time without previous notice. I understand this promotion letter constitutes employment "at-will" and no contractual relationship or actionable promises exist between the employer and employee. This term of employment is not subject to change or modification of any kind except in writing and signed by the Senior Director of Human Resources and the Chief Executive Officer of Eiger Biopharmaceuticals, Inc.

/s/ Ingrid Choong — 9/20/2023
Signature — Date

Ingrid Choong

Exhibit 31.1

Certification of Chief Executive Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, David Apelian, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Eiger BioPharmaceuticals, Inc.

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

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

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

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

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

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

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

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

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

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

Date: November 9, 2023

/s/ David Apelian

David Apelian

Director, Chief Executive Officer

Exhibit 31.2

Certification of Chief Financial Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, William G. Kachioff, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Eiger BioPharmaceuticals, Inc.

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

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

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

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

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

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

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

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

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

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

Date: November 9, 2023

/s/William G. Kachioff
William G. Kachioff
Chief Financial Officer

Exhibit 32.1

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), David Apelian, Chief Executive Officer of Eiger BioPharmaceuticals, Inc. (the "Company"), and William G. Kachioff, Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2023, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

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

Dated: November 9, 2023

/s/ David Apelian

David Apelian

Director, Chief Executive Officer

/s/ William G. Kachioff

William G. Kachioff

Chief Financial Officer

"This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Eiger BioPharmaceuticals, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing."

Eiger BioPharmaceuticals Reports Second Quarter 2023 Financial Results and Provides Business Update

Resources prioritized to advance avexitide in hyperinsulinemic hypoglycemia indications
Active discussions underway with potential partners to advance late-stage virology programs
Reduction in workforce executed to align with focus on avexitide; extends cash runway to into Q4 2024
David Apelian, MD, PhD, MBA, appointed CEO

Palo Alto, Calif., August 14, 2023 -- Eiger BioPharmaceuticals, Inc. (Nasdaq:EIGR), a commercial-stage biopharmaceutical company focused on the development of innovative therapies for rare metabolic diseases, today reported financial results for the second quarter 2023 and provided a business update.

“We reported in late June that we are deploying our resources toward recognizing the compelling potential of avexitide in metabolic diseases,” said David Apelian, MD, PhD, MBA, CEO of Eiger. “Our initial focus is on post-bariatric hypoglycemia, or PBH, and other forms of hyperinsulinemic hypoglycemia (HH) arising after gostrointestinal surgeries where we see the highest revenue potential, have demonstrated proof-of-concept in Phase 2 clinical trials, and have FDA alignment on Phase 3 endpoints, sample size, and study design. In the future, we also intend to develop avexitide for congenital hyperinsulinism as a second indication.”

Business Highlights

Avexitide for Post-Bariatric Hypoglycemia (PBH)

- A large orphan disease with a growing population; caused by complications in bariatric surgery
- Prevalence of approximately 180,000 in the US and approximately half that in the EU
- Avexitide is the only drug in development for PBH with Breakthrough Therapy designation
- FDA alignment on pivotal Phase 3 study endpoints, sample size, and design

Avexitide for Congenital Hyperinsulinism (HI)

- An ultra-rare, life-threatening, pediatric disorder of persistent hypoglycemia that results in irreversible brain damage in up to 50% of children
- Breakthrough Therapy designation from FDA
- Rare Pediatric Disease designation

Zokinvy® (lonafarnib) for Progeria and Processing-Deficient Progeroid Laminopathies

- Achieved net revenue of $4.6 million in Q2 2023

Corporate

- 25% reduction in workforce, a reduction in out-of-pocket spending related to the Company's hepatitis delta (HDV) development program and the Company's existing term loan are expected to extend the Company’s cash runway into the fourth quarter of 2024
- David Apelian, MD, PhD, MBA, appointed CEO

Cash Position

- $53.6 million in cash position as of June 30, 2023

Second Quarter 2023 Financial Results

Total revenue was $4.6 million for the second quarter of 2023, as compared to $4.1 million for the same period in 2022. The increase was primarily driven by the product sales in Germany compared to no such sales for the same period in 2022. The increase was partially offset by a decrease of certain upfront payments received under the terms of the Marketing and Distribution Agreement (MDA) with AnGes, Inc., which was executed in May 2022, relating to obtaining regulatory approval for and commercialization of Zokinvy in Japan.

Cost of sales decreased by $0.5 million in the second quarter 2023 compared to the same period in 2022. The decrease was primarily due to a reversal of an inventory accrual related to a nonconforming batch of product. During the second quarter 2023, the Company was notified by the vendor that it was no longer obligated to pay for that nonconforming batch of product.

Research and development expenses were $19.4 million for the second quarter of 2023, as compared to $17.0 million for the same period in 2022. The increase was primarily due to an increase in clinical and contract manufacturing expenditures and an increase in compensation and personnel related expense. The increase was partially offset by a decrease in outside services across programs, including consulting and advisory services due to a decline in spending on peginterferon lambda programs.

Selling, general and administrative expenses were $5.5 million for the second quarter of 2023, as compared to $7.0 million for the same period in 2022. The decrease was primarily due to a decrease in compensation and personnel related expense, including stock-based compensation, and a decrease in outside services, including consulting, advisory and accounting services.

Total operating expenses include non-cash expenses of $0.9 million for the second quarter of 2023, as compared to $4.1 million for the same period in 2022. The decrease was primarily due to a change in amortization of premiums and discounts on debt securities due to current market and economic conditions, a decrease in loss on early extinguishment of Oxford loan paid off in June 2022 and a decrease in stock based compensation expenses.

The Company reported a net loss of $20.7 million, or $0.47 per share basis for the second quarter of 2023. This compares to a net loss of $21.9 million, or $0.51 per share basis for the same period in 2022.

Cash, cash equivalents, and short-term debt securities as of June 30, 2023 totaled $53.6 million, as compared to $98.9 million as of December 31, 2022.

As of June 30, 2023, the Company had 44,296,417 common shares outstanding.

About Eiger

Eiger is a commercial-stage biopharmaceutical company focused on the development of innovative therapies for rare metabolic diseases. Eiger’s lead product candidate, avexitide, is a well characterized, first-in-class GLP-1 antagonist being developed for the treatment of post-bariatric hypoglycemia (PBH) and congenital hyperinsulinism (HI). Avexitide is the only drug in development for PBH with Breakthrough Therapy designation from the FDA.

For additional information about Eiger and its clinical programs, please visit www.eigerbio.com.

Note Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical facts, including statements regarding our future financial condition, timing for and outcomes of clinical results, prospective products, preclinical and clinical pipelines, regulatory objectives, business strategy and plans and objectives for future operations, are forward-looking statements. Forward-looking statements are our current statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, the timing of our ongoing and planned clinical development; our capability to provide sufficient quantities of any of our products or product candidates for studies or to meet anticipated full-scale commercial demands; our ability to identify, pursue and enter into partnering opportunities for our virology assets; the sufficiency of our cash, cash equivalents and investments to fund our operations into the fourth quarter of 2024, including the scope and impact of any savings from our workforce reduction and cash conservation efforts; the revenue potential of avexitide in post-bariatric hypoglycemia and congenital hyperinsulinism; our ability to finance, independently or through collaborations, the continued advancement of our development pipeline; and the potential for success of any of our products or product candidates. Various important factors could cause actual results or events to

differ materially from the forward-looking statements that Eiger makes, including additional applicable risks and uncertainties described in the “Risk Factors” section in Eiger’s Quarterly Report on Form 10-Q for the quarter ended March 31, 2023 and Eiger's subsequent filings with the SEC. The forward-looking statements contained in this press release are based on information currently available to Eiger and speak only as of the date on which they are made. Eiger does not undertake and specifically disclaims any obligation to update any forward-looking statements, whether as a result of any new information, future events, changed circumstances or otherwise.

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Eiger BioPharmaceuticals Inc.
Condensed Consolidated Balance Sheets
(in thousands)

	June 30, 2023	December 31, 2022[1]
	(Unaudited)	
ASSETS		
Cash and cash equivalents	$ 22,983	$ 25,798
Short-term debt securities	30,626	73,150
Accounts receivable	3,715	1,749
Inventories	1,098	2,853
Prepaid expenses and other current assets	12,062	13,985
Total current assets	70,484	117,535
Property and equipment, net	755	696
Operating lease right-of-use assets	329	561
Other assets	790	1,347
Total assets	$ 72,358	$ 120,139
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities	16,713	$ 25,121
Other liabilities	40,350	39,708
Stockholders' equity	15,295	55,310
Total liabilities and stockholders' equity	$ 72,358	$ 120,139

(1) Derived from the audited financial statements, included in the Company's Annual Report on Form 10-K for the year ended December 31, 2022.

Eiger BioPharmaceuticals Inc.
Condensed Consolidated Statements of Operations Financial Data
(in thousands, except per share and share amounts)

	Three Months Ended June 30, (unaudited)		Six Months Ended June 30, (unaudited)	
	2023	2022	2023	2022
Product revenue, net	$ 4,393	$ 3,341	$ 8,511	$ 6,014
Other revenue	250	750	250	750
Total revenue	4,643	4,091	8,761	6,764
Costs and operating expenses:				
Cost of sales	(310)	151	(192)	261
Research and development[(1)]	19,401	16,993	36,149	34,563
Selling, general and administrative[(1)]	5,533	7,027	15,048	13,840
Total operating expenses	24,624	24,171	51,005	48,664
Loss from operations	(19,981)	(20,080)	(42,244)	(41,900)
Interest expense	(1,343)	(934)	(2,628)	(1,820)
Interest income	660	221	1,371	266
Other income (expense), net	(29)	(1,074)	26	(1,047)
Income (loss) before provision for taxes	(20,693)	(21,867)	(43,475)	(44,501)
Provision for income taxes	2	17	4	26
Net loss	$ (20,695)	$ (21,884)	$ (43,479)	$ (44,527)
Net income (loss) per common share:				
Basic and diluted	$ (0.47)	$ (0.51)	$ (0.98)	$ (1.14)
Weighted-average common shares outstanding:				
Basic and diluted	44,296,417	43,059,809	44,221,442	39,178,043

(1) Includes stock-based compensation expense of:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Research and development	$ 517	$ 820	$ 1,351	$— $ 1,445
General and administrative	228	1,388	1,936	2,810
Total stock-based compensation expense	$ 745	$ 2,208	$ 3,287	$ 4,255