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

Form 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2019

OR

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

For the transition period from _____ to _____

Commission file number: 001-36183

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)

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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	☐	Accelerated filer	☒
Non-accelerated filer	☐	Smaller reporting company	☒
Emerging growth company	☒		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

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

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

As of May 6, 2019, the number of outstanding shares of the registrant's common stock, par value $0.001 per share, was 24,435,443.

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)

	March 31, 2019 (Unaudited)	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 63,407	$ 61,262
Debt securities, available-for-sale	22,385	39,091
Prepaid expenses and other current assets	2,594	1,492
Total current assets	88,386	101,845
Property and equipment, net	155	167
Operating lease right-of-use assets	1,861	—
Other assets	2,706	436
Total assets	$ 93,108	$ 102,448
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 5,523	$ 5,830
Accrued liabilities	4,863	4,194
Current portion of operating lease liabilities	439	—
Total current liabilities	10,825	10,024
Long term debt, net	29,844	25,620
Operating lease liabilities	1,631	—
Other long term liabilities	—	212
Total liabilities	42,300	35,856
Stockholders' equity:		
Common stock	19	19
Additional paid-in capital	239,170	237,795
Accumulated other comprehensive income (loss)	5	(25)
Accumulated deficit	(188,386)	(171,197)
Total stockholders' equity	50,808	66,592
Total liabilities and stockholders' equity	$ 93,108	$ 102,448

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 March 31,	
	2019	**2018**
Operating expenses:		
Research and development	$ 12,868	$ 5,512
General and administrative	4,057	2,994
Total operating expenses	16,925	8,506
Loss from operations	(16,925)	(8,506)
Interest expense	(765)	(398)
Interest income	511	94
Other expense, net	(10)	(21)
Net loss	$ (17,189)	$ (8,831)
Net loss per common share, basic and diluted	$ (0.90)	$ (0.84)
Weighted-average common shares outstanding, basic and diluted	19,168,448	10,529,350

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 March 31,	
	2019	**2018**
Net loss	$ (17,189)	$ (8,831)
Other comprehensive loss:		
Unrealized gain on available-for-sale debt securities, net	30	3
Comprehensive loss	$ (17,159)	$ (8,828)

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

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

	Three Months Ended March 31,	
	2019	**2018**
Shares of common stock outstanding		
Balance, beginning of period	19,211,759	10,526,599
Issuance of common stock upon stock option exercises	41,546	—
Issuance of common stock upon ESPP purchase	7,138	9,522
Balance, end of period	19,260,443	10,536,121
Common Stock		
Balance, beginning of period	$ 19	$ 11
Balance, end of period	19	11
Additional paid-in capital		
Balance, beginning of period	237,795	141,320
Issuance of common stock upon stock option exercises	65	—
Issuance of common stock upon ESPP purchase	59	34
Vesting of common stock issued under Product Development Agreement	56	—
Stock-based compensation expense	1,195	1,003
Balance, end of period	239,170	142,357
Accumulated other comprehensive income (loss)		
Balance, beginning of period	(25)	(3)
Unrealized gain on debt securities, net	30	3
Balance, end of period	5	—
Accumulated deficit		
Balance, beginning of period	(171,197)	(118,806)
Net loss	(17,189)	(8,831)
Balance, end of period	(188,386)	(127,637)
Total stockholders' equity	$ 50,808	$ 14,731

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)

	Three Months Ended March 31,	
	2019	**2018**
Operating activities		
Net loss	$ (17,189)	$ (8,831)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	13	11
Amortization of debt securities discounts	(121)	(3)
Non-cash interest expense	177	98
Amortization of operating lease right-of-use assets	97	—
Common stock issued under Product Development Agreement	56	—
Stock-based compensation	1,195	1,003
Change in operating assets and liabilities:		
Prepaid expenses and other current assets	(1,102)	95
Other assets	(2,270)	23
Accounts payable	(307)	(158)
Accrued liabilities	669	(860)
Operating lease liabilities	(100)	—
Other long term liabilities	—	50
Net cash used in operating activities	(18,882)	(8,572)
Investing activities		
Purchase of debt securities available-for-sale	(1,943)	—
Proceeds from maturities of debt securities available-for-sale	18,800	9,750
Purchase of property and equipment	(1)	—
Net cash provided by investing activities	16,856	9,750
Financing activities		
Repayment of term loan	(1,667)	—
Proceeds from borrowings in connection with term loan, net of issuance costs	6,627	—
Repayment of accrued exit fee and second amendment fee	(913)	—
Proceeds from issuance of common stock upon stock option exercises	65	—
Proceeds from issuance of common stock upon ESPP purchase	59	34
Net cash provided by financing activities	4,171	34
Net increase in cash and cash equivalents	2,145	1,212
Cash and cash equivalents at beginning of period	61,262	32,035
Cash and cash equivalents at end of period	$ 63,407	$ 33,247
Supplemental disclosure of cash flow information:		
Interest paid	$ 777	$ 297

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

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 late-stage biopharmaceutical company focused on the development and commercialization of well-characterized drugs for life-threatening, rare and ultra-rare diseases with high unmet medical needs and no approved therapies. Eiger has reported positive proof-of-concept clinical results in four programs: lonafarnib boosted with ritonavir, peginterferon, lambda, avexitide, and lonafarnib monotherapy, all with first-in-class drugs, now advancing into submission for regulatory approvals or Phase 3 clinical development.

Eiger's lead program is in Phase 3, developing lonafarnib, a first-in-class prenylation inhibitor for the treatment of Hepatitis Delta Virus ("HDV") infection. The Company is also preparing a new drug application ("NDA") and a market authorization approval ("MAA") with plans for submission in 2019, for lonafarnib in the treatment of Hutchinson-Gilford Progeria Syndrome ("HGPS" or "Progeria") and Progeroid Laminopathies. In addition, the Company recently announced positive Phase 2 data with peginterferon lambda for HDV infection and avexitide for post-bariatric hypoglycemia ("PBH").

The Company's programs have several aspects in common: the disease targets represent conditions of high unmet medical need with no approved therapies; the therapeutic approaches are supported by an understanding of disease biology and mechanism as elucidated by our academic research relationships; prior clinical experience with the product candidates guides an understanding of safety; and the development paths leverage the experience and capabilities of our experienced, commercially-focused management team. The Company's principal operations are based in Palo Alto, California, and it operates in one segment.

Liquidity

As of March 31, 2019, the Company had $63.4 million of cash and cash equivalents, $22.4 million of debt securities available-for-sale, an accumulated deficit of $188.4 million and negative cash flows from operating activities. The Company expects to continue to incur losses for the next several years.

Management believes that the currently available resources will be sufficient to fund its operations for at least the next 12 months following the issuance date of these unaudited condensed consolidated financial statements.

2. Summary of Significant Accounting Policies

Basis of Presentation

The unaudited condensed consolidated financial statements include the accounts of Eiger BioPharmaceuticals, Inc. and its wholly owned subsidiaries, EBPI Merger Inc., EB Pharma LLC and Eiger BioPharmaceuticals Europe Limited, and have been prepared in accordance with accounting principles generally accepted in the United States of America, ("U.S. GAAP") and following the requirements of the Securities and Exchange Commission (the "SEC") for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by U.S. GAAP can be condensed or omitted. These financial statements have been prepared on the same basis as the Company's annual financial statements and, in the opinion of management, reflect all adjustments, consisting only of normal recurring adjustments, which are necessary for a fair statement of the Company's financial information. These interim results are not necessarily indicative of the results to be expected for the year ending December 31, 2019 or for any other interim period or for any other future year. The balance sheet as of December 31, 2018, has been derived from audited consolidated financial statements at that date but does not include all of the information required by U.S. GAAP for complete financial statements. All intercompany balances and transactions have been eliminated in consolidation.

The accompanying unaudited condensed consolidated financial statements and related financial information should be read in conjunction with the audited consolidated financial statements and the related notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2018, filed with the Securities and Exchange Commission on March 14, 2019.

Use of Estimates

The preparation of unaudited 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 expenses during the reporting period. On an ongoing basis, the Company evaluates its estimates, including those related to clinical trial accrued liabilities, stock-based compensation and income taxes. 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.

Debt Securities

Short-term securities 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. All short-term securities are carried at fair value based upon quoted market prices. Unrealized gains and losses on available-for-sale securities are excluded from earnings and are reported as a component of accumulated other comprehensive income (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, net on the accompanying unaudited condensed consolidated statements of operations.

Accrued Research and Development Costs

The Company accrues for estimated costs of research and development activities conducted by third-party service providers, which include the conduct of preclinical and clinical studies, and contract manufacturing activities. The Company records the estimated costs of research and development activities based upon the estimated amount of services provided but not yet invoiced and includes these costs in accrued liabilities in the unaudited condensed consolidated balance sheets and within research and development expense in the unaudited condensed consolidated statements of operations. The Company accrues for these costs based on factors such as estimates of the work completed and in accordance with agreements established with its third-party service providers. The Company makes judgments and estimates in determining the accrued liabilities balance in each reporting period. As actual costs become known, the Company adjusts its accrued liabilities.

Leases

The Company has a real estate lease for its office space in Palo Alto, California. The Company determines the initial classification and measurement of its right-of-use assets and lease liabilities at the lease commencement date and thereafter if modified. The lease term includes any renewal options and termination options that the Company is reasonably assured to exercise. The present value of lease payments is determined by using the interest rate implicit in the lease, if that rate is readily determinable; otherwise, the Company uses its incremental borrowing rate. The incremental borrowing rate is determined by using the rate of interest that the Company would pay to borrow on a collateralized basis an amount equal to the lease payments for a similar term and in a similar economic environment.

Rent expense for operating leases is recognized on a straight-line basis, unless the operating lease right-of-use assets have been impaired, over the reasonably assured lease term based on the total lease payments and is included in operating expenses in the unaudited condensed consolidated statements of operations. For operating leases that reflect impairment, the Company will recognize the amortization of the operating lease right-of-use assets on a straight-line basis over the remaining lease term with rent expense still included in general and administrative expenses in the unaudited condensed consolidated statements of operations.

The Company has elected the practical expedient to not separate lease and non-lease components. The Company's non-lease components are primarily related to property maintenance and insurance, which varies based on future outcomes, and thus is recognized in general and administrative expenses when incurred.

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 all periods presented, diluted net loss per share is the same as basic net loss per share for all periods as the inclusion of all potential common shares outstanding would have been anti-dilutive.

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 March 31,	
	2019	2018
Options to purchase common stock	2,722,171	2,331,217
Warrants to purchase common stock	—	10,180
Total	2,722,171	2,341,397

Recently Adopted Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-02, *Leases (Topic 842),* which requires lessees to recognize most leases on their balance sheet. The new standard is effective for fiscal years beginning after December 15, 2018. Early adoption is permitted. Originally, entities were required to adopt ASU 2016-02 using a modified retrospective transition method. However, in July 2018, the FASB issued ASU No. 2018-11, *Targeted Improvements to Leases (Topic 842)*, which provides entities with an additional transition method. Under ASU No. 2018-11, entities have the option of recognizing the cumulative effect of applying the new standard as an adjustment to beginning retained earnings in the year of adoption while continuing to present all prior periods under previous lease accounting guidance. In July 2018, the FASB issued ASU No. 2018-10, *Codification Improvements to Leases (Topic 842)*, which clarifies how to apply certain aspects of ASU 2016-02. Additionally, in March 2019, the FASB issued ASU No. 2019-01, *Codification Improvements to Leases (Topic 842)*, which clarifies the transition disclosure requirements. The Company adopted this guidance on January 1, 2019 using the prospective transition method allowed per ASU 2018-11, and applied the standard only to leases that existed at that date. Under the prospective transition method, the Company does not need to restate the comparative period in transition and will continue to present financial information and disclosures for periods before January 1, 2019 in accordance with ASC Topic 840. The Company has elected the package of practical expedients allowed under ASC Topic 842, which permits the Company to account for its existing operating leases as operating leases under the new guidance, without reassessing the Company's prior conclusions about lease identification, lease classification and initial direct cost. As a result of the adoption of the new lease accounting guidance, the Company recognized, on January 1, 2019, operating lease right–of–use assets of $2.0 million and operating lease liabilities of $2.2 million in the unaudited condensed consolidated balance sheet. The adoption of the standard did not have a material impact on the unaudited condensed consolidated statement of operations and the unaudited condensed consolidated statement of cash flows.

Accounting Pronouncements Not Yet Adopted

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments—Credit Losses (Topic 326)*. The standard changes how entities will measure credit losses for most financial assets and certain other instruments that are not measured at fair value through net income. Financial assets measured at amortized cost will be presented at the net amount expected to be collected by using an allowance for credit losses. 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. The standard is effective for fiscal years and interim periods beginning after December 15, 2019. Early adoption is permitted for all periods beginning after December 15, 2018. The Company is currently in the process of evaluating the impact the standard will have on its consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820)*. The standard eliminates, modifies and adds disclosure requirements for fair value measurements. The pronouncement is effective for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2019, with early adoption permitted. The Company is currently in the process of evaluating the impact the standard will have on its 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). At March 31, 2019 and December 31, 2018, the carrying amount of prepaid expenses and other current assets, accounts payable and accrued liabilities approximated their estimate fair value due to their relatively short maturities. Management believes the terms of long-term debt reflects current market conditions for an instrument with similar terms and maturity, therefore the carrying value of the Company's debt approximated its fair value.

Assets and liabilities recorded at fair value on a recurring basis in the unaudited condensed consolidated balance sheets are categorized based upon the level of judgment associated with the inputs used to measure their fair values. Fair value is defined as the exchange price that would be received for an asset or an exit price that would be paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The authoritative guidance on fair value measurements establishes a three-tier fair value hierarchy for disclosure of fair value measurements as follows:

Level 1: Inputs are unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date;

Level 2: Inputs are observable, unadjusted quoted prices in active markets for similar assets or liabilities, unadjusted quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the related assets or liabilities; and

Level 3: Unobservable inputs that are significant to the measurement of the fair value of the assets or liabilities that are supported by little or no market data.

The Company's money market funds are classified as Level 1 because they are valued using quoted market prices. The Company's debt securities consist of available-for-sale securities and are classified as Level 2 because their value is based on valuations using significant inputs derived from or corroborated by observable market data. There were no assets or liabilities classified as Level 3 as of March 31, 2019 and December 31, 2018.

There were no transfers between Level 1, Level 2 or 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 (in thousands):

	March 31, 2019			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Money market funds	$ 62,604	$ —	$ —	$ 62,604
Corporate debt securities	—	16,193	—	16,193
Commercial paper	—	6,192	—	6,192
Total	$ 62,604	$ 22,385	$ —	$ 84,989

	December 31, 2018			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Money market funds	$ 45,441	$ —	$ —	$ 45,441
Corporate debt securities	—	23,474	—	23,474
Commercial paper	—	15,617	—	15,617
Total	$ 45,441	$ 39,091	$ —	$ 84,532

There were no financial liabilities as of March 31, 2019 and December 31, 2018.

The following tables summarize the estimated value of the Company's cash equivalents and debt securities and the gross unrealized holding gains and losses (in thousands):

	March 31, 2019			
	Amortized cost	Unrealized gain	Unrealized loss	Estimated Fair Value
Cash equivalents:				
Money market funds	$ 62,604	$ —	$ —	$ 62,604
Total cash equivalents	$ 62,604	$ —	$ —	$ 62,604
Debt securities:				
Corporate debt securities	$ 16,193	$ 2	$ (2)	$ 16,193
Commercial paper	6,187	5	—	6,192
Total debt securities	$ 22,380	$ 7	$ (2)	$ 22,385

	December 31, 2018			
	Amortized cost	Unrealized gain	Unrealized loss	Estimated Fair Value
Cash equivalents:				
Money market funds	$ 45,441	$ —	$ —	$ 45,441
Total cash equivalents	$ 45,441	$ —	$ —	$ 45,441
Debt securities:				
Corporate debt securities	$ 23,489	$ 1	$ (16)	$ 23,474
Commercial paper	15,627	—	(10)	15,617
Total debt securities	$ 39,116	$ 1	$ (26)	$ 39,091

As of December 31, 2018, the contractual maturity of the available-for-sale debt securities is less than one year. The Company periodically reviews the available-for-sale investments for other-than-temporary impairment loss. The Company considers factors such as the duration, severity and the reason for the decline in value, the potential recovery period and its intent to sell. For debt securities, it also considers whether (i) it is more likely than not that the Company will be required to sell the debt securities before recovery of their amortized cost basis, and (ii) the amortized cost basis cannot be recovered as a result of credit losses. During the three months ended March 31, 2019, the Company did not recognize any other-than-temporary impairment losses. All debt securities with unrealized losses have been in a loss position for less than twelve months.

4. Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	March 31, 2019	December 31, 2018
Contract research costs	$ 3,572	$ 2,191
Compensation and related benefits	727	1,705
Contract manufacturing costs	151	—
Consulting costs	75	258
Franchise tax	50	40
Other	288	—
Total accrued liabilities	$ 4,863	$ 4,194

5. Product Development Agreement

On August 11, 2018, the Company entered into a Product Development Agreement and a First Project Agreement (the "Product Agreements"), pursuant to which the Company will receive development program support services for its Hepatitis Delta Virus ("HDV") program. The services are to be provided from July 1, 2018 through the completion of the Phase 3 Clinical Study Reports and the subsequent NDA filing. As consideration, the Company has committed to pay fees of approximately $10.0 million in cash and stock over four years, including approximately $0.8 million for expert consultant fees and pass through costs to vendors, plus certain incentive-based regulatory milestone fees up to $1.0 million. In January 2019, the Company entered into the first amendment to the Product Agreements, which increased the Product Agreements' fees by $1.0 million. As part of the aggregate payment, the Company issued 115,526 shares of common stock subject to quarterly vesting requirements related to successful performance of the services and achievement of a budget timeline set forth in the Product Agreements. The Product Agreements can be terminated by either party due to material breach or by the Company without cause with 90 days prior written notice. For the three months ended March 31, 2019, the Company recognized research and development expense of $0.1 million related to the shares issued under the Product Agreements.

6. Debt

In December 2016, the Company entered into an aggregate $25.0 million loan with Oxford Finance LLC (the "Oxford Loan"). The loan matures on July 1, 2021. The Company borrowed $15.0 million in December 2016 ("Tranche A"). In May 2018, the Company entered into an amendment to the Oxford Loan and borrowed $5.0 million ("Tranche B"). On August 3, 2018, the Company borrowed the remaining $5.0 million ("Tranche C") under the Oxford Loan.

The Oxford Loan bears interest at a floating rate per annum equal to the greater of either the 30-day U.S. Dollar LIBOR reported in the Wall Street Journal plus 6.41% or 6.95%. The interest only period for borrowed funds is until February 1, 2019, followed by 30 equal monthly payments of principal plus accrued interest. At the time of final payment, the Company is required to pay an exit fee of 7.5% of the original principal balance of borrowed funds, or $1.9 million. In addition, at the time of final payment of Tranche B, the Company is required to pay an additional exit fee of $0.1 million. The Company recorded as a liability and debt discount the exit fee at the origination of the term loan. In addition, the Company incurred loan origination fees and debt issuance costs of $0.4 million which were recorded as a direct deduction from the carrying amount of the related debt liability as a debt discount.

On March 5, 2019, the Company entered into the third amendment to the Oxford Loan (the "Amended Oxford Loan") to refinance the Oxford Loan. The Amended Oxford Loan increased the aggregate amount available to be borrowed to $35.0 million, and extend the maturity date to March 1, 2024. On March 5, 2019, prior to entering into the Amended Oxford Loan, the outstanding balance of the Oxford Loan was $23.3 million. At the time of entering into the Amended Oxford Loan, the Company borrowed an additional $6.7 million in principal under the Amended Oxford Loan, which increased the total amount borrowed to $30.0 million ("Amended Tranche A"). The remaining $5.0 million ("Amended Tranche B") will be available to the Company upon the latest to occur of (i) achievement of positive Lonafarnib Phase 3 HDV topline data sufficient to file new drug application ("Clinical Milestone") and (ii) January 1, 2021.

The Amended Oxford Loan bears interest at a floating rate per annum equal to the greater of either the 30-day U.S. Dollar LIBOR reported in the Wall Street Journal plus 6.64% or 9.15%. The Amended Oxford Loan has an interest only period until April 1, 2021, followed by 36 equal monthly payments of principal and interest. Upon the receipt of Amended Tranche B, the interest only period for borrowed funds will be extended by one year until April 1, 2022, followed by 24 equal monthly payments of principal plus accrued interest. At the time of final payment, the Company is required to pay an exit fee of 7.5% of the original principal balance of borrowed funds, or $2.3 million. In addition, the Company is required to pay an additional exit fee of $1.0 million. The Company recorded as a liability and debt discount the exit fee for the Amended Oxford Loan. At the date of the Amended Oxford Loan, the Company paid $0.9 million for the accrued portion of the Oxford Loan exit fee and the Tranche B additional exit fee. The loan discount balance at the time of the Amended Oxford Loan was $0.2 million, which is being amortized over the remaining term of the Amended Oxford Loan.

The Company is also required to pay a 5.0% success fee of the total amount drawn under the Amended Oxford Loan within 30 days following the FDA's approval of the Company's first product, excluding lonafarnib in progeria and progeroid laminopathies. This fee is enforceable within 10 years from the funding of Amended Tranche A. The Company determined that the success fee met the scope exemption from derivative accounting and should be accounted for under the guidance for contingencies. Accordingly, the Company will record a liability for the success fee upon receipt of approval from the FDA. The Amended Oxford Loan includes contingent interest features and mandatory prepayment features upon an event of default that meet the definition of a derivative but were not bifurcated from the debt instrument as their fair value was deemed to be insignificant. In connection with the execution of the Oxford Loan, the Company agreed to certain customary representations and warranties.

The refinancing of the term loan did not have a material impact on terms, conditions, representations, warranties, covenants or agreements set forth in the Oxford Loan. The loan is secured by the 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 loan includes customary events of default, including failure to pay amounts due, breaches of covenants and warranties, material adverse effect events, certain cross defaults and judgments, and insolvency. If the Company is unable to comply with these covenants or if the Company defaults on any portion of the outstanding borrowings, the lenders can also impose a 5.0% penalty and restrict access to additional borrowings under the loan and security agreement. The Company was in compliance with the terms under the loan as of March 31, 2019 and December 31, 2018.

The Company is permitted to make voluntary prepayments of the Amended Oxford Loan with a prepayment fee, calculated as of the loan origination date, equal to (i) 2.0% of the loan prepaid during the first 12 months and (ii) 1.0% of the loan prepaid in months 13-24. The Company is required to make mandatory prepayments of the outstanding loan upon the acceleration by lender following the occurrence of an event of default, along with a payment of the final payment, the prepayment fee and any other obligations that are due and payable at the time of prepayment.

The Company accounts for the amortization of the debt discount utilizing the effective interest method. The Company recorded effective interest expense of $0.7 million and $0.4 million for the three months ended March 31, 2019 and 2018, respectively. Long-term debt and unamortized discount balances are as follows (in thousands):

	March 31, 2019	December 31, 2018
Face value of long term debt	$ 30,000	$ 25,000
Exit fee	3,277	1,960
Unamortized debt discount associated with exit fee, debt issuance costs and loan origination fees	(3,433)	(1,340)
Long term debt, net	$ 29,844	$ 25,620

7. Stock-Based Compensation

The following table summarizes stock option activity under the Company's stock-based compensation plan during the three months ended March 31, 2019 (in thousands, except option and share data):

	Shares Available for Grant	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in Years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2018	755,337	1,996,211	$ 11.80	7.54	$ 2,347
Additional options authorized	960,588				
Granted	(781,750)	781,750	$ 13.71		
Exercised	—	(41,546)	$ 3.36		
Canceled and forfeited	14,244	(14,244)	$ 83.57		
Outstanding as of March 31, 2019	948,419	2,722,171	$ 12.10	8.18	$ 6,532
Vested and exercisable as of March 31, 2019		1,104,111	$ 11.68	6.81	$ 3,456

During the three months ended March 31, 2019, the Company granted stock options for 781,750 shares. The weighted-average grant date fair value of these options was $9.59 for the three months ended March 31, 2019. During the three months ended March 31, 2018, the Company granted its employees stock options for 799,500 shares. The weighted-average grant date fair value of these employee options was $7.98 for the three months ended March 31, 2018.

The Company records stock-based compensation of stock options granted by estimating the fair value of stock-based awards using the Black-Scholes option pricing model and amortizes the fair value of the stock-based awards granted over the applicable vesting period of the awards on a straight-line basis. The fair value of stock options was estimated using the following weighted-average assumptions:

	Three Months Ended March 31,	
	2019	2018
Expected term (in years)	5.27-6.08	5.27-6.08
Contractual term (in years)	10.00	—
Volatility	79.62%-81.04%	84.00%-84.50%
Risk free interest rate	2.34%-2.57%	2.35%-2.68%
Dividend yield	—	—

Stock-Based Compensation Expense

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

	Three Months Ended March 31,	
	2019	2018
Research and development	$ 365	$ 323
General and administrative	830	680
Total	$ 1,195	$ 1,003

As of March 31, 2019, the total unrecognized compensation expense related to unvested options was $14.1 million, which the Company expects to recognize over an estimated weighted average period of 3.0 years.

8. Income Taxes

The tax expense for the three months ended March 31, 2019 was zero due to the Company's loss position and full valuation allowance. This is consistent with the zero-tax expense for the three months ended March 31, 2018.

9. 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 Blvd. in Palo Alto, California 94306. The lease commenced on March 1, 2018 and expires in February 2023. The lease has a three-year renewal option prior to expiration, however, the Company is not reasonably assured to exercise this option. The lease includes rent escalation clauses through the lease term. In October 2017, the Company provided a security deposit of $0.3 million. The Company also has three additional operating leases that are included in its lease accounting but are not considered significant for disclosure.

The maturity of the Company's operating lease liabilities as of March 31, 2019 and future minimum lease payments as of December 31, 2018 were as follows (in thousands):

Undiscounted lease payments	March 31, 2019	December 31, 2018
2019	$ 454	$ 593
2020	616	610
2021	633	629
2022	647	647
2023	109	109
Total undiscounted payments	2,459	$ 2,588
Less: imputed interest	389	
Present value of future lease payments	2,070	
Less: current portion of operating lease liabilities	439	
Operating lease liabilities	$ 1,631	

Rent expense recognized for the operating leases was $0.1 million and $0.2 million for the three months ended March 31, 2019 and March 31, 2018, respectively. 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 insignificant for the three months ended March 31, 2019.

The operating cash outflows for the operating leases liability was $0.1 million for the three months ended March 31, 2019. As of March 31, 2019, the weighted-average remaining lease term and weighted-average discount rate were 3.9 years and 9.15%, respectively.

10. Subsequent Events

In April 2019, the Company completed an underwritten public offering of 5,175,000 shares of common stock, including 675,000 shares of common stock purchased to the underwriter's option to purchase additional shares, at an offering price of $11.00 per share. The Company received net proceeds of approximately $53.2 million, after deducting underwriting discounts and commissions and offering expenses.

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

You should read the following discussion and analysis of Eiger's 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, 2018, included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission ("SEC") on March 14, 2019. 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 thing, our future plans, objectives, expectations, intentions, the potential for our programs, the timing of our clinical trials and financial performance 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

We are a late-stage biopharmaceutical company focused on the development and commercialization of well-characterized drugs for life-threatening, rare and ultra-rare diseases with high unmet medical needs and no approved therapies. We have reported positive proof-of-concept clinical results in four programs all with first-in-class drugs, now advancing into submission for regulatory approvals or Phase 3 clinical development.

Our lead program is in Phase 3, developing lonafarnib, a first-in-class prenylation inhibitor for the treatment of Hepatitis Delta Virus (HDV) infection. We are also preparing an NDA and MAA with plans to submit in 2019 for lonafarnib in the treatment of Hutchinson-Gilford Progeria Syndrome (HGPS or Progeria) and Progeroid Laminopathies. In addition, we recently announced positive Phase 2 data with peginterferon lambda for HDV infection and avexitide for post-bariatric hypoglycemia (PBH).

Our programs have several aspects in common: the disease targets represent conditions of high unmet medical need with no approved therapies; the therapeutic approaches are supported by an understanding of disease biology and mechanism as elucidated by our academic research relationships; prior clinical experience with the product candidates guides an understanding of safety; and the development paths leverage the experience and capabilities of our experienced, commercially-focused management team.

We have no products approved for commercial sale and have not generated any revenue from product sales. We have never been profitable and have incurred operating losses in each year since inception and we do not anticipate that we will achieve profitability in the near term. Our net losses were $17.2 million and $8.8 million for the three months ended March 31, 2019 and 2018, respectively. As of March 31, 2019, we had an accumulated deficit of $188.4 million. Substantially all of our operating losses resulted from expenses incurred in connection with our research and development programs and from 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, our product candidates and add personnel necessary to operate as a public company with an advanced clinical candidate pipeline of products. In addition, we are now operating as a publicly traded company following the merger with Celladon in March 2016, and we have and will be hiring additional financial and other personnel, upgrading our financial information systems and incurring costs associated with operating as a public company. 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 regulatory approval.

Recent Developments

Eiger BioPharmaceuticals Appoints Market Access, Public Policy Expert, and Biotech Veteran Amit K. Sachdev to Board of Directors

On April 15, 2019, we announced the appointment of Amit K. Sachdev, JD to our Board of Directors. Mr. Sachdev is currently Executive Vice President and Chief Regulatory Officer at Vertex Pharmaceuticals Incorporated, where he serves on its Executive Committee and has been an executive officer since 2007. In addition to overseeing Global Regulatory Affairs, Mr. Sachdev established and managed core business functions, including global market access, health economics and outcomes research, corporate affairs and patient advocacy to support its commercial drug launches in hepatitis C and cystic fibrosis. He established Vertex's first international commercial operations in 2010.

Prior to joining Vertex, Mr. Sachdev served as Executive Vice President at the Biotechnology Innovation Organization (BIO) and was Deputy Commissioner for Policy at the U.S. Food and Drug Administration (FDA) where he held several other senior executive appointments. Earlier in his career, Mr. Sachdev served as Majority Counsel to the Committee on Energy and Commerce in the U.S. House of Representatives and practiced law at the American Chemistry Council and the law firm Ropes & Gray. Mr. Sachdev received a BS from Carnegie Mellon University and a JD from Emory University School of Law.

Eiger Announces 36% Durable Virologic Response at 24 Weeks Post-Treatment with Peginterferon Lambda in Phase 2 LIMT HDV Study at The International Liver Congress™ 2019

On April 11, 2019, we announced an oral presentation of Phase 2 LIMT end of study results at EASL 2019 in Vienna, Austria. At Week 48, LIMT study patients treated with Lambda 180 µg experienced a mean decline in HDV-RNA of 2.3 $\log_{10}$, with 7 of 14 (50%) experiencing ≥ 2 $\log_{10}$ decline and 5 of 14 (36%) patients achieving HDV-RNA below the limit of quantification (BLQ), comparable to historical peginterferon alfa. At Week 72, a durable virologic response (DVR = HDV RNA below limit of quantitation) at 24 weeks post-treatment for Lambda 180 µg was achieved in 5 of 14 (36%), which compares favorably to historic rates for peginterferon alfa 180 µg (HIDIT-1 Study). Rates of alanine aminotransferase (ALT) normalization increased during post-treatment follow- up in LIMT HDV study patients, from 14% (2 of 14) at Week 48 to 36% (5 of 14) at Week 72. Common on-treatment adverse events included mild to moderate flu-like symptoms and elevated transaminase levels. Patients noted mild side effects while receiving Lambda therapy. Cases of jaundice and bilirubin elevations were observed in the Pakistani cohort. DILIsym® modeling of ALT and bilirubin dynamics indicate a transporter-based mechanism for the observed bilirubin elevations. Patients showed no symptoms of decompensation, no clinical abnormalities, no ascites, no worsening of synthetic function, and all patients responded favorably to dose reduction or dose discontinuation.

The durable virologic response observed 24 weeks post-treatment with Lambda may be a meaningful registrational endpoint for discussions with regulatory agencies. Lambda is now being dosed in combination with Lonafarnib and Ritonavir in HDV-infected patients in the Phase 2 LIFT study at the National Institutes of Health (NIH), and we look forward to end of treatment data later this year.

Oral Presentation of Phase 2 PREVENT Study of Avexitide in Post-Bariatric Hypoglycemia (PBH) Presented at Endocrine Society (ENDO) Meeting 2019 in New Orleans

On March 25, 2019, we announced an oral presentation of end of study results of the Phase 2 PREVENT study at ENDO 2019 in New Orleans. The primary efficacy endpoint of improved postprandial glucose nadir during mixed meal tolerance testing (MMTT) was achieved with statistical significance with avexitide 30 mg BID (57.1 vs 47.1 mg/dL; $p = 0.001$) and 60 mg QD (59.2 vs 47.1 mg/dL; $p = 0.0002$), with fewer participants requiring glycemic rescue during each of the active dosing regimens than during placebo dosing. The secondary endpoint of reduced postprandial insulin peak during MMTT was also statistically significant with avexitide 30 mg BID (349.5 vs 454.5 µIU/mL; $p < 0.03$) and 60 mg QD (357.2 vs 454.5 µIU/mL; $p = 0.04$).

Improvements in metabolic and clinical parameters were also monitored during each patients' daily routine in the outpatient setting and assessed by self-blood glucose monitoring (SBGM), electronic diary, and continuous glucose monitoring (CGM). Patients experienced fewer episodes of hypoglycemia (hypoglycemia symptoms confirmed by SBGM concentrations of <70 mg/dL), severe hypoglycemia (neuroglycopenic symptoms confirmed by SBGM concentrations <55 mg/dL) and a reduced rate of rescue during both dosing regimens of avexitide as compared to placebo. Rescue is defined as self- or third-party administration of oral or g-tube intake to prevent or treat hypoglycemia. Patients also demonstrated reductions in percent time in hypoglycemia during diurnal periods (8 am to midnight) and number of episodes of hypoglycemia as measured by CGM.

Avexitide was well-tolerated in this study. There were no treatment-related serious adverse events and no participant withdrawals. Adverse events were typically mild to moderate in severity. The most common adverse events were injection site bruising, nausea, and headache, all of which occurred with lower frequency during avexitide dosing periods than during the placebo dosing period.

Appointment of Stephana Patton as General Counsel, Corporate Secretary, and Chief Compliance Officer

On February 27, 2019, we announced the appointment of Dr. Stephana Patton as the Company's General Counsel, Corporate Secretary, and Chief Compliance Officer. Dr. Patton brings 20 years of legal experience to Eiger, and was most recently General Counsel, Corporate Secretary, and Chief Compliance Officer at BioTime, Inc., responsible for all legal and compliance matters at BioTime and its subsidiaries. Previously, Dr. Patton was Vice President, General Counsel, and Commercial Compliance Officer at BioDelivery Sciences International, Inc. Dr. Patton began her pharmaceutical industry career at Salix Pharmaceuticals, Inc., where she was Vice President of Intellectual Property and Licensing, until the company was acquired by Valeant, Inc. in 2015.

Patent Protection for Lonafarnib Boosted with Ritonavir for Treatment of Hepatitis Delta Virus Infection in Europe and Japan

On February 6, 2019, we announced that the European Patent Office and the Japan Patent Office had both issued decisions to grant patents with claims covering a broad range of lonafarnib boosted with ritonavir dosing regimens for the treatment of hepatitis delta virus (HDV) infection. A similar patent issued in the U.S. in 2018. With the grant of these new European and Japanese patents, lonafarnib boosted with ritonavir has now obtained patent protection with claims covering treatment with lonafarnib boosted with ritonavir in key major pharmaceutical markets including the U.S., Europe, and Japan. The patents, when granted, will expire in 2035. Similar patent applications are currently pending in China and Korea.

Appointment of Regulatory Expert and Industry Veteran Christine Murray, MS, RAC to Board of Directors

On January 7, 2019, we announced the appointment of Christine Murray, MS, RAC to our Board of Directors. Ms. Murray is a pharmaceutical industry veteran with broad regulatory experience spanning over two decades in large pharma and biotechnology companies across diverse therapeutic areas including liver disease, metabolic disease, antivirals, and rare and ultra-rare disease programs, with multiple successful international regulatory submissions and outcomes. Ms. Murray is currently Senior Vice President of Global Regulatory Affairs at Ultragenyx Pharmaceutical, Inc.

Financial Operations Overview

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 contract manufacturing arrangements, clinical trial material related costs and 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 months ended March 31, 2019 and 2018 (in thousands):

	Three Months Ended March 31,	
	2019	2018
Product candidates:		
Lonafarnib HDV	$ 8,153	$ 1,143
Progeria	2,362	6
Avexitide PBH	167	689
Lambda HDV	220	523
Ubenimex PAH (terminated in January 2018)	—	933
Ubenimex Lymphedema (terminated in October 2018)	—	453
Internal research and development costs	1,966	1,765
Total research and development expense	$ 12,868	$ 5,512

We expect research and development expenses will increase in the future as we 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, we continue to evaluate opportunities to acquire or in-license other product candidates and technologies, which may result in higher research and development expenses due to license fee 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.

General and Administrative Expenses

General and administrative expenses consist of personnel costs, allocated expenses and expenses for outside professional services, including legal, audit, accounting services, insurance costs and costs associated with being a public company. 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, additional insurance, investor relations, banking fees and other administrative expenses and professional services.

Interest Expense

Interest expense consists of interest and amortization of the debt discount related to the Oxford Loan borrowing in December 2016, as amended.

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 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 expenses that are not readily apparent from other sources. Actual results may differ materially from these estimates.

Refer to "New Accounting Pronouncements" and "Leases" included in Note 2, *Summary of Significant Accounting Policies*, in the "Notes to the Condensed Consolidated Financial Statements" in this Form 10-Q for a discussion of how we changed the way we account for leases under Topic 842.

Results of Operations

Comparison of the Three Months Ended March 31, 2019 and 2018

	Three Months Ended March 31,		$ Change	% Change
	2019	2018		
Operating expenses:				
Research and development	$ 12,868	$ 5,512	$ 7,356	133%
General and administrative	4,057	2,994	1,063	36%
Total operating expenses	16,925	8,506	8,419	99%
Loss from operations	(16,925)	(8,506)	(8,419)	
Interest expense	(765)	(398)	(367)	92%
Interest income	511	94	417	444%
Other expense, net	(10)	(21)	11	(52)%
Net loss	$ (17,189)	$ (8,831)	$ (8,358)	95%

Research and development expenses

Research and development expenses increased by $7.4 million to $12.9 million for the three months ended March 31, 2019, from $5.5 million for the same period in 2018. The increase was primarily due to a $7.3 million increase in consulting fees and clinical expenditures due to increased program activity and a $0.1 million increase in compensation and personnel related expenses primarily due to an increase in relocation and recruiting expenses.

General and administrative expenses

General and administrative expenses increased by $1.1 million to $4.1 million for the three months ended March 31, 2019, from $3.0 million for the same period in 2018. The increase was primarily due to a $0.6 million increase in legal, consulting, advisory and accounting services, a $0.2 million increase in compensation and personnel related expenses, a $0.2 million increase in stock-based compensation expense due to an increase in headcount and higher level of stock-based compensation expense, and a $0.1 million increase in facility and insurance expenses primarily related to increased rent expense and insurance coverage for directors and officers.

Interest expense

Interest expense increased by $0.4 million to $0.8 million for the three months ended March 31, 2019 from $0.4 million for the same period in 2018. Interest expense primarily increased due to the additional funds borrowed under the Oxford Loan in May and August 2018, and March 2019.

Interest income

Interest income increased by $0.4 million to $0.5 million for the three months ended March 31, 2019 from $0.1 million for the same period in 2018. The increase was primarily due to an increase in the amounts invested in debt securities and cash equivalents in 2019 as compared to 2018.

Liquidity and Capital Resources

Sources of Liquidity

As of March 31, 2019, we had $63.4 million of cash and cash equivalents, $22.4 million of debt securities available-for-sale and an accumulated deficit of $188.4 million. We believe that the currently available resources will be sufficient to fund our operations for at least the next 12 months following the issuance date of these unaudited condensed consolidated financial statements. However, if our anticipated operating results are not achieved in future periods, we believe that planned expenditures may need to be reduced or we would be required to raise funding in order to fund our operations.

Our primary uses of cash are to fund operating expenses, including research and development expenditures and 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.

In April 2019, the Company completed an underwritten public offering of 5,175,000 shares of common stock, including 675,000 shares of common stock purchased to the underwriter's option to purchase additional shares, at an offering price of $11.00 per share. The Company received net proceeds of approximately $53.2 million, after deducting underwriting discounts and commissions and offering expenses.

Future Funding Requirements

We have not generated any revenue from product sales. We do not know when, or if, we will generate any revenue from product sales. We do not expect to generate any revenue from product sales unless and until we obtain regulatory approval for and commercialize any of our product candidates. At the same time, 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 research efforts and the development of our product candidates, compensation and related expenses, hiring additional staff, including clinical, scientific, operational, 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 plan to continue to fund losses from operations and capital funding needs through future equity and/or debt financings, as well as potential additional collaborations or strategic partnerships with other companies. The sale of additional equity 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):

	Three Months Ended March 31,	
	2019	2018
Net cash used in operating activities	$ (18,882)	$ (8,572)
Net cash provided by investing activities	16,856	9,750
Net cash provided by financing activities	4,171	34
Net increase in cash and cash equivalents	$ 2,145	$ 1,212

Cash flows from operating activities

Cash used in operating activities for the three months ended March 31, 2019 was $18.9 million, which primarily consisted of a net loss of $17.2 million and amortization of the debt securities discount of $0.1 million, which was partially offset by stock-based compensation expense of $1.2 million and non-cash interest expense of $0.2 million. Additionally, cash used in operating activities reflected changes in net operating assets due to an increase of $2.3 million in other assets primarily related to long term deposits with IQVIA, an increase of $1.1 million in prepaid expenses and other current assets primarily due to the timing of payments, and a decrease of $0.3 million in accounts payable, which was partially offset by an increase of $0.7 million in accrued liabilities primarily associated with the increase in business activity.

Cash used in operating activities for the three months ended March 31, 2018 was $8.6 million, which primarily consisted of a net loss of $8.8 million, which was partially offset by stock-based compensation expense of $1.0 million. Additionally, cash used in operating activities reflected changes in net operating assets primarily due to a decrease of $1.0 million in accounts payable and accrued liabilities primarily associated with the timing of payments.

Cash flows from investing activities

Cash provided by investing activities was $16.9 million for the three months ended March 31, 2019, which primarily consisted of $18.8 million of proceeds from maturities of debt securities, partially offset by $1.9 million of purchases of debt securities.

Cash provided by investing activities was $9.8 million for the three months ended March 31, 2018 consisted of proceeds from maturities of debt securities.

Cash flows from financing activities

Cash provided by financing activities for the three months ended March 31, 2019 was $4.2 million, which primarily consisted of $6.6 million of proceeds from additional borrowings in connection with the Amended Oxford Loan, net of issuance costs, partially offset by $1.7 million of repayments of the Oxford Loan and $0.9 million of repayments of the accrued exit fee and second amendment fee associated with the Oxford Loan.

Cash provided by financing activities for the three months ended March 31, 2018 consisted of $34,000 of proceeds from the purchase of common stock under our ESPP.

Contractual Obligations and Other Commitments

Our contractual obligations as of March 31, 2019 have not changed from what we presented in our 2018 10-K for the year ended December 31, 2018.

We are obligated to make future payments to third parties under asset purchase and license agreements, including royalties and payments that become due and payable on the achievement of certain development and commercialization milestones. We have not included these potential payment obligations in the table above as the amount and timing of such payments are not known.

Off-Balance Sheet Arrangements

During the periods presented, we did not have, nor do we currently have, any off-balance sheet arrangements as defined under the rules of the SEC and do not have any holdings in variable interest entities.

ITEM 3. Quantitative and Qualitative Disclosures about Market Risk

As of March 31, 2019, we had market risk exposure related to our cash and cash equivalents. We had cash and cash equivalents of $63.4 million and $22.4 million of debt securities available-for-sale. Such interest-earning instruments carry a degree of interest rate risk; however, historical fluctuations of interest income have not been significant. We have not been exposed nor do we anticipate being exposed to material risks due to changes in interest rates. A hypothetical 10% change in interest rates during any of the periods presented would not have had a material impact on our unaudited condensed consolidated financial statements.

Financial instruments that potentially subject us to concentration of credit risk consist of cash and cash equivalents. We place our cash and cash equivalents with high credit quality financial institutions and pursuant to our investment policy, we limit the amount of credit exposure with any one financial institution. Deposits held with banks may exceed the amount of insurance provided on such deposits. We have not experienced any losses on our deposits of cash and cash equivalents.

We carry out some of our clinical development and supportive activities in foreign countries and payments may be due in foreign currencies. We do not participate in any foreign currency hedging activities and we do not have any other derivative financial instruments. We did not recognize any significant exchange rate losses during the three months ended March 31, 2019.

ITEM 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended), as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of the period covered by this quarterly report, our disclosure controls and procedures were, in design and operation, effective.

Changes in Internal Control

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 three months ended March 31, 2019, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on Effectiveness of Controls and Procedures

In designing and evaluating the disclosure controls and procedures and internal control over financial reporting, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures and internal control over financial reporting must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

From time to time we may become involved in legal proceedings or be subject to claims arising in the ordinary course of our business. We are not presently a party to any legal proceedings that in the opinion of our management, if determined adversely to us, would have a material adverse effect on our business, financial condition, operating results or cash flows. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

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. We have marked with an asterisk (*) those risk factors below that reflect significant changes from the risk factors included in our Annual Report on Form 10-K for the year ended December 31, 2018.

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 are a clinical development-stage biopharmaceutical company with a limited operating history. We have incurred net losses in each year since our inception. For the three months ended March 31, 2019 and 2018, we reported a net loss of $17.2 million and $8.8 million, respectively. As of March 31, 2019, we had an accumulated deficit of $188.4 million. Our prior losses, combined with expected future losses, have had and may continue to have an adverse effect on our stockholders' equity and working capital.

We believe that our currently available resources will be sufficient to fund our planned operations for at least the next 12 months following the issuance date of these consolidated financial statements. 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. 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 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 submit an NDA for regulatory approval for lonafarnib in progeria and progeroid laminopathies and advance our clinical development programs in various clinical studies. In particular, at our meetings with the FDA throughout 2018, the FDA confirmed that we could submit an NDA for lonafarnib for the progeria and progeroid laminopathies indications and additionally conduct a single, 400 patient pivotal study to support the submission of an NDA for lonafarnib for use in a hepatitis D virus indication. We would need significant additional resources in order to aggressively move lonafarnib forward successfully based on the discussions with the FDA. While we have not yet commenced pivotal clinical studies for any product candidate and it may be several years, if ever, before we complete pivotal clinical studies and have a product candidate 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 a product candidate, 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. For example, if we receive approval for lonafarnib in the progeria and progeroid laminopathies indications, we have agreed with The Progeria Research Foundation to make available lonafarnib to Hutchinson-Gilford progeria syndrome and progeroid laminopathies patients.

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 candidates and submit an NDA and MAA for lonafarnib in progeria and progeroid laminopathies in 2019;
- in-license or acquire additional product candidates;
- undertake the manufacturing or have manufactured our product candidates;
- advance our programs into larger, more expensive clinical studies;
- initiate additional nonclinical, clinical, or other studies for our product candidates;
- identify, educate and develop potential commercial opportunities, such as lonafarnib boosted with ritonavir, lonafarnib for the treatment of progeria and progeroid laminopathies, Lambda for HDV, and avexitide for PBH;
- seek regulatory and marketing approvals and reimbursement for our product candidates;
- 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;
- 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.

We have never generated any revenue from product sales and may never be profitable.

We have no products approved for commercialization and have never generated any revenue. Our ability to generate revenue and achieve profitability depends on our ability, alone or with strategic collaboration partners, to successfully complete the development of, and obtain the regulatory and marketing approvals necessary to commercialize, one or more of our product candidates. We do not anticipate generating revenue from product sales for the foreseeable future. Our ability to generate future revenue from product sales depends heavily on our success in many areas, including but not limited to:

- completing research and development of our product candidates;
- obtaining 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 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 one or more of the product candidates that we develop is approved 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 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, debt or other securities convertible into equity, your 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 Oxford Finance LLC, or Oxford Finance, in December 2016, or the Oxford Loan. The Oxford Loan is a $25.0 million debt financing arrangement with Oxford Finance wherein we borrowed the first tranche of $15.0 million upon closing of the debt financing in December 2016. In May 2018, we entered into an amendment to the Oxford Loan and borrowed $5.0 million, or, as amended the Oxford Loan. In August 2018, we drew the final $5.0 million upon achievement of certain clinical milestones. In March 2019, we entered into the third amendment to the Oxford Loan to refinance our outstanding principal balance of $23.3 million. Upon refinancing, the Oxford Loan was increased to $35.0 million in aggregate commitments. The Oxford Loan is secured by perfected first priority liens on the Company's assets, excluding intellectual property but including a commitment by the Company to not allow any liens to be placed upon such intellectual property. The Oxford Loan includes customary events of default, including failure to pay amounts due, breaches of covenants and warranties, material adverse effect 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. We cannot assure you that we will 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 Oxford 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 Oxford Loan provides for up to $35.0 million in term loans due on March 1, 2024, of which $30.0 million in principal is outstanding. All of our current and future assets, except for intellectual property, secure our borrowings under the Oxford Loan. The Oxford 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 Oxford 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 Oxford 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 and accelerate the maturity of the debt. Any default under the Oxford 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 successfully further develop, obtain regulatory approval for, and commercialize one or more of these product candidates. We plan to submit an NDA and MAA for one of these programs in 2019. We currently generate no revenue from sales of any drugs, and we may never be able to develop or commercialize a product candidate. In addition, to the extent that we receive regulatory approval for lonafarnib in progeria and progeroid laminopathies, we expect our commitment to provide access for patients with progeria and progeroid laminopathies for no or minimal cost to those patients to result in a loss to us.

With respect to potential commercial products, we currently have one product candidate that is in Phase 3 clinical trials and two Phase 2 development programs focused on two separate indications. It may be years before our studies are initiated and completed, if at all.

Our lonafarnib compound has received Rare Pediatric Disease, or RPD, designation from the FDA for the treatment of HGPS and progeroid laminopathies. The FDA defines a "rare pediatric disease" as a disease that affects fewer than 200,000 individuals in the U.S. primarily under the age of 18 years old. Under the FDA's Rare Pediatric Disease Priority Review Voucher program, upon the approval of an NDA or a biologics license application, or BLA, for the treatment of a rare pediatric disease, the sponsor of such application would be eligible for a Rare Pediatric Disease Priority Review Voucher that can be used to obtain priority review for a subsequent NDA or BLA. There is no assurance we will receive a Rare Pediatric Disease Priority Review Voucher or that it will result in a faster development process, review or approval for a subsequent marketing application. Further, this program has been subject to criticism, including by the FDA, and it is possible that even if we obtain approval for lonafarnib and qualify for such a Priority Review Voucher, the program may no longer be in effect at the time of approval. Also, although Priority Review Vouchers may be sold or transferred to third parties, there is no guaranty that we will be able to realize any value if we were to sell a Priority Review Voucher.

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.

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 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.

Our business strategy is based upon obtaining Orphan Drug designation for our product 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 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 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 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 drugs 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 not obtained regulatory approval for any product candidate, and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

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 a new drug application, or NDA, 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 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 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 four of our product candidates in our planned indications to date, there can be no assurance that the FDA will grant our similar status for our other proposed development indications or other product candidates in the future.

Drug 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 efficacy and safety with respect to the proposed indication for use sufficient to obtain regulatory approval to receive regulatory approval or market our drug candidates. For example, in 2018 we announced that two of our Phase 2 clinical trials of ubenimex in two different indications were negative results and as a result we have terminated further development of ubenimex.

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. 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.

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 and efficacy 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, or 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, or 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, or IND, or equivalent foreign application or amendment;
- delays in recruiting qualified patients in our clinical studies;
- 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 GCP requirements, or applicable foreign regulatory guidelines;
- patients dropping out of our clinical studies;
- 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 orphan drug designation exclusivity and to successfully commercialize our product candidates and may harm our business and results of operations.

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 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. There is no guarantee that additional or more severe side effects will not be identified through ongoing clinical studies by other uses of lonafarnib for other indications or our own clinical trials. Additionally, while we have a license to another farnesyltransferase inhibitor compound, tipifarnib, from Janssen Pharmaceutica, N.V., or Janssen, Janssen has granted rights of tipifarnib to Kura Oncology, Inc., or Kura, in oncology and negative results or undesirable side effects from Kura's clinical trials for a compound with a similar mechanism of action may negatively impact the perception of lonafarnib for anti-viral indications. Undesirable side effects 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 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, or 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.

Even if we obtain regulatory approval for a product candidate, we will remain subject to 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, or 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 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 and efficacy 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 drug 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 in order 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.

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 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.

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. These vendors have successfully made GMP batches for our clinical studies.

The material used for Lonafarnib HDV pivotal trails and Progeria clinical studies are sourced from Eiger controlled CMOs. These same vendors are currently under development for commercial qualification.

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 drug 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 must be approved by the FDA pursuant to inspections that will be conducted after we submit our marketing applications to the FDA. 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 or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. 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 never be able to develop a commercially viable product.

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, if any of our product candidates by the FDA 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 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, for lonafarnib and Lambda, HDV is associated with hepatitis B virus infection, which is a pre-requisite for the replication of HDV. Although we believe that the data are supportive of antiviral activity against HDV, 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, if lonafarnib receives regulatory approval for use in progeria and progeroid laminopathies, we expect that the supply of lonafarnib to patients with progeria and progeroid laminopathies will have limited profits.

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 Gilead Sciences, Merck, Roche, Holding AG, Actelion Pharmaceuticals US, Inc., Johnson & Johnson, Replicor, Inc., Myr, Arrowhead Pharmaceuticals, Novartis International AG, Zealand Pharmaceuticals and Xeris Pharmaceuticals as well as other smaller companies or biotechnology startups 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.

We currently have limited marketing and sales experience. 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 past while employed at other companies, we have no recent experience selling and marketing our product candidates and we currently have no marketing or sales organization. To successfully commercialize any products that may result from our development programs, we will need to invest in and develop 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 lack of prior experience in marketing and selling biopharmaceutical products, 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, if lonafarnib receives regulatory approval for use in progeria and progeroid laminopathies, we would be required to establish an expanded access program in order to make this product available for patients with progeria and progeroid laminopathies, which would require additional resources and costs in support of use in this indication.

The commercial success of any of our current or future product candidate 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 efficacy 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;
- the marketing, sales and distribution support for the product;
- the publicity concerning our products or competing products and treatments; and
- the pricing and availability of third-party insurance coverage and reimbursement.

Even if a product displays a favorable efficacy and safety 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.

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 product candidates 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, if lonafarnib is approved for patients with progeria and progeroid laminopathies, we would expect to provide the product under expanded access programs, which may not result in reimbursement for our supply of the product.

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

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, they may not cover or provide adequate payment for our products. We expect to experience pricing pressures in connection with products due to the increasing trend toward managed healthcare, including the increasing influence of health maintenance organizations and additional legislative changes. 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. For example, the portfolio of patents licensed from Merck expires before the anticipated launch date of the lonafarnib product candidate. 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 drug will be recovered from sales in the United States. In the European Union, or the EU, the EMA's Committee for Orphan Medicinal Products, or 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 drug 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. 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 drugs, we plan to rely on the exclusivity period under the Orphan Drug Act to maintain a competitive position. If we do not obtain orphan drug exclusivity for our drug products and biologic 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 designation for lonafarnib in the United States and Europe, 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 drugs 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 drug with the same active moiety for the same condition if the FDA or EMA concludes that the later drug 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, the patent coverage for lonafarnib expires before the anticipated launch date. 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. For example, Kura has an exclusive license to tipifarnib for use in cancer indications while we have a license for anti-viral indications. As a result of Kura's right to use the same compound in a different indication, it is possible that development and sales may impact our product development and commercialization efforts. 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.

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, or 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 Europe may be available to extend the patent or data exclusivity terms of products. With respect to lonafarnib, 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, or 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 candidate 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 candidate 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 Stanford license agreement for lonafarnib. We may not be able to achieve the required diligence milestones in a timely manner, which may result in Stanford's right to terminate the license agreement, 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 may be subject to generic competition.

Under the Hatch-Waxman Act, a pharmaceutical manufacturer may file an abbreviated new drug application, or ANDA, seeking approval of a generic copy of an approved innovator 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 (e.g., five years for new chemical entities, three years for changes to an approved drug requiring a new clinical study, seven years for orphan drugs), which preclude FDA approval (or in some circumstances, FDA filing and review of) an ANDA or 505(b)(2) NDA relying on the FDA's finding of safety and effectiveness for the innovative drug. 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 product candidates in the Orange Book, ANDAs and 505(b)(2) NDAs with respect to those product candidates 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.

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 and Nippon Kayaku, each 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 candidate 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. Likewise, certain of our license agreements, for example for ubenimex, do not include patents or patent applications outside of the United States as our licensor elected not to file in foreign jurisdictions. 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 retain our President and Chief Executive Officer and to attract, retain, and motivate other qualified personnel.

We are highly dependent on David Cory, our President and Chief Executive Officer, the loss of whose services may adversely impact the achievement of our objectives. Mr. Cory could leave our employment at any time, as he is an "at will" employee. 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, or the loss of the services of Mr. Cory may impede the progress of our research, development, and commercialization objectives and would negatively impact our ability to succeed in our in-licensing strategy.

We will need to expand our organization and we may experience difficulties in managing this growth, which could disrupt our operations.

As of March 31, 2019, we had 19 full-time employees. As our development and commercialization plans and strategies develop, we expect to need additional managerial, operational, manufacturing, sales, marketing, financial, legal, and other resources. Our management may need to divert a disproportionate amount of their attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, operational mistakes, loss of business opportunities, loss of employees, and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth.

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 could 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 HIPAA. Depending on the facts and circumstances, we could be subject to criminal penalties, including if we knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

International data protection laws, including, without limitation, the GDPR, that took effect in May 2018, and member state data protection legislation, may also apply to health-related and other personal information obtained outside of the United States. These laws impose strict obligations on the ability to process health-related and other personal information of data subjects in the EU, including in relation to use, collection, analysis, and transfer of such personal information. These laws include several requirements relating to obtaining the consent of the individuals to whom the personal data relates, limitations on data processing, establishing a legal basis for processing, notification of data processing obligations or security incidents to appropriate data protection authorities or data subjects, the security and confidentiality of the personal data and various rights that data subjects may exercise.

The GDPR prohibits the transfer, without an appropriate legal basis, of personal data to countries outside of the European Economic Area, or EEA, such as the United States, which are not considered by the European Commission to provide an adequate level of data protection. Switzerland has adopted similar restrictions. Although there are legal mechanisms to allow for the transfer of personal data from the EEA and Switzerland to the United States, uncertainty about compliance with EU data protection laws remains and such mechanisms may not be available or applicable with respect to the personal data processing activities necessary to research, develop and market our products and services. For example, ongoing legal challenges in Europe to the mechanisms allowing companies to transfer personal data from the EEA to the United States could result in further limitations on the ability to transfer personal data across borders, particularly if governments are unable or unwilling to reach new or maintain existing agreements that support cross-border data transfers, such as the European Union-U.S. and Swiss-U.S. Privacy Shield framework. Additionally, other countries have passed or are considering passing laws requiring local data residency and/or restricting the international transfer of data.

Under the GDPR, regulators may impose substantial fines and penalties for non-compliance. Companies that violate the GDPR can face fines of up to the greater of 20 million Euros or 4% of their worldwide annual turnover (revenue). The GDPR has increased our responsibility and liability in relation to personal data that we process, requiring us to put in place additional mechanisms to ensure compliance with the GDPR and other EU and international data protection rules.

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 information technology, or 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, some of our and our vendors' servers are potentially vulnerable to physical or electronic break-ins, computer viruses 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 expertise, including organized criminal groups, "hacktivists", nation states and others. The 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 prevent data security breaches or privacy violations, respond appropriately or implement satisfactory remedial measures, 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. 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 that access confidential information 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.

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.

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, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or the ACA, was passed, which substantially changes the way health care is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. Some of the provisions of the Affordable Care Act have yet to be fully implemented, and since its enactment, there have been judicial and Congressional challenges to numerous provisions of the ACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the ACA. Since January 2017, President Trump has signed two Executive Orders designed to delay the implementation of any certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain mandated fees under the ACA, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018, among other things, amends the ACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". The Trump administration has also announced that it will discontinue the payment of cost-sharing reduction, or CSR, payments to insurance companies until Congress approves the appropriation of funds for the CSR payments. The loss of the CSR payments is expected to increase premiums on certain policies issued by qualified health plans under the ACA. A bipartisan bill to appropriate funds for CSR payments has been introduced in the Senate, but the future of that bill is uncertain. Further, each chamber of Congress has put forth multiple bills designed to repeal or repeal and replace portions of the ACA. Although none of these measures has been enacted by Congress to date, Congress may consider other legislation to repeal and replace elements of the ACA. Any repeal and replace legislation may have the effect of limiting the amounts that government agencies will pay for healthcare products and services. 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. For example, in the United States, there have been several recent Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. Furthermore, 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.

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 GDPR and other regulations. These laws may impact, among other things, our proposed sales, marketing, and education 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 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;
- the federal Health Insurance Portability and Accountability Act of 1996, or 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 relating to the privacy, security, and transmission of individually identifiable health information;
- The Physician Payments Sunshine Act, which requires manufacturers of drugs, devices, biologics, and medical supplies to report annually to the U.S. Department of Health and Human Services information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations; and
- 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, 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.
- the GDPR and other EU member state data protection legislation, which require data controllers and processors, to adopt administrative, physical and technical safeguards to protect personal data, including health-related data, including mandatory contractual terms with third-party providers, requirements for establishing an appropriate legal basis for processing personal data, transparency requirements related to communications with data subjects regarding the processing their personal data, standards for obtaining consent from individuals to process their personal data, notification requirements to individuals about the processing of their personal data, an individual data rights regime, mandatory data breach notifications, limitations on the retention of personal data, increased requirements pertaining to health data, as well as strict rules and restrictions on the transfer of personal data outside of the EU, including to the U.S.

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 civil, criminal and administrative penalties, damages, fines, sanctions, exclusion from participation in government health care programs, such as Medicare and Medicaid, imprisonment, 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.

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 and are currently conducting clinical trials in the United States; Canada; Sydney, Australia; Ankara, Turkey; Hannover, Germany; Karachi, Pakistan; Auckland, New Zealand and Jerusalem and Beersheba, 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. For example, both Turkey and Pakistan are key regions for clinical activity relating to Hepatitis Delta, and further outbreaks of violence and political instability in the region could disrupt our clinical operations or otherwise limit our ability to access or conduct clinical studies in those 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 financial results.

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

Our corporate headquarters are located in the San Francisco Bay Area which has in the past experienced severe earthquakes and other natural disasters. We do not carry earthquake insurance. Earthquakes or other natural disasters could severely disrupt our operations or those of our collaborators, and have a material adverse effect on our business, results of operations, financial condition, and prospects. If a natural disaster, terrorist attack, power outage, or other event occurred that prevented us from using or damaged critical elements of our business and operations (such as the manufacturing facilities of our third-party contract manufacturers) our business may be disrupted for a substantial period of time. We have limited or no 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.

Risks Related to Ownership of our Common Stock

The market price of our common stock may 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, 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 or NDA;
- 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 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; and
- period-to-period fluctuations in our financial results.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations 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.

We will cease to be an emerging growth company effective December 31, 2019 and we will become subject to additional reporting requirements and standards and accelerated filing deadlines for our periodic reports. For example, we have incurred significant expenses and devoted substantial management effort toward ensuring compliance with the requirements of Section 404 of the Sarbanes-Oxley Act. In addition, as an emerging growth company, we have delayed the adoption of certain accounting standards. We will also be subject to enhanced disclosures obligations regarding executive compensation in our periodic reports and proxy statements and requirements to hold a nonbinding advisory vote on executive compensation. While we are taking steps to implement the systems and processes required to comply with these additional requirements, we cannot assure you that the measures we have taken to date, and are continuing to implement, will enable us to comply fully and in a timely manner.

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 DGCL, 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 Vivo Ventures Fund VI, L.P. and Interwest Partners X, L.P., 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.

The 2017 comprehensive tax reform bill could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into U.S. law tax legislation, or the Tax Act, which significantly changed the Internal Revenue Code of 1986, as amended, or the Code. The Tax Act, among other things, contained significant changes to U.S. federal income corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%; for net operating losses generated after December 31, 2017, limitation of the deduction to 80% of current year taxable income; mandatory capitalization of research and development expenses beginning in 2022; immediate deductions for certain new investments instead of deductions for depreciation expense over time; further deduction limits on executive compensation; and modifying, repealing and creating many other business deductions and credits, including the reduction in the orphan drug credit from 50% to 25% of qualifying expenditures. We continue to examine the impact this tax reform legislation may have on our business. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the Tax Act is uncertain and our business and financial condition could be adversely affected. The Tax Act could be amended or subject to technical correction, possibly with a retroactive effect, which could change the financial impacts that were recorded at December 31, 2018 or are expected to be recorded in future periods.

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

Our federal and state net operating loss, or 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. While the Tax Act allows for federal net operating losses incurred in 2018 and in future years to be carried forward indefinitely, the deductibility of such federal net operating losses incurred in 2018 and in future years will be limited. Moreover, if a corporation undergoes an "ownership change" within the meaning of Section 382 of the Code, or 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. The Merger 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. We assessed whether Eiger had an ownership change, as defined by Section 382 of the Code, as a result of the Merger that occurred from our formation through December 31, 2018. Based upon this assessment no reduction was made to Eiger's federal and state NOL carryforwards or federal and state tax credit carryforwards under these rules. Additional ownership changes in the future could result in additional limitations on the combined organization's NOL 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 losses.

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	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).
3.4	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, dated as of February 26, 2019, by and between Eiger BioPharmaceuticals, Inc. and Stephana Patton.
10.2	Offer Letter, dated as of November 30, 2018, by and between Eiger BioPharmaceuticals, Inc. and Sriram Ryali.
10.3*	Third Amendment to Loan and Security Agreement, dated March 5, 2019, by and between Eiger BioPharmaceuticals, Inc. and Oxford Finance LLC.
10.4	Eiger BioPharmaceuticals, Inc. Non-Employee Director Compensation Policy, amended on May 7, 2019.
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)
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

* Portions of this exhibit have been omitted as being immaterial and would be competitively harmful if publicly disclosed.

\+ 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.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this Quarterly Report on Form 10-Q to be signed on its behalf by the undersigned thereunto duly authorized.

Eiger BioPharmaceuticals, Inc.

Date: May 9, 2019

By: /s/ David A. Cory
David A. Cory
Director, President and Chief Executive Officer
(Principal Executive Officer)

Eiger BioPharmaceuticals, Inc.

Date: May 9, 2019

By: /s/ Sri Ryali
Sri Ryali
Chief Financial Officer
(Principal Financial Officer)

Exhibit 10.1

February 26, 2019

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

Stephana Patton
894 De Haro Street
San Francisco, CA 94107

Re: Employment Terms

Dear Stephana,

Eiger BioPharmaceuticals, Inc. ("Eiger" or the "Company") is pleased to offer you employment on the following terms.

Duties, Compensation and Benefits

You will serve as the General Counsel, Corporate Secretary, and Chief Compliance Officer, reporting to the President and Chief Executive Officer. You will work at our facility located at 2155 Park Boulevard in Palo Alto, California. Of course, Eiger may change your position, duties, and work location from time to time in its discretion.

Your salary will be $335,000 per year, less payroll deductions and withholdings. You will be paid semi-monthly.

In addition, you will be eligible for an annual bonus, targeted at 35% of your base salary. 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 must be employed on the day that your bonus (if any) is paid in order to earn the bonus. Therefore, if your employment is terminated either by you or the Company for any reason prior to the bonus being paid, you will not have earned the bonus and no partial or prorated bonus will be paid.

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.

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.

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2155 Park Boulevard
Palo Alto, CA 94306

Subject to approval by the Company's Board of Directors (the "Board"), under the Eiger Equity Incentive Plan (the "Plan"), the Company shall grant you an option to purchase 90,000 shares (the "Option") of the Company's Common Stock at fair market value as determined by the Board as of the date of grant. The Option will be subject to the terms and conditions of the Plan and your grant agreement. Your grant agreement will include a four-year vesting schedule, under which 25 percent of your shares will vest after twelve months of employment, with the remaining shares vesting monthly thereafter, until either your Option is fully vested or your employment ends, whichever occurs first.

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 Proprietary Information and Inventions 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; Severance

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.

If, after you complete one (1) year of employment with the Company, the Company terminates your employment without Cause (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), without regard to any alternative definition thereunder, a "Separation from Service"), then subject to your obligations below, you shall be entitled to receive the following severance benefits:

(i) an amount equal to six (6) months of your then current base salary, less all applicable withholdings and deductions, paid over such six (6) month period, on the schedule described below (the "Salary Continuation");

(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 six (6) 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 (the "Paid COBRA Benefits"); and

(iii) acceleration of the vesting of the Option as of the date of termination as to 50% of the then-unvested shares subject to the Option.

If, after you complete six (6) months of employment with the Company, there is a Change of Control (as defined below), and within 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 severance benefits:

(i) an amount equal to twelve (12) months of your then current base salary, less all applicable withholdings and deductions, paid over such twelve (12) month period, on the schedule described below (the "Salary Continuation");

(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 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 (the "Paid COBRA Benefits"); and

(iii) acceleration of the vesting of the Option as of the date of termination as to 100% of the then-unvested shares subject to the Option.

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2155 Park Boulevard
Palo Alto, CA 94306

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; or 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; *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 letter agreement, "Good Reason" shall mean the occurrence of any of the following without your consent: (i) relocation of your principal place of employment of over 50 miles; or (ii) a material reduction in your responsibilities or compensation (that is not otherwise applicable to the other members of the management team). 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 letter 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 Proprietary Information and Inventions Agreement or any other agreement entered into with the Company.

EIGER BIOPHARMACEUTICALS
2155 Park Boulevard
Palo Alto, CA 94306

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.

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.

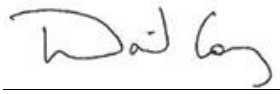
This letter, together with your Employee Proprietary Information and Inventions Agreement, forms the complete and exclusive statement of your employment agreement with Eiger. It supersedes any other agreements or promises made to you by anyone, whether oral or written. Changes in your employment terms, 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, and the enclosed Employee Proprietary Information and Inventions Agreement and return them to me by February 26, 2019, if you wish to accept employment at Eiger under the terms described above. If you accept our offer, we would like you to start on March 18, 2019.

EIGER BIOPHARMACEUTICALS
2155 Park Boulevard
Palo Alto, CA 94306

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

Sincerely,



David Cory
President and Chief Executive Officer

Accepted:

Stephana Patton

February 26, 2019
Date

Attachment: Employee Proprietary Information and Inventions Agreement

Exhibit 10.2

November 30, 2018

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

Sriram (Sri) Ryali
2905 Baze Road
San Mateo, CA 94403

Re: Employment Terms

Dear Sri,

Eiger BioPharmaceuticals, Inc. ("Eiger" or the "Company") is pleased to provide you this offer for the position of Chief Financial Officer, on the following terms.

You will be responsible for duties customarily associated with this position and will report to the President and Chief Executive Officer. You will work at our facility located at 2155 Park Boulevard in Palo Alto, California. Of course, Eiger may change your position, duties, and work location from time to time in its discretion.

You will receive a sign-on bonus of $50,000, less deductions and withholdings, payable in your first paycheck from the Company. Your salary will be $335,000 per year, less payroll deductions and withholdings. You will be paid semi-monthly. In addition, each year, you will be eligible to earn an annual incentive bonus equal to 35% of your annual base salary. Whether you receive such a bonus, and the amount of any such bonus, shall be determined by the Company in its sole discretion, and shall be based upon achievement of Company objectives and other criteria to be determined by the Company. Any bonus shall be paid within thirty (30) days after the determination that a bonus shall be awarded. You must be employed on the day that your bonus (if any) is paid in order to earn the bonus. Therefore, if your employment is terminated either by you or the Company for any reason prior to the bonus being paid, you will not have earned the bonus and no partial or prorated bonus will be paid. 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.

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.

EIGER BIOPHARMACEUTICALS
2155 Park Boulevard
Palo Alto, CA 94306

Subject to approval by the Company's Board of Directors (the "Board"), under the Eiger Equity Incentive Plan (the "Plan"), the Company shall grant you an option to purchase 90,000 shares (the "Option") of the Company's Common Stock at fair market value as determined by the Board as of the date of grant. The Option will be subject to the terms and conditions of the Plan and your grant agreement. Your grant agreement will include a four-year vesting schedule, under which 25 percent of your shares will vest after twelve months of employment, with the remaining shares vesting monthly thereafter, until either your Option is fully vested or your employment ends, whichever occurs first.

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 Proprietary Information and Inventions 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.

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.

In the event of a Change of Control of the Company after your first 6 months of employment that (i) requires a move of the Company over 50 miles or (ii) results in a substantial reduction in your responsibilities or compensation (that is not otherwise applicable to the other members of the management team):

a. You will receive 12 months of your base salary, paid in the form of continuing base salary payments, less payroll deductions and standard withholdings

b. Providing you elect COBRA in a timely manner, the Company will pay for your COBRA benefits for up to a maximum of 12 months or until you are enrolled in a separate benefits plan

c. You will receive accelerated vesting of 100% of your unvested shares under the Option

In the event of your termination without Cause after your first year of your employment:

a. You will receive 6 months of your base salary, paid in the form of continuing base salary payments, less payroll deductions and standard withholdings

b. Providing you elect COBRA in a timely manner, the Company will pay for your COBRA benefits for up to a maximum of 6 months or until you are enrolled in a separate benefits plan

c. You will receive accelerated vesting of 50% of your unvested shares under the Option

2155 Park Boulevard
Palo Alto, CA 94306

Your receipt of the severance benefits described above is conditional upon your (a) continued compliance with your legal and contractual obligations to the Company; and (b) 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 continuing base salary payments described above 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; provided, however, that no payments will be made prior to the 60th day following your last day of employment. On the 60th day following your last day of employment, 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, with the balance being paid as originally scheduled.

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; or (B) 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; *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.

"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 Proprietary Information and Inventions Agreement or any other agreement entered into with the Company.

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 Internal Revenue 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.

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2155 Park Boulevard
Palo Alto, CA 94306

This offer is contingent upon a background check clearance, reference check, satisfactory proof of your right to work in the United States, and final board approval. 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, and the enclosed Employee Proprietary Information and Inventions Agreement and return them to me by November 30, 2018, if you wish to accept employment at Eiger under the terms described above. If you accept our offer, we would like you to start on December 17, 2018.

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/ Sriram (Sri) Ryali
Sriram (Sri) Ryali

November 30, 2018
Date

Attachment: Employee Proprietary Information and Inventions Agreement

Exhibit 10.3

THIRD AMENDMENT TO
LOAN AND SECURITY AGREEMENT

THIS **THIRD AMENDMENT** to Loan and Security Agreement (this "**Amendment**") is entered into as of March 5, 2019, by and between **OXFORD FINANCE LLC**, a Delaware limited liability company with an office located at 133 North Fairfax Street, Alexandria, Virginia 22314 ("**Oxford**"), as collateral agent (in such capacity, "**Collateral Agent**"), the Lenders listed on Schedule 1.1 of the Loan Agreement (as defined below) or otherwise party thereto from time to time including Oxford in its capacity as a Lender (each a "**Lender**" and collectively, the "**Lenders**"), and EIGER BIOPHARMACEUTICALS, INC., a Delaware corporation ("**Parent**"), EB Pharma, LLC, a Delaware limited liability company ("**EB Pharma**") and EBPI Merger, Inc., a Delaware corporation ("**EBPI**"), each with offices located at 2155 Park Blvd., Palo Alto, CA 94306 (Parent, EB Pharma and EBPI, individually and collectively, jointly and severally, "**Borrower**").

Recitals

A. Collateral Agent, Lenders and Borrower have entered into that certain Loan and Security Agreement dated as of December 30, 2016 (as amended from time to time, including by that certain First Amendment to Loan and Security Agreement dated as of April 24, 2017 and that certain Second Amendment to Loan and Security Agreement dated as of May 11, 2018, the "**Loan Agreement**").

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

C. Borrower has requested that Collateral Agent and Lenders (i) extend additional credit to Borrower and (ii) make certain other revisions to the Loan Agreement as more fully set forth herein.

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

Agreement

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

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

2. Amendments to Loan Agreement.

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

"(a) Availability.

(i) Subject to the terms and conditions of this Agreement, (x) on the Effective Date, the Lenders, severally and not jointly, made term loans to Borrower in an aggregate original amount of Fifteen Million Dollars ($15,000,000.00) according to each Lender's Term A Loan Commitment as set forth on Schedule 1.1 hereto (as in effect prior to the Third Amendment Effective Date) (such term loans are hereinafter referred to singly as a "**Original Term A Loan** ", and collectively as the "**Original Term A Loans**"), (y) on the Second Amendment Effective Date, the Lenders, severally and not jointly, made term loans to Borrower in an aggregate original amount of Five Million Dollars ($5,000,000.00) according to each Lender's Term B Loan Commitment as set forth on Schedule 1.1 hereto (as in effect prior to the Third Amendment Effective Date) (the "**Original Term B Loan**") and (z) on August 3, 2018, the Lenders, severally and not jointly, made

term loans to Borrower in an aggregate original amount of Five Million Dollars ($5,000,000.00) according to each Lender's Term C Loan Commitment as set forth on Schedule 1.1 hereto (as in effect prior to the Third Amendment Effective Date) (the "**Original Term C Loan**", each such Original Term A Loan, Original Term B Loan and Original Term C Loan is hereinafter referred to singly as an "**Original Term Loan**", and collectively as the "**Original Term Loans**").

(ii) Subject to the terms and conditions of this Agreement, the Lenders agree, severally and not jointly, on the Third Amendment Effective Date to make term loans to Borrower as follows: (x) the Secured Promissory Notes issued by Borrower evidencing the Original Term Loans shall be replaced with amended and restated notes to reflect the current principal balances and (y) the Lenders, severally and not jointly, shall make one (1) new term loan to Borrower in an aggregate original amount of Six Million Six Hundred Sixty-Six Thousand Six Hundred Sixty-Six and 66/100 Dollars ($6,666,666.66) (the "**New Term A Loan**", each such Original Term Loan and New Term A Loan is hereinafter referred to singly as a " **Term A Loan** " and collectively, the "**Term A Loans**"). After repayment, no Term A Loan may be re-borrowed.

(iii) Subject to the terms and conditions of this Agreement, the Lenders agree, severally and not jointly, during the Second Draw Period, to make one (1) term loan to Borrower in an aggregate amount equal to Five Million Dollars ($5,000,000.00) according to each Lender's Term B Loan Commitment as set forth on Schedule 1.1 hereto (the "**Term B Loan**"; each Term A Loan, and Term B Loan is hereinafter referred to singly as a " **Term Loan**" and the Term A Loans, and Term B Loan are hereinafter referred to collectively as the "**Term Loans**"). After repayment, no Term B Loan may be re-borrowed."

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

"(b) Repayment. Borrower shall make monthly payments of interest only commencing on the first (1st) Payment Date following the Funding Date of each Term Loan, and continuing on the Payment Date of each successive month thereafter through and including the Payment Date immediately preceding the Amortization Date. Borrower agrees to pay, on the Funding Date of each Term Loan, any initial partial monthly interest payment otherwise due for the period between the Funding Date of such Term Loan and the first Payment Date thereof. Commencing on the Amortization Date, and continuing on the Payment Date of each month thereafter, Borrower shall make consecutive equal monthly payments of principal, together with applicable interest, in arrears, to each Lender, as calculated by Collateral Agent (which calculations shall be deemed correct absent manifest error) based upon: (1) the amount of such Lender's Term Loan then outstanding, (2) the effective rate of interest, as determined in Section 2.3(a), and (3) a repayment schedule equal to (i) if the Amortization Date is April 1, 2021, thirty-six (36) months and (ii) if the Amortization Date is April 1, 2022, twenty-four (24) months. All unpaid principal and accrued and unpaid interest with respect to each Term Loan is due and payable in full on the Maturity Date. Each Term Loan may only be prepaid in accordance with Sections 2.2(c) and 2.2(d)."

2.3 Section 2.5 (Fees). Section 2.5(b) of the Loan Agreement hereby is amended and restated in its entirety to read as follows:

"(b) Final Payment.

(i) The Final Payment, when due hereunder, to be shared between the Lenders in accordance with their respective Pro Rata Shares; and

(ii) A fully-earned, non-refundable final payment, due in connection with the Original Term Loans, in the aggregate amount of One Million Eight Hundred Seventy-Five

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Thousand Dollars ($1,875,000.00), of which (x) the portion accrued as of the Third Amendment Effective Date is Eight Hundred Forty-Eight Thousand Fourteen and 68/100 Dollars ($848,014.68) (the "**Accrued Third Amendment Final Payment**"), payable to the Lenders in accordance with their respective Pro Rata Shares (as determined immediately prior to the Third Amendment Effective Date) and due on the Third Amendment Effective Date and (y) the portion unaccrued as of the Third Amendment Effective Date is One Million Twenty-Six Thousand Nine Hundred Eighty-Five and 32/100 Dollars ($1,026,985.32) (the "**Unaccrued Third Amendment Final Payment**") payable to the Lenders in accordance with their respective Pro Rata Shares (as determined immediately prior to the Third Amendment Effective Date) and due on the same date that the Final Payment is due in accordance with Section 2.5(b)(i) hereof. For the sake of clarity, the Third Amendment Final Payment shall not reduce the Final Payment otherwise due in connection with Section 2.5(b)(i) hereof."

2.4 Section 2.5 (Fees). Section 2.5(c) of the Loan Agreement hereby is amended and restated in its entirety to read as follows:

"(c) Prepayment Fee. The Prepayment Fee, when due hereunder, to be shared between the Lenders in accordance with their respective Pro Rata Shares. For the sake of clarity, the Funding Date of each Term A Loan is the Third Amendment Effective Date; and"

2.5 Section 5.9 (Use of Proceeds). Section 5.9 of the Loan Agreement hereby is amended and restated in its entirety to read as follows:

"**5.9 Use of Proceeds**. Borrower shall use the proceeds of the Credit Extensions solely as working capital and to fund its general business requirements, and to refinance the Original Term Loans, in accordance with the provisions of this Agreement, and not for personal, family, household or agricultural purposes."

2.6 Section 6.11 (Landlord Waivers; Bailee Waivers) . Section 5.9 of the Loan Agreement hereby is amended and restated in its entirety to read as follows:

"**6.11 Landlord Waivers; Bailee Waivers.** In the event that Borrower or any of its Subsidiaries, after the Effective Date, intends to add any new offices or business locations, including warehouses, or otherwise store any portion of the Collateral (other than the Pre-Clinical and Clinical Trial Supplies) with, or deliver any portion of the Collateral (other than the Pre-Clinical and Clinical Trial Supplies) to, a bailee, in each case pursuant to Section 7.2, then Borrower or such Subsidiary will provide written notice thereof to Collateral Agent and, in the event that the new location is the chief executive office of the Borrower or such Subsidiary or the Collateral (other than the Pre-Clinical and Clinical Trial Supplies) at any such new location is valued in excess of Two Hundred Fifty Thousand ($250,000.00) in the aggregate, such bailee or landlord, as applicable, must execute and deliver a bailee waiver or landlord waiver, as applicable, in form and substance reasonably satisfactory to Collateral Agent prior to the addition of any new offices or business locations, or any such storage with or delivery to any such bailee, as the case may be."

2.7 Section 7.12 (Foreign Subsidiary Assets). New Section 7.12 hereby is added to the Loan Agreement to read as follows:

"**7.12 Foreign Subsidiary Assets**. Permit the aggregate value of cash, Cash Equivalents and other assets held by Borrower's Foreign Subsidiaries to exceed Ten Thousand Dollars ($10,000.00) (or equivalent) at any time."

2.8 Section 10 (Notices). The notice information for Collateral Agent in Section 10 of the Loan Agreement hereby is amended and restated as follows:

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

If to Borrower:	EIGER BIOPHARMACEUTICALS, INC. 2155 Park Blvd. Palo Alto, CA 94306 Attn: Chief Financial Officer Email: sryali@eigerbio.com
with a copy (which shall not constitute notice) to:	Cooley LLP 3175 Hanover Street Palo Alto, CA 94304-1130 Attn: Glen Sato Fax: (650) 849 7400 Email: gsato@cooley.com
If to Collateral Agent:	OXFORD FINANCE LLC 133 North Fairfax Street Alexandria, Virginia 22314 Attention: Legal Department Fax: (703) 519-5225 Email: LegalDepartment@oxfordfinance.com
with a copy (which shall not constitute notice) to:	DLA Piper LLP (US) 500 Eighth Street, NW Washington, DC 20004 Attn: Eric Eisenberg Fax: (202) 799-5211 Email: Eric.Eisenberg@dlapiper.com

2.9 Section 13 (Definitions). The following terms and their respective definitions hereby are added, in appropriate alphabetical order, or amended and restated in their entirety, as applicable, to Section 13.1 of the Loan Agreement as follows:

"**Amortization Date**" is April 1, 2021; provided that, if Borrower achieves the Second Draw Period Milestone, the Amortization Date shall automatically be extended to April 1, 2022.

"**Basic Rate**" is the per annum rate of interest (based on a year of three hundred sixty (360) days) equal to the sum of (a) the greater of (i) thirty (30) day U.S. LIBOR rate reported in The Wall Street Journal on the last Business Day of the month that immediately precedes the month in which the interest will accrue, and (ii) two and fifty-one one hundredths percent (2.51%), plus (b) six and sixty-four one hundredths percent (6.64%). Notwithstanding the foregoing, (x) the Basic Rate for the Term Loan for the period from the Effective Date through and including March 31, 2019 shall be nine and fifteen one hundredths percent (9.15%) and (y) the Basic Rate shall not reset below nine and fifteen one hundredths percent (9.15%). If The Wall Street Journal (or another nationally recognized rate reporting source acceptable to Collateral Agent) no longer reports the U.S. LIBOR Rate or if such interest rate no longer exists or if The Wall Street Journal no longer publishes the U.S. LIBOR Rate or ceases to exist, Collateral Agent may in good faith select a replacement interest rate or replacement publication, as the case may be.

"**Key Person**" is each of Borrower's (i) Chief Executive Officer, who is David Cory as of the Third Amendment Effective Date, (ii) Chief Financial Officer, who is Sriram Ryali as of the Third Amendment Effective Date, (iii) Chief Business Officer, who is James Shaffer as of the Third Amendment Effective Date and (iv) Executive Medical Officer, who is David Apelian as of the Third Amendment Effective Date.

"**Maturity Date**" is March 1, 2024.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

"**New Term A Loan**" is defined in Section 2.2(a)(ii) hereof.

"**Original Term A Loan(s)**" is defined in Section 2.2(a)(i) hereof

"**Original Term B Loan**" is defined in Section 2.2(a)(i) hereof

"**Original Term C Loan**" is defined in Section 2.2(a)(i) hereof

"**Original Term Loan(s)**" is defined in Section 2.2(a)(i) hereof

"**Pre-Clinical and Clinical Trial Supplies**" means active pharmaceutical ingredients, other raw materials, finished product and concomitant medication; in each case, intended for use and used in Borrower's and its Subsidiaries' pre-clinical and clinical trials.

"**Prepayment Fee**" is, with respect to any Term Loan subject to prepayment prior to the Maturity Date, whether by mandatory or voluntary prepayment, acceleration or otherwise, an additional fee payable to the Lenders in amount equal to:

(a) for a prepayment made on or after the Funding Date of such Term Loan through and including the first anniversary of the Funding Date of such Term Loan, two percent (2.00%) of the principal amount of such Term Loan prepaid;

(b) for a prepayment made after the date which is after the first anniversary of the Funding Date of such Term Loan through and including the second anniversary of the Funding Date of such Term Loan, one percent (1.00%) of the principal amount of the Term Loans prepaid; and

(c) for a prepayment made after the date which is after the second anniversary of the Funding Date of such Term Loan and prior to the Maturity Date, zero percent (0.00%) of the principal amount of the Term Loans prepaid.

"**Second Draw Period**" is the period commencing on the on the latest of (a) the date of the occurrence of the Second Draw Milestone, and (b) January 1, 2021, and ending on the earliest of (x) thirty (30) days from the occurrence of the Draw Milestone, (y) February 28, 2021, and (z) the occurrence of any Event of Default; provided, however, that the Second Draw Period shall not commence if on the date of the occurrence of the Second Draw Period Milestone an Event of Default has occurred and is continuing.

"**Second Draw Period Milestone**" means Borrower has achieved [*].

"**Success Fee Agreement**" means that certain Amended and Restated Success Fee Agreement, dated as of the Third Amendment Effective Date, by and among Borrower, the Collateral Agent and Lenders.

"**Term A Loan**" is defined in Section 2.2(a)(ii) hereof

"**Term B Loan** " is defined in Section 2.2(a)(iii) hereof

"**Term Loan(s)**" is defined in Section 2.2(a)(iii) hereof.

"**Third Amendment Effective Date**" is March 5, 2019.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

2.10 **Section 13.1 (Definitions).** The defined terms "Draw Period", "Term C Loan(s)", and "Term C Milestones" and their respective definitions are deleted in their entirety from Section 13.1 of the Loan Agreement.

2.11 Schedule 1.1 of the Loan Agreement hereby is replaced in its entirety with Schedule 1.1 attached hereto.

2.12 Exhibit D of the Loan Agreement hereby is replaced in its entirety with Exhibit D attached hereto.

2.13 Exhibit E hereby is added to the Loan Agreement in the form attached hereto.

2.14 The (i) two (2) original Secured Promissory Notes in respect of the two (2) Original Term A Loans made by the Lenders dated as of December 30, 2016, (ii) one (1) original Secured Promissory Note in respect of the Original Term B Loan made by the Lenders dated as of April 24, 2017 and (iii) one (1) original Secured Promissory Note in respect of the Original Term B Loan made by the Lenders dated as of May 11, 2018, each issued by Borrower in favor of Oxford hereby are amended and restated in the form attached as Exhibit E to the Loan Agreement, as amended by this Amendment, and such original Secured Promissory Notes that have been amended and restated are hereby cancelled, null and void and of no further force and effect. Administrative Agent and Collateral Agent hereby acknowledges and agrees on behalf of the Lenders that no Prepayment Fee shall be due and payable by Borrower in connection with this Amendment and the transactions contemplated hereby, including, without limitation, the refinancing of the Original Term Loans.

3. Limitation of Amendment.

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

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

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

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

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

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

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

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

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

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

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

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

6. Effectiveness. This Amendment shall be deemed effective upon (a) the due execution and delivery to Collateral Agent and Lenders of (i) this Amendment by each party hereto, (ii) the Disbursement Letter attached hereto, (iii) a Secured Promissory Note in favor of Oxford in respect of the New Term A Loan attached hereto, (iv) four (4) Amended and Restated Secured Promissory Notes in favor of Oxford and each attached hereto, (v) the Corporate Borrowing Certificate for each Borrower, the form of which is attached hereto, (vi) the Success Fee Agreement, and (vii) a landlord waiver for Borrowers leased location at 2155 Park Blvd., Palo Alto, CA 94306, and (b) Borrower's payment of (i) the Second Amendment Facility Fee due as specified in Section 2.5(d) of the Loan Agreement, (ii) the Accrued Third Amendment Final Payment due as specified in Section 2.5(b)(ii) of the Loan Agreement, and (iii) Borrower's payment of all Lenders' Expenses incurred through the date of this Amendment.

[***Balance of Page Intentionally Left Blank***]

[*Signature Page to Third Amendment to Loan and Security Agreement*]

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

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

BORROWER:

EIGER BIOPHARMACEUTICALS, INC.

By: /s/ Sriram Ryali
Name: Sriram Ryali
Title: CFO

EB PHARMA, LLC

By: /s/ James P. Shaffer
Name: James Shaffer
Title: Director (EB Pharma); CBO (Eiger BioPharmaceuticals, Inc.)

EBPI MERGER, INC.

By: /s/ David Cory
Name: David Cory
Title: Director (EBPI Merger); CEO (Eiger BioPharmaceuticals, Inc.)

COLLATERAL AGENT AND LENDER:

OXFORD FINANCE LLC

By: /s/ Colette H. Featherly
Name: Colette H. Featherly
Title: Senior Vice President

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

SCHEDULE 1.1

Lenders and Commitments

	Term A Loans	
Lender	**Term Loan Commitment**	**Commitment Percentage**
OXFORD FINANCE LLC	$30,000,000.00	100.00%
TOTAL	**$30,000,000.00**	**100.00%**

	Term B Loans	
Lender	**Term Loan Commitment**	**Commitment Percentage**
OXFORD FINANCE LLC	$5,000,000.00	100.00%
TOTAL	**$5,000,000.00**	**100.00%**

	Aggregate (all Term Loans)	
Lender	**Term Loan Commitment**	**Commitment Percentage**
OXFORD FINANCE LLC	$35,000,000.00	100.00%
TOTAL	**$35,000,000.00**	**100.00%**

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

DISBURSEMENT LETTER

March 5, 2018

The undersigned, being the duly elected and acting Chief Financial Officer of EIGER BIOPHARMACEUTICALS, INC., a Delaware corporation with offices located at 2155 Park Blvd., Palo Alto, CA 94306, for itself and on behalf of all Borrowers under the Loan Agreement (defined below) (" **Borrower**"), does hereby certify to **OXFORD FINANCE LLC** ("**Oxford**" and "**Lender**"), as collateral agent (the "**Collateral Agent**") in connection with that certain Loan and Security Agreement dated as of December 30, 2016, by and among Borrower, Collateral Agent and the Lenders from time to time party thereto (as amended from time to time, including by that certain First Amendment to Loan and Security Agreement dated as of April 24, 2017, that certain Second Amendment to Loan and Security Agreement dated as of May 11, 2018 and that certain Third Amendment to Loan and Security Agreement dated as of even date herewith, the "**Loan Agreement**"; with other capitalized terms used below having the meanings ascribed thereto in the Loan Agreement) that:

1. The representations and warranties made by Borrower in Section 5 of the Loan Agreement and in the other Loan Documents are true and correct in all material respects as of the date hereof.

2. No event or condition has occurred that would constitute an Event of Default under the Loan Agreement or any other Loan Document.

3. Borrower is in compliance with the covenants and requirements contained in Sections 4, 6 and 7 of the Loan Agreement.

4. All conditions referred to in Section 3 of the Loan Agreement to the making of the Loan to be made on or about the date hereof have been satisfied or waived by Collateral Agent.

5. No Material Adverse Change has occurred.

6. The undersigned is a Responsible Officer.

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[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

7. The proceeds of the Term A Loan shall be disbursed as follows:

Disbursement from Oxford:	
Loan Amount	$30,000,000.00
Plus:	
Deposit Received	$50,000.00
Less:	
Second Amendment Fee	($85,000.00)
Accrued Third Amendment Final Payment	($848,014.68)
Outstanding Principal Amount of Oxford Original Term Loans	($23,333,333.34)
Amount of Accrued Interest on Oxford Original Term Loans (3/1/2019 – 3/4/2019)	($23,075.06)
Interim Interest	($205,875.00)
Lender's Legal Fees	($19,750.00)*
TOTAL TERM A LOAN NET PROCEEDS FROM OXFORD:	**$5,534,951.96**

8. The Term A Loan shall amortize in accordance with the Amortization Table attached hereto.
9. The aggregate net proceeds of the Term A Loan shall be transferred to the Designated Deposit Account as follows:

Account Name:	EIGER BIOPHARMACEUTICALS, INC.
Bank Name:	[*]
Bank Address:	[*]
Account Number:	[*]
ABA Number:	[*]

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* Legal fees and costs are through the Third Amendment Effective Date. Postclosing legal fees and costs, payable after the Third Amendment Effective Date, to be invoiced and paid postclosing.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Dated as of the date first set forth above.

BORROWER:

EIGER BIOPHARMACEUTICALS, INC.

By: /s/ Sriram Ryali
Name: Sriram Ryali
Title: CFO

EB PHARMA, LLC

By: /s/ James P. Shaffer
Name: James Shaffer
Title: Director (EB Pharma); CBO (Eiger BioPharmaceuticals, Inc.)

EBPI MERGER, INC.

By: /s/ David Cory
Name: David Cory
Title: Director (EBPI Merger); CEO (Eiger BioPharmaceuticals, Inc.)

COLLATERAL AGENT AND LENDER:

OXFORD FINANCE LLC

By: /s/ Colette H. Featherly
Name: Colette H. Featherly
Title: Senior Vice President

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

AMORTIZATION TABLE
(Term A Loan)

[see attached]

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

EXHIBIT D

Form of Secured Promissory Note

[see attached]

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

SECURED PROMISSORY NOTE

(Term A Loan)

$6,666,666.66 Dated: March 5, 2019

FOR VALUE RECEIVED, the undersigned, EIGER BIOPHARMACEUTICALS, INC., a Delaware corporation ("**Parent**"), EB Pharma, LLC, a Delaware limited liability company ("**EB Pharma**") and EBPI Merger, Inc. ("**EBPI**"), each with offices located at 2155 Park Blvd., Palo Alto, CA 94306 (Parent, EB Pharma and EBPI, individually and collectively, jointly and severally, "**Borrower**"), HEREBY PROMISES TO PAY to the order of OXFORD FINANCE LLC ("**Lender**") the principal amount of SIX MILLION SIX HUNDRED SIXTY-SIX THOUSAND SIX HUNDRED SIXTY-SIX AND 66/100 DOLLARS ($6,666,666.66) or such lesser amount as shall equal the outstanding principal balance of the Term A Loan made to Borrower by Lender, plus interest on the aggregate unpaid principal amount of such Term A Loan, at the rates and in accordance with the terms of the Loan and Security Agreement dated December 30, 2016 by and among Borrower, Lender, Oxford Finance LLC, as Collateral Agent, and the other Lenders from time to time party thereto (as amended, restated, supplemented or otherwise modified from time to time, including by that certain First Amendment to Loan and Security Agreement dated as of April 24, 2017 and that certain Second Amendment to Loan and Security Agreement dated as of May 11, 2018, the "**Loan Agreement**"). If not sooner paid, the entire principal amount and all accrued and unpaid interest hereunder shall be due and payable on the Maturity Date as set forth in the Loan Agreement. Any capitalized term not otherwise defined herein shall have the meaning attributed to such term in the Loan Agreement.

Principal, interest and all other amounts due with respect to the Term A Loan, are payable in lawful money of the United States of America to Lender as set forth in the Loan Agreement and this Secured Promissory Note (this "**Note**"). The principal amount of this Note and the interest rate applicable thereto, and all payments made with respect thereto, shall be recorded by Lender and, prior to any transfer hereof, endorsed on the grid attached hereto which is part of this Note.

The Loan Agreement, among other things, (a) provides for the making of a secured Term A Loan by Lender to Borrower, and (b) contains provisions for acceleration of the maturity hereof upon the happening of certain stated events.

This Note may not be prepaid except as set forth in Section 2.2(c) and Section 2.2(d) of the Loan Agreement.

This Note and the obligation of Borrower to repay the unpaid principal amount of the Term A Loan, interest on the Term A Loan and all other amounts due Lender under the Loan Agreement is secured under the Loan Agreement.

Presentment for payment, demand, notice of protest and all other demands and notices of any kind in connection with the execution, delivery, performance and enforcement of this Note are hereby waived.

Borrower shall pay all reasonable fees and expenses, including, without limitation, reasonable attorneys' fees and costs, incurred by Lender in the enforcement or attempt to enforce any of Borrower's obligations hereunder not performed when due.

This Note shall be governed by, and construed and interpreted in accordance with, the internal laws of the State of New York.

The ownership of an interest in this Note shall be registered on a record of ownership maintained by Lender or its agent. Notwithstanding anything else in this Note to the contrary, the right to the principal of, and stated interest on, this Note may be transferred only if the transfer is registered on such record of ownership and the transferee is identified as the owner of an interest in the obligation. Borrower shall be entitled to treat the registered holder of this Note (as recorded on such record of ownership) as the owner in fact thereof for all purposes and shall not be bound to recognize any equitable or other claim to or interest in this Note on the part of any other person or entity.

[Balance of Page Intentionally Left Blank]

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

IN WITNESS WHEREOF, Borrower has caused this Note to be duly executed by one of its officers thereunto duly authorized on the date hereof.

BORROWER:

EIGER BIOPHARMACEUTICALS, INC.

By: _____
Name: _____
Title: _____

EB PHARMA, LLC

By: _____
Name: _____
Title: _____

EBPI MERGER, INC.

By: _____
Name: _____
Title: _____

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

LOAN INTEREST RATE AND PAYMENTS OF PRINCIPAL

Date	Principal Amount	Interest Rate	Scheduled Payment Amount	Notation By

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

EXHIBIT E

Form of Secured Amended and Restated Promissory Notes

[see attached]

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

AMENDED AND RESTATED SECURED PROMISSORY NOTE
(Original Term A Loan – original face amount of $7,500,000.00)

$7,000,000.00 Dated: March 5, 2019

FOR VALUE RECEIVED, the undersigned, EIGER BIOPHARMACEUTICALS, INC., a Delaware corporation ("**Parent**"), EB Pharma, LLC, a Delaware limited liability company ("**EB Pharma**") and EBPI Merger, Inc. ("**EBPI**"), each with offices located at 2155 Park Blvd., Palo Alto, CA 94306 (Parent, EB Pharma and EBPI, individually and collectively, jointly and severally, "**Borrower**"), HEREBY PROMISES TO PAY to the order of OXFORD FINANCE LLC ("**Lender**") the principal amount of SEVEN MILLION DOLLARS ($7,000,000.00) or such lesser amount as shall equal the outstanding principal balance of the Original Term A Loan made to Borrower by Lender, plus interest on the aggregate unpaid principal amount of such Original Term A Loan, at the rates and in accordance with the terms of the Loan and Security Agreement dated as of December 30, 2016 by and among Borrower, Lender, Oxford Finance LLC, as Collateral Agent, and the other Lenders from time to time party thereto (as amended, restated, supplemented or otherwise modified from time to time, including by that certain First Amendment to Loan and Security Agreement dated as of April 24, 2017, that certain Second Amendment to Loan and Security Agreement dated as of May 11, 2018 and that certain Third Amendment to Loan and Security Agreement dated as of even date herewith, the "**Loan Agreement**"). If not sooner paid, the entire principal amount and all accrued and unpaid interest hereunder shall be due and payable on the Maturity Date as set forth in the Loan Agreement. Any capitalized term not otherwise defined herein shall have the meaning attributed to such term in the Loan Agreement.

Principal, interest and all other amounts due with respect to the Original Term A Loan, are payable in lawful money of the United States of America to Lender as set forth in the Loan Agreement and this Secured Promissory Note (this "**Note**"). The principal amount of this Note and the interest rate applicable thereto, and all payments made with respect thereto, shall be recorded by Lender and, prior to any transfer hereof, endorsed on the grid attached hereto which is part of this Note.

This Note amends and restates, in its entirety, that certain Secured Promissory Note, dated December 30, 2016, in the original principal amount of SEVEN MILLION FIVE HUNDRED THOUSAND DOLLARS ($7,500,000.00), executed by Borrower in favor of Lender and issued pursuant to the Loan Agreement.

The Loan Agreement, among other things, (a) provides for the making of a secured Original Term A Loan by Lender to Borrower, and (b) contains provisions for acceleration of the maturity hereof upon the happening of certain stated events.

This Note may not be prepaid except as set forth in Section 2.2 (c) and Section 2.2(d) of the Loan Agreement.

This Note and the obligation of Borrower to repay the unpaid principal amount of the Original Term A Loan, interest on the Original Term A Loan and all other amounts due Lender under the Loan Agreement is secured under the Loan Agreement.

Presentment for payment, demand, notice of protest and all other demands and notices of any kind in connection with the execution, delivery, performance and enforcement of this Note are hereby waived.

Borrower shall pay all reasonable fees and expenses, including, without limitation, reasonable attorneys' fees and costs, incurred by Lender in the enforcement or attempt to enforce any of Borrower's obligations hereunder not performed when due.

This Note shall be governed by, and construed and interpreted in accordance with, the internal laws of the State of New York.

The ownership of an interest in this Note shall be registered on a record of ownership maintained by Lender or its agent. Notwithstanding anything else in this Note to the contrary, the right to the principal of, and stated interest on, this Note may be transferred only if the transfer is registered on such record of ownership and the transferee is identified as the owner of an interest in the obligation. Borrower shall be entitled to treat the registered holder of this Note (as recorded on such record of ownership) as the owner in fact thereof for all purposes and shall not be bound to recognize any equitable or other claim to or interest in this Note on the part of any other person or entity.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

IN WITNESS WHEREOF, Borrower has caused this Note to be duly executed by one of its officers thereunto duly authorized on the date hereof.

BORROWER:

EIGER BIOPHARMACEUTICALS, INC.

By: _____
Name: _____
Title: _____

EB PHARMA, LLC

By: _____
Name: _____
Title:

EBPI MERGER, INC.

By: _____
Name: _____
Title:

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

LOAN INTEREST RATE AND PAYMENTS OF PRINCIPAL

Date	Principal Amount	Interest Rate	Scheduled Payment Amount	Notation By

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

AMENDED AND RESTATED SECURED PROMISSORY NOTE
(Original Term A Loan – original face amount of $7,500,000.00)

$7,000,000.00 Dated: March 5, 2019

FOR VALUE RECEIVED, the undersigned, EIGER BIOPHARMACEUTICALS, INC., a Delaware corporation ("**Parent**"), EB Pharma, LLC, a Delaware limited liability company ("**EB Pharma**") and EBPI Merger, Inc. ("**EBPI**"), each with offices located at 2155 Park Blvd., Palo Alto, CA 94306 (Parent, EB Pharma and EBPI, individually and collectively, jointly and severally, "**Borrower**"), HEREBY PROMISES TO PAY to the order of OXFORD FINANCE LLC ("**Lender**") the principal amount of SEVEN MILLION DOLLARS ($7,000,000.00) or such lesser amount as shall equal the outstanding principal balance of the Original Term A Loan made to Borrower by Lender, plus interest on the aggregate unpaid principal amount of such Original Term A Loan, at the rates and in accordance with the terms of the Loan and Security Agreement dated as of December 30, 2016 by and among Borrower, Lender, Oxford Finance LLC, as Collateral Agent, and the other Lenders from time to time party thereto (as amended, restated, supplemented or otherwise modified from time to time, including by that certain First Amendment to Loan and Security Agreement dated as of April 24, 2017, that certain Second Amendment to Loan and Security Agreement dated as of May 11, 2018 and that certain Third Amendment to Loan and Security Agreement dated as of even date herewith, the "**Loan Agreement**"). If not sooner paid, the entire principal amount and all accrued and unpaid interest hereunder shall be due and payable on the Maturity Date as set forth in the Loan Agreement. Any capitalized term not otherwise defined herein shall have the meaning attributed to such term in the Loan Agreement.

Principal, interest and all other amounts due with respect to the Original Term A Loan, are payable in lawful money of the United States of America to Lender as set forth in the Loan Agreement and this Secured Promissory Note (this "**Note**"). The principal amount of this Note and the interest rate applicable thereto, and all payments made with respect thereto, shall be recorded by Lender and, prior to any transfer hereof, endorsed on the grid attached hereto which is part of this Note.

This Note amends and restates, in its entirety, that certain Secured Promissory Note, dated December 30, 2016, in the original principal amount of SEVEN MILLION FIVE HUNDRED THOUSAND DOLLARS ($7,500,000.00), executed by Borrower in favor of Lender and issued pursuant to the Loan Agreement.

The Loan Agreement, among other things, (a) provides for the making of a secured Original Term A Loan by Lender to Borrower, and (b) contains provisions for acceleration of the maturity hereof upon the happening of certain stated events.

This Note may not be prepaid except as set forth in Section 2.2 (c) and Section 2.2(d) of the Loan Agreement.

This Note and the obligation of Borrower to repay the unpaid principal amount of the Original Term A Loan, interest on the Original Term A Loan and all other amounts due Lender under the Loan Agreement is secured under the Loan Agreement.

Presentment for payment, demand, notice of protest and all other demands and notices of any kind in connection with the execution, delivery, performance and enforcement of this Note are hereby waived.

Borrower shall pay all reasonable fees and expenses, including, without limitation, reasonable attorneys' fees and costs, incurred by Lender in the enforcement or attempt to enforce any of Borrower's obligations hereunder not performed when due.

This Note shall be governed by, and construed and interpreted in accordance with, the internal laws of the State of New York.

The ownership of an interest in this Note shall be registered on a record of ownership maintained by Lender or its agent. Notwithstanding anything else in this Note to the contrary, the right to the principal of, and stated interest on, this Note may be transferred only if the transfer is registered on such record of ownership and the transferee is identified as the owner of an interest in the obligation. Borrower shall be entitled to treat the registered holder of this Note (as recorded on such record of ownership) as the owner in fact thereof for all purposes and shall not be bound to recognize any equitable or other claim to or interest in this Note on the part of any other person or entity.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

IN WITNESS WHEREOF, Borrower has caused this Note to be duly executed by one of its officers thereunto duly authorized on the date hereof.

BORROWER:

EIGER BIOPHARMACEUTICALS, INC.

By: _____
Name: _____
Title: _____

EB PHARMA, LLC

By: _____
Name: _____
Title: _____

EBPI MERGER, INC.

By: _____
Name: _____
Title: _____

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

LOAN INTEREST RATE AND PAYMENTS OF PRINCIPAL

Date	Principal Amount	Interest Rate	Scheduled Payment Amount	Notation By

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

AMENDED AND RESTATED SECURED PROMISSORY NOTE
(Original Term B Loan – original face amount of $5,000,000.00)

$4,666,666.67 Dated: March 5, 2019

FOR VALUE RECEIVED, the undersigned, EIGER BIOPHARMACEUTICALS, INC., a Delaware corporation ("**Parent**"), EB Pharma, LLC, a Delaware limited liability company ("**EB Pharma**") and EBPI Merger, Inc. ("**EBPI**"), each with offices located at 2155 Park Blvd., Palo Alto, CA 94306 (Parent, EB Pharma and EBPI, individually and collectively, jointly and severally, "**Borrower**"), HEREBY PROMISES TO PAY to the order of OXFORD FINANCE LLC ("**Lender**") the principal amount of FOUR MILLION SIX HUNDRED SIXTY-SIX THOUSAND SIX HUNDRED SIXTY SIX AND 67/100 DOLLARS ($4,666,666.67) or such lesser amount as shall equal the outstanding principal balance of the Original Term B Loan made to Borrower by Lender, plus interest on the aggregate unpaid principal amount of such Original Term B Loan, at the rates and in accordance with the terms of the Loan and Security Agreement dated as of December 30, 2016 by and among Borrower, Lender, Oxford Finance LLC, as Collateral Agent, and the other Lenders from time to time party thereto (as amended, restated, supplemented or otherwise modified from time to time, including by that certain First Amendment to Loan and Security Agreement dated as of April 24, 2017, that certain Second Amendment to Loan and Security Agreement dated as of May 11, 2018 and that certain Third Amendment to Loan and Security Agreement dated as of even date herewith, the "**Loan Agreement**"). If not sooner paid, the entire principal amount and all accrued and unpaid interest hereunder shall be due and payable on the Maturity Date as set forth in the Loan Agreement. Any capitalized term not otherwise defined herein shall have the meaning attributed to such term in the Loan Agreement.

Principal, interest and all other amounts due with respect to the Original Term B Loan, are payable in lawful money of the United States of America to Lender as set forth in the Loan Agreement and this Secured Promissory Note (this "**Note**"). The principal amount of this Note and the interest rate applicable thereto, and all payments made with respect thereto, shall be recorded by Lender and, prior to any transfer hereof, endorsed on the grid attached hereto which is part of this Note.

This Note amends and restates, in its entirety, that certain Secured Promissory Note, dated May 11, 2018, in the original principal amount of FIVE MILLION DOLLARS ($5,000,000.00), executed by Borrower in favor of Lender and issued pursuant to the Loan Agreement.

The Loan Agreement, among other things, (a) provides for the making of a secured Original Term B Loan by Lender to Borrower, and (b) contains provisions for acceleration of the maturity hereof upon the happening of certain stated events.

This Note may not be prepaid except as set forth in Section 2.2 (c) and Section 2.2(d) of the Loan Agreement.

This Note and the obligation of Borrower to repay the unpaid principal amount of the Original Term B Loan, interest on the Original Term B Loan and all other amounts due Lender under the Loan Agreement is secured under the Loan Agreement.

Presentment for payment, demand, notice of protest and all other demands and notices of any kind in connection with the execution, delivery, performance and enforcement of this Note are hereby waived.

Borrower shall pay all reasonable fees and expenses, including, without limitation, reasonable attorneys' fees and costs, incurred by Lender in the enforcement or attempt to enforce any of Borrower's obligations hereunder not performed when due.

This Note shall be governed by, and construed and interpreted in accordance with, the internal laws of the State of New York.

The ownership of an interest in this Note shall be registered on a record of ownership maintained by Lender or its agent. Notwithstanding anything else in this Note to the contrary, the right to the principal of, and stated interest on, this Note may be transferred only if the transfer is registered on such record of ownership and the transferee is identified as the owner of an interest in the obligation. Borrower shall be entitled to treat the registered holder of this Note (as recorded on such record of ownership) as the owner in fact thereof for all purposes and shall not be bound to recognize any equitable or other claim to or interest in this Note on the part of any other person or entity.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

IN WITNESS WHEREOF, Borrower has caused this Note to be duly executed by one of its officers thereunto duly authorized on the date hereof.

BORROWER:

EIGER BIOPHARMACEUTICALS, INC.

By: _____
Name: _____
Title: _____

EB PHARMA, LLC

By: _____
Name: _____
Title: _____

EBPI MERGER, INC.

By: _____
Name: _____
Title: _____

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

LOAN INTEREST RATE AND PAYMENTS OF PRINCIPAL

Date	Principal Amount	Interest Rate	Scheduled Payment Amount	Notation By

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

AMENDED AND RESTATED SECURED PROMISSORY NOTE
(Original Term C Loan – original face amount of $5,000,000.00)

$4,666,666.67 Dated: March 5, 2019

FOR VALUE RECEIVED, the undersigned, EIGER BIOPHARMACEUTICALS, INC., a Delaware corporation ("**Parent**"), EB Pharma, LLC, a Delaware limited liability company ("**EB Pharma**") and EBPI Merger, Inc. ("**EBPI**"), each with offices located at 2155 Park Blvd., Palo Alto, CA 94306 (Parent, EB Pharma and EBPI, individually and collectively, jointly and severally, "**Borrower**"), HEREBY PROMISES TO PAY to the order of OXFORD FINANCE LLC ("**Lender**") the principal amount of FOUR MILLION SIX HUNDRED SIXTY-SIX THOUSAND SIX HUNDRED SIXTY SIX AND 67/100 DOLLARS ($4,666,666.67) or such lesser amount as shall equal the outstanding principal balance of the Original Term C Loan made to Borrower by Lender, plus interest on the aggregate unpaid principal amount of such Original Term C Loan, at the rates and in accordance with the terms of the Loan and Security Agreement dated as of December 30, 2016 by and among Borrower, Lender, Oxford Finance LLC, as Collateral Agent, and the other Lenders from time to time party thereto (as amended, restated, supplemented or otherwise modified from time to time, including by that certain First Amendment to Loan and Security Agreement dated as of April 24, 2017, that certain Second Amendment to Loan and Security Agreement dated as of May 11, 2018 and that certain Third Amendment to Loan and Security Agreement dated as of even date herewith, the "**Loan Agreement**"). If not sooner paid, the entire principal amount and all accrued and unpaid interest hereunder shall be due and payable on the Maturity Date as set forth in the Loan Agreement. Any capitalized term not otherwise defined herein shall have the meaning attributed to such term in the Loan Agreement.

Principal, interest and all other amounts due with respect to the Original Term C Loan, are payable in lawful money of the United States of America to Lender as set forth in the Loan Agreement and this Secured Promissory Note (this "**Note**"). The principal amount of this Note and the interest rate applicable thereto, and all payments made with respect thereto, shall be recorded by Lender and, prior to any transfer hereof, endorsed on the grid attached hereto which is part of this Note.

This Note amends and restates, in its entirety, that certain Secured Promissory Note, dated August 3, 2018, in the original principal amount of FIVE MILLION DOLLARS ($5,000,000.00), executed by Borrower in favor of Lender and issued pursuant to the Loan Agreement.

The Loan Agreement, among other things, (a) provides for the making of a secured Original Term C Loan by Lender to Borrower, and (b) contains provisions for acceleration of the maturity hereof upon the happening of certain stated events.

This Note may not be prepaid except as set forth in Section 2.2 (c) and Section 2.2(d) of the Loan Agreement.

This Note and the obligation of Borrower to repay the unpaid principal amount of the Original Term C Loan, interest on the Original Term C Loan and all other amounts due Lender under the Loan Agreement is secured under the Loan Agreement.

Presentment for payment, demand, notice of protest and all other demands and notices of any kind in connection with the execution, delivery, performance and enforcement of this Note are hereby waived.

Borrower shall pay all reasonable fees and expenses, including, without limitation, reasonable attorneys' fees and costs, incurred by Lender in the enforcement or attempt to enforce any of Borrower's obligations hereunder not performed when due.

This Note shall be governed by, and construed and interpreted in accordance with, the internal laws of the State of New York.

The ownership of an interest in this Note shall be registered on a record of ownership maintained by Lender or its agent. Notwithstanding anything else in this Note to the contrary, the right to the principal of, and stated interest on, this Note may be transferred only if the transfer is registered on such record of ownership and the transferee is identified as the owner of an interest in the obligation. Borrower shall be entitled to treat the registered holder of this Note (as recorded on such record of ownership) as the owner in fact thereof for all purposes and shall not be bound to recognize any equitable or other claim to or interest in this Note on the part of any other person or entity.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

IN WITNESS WHEREOF, Borrower has caused this Note to be duly executed by one of its officers thereunto duly authorized on the date hereof.

BORROWER:

EIGER BIOPHARMACEUTICALS, INC.

By: _____
Name: _____
Title: _____

EB PHARMA, LLC

By: _____
Name: _____
Title: _____

EBPI MERGER, INC.

By: _____
Name: _____
Title: _____

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

LOAN INTEREST RATE AND PAYMENTS OF PRINCIPAL

Date	Principal Amount	Interest Rate	Scheduled Payment Amount	Notation By

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

CORPORATE BORROWING CERTIFICATE

Borrower: EIGER BIOPHARMACEUTICALS, INC. **Date**: March 5, 2019
Lender: OXFORD FINANCE LLC, as Collateral Agent and Lender

I hereby certify as follows, as of the date set forth above:

1. I am the Secretary, Assistant Secretary or other officer of Borrower. My title is as set forth below.

2. Borrower's exact legal name is set forth above. Borrower is a corporation existing under the laws of the State of Delaware.

3. Attached hereto as Exhibit A and Exhibit B, respectively, are true, correct and complete copies of (i) Borrower's Certificate of Incorporation (including amendments), as filed with the Secretary of State of the state in which Borrower is incorporated as set forth in paragraph 2 above; and (ii) Borrower's Bylaws. Neither such Certificate of Incorporation nor such Bylaws have been amended, annulled, rescinded, revoked or supplemented, and such Certificate of Incorporation and such Bylaws remain in full force and effect as of the date hereof.

4. The following resolutions were duly and validly adopted by Borrower's Board of Directors at a duly held meeting of such directors (or pursuant to a unanimous written consent or other authorized corporate action). Such resolutions are in full force and effect as of the date hereof and have not been in any way modified, repealed, rescinded, amended or revoked, and the Lenders may rely on them until each Lender receives written notice of revocation from Borrower.

[*Balance of Page Intentionally Left Blank*]

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Resolved, that **any one** of the following officers or employees of Borrower, whose names, titles and signatures are below, may act on behalf of Borrower:

Name	Title	Signature	Authorized to Add or Remove Signatories

Resolved Further, that **any one** of the persons designated above with a checked box beside his or her name may, from time to time, add or remove any individuals to and from the above list of persons authorized to act on behalf of Borrower.

Resolved Further, that such individuals may, on behalf of Borrower:

Borrow Money. Borrow money from the Lenders.

Execute Loan Documents. Execute any loan documents any Lender requires.

Grant Security. Grant Collateral Agent a security interest in any of Borrower's assets.

Negotiate Items. Negotiate or discount all drafts, trade acceptances, promissory notes, or other indebtedness in which Borrower has an interest and receive cash or otherwise use the proceeds.

Further Acts. Designate other individuals to request advances, pay fees and costs and execute other documents or agreements (including documents or agreement that waive Borrower's right to a jury trial) they believe to be necessary to effectuate such resolutions.

Resolved Further, that all acts authorized by the above resolutions and any prior acts relating thereto are ratified.

[*Balance of Page Intentionally Left Blank*]

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

5. The persons listed above are Borrower's officers or employees with their titles and signatures shown next to their names.

By: _____
Name: _____
Title: _____

**** If the Secretary, Assistant Secretary or other certifying officer executing above is designated by the resolutions set forth in paragraph 4 as one of the authorized signing officers, this Certificate must also be signed by a second authorized officer or director of Borrower.*

I, the _____ of Borrower, hereby certify as to paragraphs 1 through 5 above, as

[print title]

of the date set forth above.

By: _____
Name: _____
Title: _____

**[*Signature Page to Corporate Borrowing Certificate*
EIGER BIOPHARMACEUTICALS, INC.]

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

EXHIBIT A

Certificate of Incorporation (including amendments)

[see attached]

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

EXHIBIT B

Bylaws

[see attached]

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

CORPORATE BORROWING CERTIFICATE

Borrower: EB PHARMA, LLC **Date**: March 5, 2019
Lender: OXFORD FINANCE LLC, as Collateral Agent and Lender

I hereby certify as follows, as of the date set forth above:

1. I am the Secretary, Assistant Secretary or other officer of Borrower. My title is as set forth below.

2. Borrower's exact legal name is set forth above. Borrower is a limited liability company existing under the laws of the State of Delaware.

3. Attached hereto as Exhibit A and Exhibit B, respectively, are true, correct and complete copies of (i) Borrower's Certificate of Formation (including amendments), as filed with the Secretary of State of the state in which Borrower is incorporated as set forth in paragraph 2 above; and (ii) Borrower's operating agreement. Neither such Certificate of Formation nor such operating agreement have been amended, annulled, rescinded, revoked or supplemented, and such Certificate of Formation and such operating agreement remain in full force and effect as of the date hereof.

4. The following resolutions were duly and validly adopted by Borrower's Board of Directors at a duly held meeting of such directors (or pursuant to a unanimous written consent or other authorized corporate action). Such resolutions are in full force and effect as of the date hereof and have not been in any way modified, repealed, rescinded, amended or revoked, and the Lenders may rely on them until each Lender receives written notice of revocation from Borrower.

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[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Resolved, that **any one** of the following officers or employees of Borrower, whose names, titles and signatures are below, may act on behalf of Borrower:

Name	Title	Signature	Authorized to Add or Remove Signatories

Resolved Further, that **any one** of the persons designated above with a checked box beside his or her name may, from time to time, add or remove any individuals to and from the above list of persons authorized to act on behalf of Borrower.

Resolved Further, that such individuals may, on behalf of Borrower:

Borrow Money. Borrow money from the Lenders.

Execute Loan Documents. Execute any loan documents any Lender requires.

Grant Security. Grant Collateral Agent a security interest in any of Borrower's assets.

Negotiate Items. Negotiate or discount all drafts, trade acceptances, promissory notes, or other indebtedness in which Borrower has an interest and receive cash or otherwise use the proceeds.

Further Acts. Designate other individuals to request advances, pay fees and costs and execute other documents or agreements (including documents or agreement that waive Borrower's right to a jury trial) they believe to be necessary to effectuate such resolutions.

Resolved Further, that all acts authorized by the above resolutions and any prior acts relating thereto are ratified.

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[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

5. The persons listed above are Borrower's officers or employees with their titles and signatures shown next to their names.

By: _____
Name: _____
Title: _____

**** If the Secretary, Assistant Secretary or other certifying officer executing above is designated by the resolutions set forth in paragraph 4 as one of the authorized signing officers, this Certificate must also be signed by a second authorized officer or director of Borrower.*

I, the _____ of Borrower, hereby certify as to paragraphs 1 through 5 above, as

[print title]

of the date set forth above.

By: _____
Name: _____
Title: _____

**[*Signature Page to Corporate Borrowing Certificate*
EB PHARMA, LLC]

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

EXHIBIT A

Certificate of Formation (including amendments)

[see attached]

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

EXHIBIT B

Operating Agreement

[see attached]

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

CORPORATE BORROWING CERTIFICATE

Borrower: EBPI MERGER, INC. **Date**: March 5, 2019
Lender: OXFORD FINANCE LLC, as Collateral Agent and Lender

I hereby certify as follows, as of the date set forth above:

1. I am the Secretary, Assistant Secretary or other officer of Borrower. My title is as set forth below.

2. Borrower's exact legal name is set forth above. Borrower is a corporation existing under the laws of the State of Delaware.

3. Attached hereto as Exhibit A and Exhibit B, respectively, are true, correct and complete copies of (i) Borrower's Certificate of Incorporation (including amendments), as filed with the Secretary of State of the state in which Borrower is incorporated as set forth in paragraph 2 above; and (ii) Borrower's Bylaws. Neither such Certificate of Incorporation nor such Bylaws have been amended, annulled, rescinded, revoked or supplemented, and such Certificate of Incorporation and such Bylaws remain in full force and effect as of the date hereof.

4. The following resolutions were duly and validly adopted by Borrower's Board of Directors at a duly held meeting of such directors (or pursuant to a unanimous written consent or other authorized corporate action). Such resolutions are in full force and effect as of the date hereof and have not been in any way modified, repealed, rescinded, amended or revoked, and the Lenders may rely on them until each Lender receives written notice of revocation from Borrower.

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[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Resolved, that **any one** of the following officers or employees of Borrower, whose names, titles and signatures are below, may act on behalf of Borrower:

Name	Title	Signature	Authorized to Add or Remove Signatories

Resolved Further, that **any one** of the persons designated above with a checked box beside his or her name may, from time to time, add or remove any individuals to and from the above list of persons authorized to act on behalf of Borrower.

Resolved Further, that such individuals may, on behalf of Borrower:

Borrow Money. Borrow money from the Lenders.

Execute Loan Documents. Execute any loan documents any Lender requires.

Grant Security. Grant Collateral Agent a security interest in any of Borrower's assets.

Negotiate Items. Negotiate or discount all drafts, trade acceptances, promissory notes, or other indebtedness in which Borrower has an interest and receive cash or otherwise use the proceeds.

Further Acts. Designate other individuals to request advances, pay fees and costs and execute other documents or agreements (including documents or agreement that waive Borrower's right to a jury trial) they believe to be necessary to effectuate such resolutions.

Resolved Further, that all acts authorized by the above resolutions and any prior acts relating thereto are ratified.

[*Balance of Page Intentionally Left Blank*]

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

5. The persons listed above are Borrower's officers or employees with their titles and signatures shown next to their names.

By: _____
Name: _____
Title: _____

**** If the Secretary, Assistant Secretary or other certifying officer executing above is designated by the resolutions set forth in paragraph 4 as one of the authorized signing officers, this Certificate must also be signed by a second authorized officer or director of Borrower.*

I, the _____ of Borrower, hereby certify as to paragraphs 1 through 5 above, as

[print title]

of the date set forth above.

By: _____
Name: _____
Title: _____

**[*Signature Page to Corporate Borrowing Certificate*
EBPI MERGER, INC.]

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

EXHIBIT A

Certificate of Incorporation (including amendments)

[see attached]

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

EXHIBIT B

Bylaws

[see attached]

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Exhibit 10.4

EIGER BIOPHARMACEUTICALS, INC.
NON-EMPLOYEE DIRECTOR COMPENSATION POLICY

ADOPTED BY THE BOARD: SEPTEMBER 3, 2013
AMENDED: May 7, 2019

Each member of the Board of Directors (the ***"Board"***) who is not also serving as an employee of Eiger BioPharmaceuticals, Inc. (***"Eiger"***) or any of its subsidiaries (each such member, an ***"Eligible Director"***) will receive the compensation described in this Non-Employee Director Compensation Policy for his or her Board service. This amended policy is effective as of **May 7, 2019** and may be amended at any time in the sole discretion of the Board or the Compensation Committee of the Board.

Annual Cash Compensation

The annual cash compensation amount set forth below is payable in equal quarterly installments, payable in arrears within thirty days of the last day of each fiscal quarter in which the service occurred. If an Eligible Director joins the Board or a committee of the Board at a time other than effective as of the first day of a fiscal quarter, each annual retainer set forth below will be pro-rated based on days served in the applicable fiscal year, with the pro-rated amount paid for the first fiscal quarter in which the Eligible Director provides the service, and regular full quarterly payments thereafter. All annual cash fees are vested upon payment.

1. Annual Board Service Retainer:
   a. All Eligible Directors: $40,000
   b. Chairman of the Board Service Retainer (in addition to Eligible Director Service Retainer): $80,000

2. Annual Committee Member Service Retainer:
   a. Member of the Audit Committee: $7,500
   b. Member of the Compensation Committee: $6,000
   c. Member of the Nominating & Governance Committee: $4,000

3. Annual Committee Chair Service Retainer (in addition to Committee Member Service Retainer):
   a. Chairman of the Audit Committee: $20,000
   b. Chairman of the Compensation Committee: $12,000
   c. Chairman of the Nominating & Governance Committee: $8,000

Equity Compensation

The equity compensation set forth below will be granted under the Eiger Corporation 2013 Equity Incentive Plan (the ***"Plan"***). All stock options granted under this policy will be non-statutory stock options, with an exercise price per share equal to 100% of the Fair Market Value (as defined in the Plan) of the underlying Common Stock on the date of grant, and a term of ten years from the date of grant (subject to earlier termination in connection with a termination of service as provided in the Plan, provided that upon a termination of service other than for cause, the post- termination exercise period will be three years from the date of termination, subject to the original term of the option).

1. Initial Grant: Unless otherwise determined by the Board, on the date of the Eligible Director's initial election to the Board (or, if such date is not a market trading day, the first market trading day thereafter), the Eligible Director will be automatically, and without further action by the Board or Compensation Committee of the Board, granted a stock option for 25,000 shares (the "***Initial Grant***"). The shares subject to each Initial Grant will vest in equal monthly installments over a three year period such that the option is fully vested on the third anniversary of the date of grant, subject to the Eligible Director's Continuous Service (as defined in the Plan) through each such vesting date and will vest in full upon a Change in Control (as defined in the Plan).

2. Annual Grant: Unless otherwise determined by the Board, on the date of the Board meeting held each year at which the Board grants executives' annual equity incentive awards, each Eligible Director who served on the Board for at least six months during the prior calendar year and who continues to serve as a non-employee member of the Board, will be automatically, and without further action by the Board or Compensation Committee of the Board, be granted a stock option for 10,000 shares, or 20,000 shares for Chairman of the Board (the "***Annual Grant***"). Each Eligible Director who has served on the Board for less than six months during the prior calendar year and who continues to serve as a non-employee member of the Board, will be automatically, and without further action by the Board or Compensation Committee of the Board, be granted an Annual Grant pro-rated for the period served during the prior calendar year. The shares subject to the Annual Grant will vest over one year in twelve equal monthly installments subject to the Eligible Director's Continuous Service (as defined in the Plan) through such vesting date and will vest in full upon a Change in Control (as defined in the Plan).

Exhibit 31.1

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

I, David A. Cory, 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: May 9, 2019

/s/ David A. Cory
David A. Cory
Chief Executive Officer

Exhibit 31.2

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

I, Sriram Ryali, 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: May 9, 2019

/s/ Sriram Ryali
Sriram Ryali
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 A. Cory, Chief Executive Officer of Eiger BioPharmaceuticals, Inc. (the "Company"), and Sriram Ryali, 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 March 31, 2019, 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: May 9, 2019

/s/ David A. Cory
David A. Cory
Chief Executive Officer

/s/ Sriram Ryali
Sriram Ryali
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."