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

Form 10-Q

(Mark One)

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

For the quarterly period ended September 30, 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)

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

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

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ 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 ☒

As of November 4, 2019, the number of outstanding shares of the registrant's common stock, par value $0.001 per share, was 24,495,047.

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

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	September 30, 2019 (Unaudited)	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 19,406	$ 61,262
Debt securities, available-for-sale	90,545	39,091
Prepaid expenses and other current assets	4,459	1,492
Total current assets	114,410	101,845
Property and equipment, net	538	167
Operating lease right-of-use assets	1,659	—
Other assets	3,388	436
Total assets	$ 119,995	$ 102,448
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 9,057	$ 5,830
Accrued liabilities	7,222	4,194
Current portion of operating lease liabilities	466	—
Total current liabilities	16,745	10,024
Long-term debt, net	30,202	25,620
Operating lease liabilities	1,389	—
Other long-term liabilities	—	212
Total liabilities	48,336	35,856
Stockholders' equity:		
Common stock	24	19
Additional paid-in capital	296,121	237,795
Accumulated other comprehensive income (loss)	43	(25)
Accumulated deficit	(224,529)	(171,197)
Total stockholders' equity	71,659	66,592
Total liabilities and stockholders' equity	$ 119,995	$ 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 September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Operating expenses:				
Research and development	$ 14,059	$ 13,196	$ 39,863	$ 25,080
General and administrative	4,247	3,643	12,529	9,874
Total operating expenses	18,306	16,839	52,392	34,954
Loss from operations	(18,306)	(16,839)	(52,392)	(34,954)
Interest expense	(884)	(681)	(2,518)	(1,574)
Interest income	585	371	1,598	654
Other (expense) income, net	(11)	5	(20)	(16)
Net loss	$ (18,616)	$ (17,144)	$ (53,332)	$ (35,890)
Net loss per common share, basic and diluted	$ (0.76)	$ (1.20)	$ (2.40)	$ (2.92)
Weighted-average common shares outstanding, basic and diluted	24,437,451	14,255,843	22,261,715	12,290,500

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Net loss	$ (18,616)	$ (17,144)	$ (53,332)	$ (35,890)
Other comprehensive loss:				
Unrealized gain (loss) on available-for-sale debt securities, net	38	8	68	(3)
Comprehensive loss	$ (18,578)	$ (17,136)	$ (53,264)	$ (35,893)

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)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2018	19,211,759	$ 19	$ 237,795	$ (25)	$ (171,197)	$ 66,592
Issuance of common stock upon exercise of stock options	41,546	—	65	—	—	65
Vesting of common stock issued under Product Development Agreement	—	—	56	—	—	56
Issuance of common stock upon ESPP purchase	7,138	—	59	—	—	59
Stock-based compensation expense	—	—	1,195	—	—	1,195
Unrealized gain on debt securities, net	—	—	—	30	—	30
Net loss	—	—	—	—	(17,189)	(17,189)
Balance at March 31, 2019	19,260,443	19	239,170	5	(188,386)	50,808
Issuance of common stock upon exercise of stock options	10,304	—	62	—	—	62
Vesting of common stock issued under Product Development Agreement	—	—	55	—	—	55
Issuance of common stock upon public offering, net of $3,731 of issuance costs	5,175,000	5	53,189	—	—	53,194
Stock-based compensation expense	—	—	1,487	—	—	1,487
Net loss	—	—	—	—	(17,527)	(17,527)
Balance at June 30, 2019	24,445,747	24	293,963	5	(205,913)	88,079
Issuance of common stock upon exercise of stock options	39,875	—	379	—	—	379
Vesting of common stock issued under Product Development Agreement	—	—	59	—	—	59
Issuance of common stock upon ESPP purchase	8,563	—	71	—	—	71
Stock-based compensation expense	—	—	1,649	—	—	1,649
Unrealized gain on debt securities, net	—	—	—	38	—	38
Net loss	—	—	—	—	(18,616)	(18,616)
Balance at September 30, 2019	24,494,185	$ 24	$ 296,121	$ 43	$ (224,529)	$ 71,659

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2017	10,526,599	$ 11	$ 141,320	$ (3)	$ (118,806)	$ 22,522
Issuance of common stock upon ESPP purchase	9,522	—	34	—	—	34
Stock-based compensation expense	—	—	1,003	—	—	1,003
Unrealized gain on debt securities, net	—	—	—	3	—	3
Net loss	—	—	—	—	(8,831)	(8,831)
Balance at March 31, 2018	10,536,121	11	142,357	—	(127,637)	14,731
Issuance of common stock upon exercise of stock options	28,151	—	268	—	—	268
Issuance of common stock upon public offering, net of $3,110 of issuance costs	3,680,000	3	42,887	—	—	42,890
Stock-based compensation expense	—	—	1,321	—	—	1,321
Unrealized loss on debt securities, net	—	—	—	(14)	—	(14)
Net loss	—	—	—	—	(9,915)	(9,915)
Balance at June 30, 2018	14,244,272	14	186,833	(14)	(137,552)	49,281
Issuance of common stock issued under Product Development Agreement	115,526	—	361	—	—	361
Issuance of common stock upon exercise of stock options	11,629	—	27	—	—	27
Issuance of common stock upon ESPP purchase	7,986	—	62	—	—	62
Stock-based compensation	—	—	1,172	—	—	1,172
Unrealized gain on debt securities, net	—	—	—	8	—	8
Net loss	—	—	—	—	(17,144)	(17,144)
Balance at September 30, 2018	14,379,413	$ 14	$ 188,455	$ (6)	$ (154,696)	$ 33,767

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

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

	Nine Months Ended September 30,	
	2019	**2018**
Operating activities		
Net loss	$ (53,332)	$ (35,890)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	41	34
Amortization of debt securities discounts	(390)	(257)
Non-cash interest expense	535	393
Amortization of operating lease right-of-use assets	299	—
Common stock issued under Product Development Agreement	170	361
Stock-based compensation	4,331	3,496
Change in operating assets and liabilities:		
Prepaid expenses and other current assets	(2,967)	(1,152)
Other assets	(2,952)	(77)
Accounts payable	3,178	3,334
Accrued liabilities	2,759	(625)
Operating lease liabilities	(315)	—
Other long-term liabilities	—	214
Net cash used in operating activities	(48,643)	(30,169)
Investing activities		
Purchase of debt securities available-for-sale	(96,267)	(52,265)
Proceeds from maturities of debt securities available-for-sale	45,271	14,250
Purchase of property and equipment	(94)	(140)
Net cash used in investing activities	(51,090)	(38,155)
Financing activities		
Proceeds from issuance of common stock upon public offering, net of issuance costs	53,194	42,890
Proceeds from borrowings in connection with term loan, net of issuance costs	6,627	9,935
Repayment of accrued exit fee and second amendment fee	(913)	—
Repayment of term loan	(1,667)	—
Proceeds from issuance of common stock upon stock option exercises	506	295
Proceeds from issuance of common stock upon ESPP purchase	130	96
Net cash provided by financing activities	57,877	53,216
Net decrease in cash and cash equivalents	(41,856)	(15,108)
Cash and cash equivalents at beginning of period	61,262	32,035
Cash and cash equivalents at end of period	$ 19,406	$ 16,927
Supplemental disclosure of cash flow information:		
Interest paid	$ 1,944	$ 1,106

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 monotherapy, lonafarnib boosted with ritonavir, peginterferon lambda monotherapy and in combination with lonafarnib boosted with ritonavir, and avexitide, all with first-in-class drugs, now advancing into submission for regulatory approvals or Phase 3 clinical development.

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 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 the Company's experienced, commercially-focused management team.

Eiger's lead program is in Phase 3, developing lonafarnib, a first-in-class prenylation inhibitor, boosted with ritonavir, for the treatment of Hepatitis Delta Virus ("HDV") infection, the most severe form of human viral hepatitis for which there is currently no approved therapy. The Company is also developing lonafarnib monotherapy for treatment of Progeria and Progeroid Laminopathies. Progeria, also known as Hutchinson-Gilford Progeria Syndrome ("HGPS"), and Progeroid Laminopathies, are ultra-rare and rapidly fatal genetic conditions of accelerated aging in children. Peginterferon lambda ("lambda") is the Company's second program treating HDV. Lambda is a well-characterized, late-stage, first in class, type III interferon. The Company is developing avexitide, a well-characterized peptide, as a treatment for post-bariatric hypoglycemia ("PBH"). PBH is a debilitating and potentially life-threatening condition for which there is currently no approved therapy. Avexitide has also demonstrated clinical proof of concept for treatment of Congenital Hyperinsulinism ("CHI"), an ultra-rare pediatric metabolic disorder.

The Company's principal operations are based in Palo Alto, California, and it operates in one segment.

Liquidity

As of September 30, 2019, the Company had $109.9 million of cash, cash equivalents and investments, comprised of $19.4 million of cash and cash equivalents and $90.5 million of debt securities available-for-sale. The Company had an accumulated deficit of $224.5 million and negative cash flows from operating activities as of September 30, 2019. The Company expects to continue to incur losses for the next several years.

On April 17, 2019, the Company completed an underwritten public offering of 5,175,000 shares of its common stock, including 675,000 shares sold upon full exercise of the underwriters' option to purchase additional shares of common stock, at a price of $11.00 per share. The offering was made under Eiger's effective shelf registration statement and resulted in net proceeds to the Company of $53.2 million, after deducting underwriting discounts and commissions and offering expenses.

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, Eiger BioPharmaceuticals Europe Limited, and EigerBio Europe Limited have been prepared in accordance with accounting principles generally accepted in the United States of America, ("U.S. GAAP") and 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) income, 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 September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Options to purchase common stock	2,862,520	2,079,497	2,862,520	2,079,497
Warrants to purchase common stock	—	10,180	—	10,180
Total	2,862,520	2,089,677	2,862,520	2,089,677

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. Additionally, in May 2019, the FASB issued ASU No. 2019-05, *Financial Instruments – Credit Losses (Topic 326)*, which provides an option to irrevocably elect to measure certain individual financial assets at fair value instead of amortized cost. 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. In October 2019, the FASB proposed a deferral of the effective date for all entities, except public companies that are not smaller reporting companies, to fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. This proposal has not been finalized as of the date of this report. When finalized, the Company plans to adopt the standard on January 1, 2023. The Company does not plan to early adopt and 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 September 30, 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 reflect current market conditions for an instrument with similar terms and maturity, therefore the carrying value of the Company's debt approximated its fair value.

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 September 30, 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):

	September 30, 2019			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Money market funds	$ 15,475	$ —	$ —	$ 15,475
Corporate debt securities	—	17,639	—	17,639
Commercial paper	—	17,415	—	17,415
U.S. treasury bills	—	10,985	—	10,985
U.S. government bonds	—	44,506	—	44,506
Total	$ 15,475	$ 90,545	$ —	$ 106,020

	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 September 30, 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):

	September 30, 2019			
	Amortized cost	Unrealized gain	Unrealized loss	Estimated Fair Value
Cash equivalents:				
Money market funds	$ 15,475	$ —	$ —	$ 15,475
Total cash equivalents	$ 15,475	$ —	$ —	$ 15,475
Debt securities:				
Corporate debt securities	$ 17,628	$ 12	$ (1)	$ 17,639
Commercial paper	17,415	—	—	17,415
U.S. treasury bills	10,982	3	—	10,985
U.S. government bonds	44,477	29	—	44,506
Total debt securities	$ 90,502	$ 44	$ (1)	$ 90,545

	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 and September 30, 2019, 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 nine months ended September 30, 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):

	September 30, 2019	December 31, 2018
Contract research costs	$ 3,992	$ 2,191
Contract manufacturing costs	1,532	—
Compensation and related benefits	1,407	1,705
Consulting costs	184	258
Franchise tax	70	40
Other	37	—
Total accrued liabilities	$ 7,222	$ 4,194

5. License and Product Development Agreements

Product Development Agreement

On August 11, 2018, the Company entered into a Product Development Agreement and a First Project Agreement (the "Product Agreements") with RRD International, LLC, pursuant to which the Company will receive development program support services for its 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 and nine months ended September 30, 2019, the Company recognized research and development expense of $0.1 million and $0.2 million, respectively, related to the shares issued under the Product Agreements.

License Agreement with the Trustees of the University of Pennsylvania and the Children's Hospital of Pennsylvania

In May 2019, the Company entered into a license agreement (the "UPenn/CHOP Agreement") with the Trustees of the University of Pennsylvania ("UPenn") and the Children's Hospital of Pennsylvania ("CHOP"), under which the Company obtained an exclusive, royalty-bearing, worldwide license to develop, manufacture and sell certain Glucagon Like Peptide-1 ("GLP-1") receptor antagonist(s) products to treat all human and animal conditions. The Company also obtained an exclusive, royalty-bearing, sublicenseable, worldwide license to certain data developed by CHOP. The Company is responsible for the development and commercialization of the licensed products at its sole cost and expense.

As part of the consideration for the rights granted to the Company under the UPenn/CHOP Agreement, the Company paid UPenn a one-time, non-refundable issue fee of $1.0 million, which is recorded in research and development expenses for the nine months ended September 30, 2019. In addition, the Company is obligated to pay UPenn a specified annual license maintenance fee up to $2.5 million in certain regulatory milestones, and up to $18.0 million in commercial milestones. The Company will also be required to pay UPenn a flat royalty in the low-single digits on net sales of all licensed products by the Company, subject to specified reductions and offsets, and specified minimum annual royalty payments. The Company's obligation to pay royalties expires on a product-by-product and country-by-country basis, on the later of: (i) the expiration of the last valid claim in the licensed patents in any country, or (ii) the tenth anniversary of the first commercial sale of the product in such country. No milestones have been achieved as of September 30, 2019.

The Company may terminate the UPenn/CHOP Agreement in its entirety for any reason by providing prior written notice to UPenn and CHOP. UPenn or CHOP may terminate the UPenn/CHOP Agreement, upon a written notice, for the Company's failure to achieve the specified diligence milestones within the specified periods, subject to the Company's extension rights.

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 extended 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 September 30, 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. Long-term debt and unamortized discount balances are as follows (in thousands):

	September 30, 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	(3,075)	(1,340)
Long-term debt, net	$ 30,202	$ 25,620

7. Stock-Based Compensation

The following table summarizes stock option activity under the Company's stock-based compensation plan during the nine months ended September 30, 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	(1,079,750)	1,079,750	$ 12.93		
Exercised	—	(91,725)	$ 6.33		
Canceled and forfeited	121,716	(121,716)	$ 20.46		
Outstanding as of September 30, 2019	757,891	2,862,520	$ 12.03	7.94	$ 2,044
Vested and exercisable as of September 30, 2019		1,337,773	$ 11.86	6.86	$ 1,645

During the three and nine months ended September 30, 2019, the Company granted stock options for 217,000 and 1,079,750 shares, respectively. The weighted-average grant date fair value of these options was $7.18 and $9.01 for the three and nine months ended September 30, 2019, respectively. During the nine months ended September 30, 2018, the Company granted its employees stock options for 799,500 shares at a weighted-average grant date fair value of $7.50. There were no options granted during the three months ended September 30, 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 September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Expected term (in years)	6.02-6.08	—	5.27-6.08	5.27-6.08
Contractual term (in years)	—	—	10.00	10.00
Volatility	74.19%-75.70%	—	74.19%-83.19%	84.00%-84.50%
Risk free interest rate	1.42%-1.90%	—	1.42%-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 September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Research and development	$ 559	$ 344	$ 1,366	$ 1,138
General and administrative	1,090	828	2,965	2,358
Total	$ 1,649	$ 1,172	$ 4,331	$ 3,496

As of September 30, 2019, the total unrecognized compensation expense related to unvested options was $12.5 million, which the Company expects to recognize over an estimated weighted average period of 2.8 years.

8. Income Taxes

The Company did not record tax expense for the three and nine months ended September 30, 2019 and 2018 due to the Company's loss position and full valuation allowance.

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 throughout 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 September 30, 2019 and future minimum lease payments as of December 31, 2018 were as follows (in thousands):

Undiscounted lease payments	September 30, 2019	December 31, 2018
2019	$ 151	$ 593
2020	616	610
2021	633	629
2022	647	647
2023	109	109
Total undiscounted payments	2,156	$ 2,588
Less: imputed interest	301	
Present value of future lease payments	1,855	
Less: current portion of operating lease liabilities	466	
Operating lease liabilities	$ 1,389	

Rent expense recognized for the Company's operating leases was $0.1 million and $0.4 million for the three months ended September 30, 2019 and 2018, respectively, and $0.4 million and $0.6 million for the nine months ended September 30, 2019 and 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 $21,400 and $0.1 million for the three and nine months ended September 30, 2019, respectively.

The operating cash outflows for the operating lease liabilities were $0.5 million for the nine months ended September 30, 2019. As of September 30, 2019, the weighted-average remaining lease term and weighted-average discount rate were 3.4 years and 9.15%, respectively.

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 things, 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 serious, rare and ultra-rare diseases with high unmet medical needs and no approved therapies. We have reported positive proof-of-concept clinical results across all of our four programs, with first-in-class drugs that are advancing towards submissions for regulatory approvals, in Phase 3 clinical development, or advancing towards Phase 3 clinical development. Each one of our four programs have Breakthrough Therapy Designation.

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.

Our lead program is in Phase 3, developing lonafarnib, a first-in-class prenylation inhibitor, boosted with ritonavir, for the treatment of Hepatitis Delta Virus ("HDV") infection, the most severe form of human viral hepatitis, for which there is currently no approved therapy. The pivotal Phase 3 D-LIVR study (n=400, anticipated enrollment) is ongoing and enrolling patients. The study spans twenty countries and over one hundred sites, and has potential to generate data for two lonafarnib-based ritonavir-boosted regimens for approval. An all-oral arm of lonafarnib boosted with ritonavir and a combination arm of lonafarnib boosted with ritonavir combined with pegylated interferon-alfa-2a will each be compared to placebo. We are also developing lonafarnib monotherapy for treatment of Progeria and Progeroid Laminopathies. We plan to submit a New Drug Application ("NDA") by year-end 2019, followed by a Marketing Authorization Application ("MAA") in the first quarter 2020. Progeria, also known as Hutchinson-Gilford Progeria Syndrome ("HGPS"), and Progeroid Laminopathies, are ultra-rare and rapidly fatal genetic conditions of accelerated aging in children.

Peginterferon lambda ("lambda") is our second program treating HDV. Lambda is a well-characterized, late-stage, first in class, type III interferon. We previously reported Phase 2 LIMT (lambda mono therapy) study results (n=33) that demonstrated a 36% durable virologic response at 24 weeks post-treatment. We are planning for an End of Phase 2 meeting with the U.S. Food and Drug Administration ("FDA") for Lambda in HDV based on the LIMT data in the first quarter of 2020. In addition, Phase 2 LIFT (n=26) interim end of treatment ("Week 24") study results in HDV will be presented as a late-breaker oral presentation for the Liver Meeting, organized by the American Association for the Study of Liver Disease ("AASLD") in Boston on November 12, 2019. In the LIFT study, HDV patients were treated with a combination of our two proprietary products, Lambda and lonafarnib boosted by ritonavir. The results indicate that >50% of patients were HDV RNA undetectable or below limit of quantitation ("BLOQ") at Week 24 and 95% of patients achieved the primary end point of >2 log decline in HDV RNA at Week 24. Adverse events were mostly mild to moderate.

We are developing avexitide, a well-characterized peptide, as a treatment for post-bariatric hypoglycemia ("PBH"). PBH is a debilitating and potentially life-threatening condition for which there is currently no approved therapy. We have completed four clinical studies demonstrating proof of concept in 54 patients suffering from severe, refractory PBH, and expects to have FDA guidance on a potential Phase 3 trial by year-end 2019.

Avexitide has also demonstrated proof of concept for treatment of Congenital Hyperinsulinism ("CHI"), an ultra-rare pediatric metabolic genetic disorder.

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 $53.3 million and $35.9 million for the nine months ended September 30, 2019 and 2018, respectively. As of September 30, 2019, we had an accumulated deficit of $224.5 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, and potentially commercialize our product candidates and add personnel necessary to operate as a public company with an advanced clinical candidate pipeline of products. In addition, we will incur costs for additional personnel and upgrades to our information technology systems as we transition from an emerging growth 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

Lonafarnib for Treatment of Progeria

Successful Pre-NDA and Pre-MAA Meetings with FDA and the European Medicines Agency ("EMA"), respectively, for Lonafarnib for Treatment of Progeria and Progeroid Laminopathies

On October 8, 2019, we concluded a pre-NDA meeting with the FDA , and on July 19, 2019, we concluded an MAA pre-submission meeting with the EMA. The objectives of the meetings were to discuss the proposed regulatory submissions for lonafarnib for treatment of Progeria and Progeroid Laminopathies and to confirm clinical, non-clinical, and chemistry, manufacturing, and controls ("CMC") requirements for the submissions. We submitted briefing documents with a summary of the data package being prepared for submission, including clinical safety and efficacy, non-clinical results, and other regulatory requirements. Based on feedback from both FDA and EMA, we believe our regulatory data package will be sufficient for NDA and MAA submissions, with acceptance of the final submission subject to each agency's review of the complete package. We plan to submit the NDA by year-end 2019, followed by the MAA in first quarter 2020.

Peginterferon Lambda ("lambda") for Treatment HDV Infection

Lambda Granted Breakthrough Therapy Designation by the FDA

On August 20, 2019, we announced that the FDA granted Breakthrough Therapy Designation for lambda for treatment of HDV infection. FDA Breakthrough Therapy Designation is designed to expedite the development and review of medicines intended to treat serious or life-threatening diseases. Our application was supported by data from the Phase 2 LIMT lambda monotherapy study in 33 HDV-infected patients. Lambda is a first-in-class type III interferon for the treatment of HDV, the most severe form of human viral hepatitis for which there is no approved therapy.

Avexitide for Treatment of PBH

Completed Successful End of Phase 2 Meeting with the FDA for Avexitide for Treatment of PBH

On August 1, 2019 we conducted a successful End of Phase 2 meeting with the FDA, which included a discussion of the Phase 2 PREVENT study results. We expect to have guidance from the FDA on a potential Phase 3 by year-end for avexitide in PBH.

Rare Pediatric Disease Designation Granted for Avexitide for Treatment of CHI

On August 29, 2019, the FDA granted Rare Pediatric Disease Designation for avexitide for the treatment of CHI. The designation is designed to accelerate the development of therapies that can improve the management of serious or life-threatening conditions affecting fewer than 200,000 people in the United States and that mainly manifest in children.

Avexitide for Treatment of CHI

Avexitide for Treatment of CHI Granted Orphan Drug Designation by EMA

On October 10, 2019, the EMA granted Orphan Drug Designation to avexitide for treatment of CHI. Orphan designation in the European Union ("EU") is designed for medicines for treatment of serious or life-threatening diseases affecting fewer than five in 10,000 people across the EU. We will be able to benefit from key incentives, including reduced regulatory fees, protocol assistance, and market exclusivity to develop a medicine for the treatment of a rare disease affecting fewer than five in 10,000 people across the EU. Avexitide for treatment of CHI now has Orphan Disease designation in both the United States and the EU.

Investigational New Drug ("IND") Application for Avexitide for Treatment of CHI Accepted by FDA; Secured Freedom to Operate with Avexitide for Treatment of Hyperinsulinemic Disorders, including PBH and CHI

On October 15, 2019, the FDA accepted our IND application for avexitide for treatment of CHI. Acceptance of the IND for avexitide in the treatment of congenital hyperinsulinism will facilitate discussions with the FDA regarding potential avexitide development and registration pathways for CHI.

Previously, we acquired exclusive license to patent rights from the Trustees of the University of Pennsylvania ("UPenn") and Children's Hospital of Philadelphia ("CHOP") for avexitide and other glucagon-like-peptide-1 ("GLP-1") antagonists in multiple hyperinsulinemic disorders, including PBH and CHI. Under the terms of the agreement, we have global rights to intellectual property and to develop, manufacture, and commercialize avexitide.

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 clinical trials, including contract manufacturing arrangements, clinical trial material related costs and other research and development activities. However, we do not allocate internal research and development costs, such as salaries, benefits, stock-based compensation expense and indirect costs to product candidates on a program-specific basis. The following table shows our research and development expenses for the three and nine months ended September 30, 2019 and 2018 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Product candidates:				
Lonafarnib	$ 9,654	$ 8,232	$ 29,621	$ 12,082
Avexitide	1,349	939	2,714	2,282
Lambda	895	666	1,437	1,755
Ubenimex	—	1,788	—	4,009
Internal research and development costs	2,161	1,571	6,091	4,952
Total research and development expense	$ 14,059	$ 13,196	$ 39,863	$ 25,080

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 fees and/or milestone payments.

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

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, 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.

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 "Recently Adopted 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 September 30, 2019 and 2018

	Three Months Ended September 30,		$	%
	2019	2018	Change	Change
Operating expenses:				
Research and development	$ 14,059	$ 13,196	$ 863	7%
General and administrative	4,247	3,643	604	17%
Total operating expenses	18,306	16,839	1,467	9%
Loss from operations	(18,306)	(16,839)	(1,467)	
Interest expense	(884)	(681)	(203)	30%
Interest income	585	371	214	58%
Other (expense) income, net	(11)	5	(16)	*
Net loss	$ (18,616)	$ (17,144)	$ (1,472)	9%

* Percentage not meaningful.

Research and development expenses

Research and development expenses increased by $0.9 million to $14.1 million for the three months ended September 30, 2019, from $13.2 million for the same period in 2018. The increase was primarily due to a $0.7 million increase in compensation and personnel related expenses, including stock-based compensation expense due to an increase in headcount to support clinical programs, and a $0.2 million increase in consulting fees and clinical trial related expenditures as we advance clinical programs.

General and administrative expenses

General and administrative expenses increased by $0.6 million to $4.2 million for the three months ended September 30, 2019, from $3.6 million for the same period in 2018. The increase was primarily due to a $0.6 million increase in compensation and personnel related expenses, including stock-based compensation expense due to an increase in headcount, and a $0.1 million increase in outside professional services, including higher facilities and corporate expenses to support our growth, which was partially offset by a $0.1 million decrease in legal, accounting and advisory services.

Interest expense

Interest expense increased by $0.2 million to $0.9 million for the three months ended September 30, 2019 from $0.7 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 $0.2 million to $0.6 million for the three months ended September 30, 2019 from $0.4 million for the same period in 2018. The increase was primarily due to a higher invested cash balance.

Comparison of the Nine Months Ended September 30, 2019 and 2018

	Nine Months Ended September 30,		$ Change	% Change
	2019	2018		
Operating expenses:				
Research and development	$ 39,863	$ 25,080	$ 14,783	59%
General and administrative	12,529	9,874	2,655	27%
Total operating expenses	52,392	34,954	17,438	50%
Loss from operations	(52,392)	(34,954)	(17,438)	
Interest expense	(2,518)	(1,574)	(944)	60%
Interest income	1,598	654	944	144%
Other expense, net	(20)	(16)	(4)	*
Net loss	$ (53,332)	$ (35,890)	$ (17,442)	49%

* Percentage not meaningful.

Research and development expenses

Research and development expenses increased by $14.8 million to $39.9 million for the nine months ended September 30, 2019, from $25.1 million for the same period in 2018. The increase was primarily due to a $12.7 million increase in consulting fees and clinical trial related expenditures due to increased program activity, a $1.1 million increase in compensation and personnel related expenses, including stock-based compensation due to an increase in headcount to support clinical programs, and a $1.0 million increase in licenses and other fees.

General and administrative expenses

General and administrative expenses increased by $2.6 million to $12.5 million for the nine months ended September 30, 2019, from $9.9 million for the same period in 2018. The increase was primarily due to a $1.6 million increase in compensation and personnel related expenses, including stock-based compensation expense due to an increase in headcount, and a $1.0 million increase in outside professional services, including higher facilities and corporate expenses.

Interest expense

Interest expense increased by $0.9 million to $2.5 million for the nine months ended September 30, 2019 from $1.6 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 $1.0 million to $1.6 million for the nine months ended September 30, 2019 from $0.6 million for the same period in 2018. The increase was primarily due to a higher invested cash balance.

Liquidity and Capital Resources

Sources of Liquidity

As of September 30, 2019, we had $109.9 million of cash, cash equivalents and investments, comprised of $19.4 million of cash and cash equivalents and $90.5 million of debt securities available-for-sale, and an accumulated deficit of $224.5 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.

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):

	Nine Months Ended September 30,	
	2019	2018
Net cash used in operating activities	$ (48,643)	$ (30,169)
Net cash used in investing activities	(51,090)	(38,155)
Net cash provided by financing activities	57,877	53,216
Net decrease in cash and cash equivalents	$ (41,856)	$ (15,108)

Cash flows from operating activities

Cash used in operating activities for the nine months ended September 30, 2019 was $48.6 million, which primarily consisted of a net loss of $53.3 million and amortization of the debt securities discount of $0.4 million, partially offset by stock-based compensation expense of $4.3 million, non-cash interest expense of $0.5 million, and amortization of operating lease right-of-use assets of $0.3 million. Additionally, cash used in operating activities reflected changes in net operating assets of $0.3 million due to an increase of $3.0 million in prepaid expenses and other current assets primarily due to the timing of payments, an increase of $2.9 million in other assets primarily related to long term deposits with clinical research organizations, and a decrease of $0.3 million in operating lease liabilities, which was partially offset by an increase of $5.9 million in accounts payable and accrued liabilities due to the timing of payments.

Cash used in operating activities for the nine months ended September 30, 2018 was $30.2 million, consisting of a net loss of $35.9 million and amortization of the debt securities discount of $0.3 million, which was partially offset by stock-based compensation expense of $3.5 million, expense related to the vesting of common stock issued under the Product Development Agreement of $0.4 million, and non-cash interest expense of $0.4 million. Additionally, cash used in operating activities reflected changes in net operating assets primarily due to a $3.5 million increase in accounts payable and other long-term liabilities, which was partially offset by a $1.2 million increase in prepaid expenses and other current assets, and a $0.6 million decrease in accrued and other liabilities.

Cash flows from investing activities

Cash used in investing activities was $51.1 million for the nine months ended September 30, 2019, consisting of $96.3 million of purchases of debt securities and $0.1 million of purchases of property and equipment, partially offset by $45.3 million of proceeds from maturities of debt securities.

Cash used in investing activities was $38.2 million for the nine months ended September 30, 2018, consisting of $52.3 million of purchases of debt securities and $0.1 million of purchases of property and equipment, partially offset by $14.2 million of proceeds from maturities of debt securities.

Cash flows from financing activities

Cash provided by financing activities for the nine months ended September 30, 2019 consisted of $53.2 million of net proceeds from the issuance of common stock upon public offering in April 2019, $6.6 million of net proceeds from additional borrowings in connection with the restructuring of the Oxford Loan and $0.6 million of proceeds from the issuance of common stock upon stock option exercises and ESPP purchase, partially offset by $2.6 million in payments of principal and fees associated with the Oxford Loan.

Cash provided by financing activities for the nine months ended September 30, 2018 consisted of $42.9 million of net proceeds from the issuance of common stock upon public offering, $9.9 million of net proceeds from borrowings in connection with the Oxford Loan, and $0.4 million of proceeds from the issuance of common stock upon stock option exercises and ESPP purchase.

Contractual Obligations and Other Commitments

Our contractual obligations as of September 30, 2019 have not changed from what we presented in our Annual Report on Form 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 September 30, 2019, we had market risk exposure related to our cash and cash equivalents. We had cash and cash equivalents of $19.4 million and $90.5 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 and nine months ended September 30, 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 September 30, 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. The following description of the risk factors associated with our business includes any material changes to and supersedes the description of the risk factors associated with our business previously disclosed in Part I, Item 1A of the Annual Report 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 nine months ended September 30, 2019 and 2018, we reported a net loss of $53.3 million and $35.9 million, respectively. As of September 30, 2019, we had an accumulated deficit of $224.5 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 and MAA 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 may need significant additional resources in order to aggressively move lonafarnib forward successfully based on the discussions with the FDA. 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 lonafarnib available to Hutchinson-Gilford progeria syndrome (HGPS or Progeria) 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 and 2020;
- 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 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 and CHI;
- 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;
- develop and educate HDV markets;
- seek to maintain, protect, and expand our intellectual property portfolio;
- seek to attract and retain skilled personnel;
- create additional infrastructure to support our operations as a public company and our product development and planned future commercialization efforts; and
- experience any delays or encounter issues with the development and potential for regulatory approval of our clinical candidates such as safety issues, clinical trial accrual delays, longer follow-up for planned studies, additional major studies, or supportive studies necessary to support marketing approval.

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

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 significant 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 and maintaining any collaboration, licensing, or other arrangements into which we may enter;
- obtaining reimbursement or pricing for our product candidates that supports profitability; and
- attracting, hiring, and retaining qualified personnel.

Even if 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 was 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, of which $30.0 million in principal is outstanding. 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 in December 2019 for lonafarnib in Progeria and Progeroid Laminopathies, followed by an MAA submission in the first quarter of 2020. 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 development and two development programs focused on two separate indications that have we believe have completed Phase 2 and are advancing towards Phase 3. It may be years before our studies are initiated and completed, if at all.

Our lonafarnib and avexitide compounds have received Rare Pediatric Disease, or RPD, designation from the FDA for the treatment of Progeria and Progeroid Laminopathies and Congenital Hyperinsulinism ("CHI"), respectively. The FDA defines a "rare pediatric disease" as a disease that affects fewer than 200,000 individuals in the United States primarily under the age of 18 years. 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 guarantee 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 and maintaining 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 and maintain orphan drug designation from regulatory authorities in major markets. Without the potential protection of this regulatory exclusivity upon approval, many of our product candidates would otherwise not justify investment. While we assess the potential for obtaining orphan drug designation at the time that we contemplate the acquisition of product candidates and we intend to timely file for such designation, there can be no assurance that we will obtain orphan drug designation or be able to successfully meet the regulatory requirements to maintain that designation with the planned clinical trials for our product candidates. Failure to obtain and maintain orphan drug designation would make our product candidates significantly less competitive and potentially not viable investments for further development. Although we currently have orphan drug designation for some of our product candidates in multiple targeted indications, failure to demonstrate significant benefit over existing approved 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 for other uses of lonafarnib in other indications, or in 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. Our avexitide product candidate for treatment of PBH has been studied in 54 patients and the most common adverse events are injection site bruising, nausea, and headache. There is no guarantee that additional or more severe side effects will not be identified through ongoing clinical studies for other uses of avexitide in clinical trials.

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 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 trials and Progeria clinical studies are sourced from Eiger-controlled Contract Manufacturing Organizations, or CMOs. These same vendors are currently under development for commercial qualification. Materials used for our avexitide clinical trials are also sourced from CMOs. Our vendors have successfully made GMP batches for our clinical studies.

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 or comparable foreign regulatory authorities. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements, known as cGMPs, for manufacture of our product candidates. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA 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 of any of our product candidates by the FDA or comparable foreign regulatory authorities or the commercialization of our product candidates or result in higher costs or deprive us of potential product revenue. In addition, we rely on third parties to perform release testing on our product candidates prior to delivery to patients. If these tests are not conducted appropriately and test data is not reliable, patients could be put at risk of serious harm and could result in product liability suits.

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

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

We focus our product development principally on treatments for rare and ultra-rare diseases. Given the small number of patients who have the diseases that we are targeting, our eligible patient population and pricing estimates may differ significantly from the actual market addressable by our product candidate. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including the scientific literature, patient foundations, or market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. The number of patients may turn out to be lower than expected. For example, 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 sales 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, Xeris Pharmaceuticals, and Rezolute, Inc. 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, we have established an expanded access program in order to make lonafarnib available for patients with Progeria and Progeroid Laminopathies, which requires additional resources and costs to support.

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

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

- the 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, lonafarnib for patients with Progeria and Progeroid Laminopathies provided under an expanded access program may not result in reimbursement.

In addition, there is significant uncertainty related to the insurance coverage and reimbursement for newly approved products. In the United States, the principal decisions about coverage and reimbursement for new drugs are typically made by the Centers for Medicare & Medicaid Services, 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 lonafarnib. 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 the lonafarnib composition of matter 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. 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. 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 September 30, 2019, we had 24 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 the federal Health Insurance Portability and Accountability Act of 1996 ("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 EU General Data Protection Regulation, or 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.

In addition, in June 2018, California enacted the California Consumer Privacy Act, or CCPA, which takes effect on January 1, 2020. The CCPA gives California residents expanded rights to access and require deletion of their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that may increase data breach litigation. Although the CCPA includes exemptions for certain clinical trials data, and HIPAA protected health information, the law may increase our compliance costs and potential liability with respect to other personal information we collect about California residents. The CCPA has prompted a number of proposals for new federal and state privacy legislation that, if passed, could increase our potential liability, increase our compliance costs and adversely affect our business.

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. 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. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the ACA such as removing penalties, starting January 1, 2019, for not complying with the ACA's individual mandate to carry health insurance and delaying the implementation of certain ACA-mandated fees. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act of 2017. While the Texas U.S. District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA and our business. In addition, 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". Also, there has been heightened governmental scrutiny recently over pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products For example, the Trump administration released a "Blueprint" to lower drug prices and reduce out-of-pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out-of-pocket costs of drug products paid by consumers. 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;
- 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;
- 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; and
- 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 United States.

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, Australia, Turkey, Germany, Pakistan, New Zealand, Mongolia, Spain, France, Bulgaria, Romania, Taiwan, Sweden, Italy, Belgium, Switzerland, United Kingdom, Greece, Moldova, and Israel, and accordingly, we are subject to risks associated with doing business globally, including commercial, political, and financial risks. Emerging regions, such as Eastern Europe, Latin America, Asia, and Africa, as well as more developed markets, such as the United Kingdom, France, Germany, and Australia, provide clinical study opportunities for us. In addition, we are subject to potential disruption caused by military conflicts; potentially unstable governments or legal systems; civil or political upheaval or unrest; local labor policies and conditions; possible expropriation, nationalization, or confiscation of assets; problems with repatriation of foreign earnings; economic or trade sanctions; closure of markets to imports; anti-American sentiment; terrorism or other types of violence in or outside the United States; health pandemics; and a significant reduction in global travel. 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. 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 Delaware General Corporation Law, which prohibits stockholders owning in excess of 15% of our voting stock from merging or combining with us. Although we believe these provisions collectively will provide for an opportunity to receive higher bids by requiring potential acquirers to negotiate with our board of directors, they would apply even if the offer may be considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove then current management by making it more difficult for stockholders to replace members of the board of directors, which is responsible for appointing the members of management.

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

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

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

If existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after legal restrictions on resale lapse, the trading price of our common stock could decline. Certain of our existing stockholders, including Adage Capital Management, L.P. and Vivo Capital, LLC, 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 for Celladon and, accordingly, Celladon's NOL carryforwards and certain other tax attributes will be subject to further limitations on their use. In addition, we assessed whether Eiger had an ownership change, as defined by Section 382 of the Code, as a result of the Merger and other stock issuances that occurred from our formation through December 31, 2018. Based upon this assessment, we concluded that Eiger also experienced such an ownership change in October 2018 and therefore a Section 382 limitation also applies to Eiger's federal and state NOL carryforwards and federal and state tax credit carryforwards arising prior to such ownership change 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

On November 1, 2019, following approval by the board of directors, each of our executive officers, including our named executive officers, entered into an amended and restated offer letter that amends, restate, and supersedes each of their existing offer letters. Such amended and restated offer letters include base salary and annual bonus terms as set forth in the table below.

Name	Title	Base Salary	Annual Bonus (1)
David A. Cory	President and Chief Executive Officer	$ 570,000	50 %
Sriram Ryali	Chief Financial Officer	335,000 (2)	35% (2)
Stephana E. Patton	General Counsel, Corporate Secretary and Chief Compliance Officer	335,000 (2)	35% (2)
James P. Shaffer	Chief Business Officer	378,776	35% (2)

(1) Represents the percentage of such executive's base salary that such executive is eligible to earn as a discretionary performance bonus on an annual basis.

(2) Figure remains unchanged from existing offer letter.

Each such amended and restated offer letter provides that, upon termination without cause or resignation for good reason, such impacted executive will be entitled to receive the following severance benefits, less applicable tax withholdings and deductions:

(i) payment in an amount equal to 12 months base salary (or, in the case of Mr. Cory, 18 months base salary) and pro rata target bonus;
(ii) COBRA coverage for a period of 12 months (or, in the case of Mr. Cory, 18 months); and
(iii) 50% acceleration of the vesting of the executive's unvested equity awards held as of the date of termination, the deemed target achievement of any outstanding equity that is subject to performance-based vesting conditions, and continued exercisability of the executive's equity awards for 12 months from the date of termination.

In addition, each such amended and restated offer letter provides that, in the event of a change in control, in each case within 90 days before the closing of such change in control and ending on the date one year after the effective date of such change in control, if such executive is terminated without cause, other than as a result of death or disability, or resigns for good reason, such impacted executive will be entitled to receive the following benefits, less applicable tax withholdings and deductions:

(i) 100% acceleration of the vesting of the executive's unvested equity awards held as of the date of determination, the deemed target achievement of any outstanding equity that is subject to performance-based vesting conditions, and continued exercisability of the executive's equity awards for 12 months from the date of termination;
(ii) payment in an amount equal to 18 months base salary (or, in the case of Mr. Cory, 24 months) and pro rata target bonus; and
(iii) COBRA coverage for a period of 18 months (or, in the case of Mr. Cory, 24 months).

To receive the benefits described upon a qualifying termination, either in connection with or not in connection with a change of control, such impacted executive must deliver to us a general release of claims within 60 days of the date of termination.

The foregoing is a brief description of the material terms of the amended and restated offer letters that differ from such executives' existing offer letters and does not purport to be complete and is qualified in its entirety by reference to the full text of each amended and restated offer letter described herein. Copies of such amended and restated offer letters by and between us and each of Mr. Cory, Mr. Ryali, Dr. Patton and Mr. Shaffer, are filed herewith as exhibits 10.1, 10.2, 10.3, and 10.4, respectively, and are incorporated herein by reference.

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. On September 20, 2019 we assessed whether Eiger had an ownership change, as defined by Section 382 of the Code, from our formation through December 31, 2018. Based upon this assessment the Company determined that an ownership change occurred on October 18, 2018, the Company determined that approximately $14.4 million of the tax credit carryforwards will expire unused. Due to the full valuation allowance on the deferred tax assets there was no impact to the effective tax rate for 2019. 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 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	Amended and Restated Offer Letter Agreement, dated as of November 1, 2019, by and between Eiger Biopharmaceuticals, Inc. and David A. Cory.
10.2	Amended and Restated Offer Letter Agreement, dated as of November 1, 2019, by and between Eiger Biopharmaceuticals, Inc. and Sriram Ryali.
10.3	Amended and Restated Offer Letter Agreement, dated as of November 1, 2019, by and between Eiger Biopharmaceuticals, Inc. and Stephana E. Patton.
10.4	Amended and Restated Offer Letter Agreement, dated as of November 1, 2019, by and between Eiger Biopharmaceuticals, Inc. and James Shaffer.
10.5*	License Agreement, dated as of May 10, 2019, by and among the Trustees of the University of Pennsylvania and The Children's Hospital of Philadelphia and Eiger Biopharmaceuticals, Inc.
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

+ 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.

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

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: November 7, 2019

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

Eiger BioPharmaceuticals, Inc.

Date: November 7, 2019

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

Exhibit 10.1

1 November 2019

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

David Cory, R.Ph.

Re: Amended and Restated Employment Terms

Dear Mr. Cory,

Eiger BioPharmaceuticals, Inc. ("Eiger" or the "Company") is pleased to continue your employment on the following terms of this Amended and Restated Offer Letter Agreement ("Agreement"). In this Agreement, you and the Company hereby amend, supersede, and restate in its entirety that certain offer letter agreement between the Company and you dated 5 December 2008 (the "Employment Agreement").

Duties, Compensation and Benefits

You will continue to serve as the President and Chief Executive Officer, reporting to the Board of Directors. You will work at our facility located at 2155 Park Boulevard in Palo Alto, California.

Your salary will be $570,000 per year, less payroll deductions and withholdings. You will be paid semi-monthly, or in accordance with Company's compensation practices for other employees in place at the time.

In addition, you will be eligible for an annual bonus, targeted at 50% of your base salary, subject to applicable payroll deductions and withholdings ("Bonus"). Whether you receive this Bonus, and the amount of any such Bonus, will be determined by the Company in its sole discretion based upon your performance, the Company's performance and such other criteria that the Company deems relevant. Any Bonus shall be paid within thirty (30) days after the Company's determination that a Bonus shall be awarded. You will be eligible to earn a Bonus for any full calendar year provided that you remain employed by the Company as of December 31 of that year.

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

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

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2155 Park Boulevard
Palo Alto, CA 94306

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

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

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

At Will Employment

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

Payments upon Termination other than without Cause or with Good Reason

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

Termination without Cause or with Good Reason

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

(i) an amount equal to CEO: eighteen (18) months of your then current base salary and pro-rata target bonus, less all applicable withholdings and deductions, paid over such CEO: eighteen (18) 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 CEO: eighteen (18) 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; and

(iii) acceleration of the vesting of the Outstanding Equity as of the date of termination as to 50% of the then-unvested Outstanding Equity, any Outstanding Equity that is subject to performance-based vesting conditions will be deemed to have been achieved at target, and you shall have 12 months from the date of termination in which to exercise your shares subject to any option.

Change in Control

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

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

(ii) an amount equal to CEO: twenty-four (24) months of your then current base salary and pro-rata target bonus, less all applicable withholdings and deductions, paid in lump sum on the date your employment terminates;

(iii) 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 CEO: twenty-four (24) month period following the termination of your employment, (B) the expiration of your eligibility for the continuation coverage under COBRA, or (C) the date when you become eligible for substantially equivalent health insurance coverage in connection with new employment or self-employment. If you become eligible for coverage under another employer's group health plan or otherwise cease to be eligible for COBRA during the period provided in this clause, you must immediately notify the Company of such event, and all payments and obligations under this clause shall cease.

Your receipt of any of the severance benefits set forth above is conditional upon your continuing to comply with your legal and contractual obligations to the Company and your delivering to the Company an effective, general release of claims in favor of the Company in a form acceptable to the Company within 60 days following your termination date. The Salary Continuation will be paid in equal installments on the Company's regular payroll schedule and will be subject to applicable tax withholdings over the period outlined above following the date of your termination date; provided, however, that no payments will be made prior to the 60th day following your Separation from Service. On the 60th day following your Separation from Service, the Company will pay you in a lump sum the Salary Continuation that you would have received on or prior to such date under the original schedule but for the delay while waiting for the 60th day in compliance with Code Section 409A and the effectiveness of the release, with the balance of the Salary Continuation being paid as originally scheduled.

Definitions

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

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

For purposes of this 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 Employee Confidential Information and Inventions Assignment Agreement or any other agreement entered into with the Company.

Section 280G of the Code

If any payment or benefit (including payments and benefits pursuant to this Agreement) that you would receive in connection with a Change in Control from the Company or otherwise ("Transaction Payment") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Internal Revenue Code (the "Code"), and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "Excise Tax"), then the Company shall cause to be determined, before any amounts of the Transaction Payment are paid to you, which of the following two alternative forms of payment would result in your receipt, on an after-tax basis, of the greater amount of the Transaction Payment notwithstanding that all or some portion of the Transaction Payment may be subject to the Excise Tax: (1) payment in full of the entire amount of the Transaction Payment (a "Full Payment"), or (2) payment of only a part of the Transaction Payment so that you receive the largest payment possible without the imposition of the Excise Tax (a "Reduced Payment"). For purposes of determining whether to make a Full Payment or a Reduced Payment, the Company shall cause to be taken into account all applicable federal, state and local income and employment taxes and the Excise Tax (all computed at the highest applicable marginal rate, net of the maximum reduction in federal income taxes which could be obtained from a deduction of such state and local taxes). If a Reduced Payment is made, (x) you shall have no rights to any additional payments and/or benefits constituting the Transaction Payment, and (y) reduction in payments and/or benefits shall occur in the manner that results in the greatest economic benefit to you as determined in this paragraph. If more than one method of reduction will result in the same economic benefit, the portions of the Transaction Payment shall be reduced pro rata. Unless you and the Company otherwise agree in writing, any determination required under this paragraph shall be made in writing by the Company's independent public accountants (the "Accountants"), whose determination shall be conclusive and binding upon you and the Company for all purposes. For purposes of making the calculations required by this paragraph, the Accountants may make reasonable assumptions and approximations concerning applicable taxes and may rely on reasonable, good faith interpretations concerning the application of Sections 280G and 4999 of the

Code. You and the Company shall furnish to the Accountants such information and documents as the Accountants may reasonably request in order to make a determination under this paragraph. The Company shall bear all costs the Accountants may reasonably incur in connection with any calculations contemplated by this paragraph as well as any costs incurred by you with the Accountants for tax planning under Sections 280G and 4999 of the Code.

Section 409A

It is intended that all of the severance benefits and other payments payable under this letter satisfy, to the greatest extent possible, the exemptions from the application of Code Section 409A provided under Treasury Regulations 1.409A 1(b)(4), 1.409A 1(b)(5) and 1.409A 1(b)(9), and this letter will be construed to the greatest extent possible as consistent with those provisions. For purposes of Code Section 409A (including, without limitation, for purposes of Treasury Regulation Section 1.409A 2(b)(2)(iii)), your right to receive any installment payments under this letter (whether severance payments, reimbursements or otherwise) shall be treated as a right to receive a series of separate payments and, accordingly, each installment payment hereunder shall at all times be considered a separate and distinct payment. Notwithstanding any provision to the contrary in this letter, if you are deemed by the Company at the time of your Separation from Service to be a "specified employee" for purposes of Code Section 409A(a)(2)(B)(i), and if any of the payments upon Separation from Service set forth herein and/or under any other agreement with the Company are deemed to be "deferred compensation", then to the extent delayed commencement of any portion of such payments is required in order to avoid a prohibited distribution under Code Section 409A(a)(2)(B)(i) and the related adverse taxation under Section 409A, such payments shall not be provided to you prior to the earliest of (i) the expiration of the six-month period measured from the date of your Separation from Service with the Company, (ii) the date of your death or (iii) such earlier date as permitted under Section 409A without the imposition of adverse taxation. Upon the first business day following the expiration of such applicable Code Section 409A(a)(2)(B)(i) period, all payments deferred pursuant to this paragraph shall be paid in a lump sum to you, and any remaining payments due shall be paid as otherwise provided herein or in the applicable agreement. No interest shall be due on any amounts so deferred.

Arbitration

You and the Company agree that any and all disputes, claims, or causes of action, in law or equity, including but not limited to statutory claims, arising from or relating to the enforcement, breach, performance, or interpretation of this Agreement, your employment with the Company, or the termination of your employment, shall be resolved, to the fullest extent permitted by law, by final, binding and confidential arbitration conducted by JAMS or its successor, under JAMS' then applicable rules and procedures for employment disputes before a single arbitrator (available upon request and also currently available at http://www.jamsadr.com/rules-employment-arbitration/). You acknowledge that by agreeing to this arbitration procedure, both you and the Company waive the right to resolve any such dispute through a trial by jury or judge or administrative proceeding. In addition, all claims, disputes, or causes of action under this section, whether by you or the Company, must be brought in an individual capacity, and shall not be brought as a plaintiff (or claimant) or class member in any purported class or representative proceeding, nor joined or consolidated with the claims of any other person or entity. The arbitrator may not consolidate the claims of more than one person or entity, and may not preside over any form of representative or class

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proceeding. To the extent that the preceding sentences regarding class claims or proceedings are found to violate applicable law or are otherwise found unenforceable, any claim(s) alleged or brought on behalf of a class shall proceed in a court of law rather than by arbitration. This paragraph shall not apply to any action or claim that cannot be subject to mandatory arbitration as a matter of law, including, without limitation, claims brought pursuant to the California Private Attorneys General Act of 2004, as amended. In the event you intend to bring multiple claims, including one of the Excluded Claims listed above, the Excluded Claims may be publicly filed with a court, while any other claims will remain subject to mandatory arbitration. You will have the right to be represented by legal counsel at any arbitration proceeding. The arbitrator shall: (a) have the authority to compel adequate discovery for the resolution of the dispute and to award such relief as would otherwise be permitted by law; and (b) issue a written statement signed by the arbitrator regarding the disposition of each claim and the relief, if any, awarded as to each claim, the reasons for the award, and the arbitrator's essential findings and conclusions on which the award is based. The arbitrator shall be authorized to award all relief that you or the Company would be entitled to seek in a court of law. The Company shall pay all JAMS arbitration fees in excess of the administrative fees that you would be required to pay if the dispute were decided in a court of law. Nothing in this letter agreement is intended to prevent either you or the Company from obtaining injunctive relief in court to prevent irreparable harm pending the conclusion of any such arbitration. Any awards or orders in such arbitrations may be entered and enforced as judgments in the federal and state courts of any competent jurisdiction.

Miscellaneous

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

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

Please sign and date this letter if you wish to accept these terms to govern your employment at Eiger. We look forward to your favorable reply and to a productive and enjoyable work relationship.

Sincerely,

Sri Ryali, Chief Financial Officer

Accepted:

/s/ David Cory	November 1, 2019
David Cory	Date

Exhibit 10.2

1 November 2019

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

Mr. Sriram Ryali

Re: Amended and Restated Employment Terms

Dear Mr. Ryali,

Eiger BioPharmaceuticals, Inc. ("Eiger" or the "Company") is pleased to continue your employment on the following terms of this Amended and Restated Offer Letter Agreement ("Agreement"). In this Agreement, you and the Company hereby amend, supersede, and restate in its entirety that certain offer letter agreement between the Company and you dated 30 November 2018 (the "Employment Agreement").

Duties, Compensation and Benefits

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

Your salary will be $335,000 per year, less payroll deductions and withholdings. You will be paid semi-monthly, or in accordance with Company's compensation practices for other employees in place at the time.

In addition, you will be eligible for an annual bonus, targeted at 35% of your base salary, subject to applicable payroll deductions and withholdings ("Bonus"). Whether you receive this Bonus, and the amount of any such Bonus, will be determined by the Company in its sole discretion based upon your performance, the Company's performance and such other criteria that the Company deems relevant. Any Bonus shall be paid within thirty (30) days after the Company's determination that a Bonus shall be awarded. You will be eligible to earn a Bonus for any full calendar year provided that you remain employed by the Company as of December 31 of that year.

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

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

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

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

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

At Will Employment

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

Payments upon Termination other than without Cause or with Good Reason

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

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Termination without Cause or with Good Reason

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

(i) an amount equal to twelve (12) months of your then current base salary and pro-rata target bonus, 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; and

(iii) acceleration of the vesting of the Outstanding Equity as of the date of termination as to 50% of the then-unvested Outstanding Equity, any Outstanding Equity that is subject to performance-based vesting conditions will be deemed to have been achieved at target, and you shall have 12 months from the date of termination in which to exercise your shares subject to any option.

Change in Control

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

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

(ii) an amount equal to eighteen (18) months of your then current base salary and pro-rata target bonus, less all applicable withholdings and deductions, paid in lump sum on the date your employment terminates;

(iii) 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 eighteen (18) month period following the termination of your employment, (B) the expiration of your eligibility for the continuation coverage under COBRA, or (C) the date when you become eligible for substantially equivalent health insurance coverage in connection with new employment or self-employment. If you become eligible for coverage under another employer's group health plan or otherwise cease to be eligible for COBRA during the period provided in this clause, you must immediately notify the Company of such event, and all payments and obligations under this clause shall cease.

Your receipt of any of the severance benefits set forth above is conditional upon your continuing to comply with your legal and contractual obligations to the Company and your delivering to the Company an effective, general release of claims in favor of the Company in a form acceptable to the Company within 60 days following your termination date. The Salary Continuation will be paid in equal installments on the Company's regular payroll schedule and will be subject to applicable tax withholdings over the period outlined above following the date of your termination date; provided, however, that no payments will be made prior to the 60th day following your Separation from Service. On the 60th day following your Separation from Service, the Company will pay you in a lump sum the Salary Continuation that you would have received on or prior to such date under the original schedule but for the delay while waiting for the 60th day in compliance with Code Section 409A and the effectiveness of the release, with the balance of the Salary Continuation being paid as originally scheduled.

Definitions

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

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

For purposes of this 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 Employee Confidential Information and Inventions Assignment Agreement or any other agreement entered into with the Company.

Section 280G of the Code

If any payment or benefit (including payments and benefits pursuant to this Agreement) that you would receive in connection with a Change in Control from the Company or otherwise ("Transaction Payment") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Internal Revenue Code (the "Code"), and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "Excise Tax"), then the Company shall cause to be determined, before any amounts of the Transaction Payment are paid to you, which of the following two alternative forms of payment would result in your receipt, on an after-tax basis, of the greater amount of the Transaction Payment notwithstanding that all or some portion of the Transaction Payment may be subject to the Excise Tax: (1) payment in full of the entire amount of the Transaction Payment (a "Full Payment"), or (2) payment of only a part of the Transaction Payment so that you receive the largest payment possible without the imposition of the Excise Tax (a "Reduced Payment"). For purposes of determining whether to make a Full Payment or a Reduced Payment, the Company shall cause to be taken into account all applicable federal, state and local income and employment taxes and the Excise Tax (all computed at the highest applicable marginal rate, net of the maximum reduction in federal income taxes which could be obtained from a deduction of such state and local taxes). If a Reduced Payment is made, (x) you shall have no rights to any additional payments and/or benefits constituting the Transaction Payment, and (y) reduction in payments and/or benefits shall occur in the manner that results in the greatest economic benefit to you as determined in this paragraph. If more than one method of reduction will result in the same economic benefit, the portions of the Transaction Payment shall be reduced pro rata. Unless you and the Company otherwise agree in writing, any determination required under this paragraph shall be made in writing by the Company's independent public accountants (the "Accountants"), whose determination shall be conclusive and binding upon you and the Company for all purposes. For purposes of making the calculations required by this paragraph, the Accountants may make reasonable assumptions and approximations concerning applicable taxes and may rely on reasonable, good faith interpretations concerning the application of Sections 280G and 4999 of the Code. You and the Company shall furnish to the Accountants such information and documents as the Accountants may reasonably request in order to make a determination under this paragraph. The Company shall bear all costs the Accountants may reasonably incur in connection with any calculations contemplated by this paragraph as well as any costs incurred by you with the Accountants for tax planning under Sections 280G and 4999 of the Code.

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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.

Arbitration

You and the Company agree that any and all disputes, claims, or causes of action, in law or equity, including but not limited to statutory claims, arising from or relating to the enforcement, breach, performance, or interpretation of this Agreement, your employment with the Company, or the termination of your employment, shall be resolved, to the fullest extent permitted by law, by final, binding and confidential arbitration conducted by JAMS or its successor, under JAMS' then applicable rules and procedures for employment disputes before a single arbitrator (available upon request and also currently available at http://www.jamsadr.com/rules-employment-arbitration/). You acknowledge that by agreeing to this arbitration procedure, both you and the Company waive the right to resolve any such dispute through a trial by jury or judge or administrative proceeding. In addition, all claims, disputes, or causes of action under this section, whether by you or the Company, must be brought in an individual capacity, and shall not be brought as a plaintiff (or claimant) or class member in any purported class or representative proceeding, nor joined or consolidated with the claims of any other person or entity. The arbitrator may not consolidate the claims of more than one person or entity, and may not preside over any form of representative or class proceeding. To the extent that the preceding sentences regarding class claims or proceedings are found to violate applicable law or are otherwise found unenforceable, any claim(s) alleged or brought on behalf of a class shall proceed in a court of law rather than by arbitration. This paragraph shall not apply to any action or claim that cannot be subject to mandatory arbitration as a matter of law, including, without limitation, claims brought pursuant to the California Private Attorneys General Act of 2004, as amended. In the event you intend to bring multiple claims, including one of the Excluded Claims listed above, the

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Excluded Claims may be publicly filed with a court, while any other claims will remain subject to mandatory arbitration. You will have the right to be represented by legal counsel at any arbitration proceeding. The arbitrator shall: (a) have the authority to compel adequate discovery for the resolution of the dispute and to award such relief as would otherwise be permitted by law; and (b) issue a written statement signed by the arbitrator regarding the disposition of each claim and the relief, if any, awarded as to each claim, the reasons for the award, and the arbitrator's essential findings and conclusions on which the award is based. The arbitrator shall be authorized to award all relief that you or the Company would be entitled to seek in a court of law. The Company shall pay all JAMS arbitration fees in excess of the administrative fees that you would be required to pay if the dispute were decided in a court of law. Nothing in this letter agreement is intended to prevent either you or the Company from obtaining injunctive relief in court to prevent irreparable harm pending the conclusion of any such arbitration. Any awards or orders in such arbitrations may be entered and enforced as judgments in the federal and state courts of any competent jurisdiction.

Miscellaneous

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

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

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

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

Sincerely,

David Cory
President and Chief Executive Officer

Accepted:

/s/ Sriram Ryali	November 1, 2019
Sriram Ryali	Date

Exhibit 10.3

1 November 2019

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

Stephana E. Patton, Ph.D., J.D.

Re: Amended and Restated Employment Terms

Dear Dr. Patton,

Eiger BioPharmaceuticals, Inc. ("Eiger" or the "Company") is pleased to continue your employment on the following terms of this Amended and Restated Offer Letter Agreement ("Agreement"). In this Agreement, you and the Company hereby amend, supersede, and restate in its entirety that certain offer letter agreement between the Company and you dated 26 February 2019 (the "Employment Agreement").

Duties, Compensation and Benefits

You will continue to 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.

Your salary will be $335,000 per year, less payroll deductions and withholdings. You will be paid semi-monthly, or in accordance with Company's compensation practices for other employees in place at the time.

In addition, you will be eligible for an annual bonus, targeted at 35% of your base salary, subject to applicable payroll deductions and withholdings ("Bonus"). Whether you receive this Bonus, and the amount of any such Bonus, will be determined by the Company in its sole discretion based upon your performance, the Company's performance and such other criteria that the Company deems relevant. Any Bonus shall be paid within thirty (30) days after the Company's determination that a Bonus shall be awarded. You will be eligible to earn a Bonus for any full calendar year provided that you remain employed by the Company as of December 31 of that year.

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

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

2155 Park Boulevard
Palo Alto, CA 94306

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

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

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

At Will Employment

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

Payments upon Termination other than without Cause or with Good Reason

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

Termination without Cause or with Good Reason

If the Company terminates your employment without Cause (as defined below) or you resign for Good Reason (as defined below), and other than as a result of your death or disability, and provided such termination constitutes a "separation from service" (as defined under Treasury Regulation Section 1.409A-

1(h)), then subject to your obligations below, you shall be entitled to receive the following severance benefits:

(i) an amount equal to twelve (12) months of your then current base salary and pro-rata target bonus, 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; and

(iii) acceleration of the vesting of the Outstanding Equity as of the date of termination as to 50% of the then-unvested Outstanding Equity, any Outstanding Equity that is subject to performance-based vesting conditions will be deemed to have been achieved at target, and you shall have 12 months from the date of termination in which to exercise your shares subject to any option.

Change in Control

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

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

(ii) an amount equal to eighteen (18) months of your then current base salary and pro-rata target bonus, less all applicable withholdings and deductions, paid in lump sum on the date your employment terminates;

(iii) 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 eighteen (18) month period following the termination of your employment, (B) the expiration of your eligibility for the continuation coverage under COBRA, or (C) the date when you become eligible for substantially equivalent health insurance coverage in connection with new employment or self-employment. If you become eligible for coverage under another employer's group health plan or otherwise cease to be eligible for COBRA during the period provided in this clause, you must immediately notify the Company of such event, and all payments and obligations under this clause shall cease.

Your receipt of any of the severance benefits set forth above is conditional upon your continuing to comply with your legal and contractual obligations to the Company and your delivering to the Company an effective, general release of claims in favor of the Company in a form acceptable to the Company within 60 days following your termination date. The Salary Continuation will be paid in equal installments on the Company's regular payroll schedule and will be subject to applicable tax withholdings over the period outlined above following the date of your termination date; provided, however, that no payments will be made prior to the 60th day following your Separation from Service. On the 60th day following your Separation from Service, the Company will pay you in a lump sum the Salary Continuation that you would have received on or prior to such date under the original schedule but for the delay while waiting for the 60th day in compliance with Code Section 409A and the effectiveness of the release, with the balance of the Salary Continuation being paid as originally scheduled.

Definitions

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

For purposes of this letter agreement, "Good Reason" shall mean the occurrence of any of the following without your prior written consent: (i) relocation of your principal place of employment of over 35 miles from your then-current principal place of employment immediately prior to such relocation; (ii) a material and adverse change in your authority, duties, or responsibilities, or (iii) a reduction in your Base Salary or Bonus target percentage of Base Salary, unless the salaries or bonus target percentages of all other senior executive officers of the Company are correspondingly and proportionately reduced. You cannot terminate

your employment for Good Reason unless you have provided written notice to the Company of the existence of the circumstances providing grounds for termination for Good Reason within thirty (30) days after the existence of such event, and the Company has had at least thirty (30) days from the date on which such notice is provided to cure such circumstances, and you resign his employment within thirty (30) days after the end of such cure period.

For purposes of this 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 Employee Confidential Information and Inventions Assignment Agreement or any other agreement entered into with the Company.

Section 280G of the Code

If any payment or benefit (including payments and benefits pursuant to this Agreement) that you would receive in connection with a Change in Control from the Company or otherwise ("Transaction Payment") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Internal Revenue Code (the "Code"), and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "Excise Tax"), then the Company shall cause to be determined, before any amounts of the Transaction Payment are paid to you, which of the following two alternative forms of payment would result in your receipt, on an after-tax basis, of the greater amount of the Transaction Payment notwithstanding that all or some portion of the Transaction Payment may be subject to the Excise Tax: (1) payment in full of the entire amount of the Transaction Payment (a "Full Payment"), or (2) payment of only a part of the Transaction Payment so that you receive the largest payment possible without the imposition of the Excise Tax (a "Reduced Payment"). For purposes of determining whether to make a Full Payment or a Reduced Payment, the Company shall cause to be taken into account all applicable federal, state and local income and employment taxes and the Excise Tax (all computed at the highest applicable marginal rate, net of the maximum reduction in federal income taxes which could be obtained from a deduction of such state and local taxes). If a Reduced Payment is made, (x) you shall have no rights to any additional payments and/or benefits constituting the Transaction Payment, and (y) reduction in payments and/or benefits shall occur in the manner that results in the greatest economic benefit to you as determined in this paragraph. If more than one method of reduction will result in the same economic benefit, the portions of the Transaction Payment shall be reduced pro rata. Unless you and the Company otherwise agree in writing, any determination required under this paragraph shall be made in writing by the Company's independent public accountants (the "Accountants"), whose determination shall be conclusive and binding upon you and the Company for all purposes. For purposes of making the calculations required by this paragraph, the Accountants may make reasonable assumptions and approximations concerning applicable taxes and may rely on reasonable, good faith interpretations concerning the application of Sections 280G and 4999 of the Code. You and the Company shall furnish to the Accountants such information and documents as the Accountants may reasonably request in order to make a determination under this paragraph. The Company shall bear all costs the Accountants may reasonably incur in connection with any calculations contemplated by this paragraph as well as any costs incurred by you with the Accountants for tax planning under Sections 280G and 4999 of the Code.

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.

Arbitration

You and the Company agree that any and all disputes, claims, or causes of action, in law or equity, including but not limited to statutory claims, arising from or relating to the enforcement, breach, performance, or interpretation of this Agreement, your employment with the Company, or the termination of your employment, shall be resolved, to the fullest extent permitted by law, by final, binding and confidential arbitration conducted by JAMS or its successor, under JAMS' then applicable rules and procedures for employment disputes before a single arbitrator (available upon request and also currently available at http://www.jamsadr.com/rules-employment-arbitration/). You acknowledge that by agreeing to this arbitration procedure, both you and the Company waive the right to resolve any such dispute through a trial by jury or judge or administrative proceeding. In addition, all claims, disputes, or causes of action under this section, whether by you or the Company, must be brought in an individual capacity, and shall not be brought as a plaintiff (or claimant) or class member in any purported class or representative proceeding, nor joined or consolidated with the claims of any other person or entity. The arbitrator may not consolidate the claims of more than one person or entity, and may not preside over any form of representative or class proceeding. To the extent that the preceding sentences regarding class claims or proceedings are found to violate applicable law or are otherwise found unenforceable, any claim(s) alleged or brought on behalf of a class shall proceed in a court of law rather than by arbitration. This paragraph shall not apply to any action or claim that cannot be subject to mandatory arbitration as a matter of law, including, without limitation, claims brought pursuant to the California Private Attorneys General Act of 2004, as amended. In the event you intend to bring multiple claims, including one of the Excluded Claims listed above, the

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Excluded Claims may be publicly filed with a court, while any other claims will remain subject to mandatory arbitration. You will have the right to be represented by legal counsel at any arbitration proceeding. The arbitrator shall: (a) have the authority to compel adequate discovery for the resolution of the dispute and to award such relief as would otherwise be permitted by law; and (b) issue a written statement signed by the arbitrator regarding the disposition of each claim and the relief, if any, awarded as to each claim, the reasons for the award, and the arbitrator's essential findings and conclusions on which the award is based. The arbitrator shall be authorized to award all relief that you or the Company would be entitled to seek in a court of law. The Company shall pay all JAMS arbitration fees in excess of the administrative fees that you would be required to pay if the dispute were decided in a court of law. Nothing in this letter agreement is intended to prevent either you or the Company from obtaining injunctive relief in court to prevent irreparable harm pending the conclusion of any such arbitration. Any awards or orders in such arbitrations may be entered and enforced as judgments in the federal and state courts of any competent jurisdiction.

Miscellaneous

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

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

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

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

Sincerely,

David Cory
President and Chief Executive Officer

Accepted:

/s/ Stephana Patton	November 1, 2019
Stephana Patton	Date

Exhibit 10.4

2155 Park Boulevard
Palo Alto, CA 94306

1 November 2019

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

Mr. James Shaffer

Re: Amended and Restated Employment Terms

Dear Mr. Shaffer,

Eiger BioPharmaceuticals, Inc. ("Eiger" or the "Company") is pleased to continue your employment on the following terms of this Amended and Restated Offer Letter Agreement ("Agreement"). In this Agreement, you and the Company hereby amend, supersede, and restate in its entirety that certain offer letter agreement between the Company and you dated 31 July 2015 (the "Employment Agreement").

Duties, Compensation and Benefits

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

Your salary will be $378,731 per year, less payroll deductions and withholdings. You will be paid semi-monthly, or in accordance with Company's compensation practices for other employees in place at the time.

In addition, you will be eligible for an annual bonus, targeted at 35% of your base salary, subject to applicable payroll deductions and withholdings ("Bonus"). Whether you receive this Bonus, and the amount of any such Bonus, will be determined by the Company in its sole discretion based upon your performance, the Company's performance and such other criteria that the Company deems relevant. Any Bonus shall be paid within thirty (30) days after the Company's determination that a Bonus shall be awarded. You will be eligible to earn a Bonus for any full calendar year provided that you remain employed by the Company as of December 31 of that year.

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

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

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

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

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

At Will Employment

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

Payments upon Termination other than without Cause or with Good Reason

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

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Termination without Cause or with Good Reason

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

(i) an amount equal to twelve (12) months of your then current base salary and pro-rata target bonus, 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; and

(iii) acceleration of the vesting of the Outstanding Equity as of the date of termination as to 50% of the then-unvested Outstanding Equity, any Outstanding Equity that is subject to performance-based vesting conditions will be deemed to have been achieved at target, and you shall have 12 months from the date of termination in which to exercise your shares subject to any option.

Change in Control

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

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

(ii) an amount equal to eighteen (18) months of your then current base salary and pro-rata target bonus, less all applicable withholdings and deductions, paid in lump sum on the date your employment terminates;

(iii) 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 eighteen (18) month period following the termination of your employment, (B) the expiration of your eligibility for the continuation coverage under COBRA, or (C) the date when you become eligible for substantially equivalent health insurance coverage in connection with new employment or self-employment. If you become eligible for coverage under another employer's group health plan or otherwise cease to be eligible for COBRA during the period provided in this clause, you must immediately notify the Company of such event, and all payments and obligations under this clause shall cease.

Your receipt of any of the severance benefits set forth above is conditional upon your continuing to comply with your legal and contractual obligations to the Company and your delivering to the Company an effective, general release of claims in favor of the Company in a form acceptable to the Company within 60 days following your termination date. The Salary Continuation will be paid in equal installments on the Company's regular payroll schedule and will be subject to applicable tax withholdings over the period outlined above following the date of your termination date; provided, however, that no payments will be made prior to the 60th day following your Separation from Service. On the 60th day following your Separation from Service, the Company will pay you in a lump sum the Salary Continuation that you would have received on or prior to such date under the original schedule but for the delay while waiting for the 60th day in compliance with Code Section 409A and the effectiveness of the release, with the balance of the Salary Continuation being paid as originally scheduled.

Definitions

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

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

For purposes of this 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 Employee Confidential Information and Inventions Assignment Agreement or any other agreement entered into with the Company.

Section 280G of the Code

If any payment or benefit (including payments and benefits pursuant to this Agreement) that you would receive in connection with a Change in Control from the Company or otherwise ("Transaction Payment") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Internal Revenue Code (the "Code"), and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "Excise Tax"), then the Company shall cause to be determined, before any amounts of the Transaction Payment are paid to you, which of the following two alternative forms of payment would result in your receipt, on an after-tax basis, of the greater amount of the Transaction Payment notwithstanding that all or some portion of the Transaction Payment may be subject to the Excise Tax: (1) payment in full of the entire amount of the Transaction Payment (a "Full Payment"), or (2) payment of only a part of the Transaction Payment so that you receive the largest payment possible without the imposition of the Excise Tax (a "Reduced Payment"). For purposes of determining whether to make a Full Payment or a Reduced Payment, the Company shall cause to be taken into account all applicable federal, state and local income and employment taxes and the Excise Tax (all computed at the highest applicable marginal rate, net of the maximum reduction in federal income taxes which could be obtained from a deduction of such state and local taxes). If a Reduced Payment is made, (x) you shall have no rights to any additional payments and/or benefits constituting the Transaction Payment, and (y) reduction in payments and/or benefits shall occur in the manner that results in the greatest economic benefit to you as determined in this paragraph. If more than one method of reduction will result in the same economic benefit, the portions of the Transaction Payment shall be reduced pro rata. Unless you and the Company otherwise agree in writing, any determination required under this paragraph shall be made in writing by the Company's independent public accountants (the "Accountants"), whose determination shall be conclusive and binding upon you and the Company for all purposes. For purposes of making the calculations required by this paragraph, the Accountants may make reasonable assumptions and approximations concerning applicable taxes and may

rely on reasonable, good faith interpretations concerning the application of Sections 280G and 4999 of the Code. You and the Company shall furnish to the Accountants such information and documents as the Accountants may reasonably request in order to make a determination under this paragraph. The Company shall bear all costs the Accountants may reasonably incur in connection with any calculations contemplated by this paragraph as well as any costs incurred by you with the Accountants for tax planning under Sections 280G and 4999 of the Code.

Section 409A

It is intended that all of the severance benefits and other payments payable under this letter satisfy, to the greatest extent possible, the exemptions from the application of Code Section 409A provided under Treasury Regulations 1.409A 1(b)(4), 1.409A 1(b)(5) and 1.409A 1(b)(9), and this letter will be construed to the greatest extent possible as consistent with those provisions. For purposes of Code Section 409A (including, without limitation, for purposes of Treasury Regulation Section 1.409A 2(b)(2)(iii)), your right to receive any installment payments under this letter (whether severance payments, reimbursements or otherwise) shall be treated as a right to receive a series of separate payments and, accordingly, each installment payment hereunder shall at all times be considered a separate and distinct payment. Notwithstanding any provision to the contrary in this letter, if you are deemed by the Company at the time of your Separation from Service to be a "specified employee" for purposes of Code Section 409A(a)(2)(B)(i), and if any of the payments upon Separation from Service set forth herein and/or under any other agreement with the Company are deemed to be "deferred compensation", then to the extent delayed commencement of any portion of such payments is required in order to avoid a prohibited distribution under Code Section 409A(a)(2)(B)(i) and the related adverse taxation under Section 409A, such payments shall not be provided to you prior to the earliest of (i) the expiration of the six-month period measured from the date of your Separation from Service with the Company, (ii) the date of your death or (iii) such earlier date as permitted under Section 409A without the imposition of adverse taxation. Upon the first business day following the expiration of such applicable Code Section 409A(a)(2)(B)(i) period, all payments deferred pursuant to this paragraph shall be paid in a lump sum to you, and any remaining payments due shall be paid as otherwise provided herein or in the applicable agreement. No interest shall be due on any amounts so deferred.

Arbitration

You and the Company agree that any and all disputes, claims, or causes of action, in law or equity, including but not limited to statutory claims, arising from or relating to the enforcement, breach, performance, or interpretation of this Agreement, your employment with the Company, or the termination of your employment, shall be resolved, to the fullest extent permitted by law, by final, binding and confidential arbitration conducted by JAMS or its successor, under JAMS' then applicable rules and procedures for employment disputes before a single arbitrator (available upon request and also currently available at http://www.jamsadr.com/rules-employment-arbitration/). You acknowledge that by agreeing to this arbitration procedure, both you and the Company waive the right to resolve any such dispute through a trial by jury or judge or administrative proceeding. In addition, all claims, disputes, or causes of action under this section, whether by you or the Company, must be brought in an individual capacity, and shall not be brought as a plaintiff (or claimant) or class member in any purported class or representative proceeding, nor joined or consolidated with the claims of any other person or entity. The arbitrator may not consolidate the claims of more than one person or entity, and may not preside over any form of representative or class proceeding. To the extent that the preceding sentences regarding class claims or proceedings are found to

EIGER BIOPHARMACEUTICALS
2155 Park Boulevard
Palo Alto, CA 94306

violate applicable law or are otherwise found unenforceable, any claim(s) alleged or brought on behalf of a class shall proceed in a court of law rather than by arbitration. This paragraph shall not apply to any action or claim that cannot be subject to mandatory arbitration as a matter of law, including, without limitation, claims brought pursuant to the California Private Attorneys General Act of 2004, as amended. In the event you intend to bring multiple claims, including one of the Excluded Claims listed above, the Excluded Claims may be publicly filed with a court, while any other claims will remain subject to mandatory arbitration. You will have the right to be represented by legal counsel at any arbitration proceeding. The arbitrator shall: (a) have the authority to compel adequate discovery for the resolution of the dispute and to award such relief as would otherwise be permitted by law; and (b) issue a written statement signed by the arbitrator regarding the disposition of each claim and the relief, if any, awarded as to each claim, the reasons for the award, and the arbitrator's essential findings and conclusions on which the award is based. The arbitrator shall be authorized to award all relief that you or the Company would be entitled to seek in a court of law. The Company shall pay all JAMS arbitration fees in excess of the administrative fees that you would be required to pay if the dispute were decided in a court of law. Nothing in this letter agreement is intended to prevent either you or the Company from obtaining injunctive relief in court to prevent irreparable harm pending the conclusion of any such arbitration. Any awards or orders in such arbitrations may be entered and enforced as judgments in the federal and state courts of any competent jurisdiction.

Miscellaneous

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

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

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

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

Sincerely,

David Cory
President and Chief Executive Officer

Accepted:

/s/ James Shaffer	November 1, 2019
James Shaffer	Date

Exhibit 10.5

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

Execution Copy

LICENSE AGREEMENT

DATED AS OF May 10, 2019

BY AND AMONG

THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA AND THE CHILDREN'S HOSPITAL OF PHILADELPHIA

AND

EIGER BIOPHARMACEUTICALS, INC.

TABLE OF CONTENTS

LICENSE AGREEMENT

This License Agreement (this "**Agreement**") is dated as of May 10, 2019 (the "**Effective Date**") by and among The Trustees of the University of Pennsylvania, a Pennsylvania nonprofit corporation ("**Penn**"), The Children's Hospital of Philadelphia ("**CHOP**") (Penn and CHOP, collectively, "**Institutions**"), and Eiger BioPharmaceuticals, Inc., a Delaware corporation ("**Licensee**"). Institutions and Licensee may be referred to herein as a "**Party**" or, collectively, as "**Parties**".

RECITALS:

WHEREAS, Institutions own and control certain innovative technology for the therapeutic application of incretin antagonists in subjects with hypoglycemic disorders as further defined herein (Penn Reference [***], CHOP Reference [***]), that were developed by [***] (the "**Inventor(s)**");

WHEREAS, Penn and CHOP each desire to license to Licensee, Institutions' intellectual property rights in such technology, in a manner that will benefit the public and best facilitate the distribution of useful products and the utilization of new technology, consistent with Institutions' educational and research missions and goals; and

WHEREAS, Licensee desires to license from Institutions, Institutions' intellectual property rights in such technology, to develop, manufacture and commercialize such technology, all on the terms and conditions of this Agreement.

NOW, THEREFORE, in consideration of the various promises and undertakings set forth herein, the Parties agree as follows:

ARTICLE 1
DEFINITIONS

Unless otherwise specifically provided herein, the following terms shall have the following meanings:

1.1 "**Achievement Date**" means, with respect to a Diligence Event, the corresponding date such Diligence Event is to be achieved as provided in **Exhibit C** attached hereto subject to modification pursuant to Section 3.3 below.

1.2 "**Affiliate**" means a Person that controls, is controlled by or is under common control with a Party, but only for so long as such control exists. For the purposes of this Section 1.2, the word "control" (including, with correlative meaning, the terms "controlled by" or "under the common control with") means the actual power, either directly or indirectly through one or more intermediaries, to direct the management and policies of such Person or entity, whether by the ownership of more than fifty percent (50%) of the voting stock of such entity, or by contract or otherwise.

1.3 "**Clinical Trial**" means any Phase I Clinical Trial, Phase II Clinical Trial, Phase III Clinical Trial, Pivotal Clinical Trial or a variation or subset of such trials.

1.4 "**Commercially Reasonable Efforts**" means the efforts and resources that a similarly situated biotechnology company would use for its own internally discovered or exclusively licensed technology of similar commercial potential and similar stage of development, taking into account the likely timing of the technology's entry into the market, any patent and other proprietary position, and any other relevant scientific, technical, regulatory or commercial factors. Without limiting the foregoing, Commercially Reasonable Efforts requires, with respect to such obligations, that [***]. With respect to the development and commercialization of any Product, Commercially Reasonable Efforts will be determined on a country-by-country basis. For clarity, Commercially Reasonable Efforts will not mean that a Party guarantees that it will actually accomplish the applicable task or objective.

1.5 "**Confidential Information**" of a Party, means (i) information relating to the business, operations or products of a Party or any of its Affiliates, including any know-how, that such Party discloses to the other Party under this Agreement, or otherwise becomes known to the other Party by virtue of this Agreement, and (ii) the terms of this Agreement; provided that Confidential Information shall not include information that:

(a) is or becomes generally available to the public other than as a result of disclosure by the recipient;

(b) is already known by or in the possession of the recipient at the time of disclosure by the disclosing Party;

(c) is independently developed by recipient without use of or reference to the disclosing Party's Confidential Information; or

(d) is obtained by recipient from a Third Party that has not breached any obligations of confidentiality.

1.6 "**Controlled**" means, with respect to intellectual property rights, that a Party or one of its Affiliates owns or has a license or sublicense to such intellectual property rights and has the ability to provide to, grant a license or sublicense to, or assign its right, title and interest in and to, such intellectual property rights as provided for in this Agreement without violating the terms of any agreement or other arrangement with any Third Party.

1.7 "**Data Lock**" means, with respect to a Clinical Trial being conducted by or on behalf of a Person, the locking (no additional data collected and no data is removed) by or on behalf of such Person of the database that contains the data collected from such Clinical Trial in a manner consistent with industry standards and Laws to enable data analysis and reporting of such Clinical Trial.

1.8 "**Development Plan**" means the development plan provided by Licensee to Penn that provides the activities, and the associated timelines of when such activities shall be conducted (including in detail the activities that shall be conducted in the calendar year following the submission of such Development Plan to Penn), in order to develop a Product for commercialization. The initial Development Plan is attached hereto as **Appendix III**.

1.9 "**Diligence Event**" means each of the events that Licensee is expected to accomplish in the development of a Product as provided in **Exhibit C** attached hereto.

1.10 "**Field of Use**" means use of any Glucagon Like Peptide-1(GLP-1) receptor antagonist(s) to treat any and all human and animal conditions, including, without limitation, the treatment of any disease in which inhibition of insulin secretion may or does provide therapeutic benefit.

1.11 "**First Commercial Sale**" means, on a country-by-country basis, the first commercial transfer or disposition for value of Product in such country to a Third Party by Licensee, or any of its Affiliates or Sublicensees, in each case after all Governmental Approvals have been obtained for such country.

1.12 "**GAAP**" means United States generally accepted accounting principles applied on a consistent basis.

1.13 "**Governmental Approval**" means, with respect to a Product in a country or region, all approvals, clearances, licenses, registrations and authorizations of the relevant Governmental Body, if applicable, required for the commercialization of such Product in such country.

1.14 "**Governmental Body**" means any: (a) nation, principality, state, commonwealth, province, territory, county, municipality, district or other jurisdiction of any nature; (b) federal, provincial, state, local, municipal, foreign or other government; (c) governmental or quasi-governmental authority of any nature (including any governmental division, subdivision, department, agency, bureau, branch, office, commission, council, board, instrumentality, officer, official, representative, organization, unit, body or entity and any court or other tribunal); (d) multi-national or supranational organization or body; or (e) individual, entity, or body exercising, or entitled to exercise, any executive, legislative, judicial, administrative, regulatory, police, military or taxing authority or power of any nature.

1.15 "**Indication**" means a human disease or medical condition for which a separate Governmental Approval or a label expansion of a Governmental Approval can be obtained, provided that such separate Governmental Approval or label expansion (a) requires additional Clinical Trial(s), (b) is not solely to treat an expanded set of patients for the previously approved disease or medical condition, and (c) is not solely for use as a different line of therapy for the previously approved disease or medical condition.

1.16 "**Initiation**" means with respect to a Clinical Trial, first dosing of the first human subject in such Clinical Trial.

1.17 "**Institutions Patent Rights**" means (a) the Patent Rights listed in **Exhibit A** Controlled by Institutions as of the Effective Date, (b) any continuations, provisionals, continued prosecution applications, substitutions, extensions and term restorations, registrations, confirmations, reexaminations, renewals or reissues thereof, including divisions, but excluding continuations-in-part except to the extent of claims entitled to the priority date of the parent application, and (c) any corresponding foreign Patent Rights to the foregoing. Notwithstanding the above, Institutions Patent Rights does not include the Carve-Out Patent Rights.

1.18 "**Intellectual Property**" means the Institutions Patent Rights.

1.19 "**Law**" or "**Laws**" means all applicable laws, statutes, rules, regulations, ordinances and other pronouncements having the binding effect of law of any Governmental Body.

1.20 "**Licensed Data**" means data and information developed [***] in the Field of Use and defined in Exhibit B, including [***] of the foregoing that is Controlled by CHOP as of the Effective Date that is necessary to research, develop, make, have made, use, sell, have sold or import any Product, including the data and information listed on Exhibit B.

1.21 "[***]" means [***].

1.22 "**NDA**" means a new drug application filed under Section 505 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 et seq.), or similar application for Governmental Approval of a Product in the Field of Use submitted to a Governmental Body.

1.23 "**Net Sales**" means the gross consideration invoiced or received by Licensee or any of its Affiliates or Sublicensees for Sales of Product (including any cash amounts plus the fair market value of any other forms of consideration), less the following deductions [***] to the extent reasonable and customary and solely related to the sale of the Product(s):

[***]

Even if there is overlap between any of deductions described above, each individual item shall only be deducted once in the overall Net Sales calculation. Each of the above deductions to Net Sales shall be calculated in accordance with US GAAP.

1.24 "**Patent Rights**" means any of the following, whether existing now or in the future anywhere in the world: issued patent, including inventor's certificates, substitutions, extensions, confirmations, reissues, re-examination, renewal or any like governmental grant for protection of inventions, and any pending application for any of the foregoing.

1.25 "**Person**" means any natural person, corporation, firm, business trust, joint venture, association, organization, company, partnership or other business entity, or any government or agency or political subdivision thereof.

1.26 "**Phase I Clinical Trial**" means a human clinical trial of a product designed to satisfy the requirements of 21 C.F.R. § 312.21(a) and intended to determine pharmacokinetic and pharmacodynamic actions of the product in humans, and the side effects associated therewith, whether in single or multiple doses and whether in static or increasing doses, or any comparable trial under Laws in any country or group of countries outside of the United States.

1.27 "**Phase II Clinical Trial**" means a human clinical trial of a product designed to satisfy the requirements of 21 C.F.R. § 312.21(b) and intended to explore a variety of doses, dose response, and duration of effect, and to generate preliminary data on side effects and clinical efficacy for a particular indication or indications in a target patient population, or any comparable trial under Laws in any country or group of countries outside of the United States.

1.28 "**Phase III Clinical Trial**" means a human clinical trial of a product designed to satisfy the requirements of 21 C.F.R. § 312.21(c) and intended to (a) establish that the product is safe and efficacious for its intended use, (b) define contraindications, warnings, precautions and adverse reactions that are associated with the product in the dosage range to be prescribed, and (c) support Governmental Approval for such product, or any comparable trial under Laws in any country or group of countries outside of the United States.

1.29 "**Pivotal Clinical Trial**" means a pivotal human clinical trial of a product (whether or not denominated a "Phase III Clinical Trial" under applicable regulations) with a defined dose or a set of defined doses of such product designed to ascertain efficacy and safety of such product for the purpose of enabling the preparation and submission of an application for a Governmental Approval.

1.30 "**Product**" means any (a) process, service or method covered by a Valid Claim or whose use or practice would, absent the License, constitute an infringement, inducement of infringement or contributory infringement of any Valid Claim ("**Method**"), (b) article, composition, apparatus, substance, chemical or any other material covered by a Valid Claim or whose manufacture, import, use offer for sale or sale would, absent the License, constitute an infringement, inducement of infringement or contributory infringement of any Valid Claim; (c) service, article, composition, apparatus, chemical, substance or any other material imported, made, used or sold by or utilizing or practicing a Method; or (d) [***].

1.31 "**Royalty Term**" means, with respect to a Product and on a country by country basis, the period commencing on the Effective Date and ending on the later of (a) expiration or abandonment of the last Valid Claim in the country where the Product is either made, used, sold, offered for sale or imported, or (b) ten (10) years from the First Commercial Sale of such Product.

1.32 "**Sale**" means any transaction for which consideration is received or expected by Licensee, its Affiliates or Sublicensees for sale, use, lease, transfer or other disposition of a Product to or for the benefit of a Third Party. For clarity, sale, use, lease, transfer or other disposition of a Product by Licensee or any of its Affiliates or Sublicensees to another of these entities for resale by such entity to a Third Party shall not be deemed a Sale.

1.33 "**Sublicensee**" means a Person (including any Affiliate) to which a Sublicense is granted pursuant to the terms of Section 2.4.

1.34 "**Sublicense Documents**" means any and all agreements, amendments or written understandings entered into with a Sublicensee (including any of its Affiliates) that [***]. For clarity, a [***] is a Sublicense Document.

1.35 "**Sublicense Income**" means income received by Licensee or its Affiliates in consideration for a Sublicense [***]. Sublicense Income includes income received from a Sublicensee in the form of license issue fees, milestone payments and similar payments but specifically excludes [***]. For clarity, a wholesaler or distributor that purchases Product in a *bona fide* arm's length transaction from Licensee or its Affiliates or Sublicensees and with respect to which such Licensee, its Affiliates or Sublicensees do not receive additional consideration for such Sale from a wholesaler or distributor, such consideration for such purchase shall not be deemed to be a Sublicensing Income but shall be subject to a Royalty under Section 4.4; provided that, to the extent that any additional consideration is paid by any wholesaler or distributor to Licensee or its Affiliates or Sublicensees in connection with such Sale of Product, then any such additional consideration shall be deemed Sublicensing Income. In any event, any agreement entered into with a wholesaler or distributor for sales of Product shall be consistent with the following sections of this Agreement: Section 9.4 (Use of Names); and Article 7 (INDEMNIFICATION, INSURANCE AND LIMITATION OF LIABILITY).

1.36 "**Tax**" means all taxes, duties, fees, premiums, assessments, imposts, levies, rates, withholdings, dues, government contributions and other charges of any kind whatsoever, whether direct or indirect, together with all interest, penalties, fines, additions to tax or other additional amounts, imposed by any Governmental Body.

1.37 "**Third Party**" means any Person other than CHOP or Penn, Licensee or any of their respective Affiliates.

1.38 "**United States**" or "**US**" means the United States of America, its territories and possessions.

1.39 "**USD**" or "**$**" means the lawful currency of the United States of America.

1.40 "**Valid Claim**" means a claim of (a) an issued and unexpired patent in Institutions Patent Rights which claim has not been revoked or held unenforceable or invalid by a decision of a court of governmental agency of competent jurisdiction from which no further appeal can be taken or has been taken within the time allowed for appeal, and has not been abandoned, disclaimed, denied or admitted to be invalid or unenforceable through reissue or disclaimer; or (b) a pending patent application that (i) is included in Institutions Patent Rights which was filed and is being prosecuted in good faith, (ii) has not been pending for more than [***] from the first substantive office action with respect to such pending claim and has not been abandoned or finally rejected without the possibility of appeal or refiling or without such appeal having been taken or refiling having been made within the applicable time periods; provided that a claim of any pending patent application that is deemed not to be a Valid Claim as a result of the limitation in clause (ii) shall thereafter be considered a Valid Claim if such claim subsequently issues in an issued patent, or (iii) has not been abandoned or finally disallowed without the possibility of appeal or refiling of the application. For clarity, "refiling the application" includes filing a continuing or divisional application claiming the same subject matter.

1.41 **Other Terms**. The definition of each of the following terms is set forth in the section of the Agreement indicated below:

Defined Term	**Section**
Advance Payment	5.2.3
Agreement	Preamble
Bankruptcy Action	8.3.5
Carve-Out Patent Rights	5.1.2
Disclosure	Recitals
Effective Date	Preamble
Financial Report	4.7
Historic Patent Cost	5.2.1
Infringement Notice	5.4.1
Inventor(s)	Recitals
Issue Fee	4.1
License	2.1
Institutions	Preamble
Institutions Indemnitees	7.1.1
Licensee	Preamble

Maintenance Fee	4.2
Method	1.30
Milestone	4.3.1
Milestone Payment	4.3.1
Minimum Annual Royalty	4.4.6
Ongoing Patent Costs	5.2.2
Parties	Preamble
Party	Preamble
Patent Costs	5.2.1
Patent Counsel	5.1.1
Patent Termination Notice	5.3
Progress Reports	3.4.1
Prosecution Request	5.1.2
Royalty	4.4.1
Sublicense	2.4.1
Term	8.1

ARTICLE 2
LICENSES AND OTHER RIGHTS

2.1 **Grant of License**. Subject to the terms and conditions of this Agreement, Institutions hereby grant to Licensee an exclusive, royalty-bearing right and license (with the right to sublicense as provided in, and subject to, the provisions of Section 2.4) under Institutions Patent Rights, in all jurisdictions where Institutions Patent Rights exist, to, make, have made, use, sell, offer for sale and import Product in the Field of Use during the Term (the "**License**"). Subject to the terms and conditions of this Agreement, CHOP hereby grants to Licensee an exclusive, royalty-bearing right and license without right to sublicense except in conjunction with a sublicense to the Institutions Patent Rights, in all jurisdictions where Institutions Patent Rights exist under Licensed Data.

2.2 **Retained Rights**. Notwithstanding the License, each of Penn and CHOP retains the right under Institutions Patent Rights and CHOP under the Licensed Data to (a) conduct educational and research and clinical activities itself and (b) authorize non-commercial Third Parties to conduct education and research activities.

2.3 **U.S. Government Rights**. The License is expressly subject to all applicable provisions of any license to the United States Government executed by either Penn, CHOP or Institutions and is subject to any overriding obligations to the United States Federal Government under 35 U.S.C. §§200-212, applicable governmental implementing regulations, and the U.S. Government sponsored research agreement or other guidelines, including that products that result from intellectual property funded by the United States Federal Government that are sold in the United States be substantially manufactured in the United States. In the event that Licensee believes in good faith that substantial manufacture of such product is not commercially feasible in the United States and makes a request to Penn in writing to assist in obtaining a waiver of such requirement from the United States Government, then Institutions shall, at the expense of Licensee, use reasonable efforts to assist in obtaining such waiver. In addition, Licensee acknowledges the obligations to the United States Federal Government under 37 Code of Federal Regulations, Part 401 and shall provide information to the extent necessary to satisfy any such applicable obligations to the United States Federal Government thereunder.

2.4 **Grant of Sublicense by Licensee**.

2.4.1 Institutions grant to Licensee the right to grant sublicenses, in multiple tiers and in whole or in part, under the License (each, a "**Sublicense**") subject to the terms and conditions of this Agreement and specifically this Section 2.4. The term Sublicense shall include any grant of rights under the License by a Sublicensee to any downstream Third Party and any such downstream Third Party shall also be considered a Sublicensee for purposes of this Agreement.

2.4.2 All Sublicenses will (i) be issued in writing, (ii) to the extent applicable, include all of the rights of Institutions and require the performance of obligations due to Penn (and, if applicable, the U.S. Government under 35 U.S.C. §§200-212) contained in this Agreement and (iii) include the following terms and conditions:

(a) Reasonable record keeping, audit and reporting obligations sufficient to enable Licensee and Penn to reasonably verify the payments due to Licensee and Penn under such Sublicense and to reasonably monitor such Sublicensee's progress in developing and/or commercializing Product, provided that such obligations shall be no less stringent that those provided in this Agreement for Licensee.

(b) Infringement and enforcement provisions with respect to the Institutions Patent Rights and Licensed Data that do not conflict with the restrictions and procedural requirements imposed on Licensee and do not provide greater rights to Sublicensee than those provided to Licensee as provided in Section 5.4.

(c) Confidentiality provisions with respect to Confidential Information of Institutions consistent with the restrictions on Licensee in Section 5.6 of this Agreement.

(d) Covenants by Sublicensee that are not less protective of the rights of Institutions than to those made by Licensee in Section 6.5.

(e) A requirement of indemnification of Institutions by Sublicensee that is not less protective of the rights of Institutions to indemnification by Licensee under Section 7.1 of this Agreement.

(f) A requirement of obtaining and maintaining insurance by Sublicensee that is not less coverage of Institutions than the insurance requirements of Licensee under Section 7.2 of this Agreement, including coverage under such insurance of Institutions as provided in Section 7.2.

(g) Restriction on use of Institutions' names etc. consistent with Section 9.4 of this Agreement.

(h) A requirement of antidiscrimination by Sublicensee no less stringent than that provided in Section 9.5 of this Agreement.

(i) A requirement that [***] due to Institutions under this Agreement.

Any Sublicense that does not include all of the terms and conditions set forth in this Section 2.4.2 or which is not issued in accordance with the terms and conditions set forth in this Section 2.4, shall be considered null and void with no further notice from Institutions.

2.4.3 Within [***] after of the execution of a Sublicense Document, Licensee shall provide a complete and accurate copy of such Sublicense Document to Penn, in the English Language, provided that Licensee shall have the right to redact such Sublicense Document to remove sensitive confidential information that does not relate to the Institutions Patent Rights or is not necessary for Penn, in Penn's reasonable discretion, to verify compliance with the terms of this Agreement. Penn's receipt of a Sublicense Document, however, will constitute neither an approval nor disapproval of the Sublicense Document nor a waiver of any right of Penn or obligation of Licensee under this Agreement. Any Sublicense Document provided by Licensee to Penn shall be deemed the Confidential Information of Licensee and shall be marked as Confidential.

2.4.4 Licensee shall provide an [***] Sublicense Development Report on or before [***] during the Term ("SDR Report") a form of which is attached hereto as **Appendix IV**.

2.5 **No Implied License**. Each Party acknowledges that the rights and licenses granted in this Agreement are limited to the scope expressly granted. Accordingly, except for the rights expressly granted under this Agreement, no right, title, or interest of any nature whatsoever is granted whether by implication, estoppel, reliance, or otherwise, by either Party to the other Party. All rights with respect to any know-how, patent or other intellectual property rights that are not specifically granted herein are reserved to the owner thereof.

ARTICLE 3
DILIGENCE

3.1 **Development Plan**. No later than [***] during the Term, Licensee shall submit to Penn an updated Development Plan, which shall include amendments and revisions to any long term development activities and detailed activities to be conducted in the following [***], provided that such updated Development Plan for a given Product shall not be due after the First Commercial Sale of that Product in the United States.

3.2 **General Diligence**. Licensee shall use Commercially Reasonable Efforts to develop and commercialize either a Product for [***] Indications or [***] Products in the Field of Use in the [***]. The Parties acknowledge that any development and commercialization of a Product [***] with respect to this Section 3.2. If Licensee determines that the development of a [***] in accordance with the preceding sentence, it will notify Penn and the Parties shall confer and discuss in good faith alternatives based on such discussions.

3.3 **Diligence Events**.

3.3.1 Licensee shall achieve each Diligence Event by the corresponding Achievement Date; provided, however, that if Licensee fails to achieve any such Diligence Event by the corresponding Achievement Date as a result of a delay due to a bona fide Product safety or efficacy reason or [***], and Licensee provides notice to Penn [***] prior to such Achievement Date, the Parties shall meet and discuss in good faith an extension to the applicable Achievement Date by [***]. In any event, Licensee may extend any Achievement Date, for a Diligence Event by [***] increments, but not more than [***], by making a [***] payment to Penn prior to the expiration of the Achievement Date for such Diligence Event.

3.3.2 Penn's sole and exclusive remedy with respect to Licensee's failure to achieve a Diligence Event by the corresponding Achievement Date shall be its right to terminate this Agreement.

3.4 **Progress Reports**.

3.4.1 So long as Licensee continues to develop Products, Licensee on an [***] basis, but in no event later than [***], shall submit to Penn a progress report (each, a "**Progress Report**") covering Licensee's (and any Affiliates' and Sublicensees') activities related to the development of all Products and the obtaining of Governmental Approvals necessary for commercialization of Products.

3.4.2 Each Progress Report must include the following, to the extent applicable, for each annual period:

(a) Summary of work completed, including against the Development Plan for such period;

(b) Key scientific discoveries;

(c) Summary of work in progress [***] on Product development;

(d) Current schedule of anticipated events or milestones, including anticipated timeline for achievement of Diligence Events;

(e) Market plans for introduction of Product;

(f) An updated SDR that lists any and all Sublicenses granted by Licensee;

(g) [***]; and

(h) [***].

ARTICLE 4
FINANCIAL PROVISIONS

4.1 **Issue Fee**. In partial consideration of the License, Licensee will pay to Penn within [***] of the Effective Date a license issue fee of one million USD ($1,000,000) ("**Issue Fee**"). The Issue Fee is non-refundable and non-creditable against any other amounts, including any royalties due by Licensee.

4.2 **License Maintenance Fee**. As further consideration for the License, Licensee will pay an annual maintenance fee ("**Maintenance Fee**") as set forth on **Exhibit C** attached hereto beginning on the first anniversary of the Effective Date. The Maintenance Fee will not be due and payable on any anniversary of the Effective Date if on that date Licensee is paying a Royalty or the Minimum Annual Royalty. For clarity, the Maintenance Fee is [***].

4.3 **Milestone Payments**.

4.3.1 As additional consideration for the License, Licensee will pay Penn the milestone payments (each, a "**Development Milestone Payment**" or a "**Sales Milestone Payment**" as applicable and any Development Milestone Payment or Sales Milestone Payment, a "**Milestone Payment**") provided in **Exhibit C** attached hereto upon each Product to achieve the corresponding milestone (each, a "**Development Milestone**" or a "**Sales Milestone**", as applicable and any Development Milestone or Sales Milestone, a "**Milestone**"), whether achieved by Licensee or an Affiliate or Sublicensee. Licensee shall promptly notify Penn in writing of the achievement of any such Milestone and Licensee shall pay Penn in full the corresponding Milestone Payment within [***] of such achievement. For clarity, each Milestone Payment is [***].

4.3.2 Each time a Milestone is achieved, then any other applicable Milestone Payments with respect to earlier applicable Milestones that have not yet been paid will be due and payable together with the Milestone Payment for the Milestone that is actually achieved.

4.4 **Royalties**.

4.4.1 Subject to Sections 4.4.2, 4.4.3 and 4.4.6, as further consideration for the License, Licensee shall pay to Penn a non-refundable, non-creditable royalty of [***] on the Net Sales of Product during the Royalty Term for such Product ("**Royalty**").

If Licensee [***], Licensee shall deduct from the Royalties payable in a given calendar quarter [***] in such calendar quarter [***], provided that (a) [***].

4.4.2 With respect to any Product whose manufacture, use, sale and import is [***], then the Royalty with respect to such Product shall be reduced by [***].

4.4.3 Notwithstanding sections 4.4.2 and 4.4.3, the Royalty on Net Sales shall [***] on Net Sales of a Product during the Royalty Term for such Product.

4.4.4 Licensee must pay Royalties owed to Penn on a calendar quarter basis on or before the following dates:

(a) [***] for any Sales that took place on or before the last day of the calendar quarter ending [***], of the prior year;

(b) [***] for any Sales that took place on or before the last day of the calendar quarter ending [***] of such calendar year;

(c) [***] for any Sales that took place on or before the last day of the calendar quarter ending [***] of such calendar year; and

(d) [***] for any Sales that took place on or before the last day of the calendar quarter ending [***] of such calendar year.

4.4.5 Licensee shall pay to Penn the minimum annual royalties ("**Minimum Annual Royalty**") provided in **Exhibit C** attached hereto commencing on the first full calendar year [***]. Licensee will pay the Minimum Annual Royalty on [***] of each calendar year it is due, provided that the [***].

4.5 **Institutions Sublicense Income**. Licensee will pay to Penn a percentage of Sublicense Income as provided in **Exhibit C** attached hereto (such percentage, the "**Institutions Sublicense Income**"). Licensee will make such payment to Penn on or before the following dates:

4.5.1 [***] for any Sublicense Income received by Licensee on or before the last day of the calendar quarter ending [***], of the prior year;

4.5.2 [***] for any Sublicense Income received by Licensee on or before the last day of the calendar quarter ending [***] of such calendar year;

4.5.3 [***] for any Sublicense Income received by Licensee on or before the last day of the calendar quarter ending [***] of such calendar year; and

4.5.4 [***] for any Sublicense Income received by Licensee on or before the last day of the calendar quarter ending [***] of such calendar year.

4.6 **Mode of Payment and Currency**. All payments to Penn hereunder shall be made by deposit of USD in the requisite amount to the "The Trustees of the University of Pennsylvania" and will be made by delivery to any one of the following:

[[***] **[**[***]

Payments under this Agreement shall be made in USD. All Royalties payable shall be calculated [***]. The exchange rate for such conversion shall be the average of the rate quoted in The Wall Street Journal for the last business day of each month in the calendar quarter for such Royalty payment made.

4.7 **Royalty and Institutions Sublicense Income Reports**. Within [***] after the end of each calendar quarter [***], Licensee shall deliver to Penn a report ("**Financial Report**") setting out all details necessary to calculate the Royalty and Institutions Sublicense Income due under this Article 4 for such calendar quarter, including to the extent applicable:

4.7.1 [***]

Each Financial Report shall be in the form of the sample report attached hereto as **Appendix I**. Each Financial Report shall be the Confidential Information of Licensee.

4.8 **Late Payments**. In addition to any other remedies available to Penn, including the right to terminate this Agreement, any failure by Licensee to make a payment within [***] after the date when due shall obligate Licensee to pay computed interest, the interest period commencing on the due date and ending on the actual payment date, to Penn at a rate per annum equal to [***] per month, or the highest rate allowed by Law, whichever is lower.

4.9 **Default Payment**. In the event of default in payment of any payment owing to Penn under the terms of this Agreement, and if it becomes necessary for Penn to undertake legal action to collect said payment, in the event that Licensee is found liable in a court of competent jurisdiction, then Licensee shall [***].

4.10 **Accounting**. Each Party shall calculate all amounts, and perform other accounting procedures required, under this Agreement and applicable to it in accordance with GAAP.

4.11 **Books and Records**. Licensee will keep accurate books and records of all Products developed, manufactured, used or sold and all Sublicenses, collaboration agreements and joint venture agreements entered into by Licensee that involved Institutions Patent Rights. Licensee will preserve these books and records for [***]. Upon reasonable notice, key personnel, books and records will be made reasonably available and will be open to examination by representatives or agents of Penn during regular office hours to determine their accuracy and assess Licensee's compliance with the terms of this Agreement, provided that Licensee shall not have an obligation to provide access more than [***] and provided that such representatives or agents of Penn agree to be bound by written confidentiality obligations at least as stringent as those contained in this Agreement. Such books and records shall be the Confidential Information of Licensee.

4.12 **Audits**. In addition to the right of Penn to examine the books and records as provided in Section 4.11 above, Penn, [***], through an independent auditor reasonably acceptable to Licensee (and who has executed an appropriate confidentiality agreement reasonably acceptable to Licensee that requires the auditor to keep any information learned by it confidential except as needed to report its audit conclusions to Penn), may inspect and audit the relevant records of Licensee pertaining to the calculation of any Milestones, Royalties and Institutions Sublicense Income due to Penn under this Agreement. Licensee shall provide such auditors with access to the records during reasonable business hours. Such access need not be given to any such set of records more often than [***] or more than [***] after the date of any report to be audited. Penn shall provide Licensee with written notice of its election to inspect and audit the records related to the Milestones and Royalties due hereunder not less than [***] prior to the proposed date of review of Licensee's records by Penn's auditors. Should the auditor find any underpayment of Milestone Payments, Royalties or Institutions Sublicense Income by Licensee, Licensee shall (a) promptly pay Institutions the amount of such

underpayment; (b) shall reimburse Penn for the cost of the audit, [***]; and (c) provide such auditors with an audit right exercisable within [***] after Institutions receives the audit report. If the auditor finds overpayment by Licensee, then Licensee shall have the right to deduct the overpayment from any future Milestone Payments, Royalties, Minimum Annual Royalty or Institutions Sublicense Income due to Penn by Licensee or, if no such future Milestone Payments, Royalties, Minimum Annual Royalty or Institutions Sublicense Income are payable, then Penn shall refund the overpayment to Licensee within [***] after Penn receives the audit report. Licensee may designate competitively sensitive information which such auditor may see and review but which it may not disclose to Penn; provided, however, that such designation shall not restrict the auditor's investigation or conclusions.

4.13 **Taxes**. All payments made by Licensee to Penn under the Agreement shall be made [***] Taxes on or with respect to such payments.

ARTICLE 5
INTELLECTUAL PROPERTY

5.1 **Patent Filing Prosecution and Maintenance**.

5.1.1 Institutions Patent Rights will be held in the name of Penn and CHOP and obtained with counsel selected by Penn and reasonably acceptable to Licensee ("**Patent Counsel**"). Penn shall control all actions and decisions with respect to the filing, prosecution and maintenance of Institutions Patent Rights and will consider in good faith the incorporation of any reasonable comments or suggestions by Licensee with respect to such filing, prosecution and maintenance. Penn will instruct Patent Counsel to copy Licensee on all correspondence related to Institutions Patent Rights (including copies of each patent application, office action, response to office action, request for terminal disclaimer, and request for reissue or reexamination of any patent or patent application) and to interact with Licensee with respect to the preparation, filing, prosecution and maintenance of Institutions Patent Rights. Penn has the right to take action to preserve rights and minimize cost whether or not Licensee has commented, and will use reasonable efforts to not allow any Institutions Patent Rights for which Licensee is licensed and is underwriting the costs to lapse or become abandoned without Licensee's written authorization under this Agreement, except for filing of continuations, divisionals, or the like that substitute for the lapsed application, provided that, Institutions shall [***] as set forth in this Agreement. For the purposes of this Agreement, "maintenance" of the Institutions Patent Rights includes inter partes patent review proceedings before the USPTO or a similar patent administration outside the US. For further clarity, validity challenges raised in infringement litigation will be handled per Section 5.4, Infringement.

5.1.2 Licensee has the right to request a country filing via a written request to Penn [***] prior to the deadline set by the patent office in the territory in which filing is to take place ("**Prosecution Request**"). [***] such patent application(s) and patent(s) ("**Carve-Out Patent Rights**") will not be part of Institutions Patent Rights and therefore not subject to this Agreement, including the License, and Licensee will have no further rights, obligations or license to them; If, and during such time that [***], then Penn and Licensee will [***], in lieu of Section 5.1.1, provided that upon the termination of such agreement, the management of Institutions Patent Rights shall be in accordance with Section 5.1.1.

5.1.3 Licensee shall have the first right, but not the obligation, to make decisions regarding, and to apply for, patent term extensions for the Institutions Patent Rights in the United States with respect to extensions pursuant to 35 U.S.C. §156 et. seq. and in other jurisdictions pursuant to supplementary protection certificates, and in all jurisdictions with respect to any other extensions that are now or become available in the future, wherever applicable, provided that Licensee shall consult in good faith with Institutions prior to making any such decisions with respect to such extensions or supplementary protection certificates. Institutions shall provide prompt and reasonable assistance, and execute any documents to effect the patent term extension, [***], as requested by Licensee, to apply for and obtain any such extensions or supplementary protection certificates at Licensee's direction.

5.2 **Patent Costs**.

5.2.1 Within [***] of the Effective Date, Licensee will reimburse Penn for all documented out-of-pocket costs for the filing, prosecution and maintenance of Institutions Patent Rights, including all accrued documented attorney fees, expenses, official and filing fees ("**Patent Costs**"), incurred by Penn prior to the Effective Date if Licensee is the only licensee for the Institutions Patent Rights obligated to pay Patent Costs prior to the Effective Date and a pro rata share of such Patent Costs incurred by Penn prior to the Effective Date if there is more than one licensee for the Institutions Patent Rights obligated to pay Patent Costs prior to the Effective Date ("**Historic Patent Costs**").

5.2.2 Licensee will bear all Patent Costs incurred by Penn during the Term for which Licensee is the only licensee for the Institutions Patent Rights obligated to pay Patent Costs and a pro rata share of Patent Costs incurred by Penn during the Term for which there is more than one licensee for the Institutions Patent Rights ("**Ongoing Patent Costs**").

5.2.3 Subject to Section 5.2.2, at any time, at Penn's request, Licensee shall [***]. Notwithstanding whether [***], Licensee shall bear all Patent Costs incurred during the Term in accordance with Section 5.2.2 and shall pay such amounts within [***] of receipt of an invoice from Penn for such patent actions. For clarity, the term "Patent Costs" means and includes Historic Patent Costs and Ongoing Patent Costs]. For further clarity, this Section 5.2.3 shall not apply during any period during the Term where a Client and Billing Agreement is in effect.

5.3 **Termination of Rights in, and Obligations with respect to, Certain Institutions Patent Rights**. Licensee may terminate its rights in, and obligations with respect to any or all of Institutions Patent Rights by providing written notice to Penn ("**Patent Termination Notice**"). Termination of Licensee's rights in and obligation with respect to such Patent Right will be effective [***] after receipt of such Patent Termination Notice by Penn. Penn will use reasonable efforts to curtail Patent Costs chargeable to Licensee under this Agreement after receipt of the Patent Termination Notice. Institutions may continue prosecution and maintenance of such Patent Rights at their sole discretion [***], and such Patent Rights will then be Carve-Out Patent Rights and therefore not subject to this Agreement, including the License, and Licensee will have no further rights, obligations (unless accrued prior to the effective date of the termination of Licensee's rights) or license to them.

5.4 **Infringement**.

5.4.1 If either Party believes that an infringement by a Third Party with respect to any Institutions Patent Right is occurring or may potentially occur, the knowledgeable Party will provide the other Party with (a) written notice of such infringement or potential infringement and (b) evidence of such infringement or potential infringement (the "**Infringement Notice**"). During the period in which, and in the jurisdiction where, Licensee has exclusive rights under this Agreement, [***] of such infringement or potential infringement or [***] of Institutions Patent Rights [***]. If [***] of any Institutions Patent Right [***], then [***] right to initiate a suit under Section 5.4.2 below will terminate immediately without the obligation of [***] to provide notice to [***], such consent not to be unreasonably withheld, conditioned or delayed. Both Penn and Licensee will use their reasonably diligent efforts to cooperate with each other to terminate such infringement without litigation.

If, with respect to an infringement or potential infringement described in an Infringement Notice, such infringement or potential infringement has not been abated within [***] (or within [***]) following the date of such Infringement Notice , then during the period in which, and in the jurisdiction where, [***] under the Institutions Patent Rights that are the subject of such infringement or potential infringement, Licensee shall have the first right, but not the obligation, to institute suit for patent infringement against the infringer after providing Penn [***]. For clarity, the information provided by Licensee to Institutions pursuant to the foregoing sentence shall be deemed the Confidential Information of Licensee and Institutions. Institutions may voluntarily join such suit at [***], but may not thereafter commence suit against the infringer for the acts of infringement that are the subject of Licensee's suit or any judgment rendered in such suit. Licensee may not join Institutions, unless Institutions are a necessary party, in a suit initiated by Licensee without Institutions' prior written consent, such consent not to be unreasonably withheld, conditioned or delayed. If in a suit initiated by Licensee, Institutions are involuntarily joined other than by Licensee, then Licensee will [***], provided, however, that if [***]. Licensee shall be free to enter into a settlement, consent judgment or other voluntary disposition, provided that any settlement, consent judgment or other voluntary disposition that (i) limits the scope, validity or enforcement of Institutions Patent Rights or (ii) admits fault or wrongdoing on the part of Licensee or Institutions must be approved in advance by Institutions in writing. Licensee's request for such approval shall include [***]. Institutions shall provide Licensee notice of its approval or denial within [***] of any request for such approval by Licensee, provided that [***].

5.4.2 If, within [***] following the date the Infringement Notice was provided, the infringement or potential infringement that is the subject of such Infringement Notice has not been abated and if Licensee has not brought suit against the infringer pursuant to Section 5.4, then Penn may institute suit for patent infringement against the infringer. If Penn institutes such suit, then Licensee may not voluntarily join such suit without the prior written consent of Penn and may not thereafter commence suit against the infringer for the acts of infringement that are the subject of Penn's suit or any judgment rendered in such suit.

5.4.3 Notwithstanding Sections 5.4.1 and 5.4.2, in the event that any Institutions Patent Rights are infringed by a Third Party [***] regarding such infringement, the Parties

shall discuss, and will mutually agree, in writing, as to how to handle such infringement by such Third Party.

5.4.4 The recovery or settlement paid in any infringement suit, if the patents subject to this Agreement are not the only patents enforced in such suit, will first be [***] the recovery or settlement amount received in connection with any suits herein, such determination to be made by an independent third party selected by mutual agreement of the Parties.

5.4.5 Any recovery or settlement received in connection with any suit involving the Institutions Patent Rights will first be [***] and next shall be [***]. Any remaining recoveries shall be allocated as follows:

For any portion of the recovery or settlement attributed to the Institutions Patent Rights will, [***]:

(a) for any suit that is [***], Penn shall receive [***] of the recovery and the Licensee shall receive the remainder; and

(b) for any suit that is [***]. The initiating party shall receive the remainder of any such recovery.

For any portion of the recovery or settlement attributed to the Institutions Patent Rights will [***]:

(c) for any suit that is [***], Penn shall receive [***] and Licensee shall receive the remainder; and

(d) for any suit that is [***], Penn shall receive [***] and Licensee shall receive the remainder.

For any portion of the recovery or settlement received in connection with any suit that is [***], any recovery in excess of litigation costs will [***].

5.4.6 Each Party will reasonably cooperate and assist with the other in litigation proceedings instituted hereunder but at the expense of the Party who initiated the suit (unless such suit is being jointly prosecuted by the Parties). For clarity, such requirement does not require a Party to join a suit unless otherwise specifically required under this Agreement. If Penn is subjected to third party discovery related to the Institutions Patent Rights or Products licensed to Licensee hereunder, Licensee will [***].

5.5 **Patent Marking**. Licensee shall place in a conspicuous (including virtual marking) location on any Product (or its packaging where appropriate and practicable) made, imported and/or sold under this Agreement a patent notice that is in accordance with the Laws concerning the marking of patented articles where such Product is made, used, imported and/or sold, as applicable. Upon request from Penn, Licensee shall provide evidence of proper marking.

5.6 **Confidentiality**.

5.6.1 Each Party agrees that, for the Term and for [***] thereafter, such Party shall (a) use the same degree of care to maintain the secrecy of the Confidential Information of the other Party that it uses to maintain the secrecy of its confidential or proprietary information of like kind which in any event shall be no less than a reasonable standard of care, (b) use the Confidential Information of the other Party only to accomplish the purpose of this or for audit or management purposes and (c) ensure that any employees, customers, and distributors who have access to such Confidential Information are bound to it by obligations of confidence not less protective than provided in this Agreement and that such disclosures are only as required to accomplish the purposes of this Agreement.

5.6.2 Notwithstanding Section 5.6.1, each Party may disclose the Confidential Information of the other Party to the extent such disclosure is reasonably necessary in the following instances:

(a) preparing and submitting regulatory filings for Products that such Party has a license or right to develop and commercialize hereunder;

(b) prosecuting or defending litigation as permitted by this Agreement;

(c) disclosure to its employees, agents, consultants, contractors, licensees, or Sublicensees, in each case on a need-to-know basis for the sole purpose of performing its obligations or exercising its rights under this Agreement, and in each case under written obligations of confidentiality and non-use consistent with those contained in this Agreement;

(d) disclosure to potential and actual investors, acquirers, licensees, and other financial or commercial partners solely for the purpose of evaluating or carrying out an actual or potential investment, acquisition, or collaboration, in each case under appropriate obligations of confidentiality and non-use consistent with those contained in this Agreement; or

(e) required by Law or court order; provided, however, that the recipient promptly provides to the disclosing Party prior written notice of such disclosure and provides reasonable assistance in obtaining an order or other remedy protecting or limiting the Confidential Information from public disclosure.

ARTICLE 6
REPRESENTATIONS, WARRANTIES AND COVENANTS

6.1 **Mutual Representations and Warranties**. Each Party represents and warrants to the other Party that, as of the Effective Date:

6.1.1 such Party is duly organized and validly existing under the Laws of the jurisdiction of its incorporation or organization;

6.1.2 such Party has taken all action necessary to authorize the execution and delivery of this Agreement and the performance of its obligations under this Agreement;

6.1.3 this Agreement is a legal and valid obligation of such Party, binding upon such Party and enforceable against such Party in accordance with the terms of this Agreement, except as enforcement may be limited by applicable bankruptcy, fraudulent conveyance, insolvency, reorganization, moratorium and other laws relating to or affecting creditors' rights generally and by general equitable principles; and

6.1.4 such Party has all right, power and authority to enter into this Agreement, to perform its obligations under this Agreement.

6.2 **Additional Penn Representations**.

Penn represents, through the Penn Center for Innovation to the Licensee that, to The Penn Center for Innovation's knowledge, as of the time of signing this Agreement:

6.2.1 Penn is an owner of, and has title to the Institutions Patent Rights;

6.2.2 CHOP is the sole co-owner of the Institutions Patent Rights;

6.2.3 Penn and CHOP have executed a written agreement granting Penn the right to administer Institutions Patent Rights and Licensed Data as provided herein;

6.2.4 Penn has the lawful right to grant the license to the Licensee in this Agreement; and

6.2.5 Penn has not granted to any Third Party any license or other right with respect to the Penn's Patent Rights that conflict with the License granted to the Licensee in this Agreement.

6.3 **Additional CHOP Representations**.

CHOP represents, through its Office of Technology Transfer to the Licensee that, to its knowledge, at the time of signing this Agreement:

6.3.1 CHOP is an owner of and has title to the Institutions Patent Rights and Licensed Data;

6.3.2 Penn is the sole co-owner of the Institutions Patent Rights;

6.3.3 CHOP has the lawful right to grant the license and other rights granted to the Licensee in this Agreement; and

6.3.4 CHOP has not granted to any Third Party any license or other right with respect to the Institutions Patent Rights or Licensed Data that conflict with the License or any other rights granted to the Licensee in this Agreement.

6.4 **Disclaimer of Representations and Warranties**.

6.4.1 Other than the representations and warranties provided in Section 6.1, Section 6.2 and Section 6.3 above, **NO PARTY MAKES ANY REPRESENTATIONS AND WARRANTIES, WHETHER EXPRESS OR IMPLIED, AND EXPLICITLY DISCLAIMS ANY REPRESENTATION AND WARRANTY, INCLUDING WITH RESPECT TO ANY ACCURACY, COMPLETENESS, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, COMMERCIAL UTILITY, NON-INFRINGEMENT OR TITLE FOR THE INTELLECTUAL PROPERTY, PATENT RIGHTS, LICENSE AND ANY PRODUCT**.

6.4.2 Furthermore, nothing in this Agreement will be construed as:

(a) A representation or warranty by Institutions as to the validity or scope of any Institutions Patent Right;

(b) A representation or warranty that anything made, used, sold or otherwise disposed of under the License is or will be free from infringement of patents, copyrights, trademarks or any other forms of intellectual property rights or tangible property rights of Third Parties;

(c) Obligating Institutions to bring or prosecute actions or suits against Third Parties for patent, copyright or trademark infringement;

(d) Conferring by implication, estoppel or otherwise any license or rights under any Patent Rights of Institutions other than Institutions Patent Rights as defined herein, regardless of whether such Patent Rights are dominant or subordinate to Institutions Patent Rights; and

(e) Obligating Institutions to furnish any know-how.

6.5 **Covenants of Licensee**.

6.5.1 Licensee and its Affiliates will not, directly or indirectly (including where such is done by a Third Party on behalf of Licensee or its Affiliates, at the urging of Licensee or its Affiliates or with the assistance of the Licensee or its Affiliates) challenge the validity, scope, or enforceability of or otherwise oppose any Institutions Patent Right, provided that if any Institutions Patent Right is asserted against Licensee or its Affiliate for activities authorized under this Agreement, then such Licensee or its Affiliates is entitled to all and any defenses available to it including challenging the validity or enforceability of such Patent Right.

6.5.2 Licensee will comply with all Laws that apply to its activities or obligations under this Agreement. For example, Licensee will comply with applicable United States export laws and regulations. The transfer of certain technical data and commodities may require a license from the applicable agency of the United States government and/or written assurances by Licensee that Licensee will not export data or commodities to certain foreign countries without prior approval of the agency.

6.5.3 Licensee will not grant a security interest in any Institutions Patent Right licensed under this Agreement.

ARTICLE 7
INDEMNIFICATION; INSURANCE AND LIMITATION OF LIABILITY

7.1 **Indemnification by Licensee**.

7.1.1 Licensee shall, and shall require its Sublicensees to, defend, indemnify and hold Institutions and its respective trustees, officers, faculty, students, employees, contractors and agents (the "**Institutions Indemnitees**") harmless from and against any and all liability, damage, loss, cost or expense (including reasonable attorneys' fees), including, without limitation, bodily injury, risk of bodily injury, death and property damage to the extent arising out of Third Party claims or suits related to (a) this Agreement including (i) the development, testing, use, manufacture, promotion, sale or other disposition of any Product (including any product liability claim), (ii) any enforcement action or suit brought by Licensee against a Third Party for infringement of Institutions Patent Rights, (iii) any claim by a Third Party that [***] the design, composition, manufacture, use, sale or other disposition of any Product, infringes or violates any patent, copyright, trade secret, trademark or other intellectual property right of such Third Party, (iv) any breach of this Agreement or Laws by Licensee, its Affiliates or Sublicensees and (b) Licensee's gross negligence or willful misconduct, provided that Licensee's obligations pursuant to this Section 7.1 shall not apply to the extent such claims or suits result from the gross negligence or willful misconduct of any of Institutions Indemnitees, in each case as determined by a court of law.

7.1.2 As a condition to a Institutions Indemnitee's right to receive indemnification under this Section 7.1, Institutions shall: (a) promptly notify Licensee as soon as it becomes aware of a claim or suit for which indemnification may be sought pursuant hereto; (b) reasonably cooperate, and cause the individual Institutions Indemnitees to reasonably cooperate, with Licensee in the defense, settlement or compromise of such claim or suit; and (c) permit the Licensee to control the defense, settlement or compromise of such claim or suit, including the right to select defense counsel. In no event, however, may Licensee compromise or settle any claim or suit in a manner which (a) admits fault or negligence on the part of Institutions or any other Institutions Indemnitee; (b) commits Institutions or any other Institutions Indemnitee to take, or forbear to take, any action, without the prior written consent of Institutions, or (c) grant any rights under the Institutions Patent Rights except for Sublicenses permitted under Article 2. Institutions shall reasonably cooperate with Licensee and its counsel in the course of the defense of any such suit, claim or demand, such cooperation to include without limitation using reasonable efforts to provide or make available documents, information and witnesses.

7.1.3 Notwithstanding Section 7.1.2 above, in the event that a reasonable and bona fide conflict exists between Licensee and Institutions or any other Institutions Indemnitee with respect to a claim or suit subject to indemnification hereunder, then Institutions or such other Institutions Indemnitee shall have the right to defend against any such claim or suit itself, including by selecting its own counsel, with any documented attorney's fees and litigation expenses being paid for by Licensee. Licensee will pay such fees and expenses either directly or will reimburse Institutions within thirty (30) days of Licensee's receipt of invoices for such fees and expenses.

7.2 **Insurance**.

7.2.1 Licensee, at its sole cost and expense, must insure its activities in connection with the exercise of its rights under this Agreement and obtain, and keep in force and maintain Commercial Form General Liability Insurance (contractual liability included) with limits as follows:

(a) [***]

Penn may review periodically the adequacy of the minimum amounts of insurance for each coverage required by this Section 7.2.1, and the Parties agree to discuss in good faith reasonable adjustments to such minimum amounts.

7.2.2 If the above insurance is written on a claims-made form, it shall continue for [***] following termination or expiration of this Agreement. The insurance shall have a retroactive date of placement prior to or coinciding with the Effective Date of this Agreement.

7.2.3 Licensee expressly understands, however, that [***]. Licensee's insurance will:

(a) [***]

7.2.4 Licensee must furnish to Penn with (a) valid certificate of insurance evidencing compliance with all requirements of this Agreement and (b) additional insured endorsements for Licensee's applicable policies naming "The Trustees of the University of Pennsylvania" as an additional insured. Licensee shall furnish both documents upon Penn's reasonable request.

7.3 **LIMITATION OF LIABILITY**.

IN NO EVENT SHALL EITHER PARTY OR ANY OF ITS AFFILIATES BE LIABLE TO THE OTHER PARTY OR ANY OF ITS AFFILIATES FOR SPECIAL, INDIRECT, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES, INCLUDING LOSS OF PROFITS, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE ARISING OUT OF OR RELATING TO THIS AGREEMENT, THE TRANSACTIONS CONTEMPLATED HEREIN OR ANY BREACH HEREOF. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS AGREEMENT SHALL LIMIT LICENSEE'S INDEMNIFICATION OBLIGATIONS UNDER SECTION 7.1, OR SHALL LIMIT INSTITUTIONS REMEDIES OR ABILITY TO RECOVER DAMAGES, INCLUDING INCREASED DAMAGES, FOR WILLFUL INFRINGEMENT IN THE EVENT INSTITUTIONS ASSERT THEIR INTELLECTUAL PROPERTY RIGHTS.

ARTICLE 8
TERM AND TERMINATION

8.1 **Term**. The term of this Agreement (the "**Term**") shall commence on the Effective Date and, unless terminated sooner as provided below, shall continue in full force and effect on a country-by-country basis until the later of (a) the expiration or abandonment of the last Institutions Patent Right, or (b) ten (10) years from the First Commercial Sale of a Product. Following expiration of the Royalty Term, the license to Licensed Data hereunder shall be fully-paid and royalty-free non-exclusive license.

8.2 **Termination of the Agreement for Convenience**. At any time during the Term, Licensee may, at its convenience, terminate this Agreement upon providing at least sixty (60) days prior written notice to Institutions of such intention to terminate, provided that Licensee ceases using the License or making, using, or selling Products following the effective date of termination.

8.3 **Termination For Cause**.

8.3.1 If Licensee fails to fulfill its obligations under Section 3.2 (i.e. use Commercially Reasonable Efforts to develop and commercialize a Product), Penn may provide written notice to Licensee of such failure. If Licensee fails to address such failure to the reasonable satisfaction of Penn within three (3) months of receiving such written notice, Penn may terminate this Agreement upon written notice to Licensee; provided, however, that if the Parties mutually agree that such failure is incapable of being addressed to the reasonable satisfaction of Penn within three (3) months, then Licensee and Penn will confer and mutually agree on a reasonable extension to address such failure to the reasonable satisfaction of Penn.

8.3.2 In the event Licensee fails to achieve any Diligence Event by the corresponding Achievement Date subject to any delays or extensions in accordance with Section 3.3.1, Penn has the right and option to terminate this Agreement, upon written notice, with immediate effect.

8.3.3 If Licensee materially breaches any of its material obligations under this Agreement, Penn may give to Licensee a written notice specifying the nature of the default, requiring it to cure such breach, and stating its intention to terminate this Agreement. If such breach is not cured within sixty (60) days of such notice, such termination shall become effective upon a notice of termination by Institutions thereafter. For clarity, a breach of a material obligation includes:

(a) [***]

8.3.4 In addition to all other remedies available to it, Penn may terminate this Agreement, upon written notice, with immediate effect, upon a breach of Section 6.5, Covenants of Licensee; provided, however, that with respect to Licensee's covenant to comply with all Laws set forth in Section 6.5.2, Penn may, at its sole discretion, allow Licensee a [***] period to remedy such lack of compliance, if a remedy is possible and permitted by Law.

8.3.5 Penn may terminate this Agreement, upon written notice, with immediate effect if, at any time, Licensee files in any court or agency pursuant to any statute or regulation of any state, country or jurisdiction, a petition in bankruptcy or insolvency or for an arrangement or for the appointment of a receiver or trustee of Licensee or of its assets, or if Licensee is served with an involuntary petition against it, filed in any insolvency proceeding, or if Licensee proposes or is a party to any dissolution or liquidation, or if Licensee makes an assignment for the benefit of its creditors of all or substantially all its assets (in each case, "**Bankruptcy Action**"). The foregoing notwithstanding, if Licensee files for Chapter 11 Bankruptcy reorganization protection ("**Bankruptcy Reorganization**") and notifies Penn in writing in advance of such Bankruptcy Reorganization Licensee shall have a [***] to reorganize and restructure its debts ("**Reorganization Period**"). If such Bankruptcy Reorganization petition as described in this Section 8.3.5 is not withdrawn or dismissed within the Reorganization Period, Penn shall have the right to terminate the agreement, immediately upon the expiration of the [***] Reorganization Period.

8.4 **Effects of Termination**.

8.4.1 Notwithstanding the termination of this Agreement, the following provisions shall survive: Sections 4.7-4.12, inclusive, 5.6 and 8.4 and Articles 1, 6, 7 and 9.

8.4.2 Termination of this Agreement shall not relieve the Parties of any obligation or liability that, at the time of termination, has already accrued hereunder, or which is attributable to a period prior to the effective date of such termination. Termination of this Agreement shall not preclude either Party from pursuing all rights and remedies it may have hereunder or at Law or in equity with respect to any breach of this Agreement nor prejudice either Party's right to obtain performance of any obligation.

8.4.3 If this Agreement is terminated for any reason, all outstanding Sublicenses (including all Sublicense Documents for each Sublicense) not in default will be assigned by Licensee to Institutions, and such assignment will be accepted by Institutions. Each assigned Sublicense will remain in full force and effect with Institutions as the licensor or sublicensor instead of Licensee, but the duties and obligations of Institutions under the assigned Sublicenses will not be greater than the duties of Institutions under this Agreement, and the rights of Institutions under the assigned Sublicenses will not be less than the rights of Institutions under this Agreement, including all financial consideration and other rights of Institutions. Institutions may, at their sole discretion, [***].

ARTICLE 9
ADDITIONAL PROVISIONS

9.1 **Relationship of the Parties**. Nothing in this Agreement is intended or shall be deemed, for financial, tax, legal or other purposes, to constitute a partnership, agency, joint venture or employer-employee relationship between the Parties. The Parties are independent contractors and at no time will either Party make commitments or incur any charges or expenses for or on behalf of the other Party.

9.2 **Expenses**. Except as otherwise provided in this Agreement, each Party shall pay its own expenses and costs incidental to the preparation of this Agreement and to the consummation of the transactions contemplated hereby

9.3 **Third Party Beneficiary**. The Parties agree that each Sublicensee is a third party beneficiary of this Agreement with respect to Section 8.4.3.

9.4 **Use of Names**. Licensee, its Affiliates and Sublicensees may not use the name, logo, seal, trademark, or service mark (including any adaptation of them) of Institutions or any Institutions school, organization, employee, student or representative, without the prior written consent of Institutions. Notwithstanding the foregoing, Licensee may use the name of Institutions in a non-misleading and factual manner solely in (a) executive summaries, business plans, offering memoranda and other similar documents used by Licensee for the purpose of raising financing for the operations of Licensee as related to Product, or entering into commercial contracts with Third Parties, but in such case only to the extent necessary to inform a reader that the Institutions' Patent Rights has been licensed by Licensee from Institutions, and to inform a reader of the identity and published credentials of Inventors of the Intellectual Property, and (b) any securities reports required to be filed with the Securities and Exchange Commission.

9.5 **No Discrimination**. Neither Institutions nor Licensee will discriminate against any employee or applicant for employment because of race, color, sex, sexual or affectional preference, age, religion, national or ethnic origin, handicap, or veteran status.

9.6 **Successors and Assignment**.

9.6.1 The terms and provisions hereof shall inure to the benefit of, and be binding upon, the Parties and their respective successors and permitted assigns.

9.6.2 Licensee may not assign or transfer this Agreement or any of Licensee's rights or obligations created hereunder, by operation of law or otherwise, without the prior written consent of Institutions, provided that Institutions shall not unreasonably withhold, condition or delay their consent. The foregoing sentence notwithstanding, it shall not be necessary for Licensee to obtain Institutions' consent to the assignment of this Agreement in its entirety in connection with the sale or transfer of all or substantially all of Licensee's assets, provided that (a) there exists no material breach by the Licensee or its Affiliates of any material term of this Agreement, including those caused by a Sublicensee; (b) at least [***] before the proposed assignment, Licensee will have given notice of the transaction; and (c) the assignee agrees in writing to (i) be legally bound by this Agreement, (ii) assume responsibility for any and all liabilities that arose under this Agreement prior to the effective date of the proposed assignment of this Agreement; and (iii) agrees to deliver to Penn an updated Development Plan within [***] after the closing of the proposed transaction. Any permitted assignment will not relieve Licensee of responsibility for performance of any obligation of Licensee that has accrued at the time of the assignment. Licensee will not grant a security interest in the License or this Agreement during the term. Any prohibited assignment or security interest will be null and void.

9.6.3 Any assignment not in accordance with this Section 9.6 shall be void.

9.7 **Further Actions**. Each Party agrees to execute, acknowledge and deliver such further instruments and to do all such other acts as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

9.8 **Entire Agreement of the Parties; Amendments**. This Agreement, the Exhibits and Appendices or Schedules hereto constitute and contain the entire understanding and agreement of the Parties respecting the subject matter hereof and cancel and supersede any and all prior negotiations, correspondence, understandings and agreements between the Parties, whether oral or written, regarding such subject matter. No waiver, modification or amendment of any provision of this Agreement shall be valid or effective unless made in a writing referencing this Agreement and signed by a duly authorized officer of each Party signing this Agreement.

Any amendment that alters the rights or obligations of CHOP hereunder will also require the written consent of CHOP, as applicable.

9.9 **Governing Law**. This Agreement shall be governed by and interpreted in accordance with the laws of the Commonwealth of Pennsylvania, excluding application of any conflict of laws principles that would require application of the law of a jurisdiction outside of the Commonwealth of Pennsylvania.

9.10 **Dispute Resolution**. If a dispute arises between the Parties concerning this Agreement, then the Parties will confer, as soon as practicable, in an attempt to resolve the dispute. If the Parties are unable to resolve such dispute amicably, then the Parties will submit to the exclusive jurisdiction of, and venue in, the state and Federal courts located in the Eastern District of Pennsylvania.

9.11 **Notices and Deliveries**. Any notice, request, approval or consent required or permitted to be given under this Agreement shall be in writing and directed to a Party at its address or facsimile number shown below or such other address or facsimile number as such Party shall have last given by notice to the other Party. A notice will be deemed received: if delivered personally, on the date of delivery; if mailed, five (5) days after deposit in the United States mail; if sent via courier, one (1) business day after deposit with the courier service; or if sent via facsimile, upon receipt of confirmation of transmission provided that a confirming copy of such notice is sent by certified mail, postage prepaid, return receipt requested.

**[*****]

9.12 **Waiver**. A waiver by either Party of any of the terms and conditions of this Agreement in any instance shall not be deemed or construed to be a waiver of such term or condition for the future, or of any other term or condition hereof. All rights, remedies, undertakings, obligations and agreements contained in this Agreement shall be cumulative and none of them shall be in limitation of any other remedy, right, undertaking, obligation or agreement of either Party.

9.13 **Severability**. When possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under law, but if any provision of this Agreement is held to be prohibited by or invalid under law, such provision will be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of this Agreement. The Parties shall make a good faith effort to replace the invalid or unenforceable provision with a valid one which in its economic effect is most consistent with the invalid or unenforceable provision.

9.14 **Interpretation**. The words "include," "includes" and "including" shall be deemed to be followed by the phrase "without limitation." All references herein to Articles, Sections, Schedules and Exhibits shall be deemed references to Articles and Sections of, Schedules and Exhibits to, this Agreement unless the context shall otherwise require. Except as otherwise expressly provided herein, all terms of an accounting or financial nature shall be construed in accordance with GAAP, as in effect from time to time. Unless the context otherwise requires, countries shall include territories. References to any specific Law or article, section or other division thereof, shall be deemed to include the then-current amendments or any replacement Law thereto.

9.15 **Counterparts**. This Agreement may be executed in counterparts, each of which will be deemed an original, and all of which together will be deemed to be one and the same instrument. A facsimile or a portable document format (PDF) copy of this Agreement, including the signature pages, will be deemed an original.

9.16 **Timely Countersignature.** The terms and conditions of this Agreement shall, at Institutions' sole option, be considered by Institutions to be withdrawn from Licensee's consideration and the terms and conditions of this Agreement, and the Agreement itself to be null and void, unless this Agreement is executed by Licensee and a fully executed original is received by Institutions within [***] from the date of Institutions' signature found below.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, duly authorized representatives of the Parties have executed this Agreement as of the Effective Date.

THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA

By: [***]
Name: [***]
Title:

THE CHILDREN'S HOSPITAL OF PHILADELPHIA

By:
Name: [***]
Title: [***]

EIGER BIOPHARMACEUTICALS, INC.

By: [***]
Name: [***]
Title: Eiger BioPharmaceuticals, Inc.

Exhibit A
Institutions Patent Rights

[***]

Exhibit B
Licensed Data

[***]

Exhibit C
Certain Financial Terms

<table>
<tr>
<td>DEVELOPMENT & COMMERCIALIZATION</td>
<td>
<table>
<tr><th>Diligence Event</th><th>Achievement Date</th></tr>
<tr><td>[***]</td><td>[***]</td></tr>
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Licensee may extend any Achievement Date for a Diligence Event by [***] increments, but not more than [***] by making a [***] to Penn [***] of such Achievement Date for such Diligence Event.

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<tr>
<td>CERTAIN FINANCIAL TERMS</td>
<td>

Issue Fee. $1,000,000.
License Maintenance Fee. $[***].
Development Milestone Payments. Payable once per Product or if the same Product is developed for a second Indication once per Indication.

<table>
<tr><th>Development Milestone</th><th>Development Milestone Payment</th></tr>
<tr><td>[***]</td><td>[***]</td></tr>
<tr><td>[***]</td><td>[***]</td></tr>
<tr><td>Total Development Milestone Payments Due:</td><td>[***]</td></tr>
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	• **Sales Milestone Payments. Payable only once upon first achievement.** **Sales Milestone (Aggregate Annual Net Sales)** / **Sales Milestone Payment** [***] / [***] [***] / [***] [***] / [***] [***] / [***] **Total Sales Milestone Payments Due**: / [***]
	• **Royalty. [***] on all Net Sales of all Products.** • **Minimum Annual Royalties.** [***]. • **Institutions Sublicense Income.** **Stage of development of Product at the time when the Sublicense is granted** / **Institutions Sublicense Income** [***] / [***] [***] / [***] [***] / [***] [***] / [***]

Appendix I
Form of Financial Report

[***]

APPENDIX II

[***]

APPENDIX III
Development Plan

[***]

APPENDIX IV

Form of Sublicense Development Report

[***]

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: November 7, 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: November 7, 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 September 30, 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: November 7, 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."