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 June 30, 2018

OR

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

For the transition period from _____ to _____

Commission file number: 001-36183

Eiger BioPharmaceuticals, Inc.

(Exact Name of Registrant as Specified in its Charter)

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post 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. (Check one):

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☐ (Do not check if a smaller reporting company)	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 August 6, 2018, the number of outstanding shares of the registrant's common stock, par value $0.001 per share, was 14,244,272.

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)

	June 30, 2018 (Unaudited)	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 33,323	$ 32,035
Debt securities, available-for-sale	40,169	9,744
Prepaid expenses and other current assets	1,485	712
Total current assets	74,977	42,491
Property and equipment, net	71	79
Other assets	290	312
Total assets	$ 75,338	$ 42,882
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,438	$ 3,183
Accrued liabilities	1,152	2,084
Current portion of long term debt	3,242	2,002
Total current liabilities	8,832	7,269
Long term debt, net	17,032	13,091
Other long term liabilities	193	—
Total liabilities	26,057	20,360
Stockholders' equity:		
Common stock	14	11
Additional paid-in capital	186,833	141,320
Accumulated other comprehensive loss	(14)	(3)
Accumulated deficit	(137,552)	(118,806)
Total stockholders' equity	49,281	22,522
Total liabilities and stockholders' equity	$ 75,338	$ 42,882

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 June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Operating expenses:				
Research and development	$ 6,372	$ 8,131	$ 11,884	$ 15,595
General and administrative	3,237	2,946	6,231	6,468
Total operating expenses	9,609	11,077	18,115	22,063
Loss from operations	(9,609)	(11,077)	(18,115)	(22,063)
Interest expense	(495)	(378)	(893)	(741)
Interest income	189	113	283	223
Other income (expense), net	—	196	(21)	196
Net loss	$ (9,915)	$ (11,146)	$ (18,746)	$ (22,385)
Net loss per common share, basic and diluted	$ (0.82)	$ (1.33)	$ (1.66)	$ (2.68)
Weighted-average common shares outstanding, basic and diluted	12,045,355	8,367,030	11,291,540	8,363,803

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 June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Net loss	$ (9,915)	$ (11,146)	$ (18,746)	$ (22,385)
Other comprehensive loss:				
Unrealized (loss) gain on available-for-sale debt securities	(14)	2	(11)	9
Comprehensive loss	$ (9,929)	$ (11,144)	$ (18,757)	$ (22,376)

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)

	Six Months Ended June 30,	
	2018	**2017**
Operating activities		
Net loss	$ (18,746)	$ (22,385)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	22	19
Amortization of debt securities discounts	(45)	(73)
Non-cash interest expense	218	171
Stock-based compensation	2,324	2,270
Change in operating assets and liabilities:		
Prepaid expenses and other current assets	(773)	(388)
Other non-current assets	22	62
Accounts payable	1,255	1,829
Accrued and other liabilities	(932)	(1,427)
Other long term liabilities	193	—
Net cash used in operating activities	(16,462)	(19,922)
Investing activities		
Purchase of debt securities available-for-sale	(40,141)	(17,550)
Proceeds from maturities of debt securities available-for-sale	9,750	20,700
Proceeds from intellectual property sale	—	200
Purchase of property and equipment	(14)	(44)
Net cash (used in) provided by investing activities	(30,405)	3,306
Financing activities		
Proceeds from issuance of common stock upon public offering, net of issuance cost	42,890	—
Proceeds from borrowings in connection with term loan, net of issuance cost	4,963	—
Proceeds from issuance of common stock upon stock option exercises	268	—
Proceeds from issuance of common stock upon ESPP purchase	34	57
Net cash provided by financing activities	48,155	57
Net increase (decrease) in cash and cash equivalents	1,288	(16,559)
Cash and cash equivalents at beginning of period	32,035	27,756
Cash and cash equivalents at end of period	$ 33,323	$ 11,197

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

1. Description of Business

Eiger BioPharmaceuticals, Inc. (the "Company") is a clinical-stage biopharmaceutical company committed to bringing to market novel products for the treatment of rare diseases. The Company innovates by developing well characterized drugs acting on newly identified or novel targets in rare diseases. The Company's mission is to systematically reduce the time and cost of the drug development process to more rapidly deliver important medicines to patients with rare diseases. Their lead program in Hepatitis Delta Virus (HDV) infection, is moving into Phase 3 with a single, pivotal trial planned to initiate by the end of the year. The Company's principal operations are based in Palo Alto, California and it operates in one segment.

Liquidity

As of June 30, 2018, the Company had $33.3 million of cash and cash equivalents, $40.2 million of debt securities available-for-sale, an accumulated deficit of $137.6 million and negative cash flows from operating activities. The Company expects to continue to incur losses for the next several years.

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

2. Summary of Significant Accounting Policies

Basis of Presentation

The unaudited condensed consolidated financial statements include the accounts of Eiger BioPharmaceuticals, Inc. and its wholly owned subsidiaries, EBPI Merger Inc., EB Pharma LLC and Eiger BioPharmaceuticals Europe Limited, and have been prepared in accordance with accounting principles generally accepted in the United States of America, ("U.S. GAAP") and following the requirements of the Securities and Exchange Commission (the "SEC") for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by U.S. GAAP can be condensed or omitted. These financial statements have been prepared on the same basis as the Company's annual financial statements and, in the opinion of management, reflect all adjustments, consisting only of normal recurring adjustments, which are necessary for a fair statement of the Company's financial information. These interim results are not necessarily indicative of the results to be expected for the year ending December 31, 2018 or for any other interim period or for any other future year. The balance sheet as of December 31, 2017, 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, 2017, filed with the Securities and Exchange Commission on March 9, 2018.

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 debt 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 debt securities are carried at fair value based upon quoted market prices. Unrealized gains and losses on available-for-sale debt securities are excluded from earnings and are reported as a component of accumulated other comprehensive loss. The cost of available-for-sale debt securities sold is based on the specific-identification method. Realized gains and losses on the sale of debt securities are determined using the specific-identification method and recorded in other expense, net on the accompanying unaudited condensed consolidated statements of operations.

Accrued Research and Development Costs

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

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 June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Options to purchase common stock	2,129,491	1,593,560	2,129,491	1,593,560
Warrants to purchase common stock	10,180	10,180	10,180	10,180
Total	2,139,671	1,603,740	2,139,671	1,603,740

Recent Accounting Pronouncements

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*, which requires lessees to recognize most leases on their balance sheet. The standard requires use of the modified retrospective transition method, with elective relief, which requires application of the guidance for all periods presented. The new standard will be effective for fiscal years beginning after December 15, 2018. Early adoption is permitted. The Company is currently in the process of evaluating the impact that the standard will have on its consolidated financial statements.

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. The standard is effective for fiscal years and interim periods beginning after December 15, 2019. Early adoption is permitted for all periods beginning after December 15, 2018. The Company is currently in the process of evaluating the impact the standard will have on its consolidated financial statements.

In June 2018, the FASB issued ASU No. 2018-07, *Compensation—Stock Compensation (Topic 718)*, which expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. An entity should apply the requirements of Topic 718 to nonemployee awards except for certain exemptions specified in the amendment. The standard is effective for fiscal years beginning after December 15, 2018, including interim reporting periods within that fiscal year. Early adoption is permitted, but no earlier than the Company's adoption date of ASU No. 2014-09, *Revenue from Contracts with Customers* (Topic 606). The Company elected to early adopt this standard on January 1, 2018. The adoption did not have a material impact on the Company's condensed consolidated financial statements.

3. Fair Value Measurements

Fair value accounting is applied for all financial assets and liabilities that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually). At June 30, 2018 and December 31, 2017, the carrying amount of prepaid expenses, 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 June 30, 2018 and December 31, 2017.

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):

	June 30, 2018			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Money market fund	$ 14,999	$ —	$ —	$ 14,999
Corporate debt securities	—	25,270	—	25,270
Commercial paper	—	24,277	—	24,277
Total	$ 14,999	$ 49,547	$ —	$ 64,546

	December 31, 2017			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Money market funds	$ 19,612	$ —	$ —	$ 19,612
Corporate debt securities	—	6,501	—	6,501
Commercial paper	—	3,243	—	3,243
Total	$ 19,612	$ 9,744	$ —	$ 29,356

There were no financial liabilities as of June 30, 2018 and December 31, 2017.

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):

	June 30, 2018			
	Amortized cost	Unrealized gain	Unrealized loss	Estimated Fair Value
Cash equivalents:				
Money market funds	$ 14,999	$ —	$ —	$ 14,999
Corporate debt securities	6,382	—	—	6,382
Commercial paper	2,996	—	—	2,996
Total cash equivalents	$ 24,377	$ —	$ —	$ 24,377
Debt securities:				
Corporate debt securities	$ 18,903	$ —	$ (15)	$ 18,888
Commercial paper	21,280	2	(1)	21,281
Total debt securities	$ 40,183	$ 2	$ (16)	$ 40,169

	December 31, 2017			
	Amortized cost	Unrealized gain	Unrealized loss	Estimated Fair Value
Cash equivalents:				
Money market funds	$ 19,612	$ —	$ —	$ 19,612
Total cash equivalents	$ 19,612	$ —	$ —	$ 19,612
Debt securities:				
Corporate debt securities	$ 6,503	$ —	$ (2)	$ 6,501
Commercial paper	3,244	—	(1)	3,243
Total debt securities	$ 9,747	$ —	$ (3)	$ 9,744

As of December 31, 2017, the contractual maturity of the available-for-sale debt securities is less than one year. The Company periodically reviews the available-for-sale investments for other-than-temporary impairment loss. The Company considers factors such as the duration, severity and the reason for the decline in value, the potential recovery period and its intent to sell. For debt securities, it also considers whether (i) it is more likely than not that the Company will be required to sell the debt securities before recovery of their amortized cost basis, and (ii) the amortized cost basis cannot be recovered as a result of credit losses. During the three and six months ended June 30, 2018, the Company did not recognize any other-than-temporary impairment losses.

4. Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	June 30, 2018	December 31, 2017
Compensation and related benefits	$ 792	$ 1,262
Contract research costs	271	634
Consulting costs	69	87
Franchise tax	20	56
Contract manufacturing costs	—	4
Other	—	41
Total accrued liabilities	$ 1,152	$ 2,084

5. License and Collaboration Agreements

Merck License Agreement

On May 15, 2018, the Company entered into an amendment to the license agreement with Merck Sharp & Dohme Corp. (“Merck”) dated September 2, 2010, as amended, which provides for expansion of the existing exclusively licensed field of use under the license agreement with Merck to include all uses of lonafarnib related to the treatment of Hutchinson-Gilford Progeria Syndrome (“HGPS” or “Progeria”) in humans at no cost to the Company. The Company has the sole responsibility and the continuing obligation for the manufacture and supply of lonafarnib to the Progeria Research Foundation (“PRF”). Merck will not receive milestone payments in relation to lonafarnib for the treatment of progeria and progeroid laminopathies and any royalty payments for sales of a specified quantity of lonafarnib to treat the currently estimated progeria and progeroid laminopathies patient population worldwide.

PRF Collaboration Agreement

On May 15, 2018, the Company entered into a Collaboration and Supply Agreement (the “PRF Collaboration Agreement”) with PRF. Under the PRF Collaboration Agreement, the parties agreed to collaborate with respect to the development and pursuit of regulatory approval of lonafarnib for the treatment of progeria in humans. PRF granted the Company a non-exclusive, world-wide, royalty-free, sub-licensable license pertaining to all intellectual property and data controlled by PRF to prepare and file any new drug application (“NDA”) for a product containing lonafarnib for progeria and progeroid laminopathies. The Company is obligated to: (i) exclusively supply lonafarnib to PRF for use in clinical trials and non-clinical research in Progeria at the Company’s expense, (ii) prepare and be the sponsor of any NDA submission for lonafarnib to the FDA, (iii) use commercially reasonable efforts to file a NDA for Progeria by a specified date, (iv) submit a rare pediatric disease designation and a request for expedited approval in connection with a NDA filing, (v) establish a patient support program in progeria and progeroid laminopathies, and (vi) use commercially reasonable efforts to develop a pediatric formulation of lonafarnib for use in progeria and progeroid laminopathies.

Under the PRF Collaboration Agreement, the Company is solely responsible for any additional studies necessary for obtaining an NDA for progeria and progeroid laminopathies and is also responsible for any additional costs for such studies up to $2.0 million. The PRF Collaboration Agreement continues for an initial term of ten years and automatically renews for subsequent renewal terms of two years each unless either party terminates earlier.

Clinigen Master Service Agreement

On April 26, 2018, the Company entered into a master service agreement with Clinigen Healthcare Ltd. ("Clinigen") in anticipation of its obligations under the PRF Collaboration Agreement to establish an Expanded Access Program for children with progeria and progeroid laminopathies. On May 23, 2018, the Company entered into the first statement of work ("SOW") under the agreement. Pursuant to the SOW, Clinigen became an authorized non-exclusive worldwide distributor of lonafarnib, the unlicensed pharmaceutical product (the "Product"). The Company is responsible for supply of the Product to Clinigen and Clinigen is responsible for selling the Product to patients as part of the patient support program. Clinigen is also obligated to set up, manage and close-out the patient support program. The agreement will continue on a country-by-country basis until the Product is commercially available in that country. No charges have been recognized under this agreement as of June 30, 2018.

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 (the "Amendment") and borrowed $5.0 million ("Amended Tranche B"). The remaining $5.0 million ("Amended Tranche C") will be available to the Company upon achievement of positive top line data from the lonafarnib Phase 2 trial in HDV, which was achieved in the fourth quarter of 2016, plus positive top line Phase 2 data from at least one of the following programs: (i) pegylated interferon lambda (Lambda) in HDV, (ii) exendin 9-39 in PBH based on the Company's own IND, or (iii) ubenimex in lymphedema. As of June 30, 2018, the Company did not meet any of the clinical milestones and is not eligible to access the final $5.0 million 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%. Commencing on the first day of the month following the funding of Tranche A, the Company is required to repay the Tranche A in 18 monthly interest only payments, and starting on August 1, 2018, 36 equal monthly payments of principal and interest. Upon the receipt of Amended Tranche B, the interest only period for borrowed funds was extended by six months 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 each tranche, which will be $1.1 million for Tranche A and $0.4 million for Amended Tranche B. In addition, at the time of final payment of Amended 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 $0.3 million which were recorded as a direct deduction from the carrying amount of the related debt liability. The Company is also required to pay a 5.0% success fee within 30 days following the FDA's approval of the Company's first product. This fee is enforceable within 10 years from the funding of Tranche A. In connection with the execution of the Loan Agreement, the Company agreed to certain customary representations and warranties.

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 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 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 Oxford Loan as of June 30, 2018 and December 31, 2017.

The Company is permitted to make voluntary prepayments of the Oxford Loan with a prepayment fee, calculated as of the loan origination date, equal to (i) 3.0% of the loan prepaid during the first 12 months, (ii) 2.0% of the loan prepaid in months 13-24 and (iii) 1.0% of the loan prepaid thereafter. The Company is required to make mandatory prepayments of the outstanding loan upon the acceleration by lender following the occurrence of an event of default, along with a payment of the final payment, the prepayment fee and any other obligations that are due and payable at the time of prepayment.

The Company accounts for the amortization of the debt discount utilizing the effective interest method. The Company recorded interest expense of $0.5 million and $0.9 million for the three and six months ended June 30, 2018. Long-term debt and unamortized discount balances are as follows (in thousands):

	June 30, 2018	December 31, 2017
Face value of long term debt	$ 20,000	$ 15,000
Exit fee	1,585	1,125
Unamortized debt discount associated with exit fee, debt issuance costs and loan origination fees	(1,311)	(1,032)
Total long term debt	20,274	15,093
Less: current portion of long term debt	(3,242)	(2,002)
Long term debt, net	$ 17,032	$ 13,091

7. Stock-Based Compensation

The following table summarizes stock option activity under the Company's stock-based compensation plan during the six months ended June 30, 2018 (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, 2017	799,375	1,467,051	$ 12.70	8.41	$ 4,511
Additional options authorized	526,330				
Granted	(867,500)	867,500	$ 10.34		
Exercised		(28,151)	$ 9.55		
Canceled and forfeited	176,909	(176,909)	$ 13.22		
Outstanding as of June 30, 2018	635,114	2,129,491	$ 11.74	8.39	$ 4,623
Vested and exercisable as of June 30, 2018		772,552	$ 12.80	7.28	$ 2,017

During the three and six months ended June 30, 2018, the Company granted employees stock options for zero and 799,500 shares, respectively. The weighted-average grant date fair value of these options was zero and $7.50 for the three and six months ended June 30, 2018, respectively. During the three and six months ended June 30, 2017, the Company granted employees stock options for 60,000 and 523,700 shares, respectively. The weighted-average grant date fair value of these options was $5.41 and $7.69 for the three and six months ended June 30, 2017, respectively.

The Company records stock-based compensation of stock options granted to employees 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 employee stock options was estimated using the following weighted-average assumptions:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Expected term (in years)	—	5.27-6.02	5.27-6.08	5.27-6.02
Volatility	—	79.0%-80.0%	84.00%-84.50%	79.0%-80.0%
Risk free interest rate	—	1.6%-1.9%	2.35%-2.68%	1.6%-2.2%
Dividend yield	—	—	—	—

Stock-Based Compensation Expense

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Research and development	$ 471	$ 215	$ 794	$ 498
General and administrative	850	731	1,530	1,772
Total	$ 1,321	$ 946	$ 2,324	$ 2,270

As of June 30, 2018, the total unrecognized compensation expense related to unvested options was $11.1 million, which the Company expects to recognize over an estimated weighted average period of 2.9 years.

8. Income Taxes

The tax expense for the three and six months ended June 30, 2018 was zero due to the Company's loss position and full valuation allowance. This is consistent with the zero-tax expense for the three and six months ended June 30, 2017.

9. Legal Matters

In July 2015, following Celladon's announcements of the negative CUPID 2 data and the suspension of further research and development activities and the subsequent declines of the price of its common stock, three putative class actions were filed in the U.S. District Court for the Southern District of California against Celladon and certain of its current and former officers. The complaints generally alleged that the defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), by making materially false and misleading statements regarding the clinical trial program for MYDICAR, thereby artificially inflating the price of Celladon's common stock. The complaints sought unspecified monetary damages and other relief, including attorneys' fees. On December 9, 2015, the district court consolidated the three putative securities class actions and appointed a lead plaintiff to represent the putative class. The lead plaintiff filed a consolidated amended complaint on February 29, 2016.

On October 7, 2016, the district court granted defendants' motion to dismiss the consolidated amended complaint and granted leave to amend within 60 days from the date of the district court's order. The lead plaintiff subsequently filed a notice of intent not to amend the consolidated amended complaint and instead indicated that it intended to appeal the district court's decision. On December 9, 2016, the district court closed the case.

On December 28, 2016, the lead plaintiff filed a notice to the United States Court of Appeals for the Ninth Circuit appealing the district court's order dismissing the consolidated amended complaint. On May 5, 2017, the lead plaintiff and appellant filed his opening appellate brief. On July 5, 2017, defendants filed their answering appellate brief response. The Plaintiff subsequently filed their response to the Company's July 5, 2017 filing on August 19, 2017. Oral arguments are scheduled to be heard on August 28, 2018 before the Ninth Circuit Court of Appeals.

It is possible that additional suits will be filed, or allegations made by stockholders, with respect to these same or other matters and also naming the Company and/or Celladon's former officers and directors as defendants. The Company believes that it has meritorious defenses and intends to defend these lawsuits vigorously. Due to the early stage of these proceedings, the Company is not able to predict or reasonably estimate the ultimate outcome or possible losses relating to these claims.

10. Commitments and Contingencies

Lease Agreement

In October 2017, the Company entered into a non-cancelable 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 one three-year renewal option prior to expiration and includes rent escalation clauses through the lease term. In October 2017, the Company provided a security deposit of $0.3 million. The future minimum rent payable under the new lease agreement is approximately $0.6 million per year.

There were no other changes in commitments and contingencies during the three and six months ended June 30, 2018.

11. Subsequent Events

On August 3, 2018, the Company borrowed the final $5.0 million under the Oxford Loan upon achievement of certain clinical milestones. The final borrowing did not have any impact on terms, conditions, representations, warranties, covenants or agreements set forth in the Oxford Loan.

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, Eiger's consolidated financial statements and related notes thereto for the year ended December 31, 2017, included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission ("SEC") on March 9, 2018. This discussion and other parts of this report contain forward-looking statements that involve risks and uncertainties, such as our plans, objectives, expectations, intentions and beliefs. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified below and those discussed in the section entitled "Risk Factors" included elsewhere in this report.

Forward-Looking Statements

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

Overview

We are a clinical stage biopharmaceutical company focused on bringing to market novel product candidates for the treatment of rare diseases. Since our founding in 2008, we have worked with investigators at Stanford University and evaluated a number of potential development candidates from pharmaceutical companies to comprise a pipeline of novel product candidates. Our resulting pipeline includes our lead program which is about to initiate Phase 3 clinical development and three Phase 2 candidates addressing three distinct rare diseases. In May, we added a fifth program to our pipeline to develop lonafarnib for the treatment of Hutchinson-Gilford Progeria Syndrome (HGPS or Progeria) and progeroid laminopathies, rare and fatal genetic conditions characterized by accelerated aging in children.

Our programs have several aspects in common: the disease targets represent conditions of high medical need which are inadequately treated by current standard of care; 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 pipeline includes lonafarnib, our lead program addressing Hepatitis Delta Virus, or HDV, pegylated interferon, lambda (Lambda) for HDV, lonafarnib for progeria and progeroid laminopathies, exendin 9-39 for post-bariatric hypoglycemia, or PBH, and ubenimex for lymphedema. For Lambda in HDV, exendin 9-39 in PBH, and ubenimex in lymphedema, we plan to deliver Phase 2 data by the end of the year. For lonafarnib in progeria and progeroid laminopathies, we plan to receive regulatory guidance on next steps from FDA and EMA by the end of the year.

In January 2018, we announced that Phase 2 LIBERTY study results in pulmonary arterial hypertension (PAH) demonstrated no improvement overall or in key subgroups for both the primary efficacy endpoint of pulmonary vascular resistance (PVR) and the secondary endpoint of 6-minute walk distance. The company discontinued development of ubenimex in PAH based on these results.

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 $18.7 million and $22.4 million for the six months ended June 30, 2018 and 2017, respectively. As of June 30, 2018, we had an accumulated deficit of $137.6 million. Substantially all of our operating losses resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations.

We expect to incur significant expenses and increasing operating losses for at least the next several years as we initiate and continue the clinical development of, and seek regulatory approval for, our product candidates and add personnel necessary to operate as a public company with an advanced clinical candidate pipeline of products. We have and will be hiring additional financial and other personnel, upgrading our financial information systems and incurring costs associated with operating as a public company. We expect that our operating losses will fluctuate significantly from quarter to quarter and year to year due to timing of clinical development programs and efforts to achieve regulatory approval.

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 manufacturing capabilities, and research and development activities. However, we do not allocate internal research and development costs, such as salaries, benefits, stock-based compensation expense and indirect costs to product candidates on a program-specific basis. The following table shows our research and development expenses for the three and six months ended June 30, 2018 and 2017 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Product candidates:				
Lonafarnib HDV	$ 2,663	$ 1,271	$ 3,806	$ 2,390
Ubenimex PAH (terminated in January 2018)	495	3,012	1,428	5,639
Exendin 9-39 PBH	654	1,096	1,343	1,819
Lambda HDV	566	739	1,089	1,422
Ubenimex Lymphedema	340	373	793	859
Internal research and development costs	1,654	1,640	3,425	3,466
Total research and development expense	$ 6,372	$ 8,131	$ 11,884	$ 15,595

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

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

General and Administrative Expenses

General and administrative expenses consist of personnel costs, allocated expenses and expenses for outside professional services, including legal, audit, accounting services, insurance costs and costs associated with being a public company. Personnel costs consist of salaries, benefits and stock-based compensation. Allocated expenses consist of facilities and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, depreciation expense and other supplies. Our expenses include costs related to compliance with the rules and regulations of the SEC and NASDAQ, additional insurance, investor relations, banking fees and other administrative expenses and professional services.

Interest Expense

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

Interest Income

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

Critical Accounting Policies and Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our unaudited condensed consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of these unaudited condensed consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses. On an ongoing basis, we evaluate these estimates and judgments. We base our estimates on historical experience and on various assumptions that we believe to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities and the recording of expenses that are not readily apparent from other sources. Actual results may differ materially from these estimates.

There have been no material changes to our critical accounting policies during the six months ended June 30, 2018 as compared to the critical accounting policies disclosed in our Annual Report on Form 10-K for the year ended December 31, 2017.

Results of Operations

Comparison of the Three Months Ended June 30, 2018 and 2017

	Three Months Ended June 30,		$	%
	2018	2017	Change	Change
Operating expenses:				
Research and development	$ 6,372	$ 8,131	$ (1,759)	(22%)
General and administrative	3,237	2,946	291	10%
Total operating expenses	9,609	11,077	(1,468)	(13%)
Loss from operations	(9,609)	(11,077)	1,468	
Interest expense	(495)	(378)	(117)	31%
Interest income	189	113	76	67%
Other income, net	—	196	(196)	(100%)
Net loss	$ (9,915)	$ (11,146)	$ 1,231	(11%)

Research and development expenses

Research and development expenses decreased by $1.7 million to $6.4 million for the three months ended June 30, 2018, from $8.1 million for the same period in 2017. The decrease was primarily due to a $1.7 million decrease in consulting fees and clinical expenditures due to decreased program activity and a $0.3 million decrease in compensation and personnel related expenses due to a decrease in headcount and recruitment activity. The decrease was partially offset by a $0.3 million increase in stock-based compensation expense due to options granted in 2018.

General and administrative expenses

General and administrative expenses increased by $0.3 million to $3.2 million for the three months ended June 30, 2018, from $2.9 million for the same period in 2017. The increase was primarily due to a $0.2 million increase in facility and insurance expenses related to the new office lease and a $0.2 million increase in compensation and personnel related expenses due to increased travel expenses and higher salaries and benefits in 2018. The increase was partially offset by a $0.1 million decrease in legal, consulting, advisory, and accounting services.

Interest expense

Interest expense increased by $0.1 million to $0.5 million for the three months ended June 30, 2018 from $0.4 million for the same period in 2017. Interest expense primarily increased due to a draw of $5.0 million under the Oxford Loan in the second quarter of 2018.

Interest income

Interest income increased by $0.1 million to $0.2 million for the three months ended June 30, 2018 from $0.1 million for the same period in 2017. The increase was primarily due to an increase in the interest earned on our investments in debt securities and cash equivalents in 2018 as compared to 2017.

Other income, net

Other income, net in 2017 primarily consisted of the payment received from Theragene for MYDICAR sale, and there was no such income earned for the three months ended June 30, 2018.

Comparison of the Six Months Ended June 30, 2018 and 2017

	Six Months Ended June 30,		$	%
	2018	2017	Change	Change
Operating expenses:				
Research and development	$ 11,884	$ 15,595	$ (3,711)	(24%)
General and administrative	6,231	6,468	(237)	(4%)
Total operating expenses	18,115	22,063	(3,948)	(18%)
Loss from operations	(18,115)	(22,063)	3,948	
Interest expense	(893)	(741)	(152)	21%
Interest income	283	223	60	27%
Other (expense) income, net	(21)	196	(217)	(111%)
Net loss	$ (18,746)	$ (22,385)	$ 3,639	(16%)

Research and development expenses

Research and development expenses decreased by $3.7 million to $11.9 million for the six months ended June 30, 2018 from $15.6 million compared the same period in 2017. The decrease was primarily due to a $3.7 million decrease in consulting fees and clinical expenditures related to a decrease program activity and a $0.3 million decrease compensation and personnel related expenses due to a decrease in headcount. The decrease was partially offset by a $0.3 million increase in stock-based compensation expense due to options granted in 2018.

General and administrative expenses

General and administrative expenses decreased by $0.3 million to $6.2 million for the six months ended June 30, 2018 from $6.5 million for the same period in 2017. The decrease was primarily due to a $0.3 million decrease in advisory, consulting, legal and accounting services.

Interest expense

Interest expense increased by $0.2 million to $0.9 million for the six months ended June 30, 2018 from $0.7 million for the same period in 2017. Interest expense primarily increased due a draw of $5.0 million under the Oxford Loan in the second quarter of 2018.

Interest income

Interest income increased by $0.1 million to $0.3 million for the six months ended June 30, 2018 from $0.2 million for the same period in 2017. The increase was primarily due to an increase in the interest earned on our investments in debt securities and cash equivalents in 2018 as compared to 2017.

Other (expense) income, net

Other (expense) income, net in 2017 primarily consisted of the payment received from Theragene for MYDICAR sale, and there was no such income earned for the six months ended June 30, 2018.

Liquidity and Capital Resources

Sources of Liquidity

As of June 30, 2018, we had $33.3 million of cash and cash equivalents, $40.2 million of debt securities available-for-sale and an accumulated deficit of $137.6 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):

	Six Months Ended June 30,	
	2018	2017
Net cash used in operating activities	$ (16,462)	$ (19,922)
Net cash (used in) provided by investing activities	(30,405)	3,306
Net cash provided by financing activities	48,155	57
Net increase (decrease) in cash and cash equivalents	$ 1,288	$ (16,559)

Cash flows from operating activities

Cash used in operating activities for the six months ended June 30, 2018 was $16.5 million, consisting of a net loss of $18.7 million, which was partially offset by stock-based compensation expense of $2.3 million and non-cash interest expense of $0.2 million. Additionally, cash used in operating activities reflected changes in net operating assets primarily due to a $0.9 million decrease in accrued and other liabilities, a $0.8 million increase in prepaid expenses and other current assets, which was partially offset by a $1.4 million increase in accounts payable and other long-term liabilities.

Cash used in operating activities for the six months ended June 30, 2017 was $19.9 million, consisting of a net loss of $22.4 million, which was partially offset by stock-based compensation expense of $2.3 million and amortization of debt discount of $0.2 million.

Cash flows from investing activities

Cash used in investing activities was $30.4 million for the six months ended June 30, 2018 consisted of $40.1 million purchases of debt securities, which was partially offset by $9.8 million proceeds from maturities of debt securities.

Cash provided by investing activities was $3.3 million for the six months ended June 30, 2017, and primarily consisted of $20.7 million proceeds from maturities of debt securities and $0.2 million proceeds from MYDICAR sale, which was partially offset by $17.6 million purchase of debt securities.

Cash flows from financing activities

Cash provided by financing activities for the six months ended June 30, 2018 consisted of $42.9 million of net proceeds from the issuance of common stock upon public offering, $5.0 million of net proceeds from borrowings in connection with the Oxford Loan, and $0.3 million of proceeds from the issuance of common stock upon stock option exercises.

Cash provided by financing activities for the six months ended June 30, 2017 consisted of $0.1 million of proceeds from the purchase of common stock under our ESPP.

Contractual Obligations and Other Commitments

The following table summarizes our contractual obligations at December 31, 2017 (in thousands):

	Payments due by period				
	Total	Less than 1 year	1 – 3 Years	3 – 5 Years	More than 5 years
Operating lease obligations (1)	$ 3,222	$ 634	$ 1,203	$ 1,276	$ 109
Term loan debt (2)	$ 15,000	$ 2,083	$ 10,000	$ 2,917	$ —
Interest on term loan debt (3)	$ 3,641	$ 1,156	$ 1,284	$ 1,201	$ —
Total	$ 21,863	$ 3,873	$ 12,487	$ 5,394	$ 109

(1) Represents future rent payments under two Palo Alto facility lease contracts.
(2) Represents the Oxford first tranche Loan of $15.0 million.
(3) Includes an exit fee on the Oxford Loan of $1.125 million due at maturity.

On May 11, 2018, we entered into an amendment to the Oxford Loan and borrowed $5.0 million ("Amended Tranche B"). In accordance with Oxford Loan, upon the receipt of Amended Tranche B, the interest only period for borrowed funds was extended by six months until February 1, 2019, followed by 30 equal monthly payments of principal plus accrued interest. The term loan debt and interest amounts above do not reflect our future payments under the amended Oxford Loan.

On August 3, 2018, we borrowed the final $5.0 million under the Oxford Loan upon achievement of certain clinical milestones. The final borrowing did not have any impact on terms, conditions, representations, warranties, covenants or agreements set forth in the Oxford Loan.

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 June 30, 2018, we had market risk exposure related to our cash and cash equivalents. We had cash and cash equivalents of $33.3 million and $40.2 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 six months ended June 30, 2018.

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 and six months ended June 30, 2018, 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

See Note 9 of the Notes to the unaudited Condensed Consolidated Financial Statements contained within this Quarterly Report on Form 10-Q for a further discussion of our legal proceedings.

ITEM 1A. RISK FACTORS

You should carefully consider the following risk factors, as well as the other information in this Quarterly Report on Form 10-Q, and in our other public filings. The occurrence of any of the following risks could harm our business, financial condition, results of operations and/or growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this Quarterly Report on Form 10-Q and those we may make from time to time. You should consider all of the risk factors described when evaluating our business. We have marked with an asterisk (*) those risk factors below that reflect significant changes from the risk factors included in our Annual Report on Form 10-K for the year ended December 31, 2017.

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 six months ended June 30, 2018 and 2017, we reported a net loss of $18.7 million and $22.4 million, respectively. As of June 30, 2018, we had an accumulated deficit of $137.6 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 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. We will continue to require substantial additional capital to continue our clinical development, manufacturing efforts and potential commercialization activities. Accordingly, we will need to raise substantial additional capital to continue to fund our operations. The amount and timing of our future funding requirements will depend on many factors, including 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 advance our four clinical development programs for potentially three indications. In addition, at our recent meeting with the FDA in February 2018, the FDA confirmed that a single, 300 patient pivotal study would be required for the filing of an NDA with the FDA and would need significant additional resources in order to fund such potential pivotal study. While we have not yet commenced pivotal clinical studies for any product candidate and it may be several years, if ever, before we complete pivotal clinical studies and have a product candidate approved for commercialization, we expect to invest significant funds into these 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.

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;
- in-license or acquire additional product candidates;
- undertake the manufacturing or have manufactured our product candidates;

- advance our programs into larger, more expensive clinical studies;
- initiate additional nonclinical, clinical, or other studies for our product candidates;
- identify, educate and develop potential commercial opportunities, such as lonafarnib for HDV, Lambda for HDV, exendin 9-39 for PBH and ubenimex for lymphedema;
- seek regulatory and marketing approvals and reimbursement for our product candidates;
- establish a sales, marketing, and distribution infrastructure to commercialize any products for which we may obtain marketing approval and market ourselves;
- seek to identify, assess, acquire, and/or develop other product candidates;
- make milestone, royalty or other payments under third-party license agreements;
- seek to maintain, protect, and expand our intellectual property portfolio;
- seek to attract and retain skilled personnel;
- create additional infrastructure to support our operations as a public company and our product development and planned future commercialization efforts; and
- experience any delays or encounter issues with the development and potential for regulatory approval of our clinical candidates such as safety issues, clinical trial accrual delays, longer follow-up for planned studies, additional major studies, or supportive studies necessary to support marketing approval.

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

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

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

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

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

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

To the extent that we raise additional capital through the sale of equity, debt or other securities convertible into equity, your ownership interest will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect your rights as a common stockholder such as the Loan and Security Agreement we entered into with Oxford Finance LLC, or Oxford Finance, in December 2016, or the Oxford Loan. This 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. Our ability to access the final $5.0 million under the Oxford Loan was subject to our ability to achieve certain clinical milestones. In August 2018, we drew the final $5.0 million. The Oxford 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 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 manage our covenants, our financial conditions and results of operations could be adversely affected.

The Oxford Loan provides for up to $25.0 million in term loans due on July 1, 2021, of which all $25.0 million in term loans have been borrowed to date. All of our current and future assets, except for intellectual property, are secured for 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, or to refuse to permit additional borrowings under the Oxford Loan. 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, which 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 restrict access to additional borrowings under the Oxford Loan. We satisfied ourselves that we will have access to future alternate sources of capital, including cash flow from our own operations, equity capital markets or debt capital markets in order to repay any principal borrowed, which we may be unable to do, in which case, our liquidity and ability to fund our operations may be substantially impaired.

Risks Related to the Development of our Product Candidates

We are heavily dependent on the success of our product candidates, which are in the early 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 currently generate no revenue from sales of any drugs, and we may never be able to develop or commercialize a product candidate.

We currently have one product candidate that is about to enter Phase 3 clinical trials and three Phase 2 development programs focused on three separate indications. We also expanded our pipeline by adding lonafarnib for the treatment of progeria and progeroid laminopathies. For one of our product candidates, ubenimex, data to date has been developed for use in indications other than those that we have rights to or in which we plan to develop the product candidate and most of the data has been developed for a dose lower than in our current studies. In January 2018, we announced that Phase 2 LIBERTY study results for the use of ubenimex in pulmonary arterial hypertension (PAH) demonstrated no improvement overall or in key subgroups for both the primary efficacy endpoint of pulmonary vascular resistance (PVR) and the secondary endpoint of 6-minute walk distance. The company has discontinued development of ubenimex in PAH based on these results.

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.

In addition, none of our product candidates have advanced into a pivotal study for our proposed indications and it may be years before such studies are initiated and completed, if at all. At our February 2018 meeting with the FDA with respect to the positive entry of lonafarnib into pivotal clinical trial, the FDA agreed that a successful single pivotal trial would enable an NDA filing, however, additional details of the proposed pivotal study will need to be discussed and finalized with the FDA. The timing of these discussions with the FDA are uncertain and may not meet our timelines for the planned initiation of a Phase 3 study of lonafarnib by the end of 2018.

We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates. We cannot be certain that any of our product candidates will be successful in clinical studies or receive regulatory approval. Further, our product candidates may not receive regulatory approval even if they are successful in clinical studies. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations.

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

Our approach to identifying and developing product candidates depends, in large part, on our ability to obtain orphan drug designation from regulatory authorities in major markets. Without the potential protection of this regulatory exclusivity upon approval, many of our product candidates would otherwise not justify investment. While we assess the potential for obtaining orphan drug designation at the time that we contemplate the acquisition of product candidates and we intend to timely file for such designation, there can be no assurance that we will obtain orphan drug designation or be able to successfully meet the regulatory requirements to maintain that designation with the planned clinical trials for our product candidates. Failure to obtain orphan drug designation would make our product candidates significantly less competitive and potentially not viable investments for further development. Although we already obtained orphan drug designation for four of our product candidates in three 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.

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.

For example, our lonafarnib product candidate has been studied in thousands of oncology patients and the most common non-hematologic adverse events of any grade were gastrointestinal system disorders (nausea, anorexia, diarrhea and vomiting), weight loss, fatigue and rash. There is no guarantee that additional or more severe side effects will not be identified through ongoing clinical studies by other uses of lonafarnib for other indications or our own clinical trials. Additionally, while we have a license to another farnesyltransferase inhibitor compound, tipifarnib, from Janssen Pharmaceutica, N.V., or Janssen, Janssen has granted rights of tipifarnib to Kura Oncology, Inc., or Kura, in oncology and negative results or undesirable side effects from Kura's clinical trials for a compound with a similar mechanism of action may negatively impact the perception of lonafarnib for anti-viral indications. Merck may also grant rights to other anti-viral or potentially other indications to other third parties. Undesirable side effects and negative results for other indications may negatively impact the development and potential for approval of our product candidates for our proposed indications.

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

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

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

Even if we obtain regulatory approval for a product candidate, we will remain subject to ongoing regulatory requirements.

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

Manufacturers and manufacturers' facilities are required to continuously comply with FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to current Good Manufacturing Practices, or cGMP, regulations and corresponding foreign regulatory manufacturing requirements. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any NDA or marketing authorization application, 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 IV clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. We will be required to report certain adverse reactions and production problems, if any, to the FDA and comparable foreign regulatory authorities.

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

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing, or labeling of a product, the regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

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

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

We rely on third parties to conduct our clinical studies, manufacture our product candidates and perform other services. If these third parties do not successfully perform and comply with regulatory requirements, we may not be able to successfully complete clinical development, obtain regulatory approval or commercialize our product candidates and our business could be substantially harmed.

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

If any of our relationships with investigators or third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs in a timely manner or do so on commercially reasonable terms. In addition, our CROs may not prioritize our clinical studies relative to those of other customers and any turnover in personnel or delays in the allocation of CRO employees by the CRO may negatively affect our clinical studies. If investigators or CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, our clinical studies may be delayed or terminated and we may not be able to meet our current plans with respect to our product candidates. CROs may also involve higher costs than anticipated, which could negatively affect our financial condition and operations.

In addition, we do not currently have, nor do we plan to establish the capability to manufacture product candidates for use in the conduct of our clinical studies, 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 future clinical studies. With respect to our Lambda program, as part of the license agreement, we obtained a substantial inventory of product from BMS sufficient to initiate our clinical trials. During 2017 we transferred the manufacturing technology to our third-party vendors. With respect to our ubenimex programs we have relied on Nippon Kayaku to provide us with product to conduct our trials in 2016 and 2017 and have now completed the process of transferring the manufacturing of ubenimex to our third-party vendors in the United States and such drug product will be adequate to complete ongoing and future 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. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements, known as cGMPs, for manufacture of our product candidates. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

We do not yet have sufficient information to reliably estimate the cost of the commercial manufacturing of our product candidates, and the actual cost to manufacture our product candidates could materially and adversely affect the commercial viability of our product candidates. As a result, we may never be able to develop a commercially viable product.

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

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

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

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

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

We focus our product development principally on treatments for rare diseases. Given the small number of patients who have the diseases that we are targeting, our eligible patient population and pricing estimates may differ significantly from the actual market addressable by our product candidate. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including the scientific literature, patient foundations, or market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. The number of patients may turn out to be lower than expected. For example, for lonafarnib and Lambda, HDV is associated with hepatitis B virus infection, which is a pre-requisite for the replication of HDV. Although we believe that the data are supportive of the increased severity of hepatitis in the presence of hepatitis D and hepatitis B virus co-infection compared to hepatitis B alone, 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.

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., Hepatera, Arrowhead Pharmaceuticals, Novartis International AG, and Xeris Pharmaceuticals as well as other smaller companies or biotechnology startups and large multinational pharmaceutical companies. Many of our competitors have substantially greater financial, technical, and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations. Additional mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. As a result, these companies may obtain regulatory approval more rapidly than we are able to and may be more effective in selling and marketing their products as well. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring, or licensing on an exclusive basis, products that are more effective or less costly than any product candidate that we may develop, or achieve earlier patent protection, regulatory approval, product commercialization, and market penetration than we do. Additionally, technologies developed by our competitors may render our potential product candidates uneconomical or obsolete, and we may not be successful in marketing our product candidates against competitors.

We currently have limited marketing and sales experience. If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate any revenue.

Although certain of our employees may have marketed, launched and sold other pharmaceutical products in the past while employed at other companies, we have no recent experience selling and marketing our product candidates and we currently have no marketing or sales organization. To successfully commercialize any products that may result from our development programs, we will need to invest in and develop these capabilities, either on our own or with others, which would be expensive, difficult and time consuming. Any failure or delay in the timely development of our internal commercialization capabilities could adversely impact the potential for success of our products.

Further, given our lack of prior experience in marketing and selling biopharmaceutical products, we may rely on future collaborators to commercialize our products. If collaborators do not commit sufficient resources to commercialize our future products and we are unable to develop the necessary marketing and sales capabilities on our own, we will be unable to generate sufficient product revenue to sustain or grow our business. We may be competing with companies that currently have extensive and well-funded marketing and sales operations, in particular in the markets our product candidates are intended to address. Without appropriate capabilities, whether directly or through third-party collaborators, we may be unable to compete successfully against these more established companies.

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

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

- the efficacy of the product as demonstrated in clinical studies and potential advantages over competing treatments;
- the prevalence and severity of the disease and any side effects;
- the clinical indications for which approval is granted, including any limitations or warnings contained in a product's approved labeling;
- the convenience and ease of administration;
- the cost of treatment;
- the willingness of the patients and physicians to accept these therapies;
- the marketing, sales and distribution support for the product;
- the publicity concerning our products or competing products and treatments; and
- the pricing and availability of third-party insurance coverage and reimbursement.

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

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

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

In addition, there is significant uncertainty related to the insurance coverage and reimbursement for newly approved products. In the United States, the principal decisions about coverage and reimbursement for new drugs are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services, as CMS decides whether and to what extent a new drug will be covered and reimbursed under Medicare. Private payors tend to follow the coverage reimbursement policies established by CMS to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement for products such as ours and what reimbursement codes our products may receive.

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

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to limit or reduce healthcare costs may result in restrictions on coverage and the level of reimbursement for new products and, as a result, they may not cover or provide adequate payment for our products. We expect to experience pricing pressures in connection with products due to the increasing trend toward managed healthcare, including the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs has and is expected to continue to increase in the future. As a result, profitability of our products may be more difficult to achieve even if they receive regulatory approval.

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

Our business strategy is to focus on product candidates for which orphan drug designation may be obtained in the major markets of the world. In addition, we rely or will rely upon a combination of patents, trade secret protection, and confidentiality agreements to protect the intellectual property related to our technologies and product candidates. For example, the portfolio of patents licensed from Merck expires before the anticipated launch date of the lonafarnib product candidate. Our success depends in large part on our and our licensors' ability to obtain regulatory exclusivity and maintain patent and other intellectual property protection in the United States and in other countries with respect to our proprietary technology and products.

Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is intended to treat a rare disease or condition, defined as a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the European Union, or the EU, the EMA's Committee for Orphan Medicinal Products, or COMP, grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention, or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the EU. Additionally, designation is granted for products intended for the diagnosis, prevention, or treatment of a life-threatening, seriously debilitating or serious and chronic condition when, without incentives, it is unlikely that sales of the drug in the EU would be sufficient to justify the necessary investment in developing the drug or biological product or where there is no satisfactory method of diagnosis, prevention, or treatment, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition.

In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. In addition, if a product receives the first FDA approval for the indication for which it has orphan drug designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity or where the manufacturer is unable to assure sufficient product quantity. In the EU, orphan drug designation entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity following drug or biological product approval. This period may be reduced to six years if the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity.

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

Even though we have orphan drug designation for lonafarnib in the United States and Europe, we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing pharmaceutical products. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition. Even after an orphan drug is approved, the FDA or EMA can subsequently approve the same drug with the same active moiety for the same condition if the FDA or EMA concludes that the later drug is safer, more effective, or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a product candidate nor gives the product candidate any advantage in the regulatory review or approval process.

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

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

We, independently or together with our licensors, have filed several patent applications covering various aspects of our product candidates. We cannot offer any assurances about which, if any, patents will issue, the breadth of any such patent or whether any issued patents will be found invalid and unenforceable or will be threatened by third parties. Any successful opposition to these patents or any other patents owned by or licensed to us after patent issuance could deprive us of rights necessary for the successful commercialization of any product candidates that we may develop. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced.

Although we have licensed a number of patents covering methods of use and certain compositions of matter, we do not have complete patent protection for our product candidates. For example, the patent coverage for lonafarnib expires before the anticipated launch date. Likewise, most of the patents or applications covering products that we have licensed in from Stanford have limited protection outside of the United States. Therefore, a competitor could develop the same or similar product that may compete with our product candidate.

Certain of our product licenses are limited to specified indications or therapeutic areas which may result in the same compound being developed and commercialized by a third party whom we have no control over or rights against. This may result in safety data, pricing or off label uses from that third party's product that may negatively affect the development and commercialization of our product candidates. For example, Kura has an exclusive license to tipifarnib for use in cancer indications while we have a license for anti-viral indications. As a result of Kura's right to use the same compound in a different indication, it is possible that development and sales may impact our product development and commercialization efforts. If we cannot obtain and maintain effective protection of exclusivity from our regulatory efforts and intellectual property rights, including patent protection, for our product candidates, we may not be able to compete effectively and our business and results of operations would be harmed.

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

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

Patent term extensions under the Hatch-Waxman Act in the United States and under supplementary protection certificates in Europe may be available to extend the patent or data exclusivity terms of products. With respect to ubenimex, lonafarnib, Lambda and exendin 9-39, 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 agreements for our ubenimex and lonafarnib product candidates. 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, and other obligations on us. If we fail to comply with our obligations under these agreements, or we are subject to a bankruptcy, our agreements may be subject to termination by the licensor, in which event we would not be able to develop, manufacture or market products covered by the license or subject to supply commitments.

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

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

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

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions, or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

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

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

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

Filing, prosecuting, and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. Likewise, certain of our license agreements, for example for ubenimex, do not include patents or patent applications outside of the United States as our licensor elected not to file in foreign jurisdictions. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may also export infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

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

Risks Related to our Business Operations

Our future success depends in part on our ability to retain our President and Chief Executive Officer and to attract, retain, and motivate other qualified personnel.

We are highly dependent on David Cory, our President and Chief Executive Officer, the loss of whose services may adversely impact the achievement of our objectives. Mr. Cory could leave our employment at any time, as he is an "at will" employee. Recruiting and retaining other qualified employees, consultants, and advisors for our business, including scientific and technical personnel, will also be critical to our success. There is currently a shortage of highly qualified personnel in our industry, which is likely to continue. As a result, competition for personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for individuals with similar skill sets. In addition, failure to succeed in development and commercialization of our product candidates may make it more challenging to recruit and retain qualified personnel. The inability to recruit and retain qualified personnel, or the loss of the services of Mr. Cory may impede the progress of our research, development, and commercialization objectives and would negatively impact our ability to succeed in our in-licensing strategy.

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

As of June 30, 2018, we had 16 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 in our information technology and storage systems, including data breaches subject to the new General Data Protection Regulation in the European Union, 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. IT systems are vulnerable to risks and damages from a variety of sources, including telecommunications or network failures, malicious human acts and natural disasters. 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.

Specifically, data security breaches, whether by employees or others, may expose sensitive data to unauthorized persons. Effective May 25, 2018, the EU will implement the General Data Protection Regulation, or GDPR, a broad data protection framework that expands the scope of current EU data protection law to non-European Union entities that process, or control the processing of, the personal information of EU subjects, including clinical trial data The GDPR allows for the imposition of fines and/or corrective action on entities that improperly use or disclose the personal information of EU subjects, 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 patient information, including personally identifiable information or protected health information, could 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. The GDPR will impose several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, the security and confidentiality of the personal data, data breach notification and the use of third party processors in connection with the processing of personal data. The GDPR will also impose strict rules on the transfer of personal data out of the EU to the United States, will provide an enforcement authority and will impose large penalties for noncompliance, including the potential for fines of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. The GDPR will increase our responsibility and liability in relation to personal data that we process, including in clinical trials, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, which could divert management's attention and increase our cost of doing business. If we are unable to prevent such data security breaches

or privacy violations or implement satisfactory remedial measures, our operations could be disrupted, and we may suffer 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 can be difficult to detect, and any delay in identifying 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 to protect our data security and information technology systems, such measures may not prevent such events.

Despite precautionary measures to prevent unanticipated problems, including data breaches, that could affect our IT systems, sustained or repeated system failures that interrupt our ability to generate and maintain data could adversely affect our ability to operate our business.

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

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

- our research or business development methodology or search criteria and process may be unsuccessful in identifying potential product candidates;
- we may not be able or willing to assemble sufficient resources to acquire or discover additional product candidates;
- our product candidates may not succeed in preclinical or clinical testing;
- our potential product candidates may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- product candidates we develop may be covered by third parties' patents or other exclusive rights;
- the market for a product candidate may change during our program so that such a product may become unreasonable to continue to develop;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by patients, the medical community, or third-party payors.

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

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

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or the ACA, was passed, which substantially changes the way health care is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. Some of the provisions of the Affordable Care Act have yet to be fully implemented, and since its enactment, there have been judicial and Congressional challenges to numerous provisions of the ACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the ACA. Since January 2017, President Trump has signed two Executive Orders designed to delay the implementation of any certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain mandated fees under the ACA, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018, among other things, amends the ACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". The Trump administration has also announced that it will discontinue the payment of cost-sharing reduction, or CSR, payments to insurance companies until Congress approves the

appropriation of funds for the CSR payments. The loss of the CSR payments is expected to increase premiums on certain policies issued by qualified health plans under the ACA. A bipartisan bill to appropriate funds for CSR payments has been introduced in the Senate, but the future of that bill is uncertain. Further, each chamber of Congress has put forth multiple bills designed to repeal or repeal and replace portions of the ACA. Although none of these measures has been enacted by Congress to date, Congress may consider other legislation to repeal and replace elements of the ACA. Any repeal and replace legislation may have the effect of limiting the amounts that government agencies will pay for healthcare products and services. Policy changes, including potential modification or repeal of all or parts of the ACA or the implementation of new health care legislation could result in significant changes to the health care system, which may prevent us from being able to generate revenue, attain profitability or commercialize our drugs. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand or lower pricing for our product candidates, or additional pricing pressures.

In the United States, the EU and other potentially significant markets for our product candidates, government authorities and third-party payors are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which has resulted in lower average selling prices. For example, in the United States, there have been several recent Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. Furthermore, the increased emphasis on managed healthcare in the United States and on country and regional pricing and reimbursement controls in the EU will put additional pressure on product pricing, reimbursement and usage, which may adversely affect our future product sales and results of operations. These pressures can arise from rules and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and healthcare reform, pharmaceutical reimbursement policies and pricing in general.

We may be subject, directly or indirectly, to 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 has not fully complied, with such laws, it could face substantial penalties.

If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our operations may be subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, the federal False Claims Act, and physician sunshine laws and 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 both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology and Clinical Health Act, or HITECH, and our implementing regulations, which imposes certain requirements relating to the privacy, security, and transmission of individually identifiable health information;
- The Physician Payments Sunshine Act requires manufacturers of drugs, devices, biologics, and medical supplies to report annually to the U.S. Department of Health and Human Services information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations; and

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payors, including commercial insurers, state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

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 and criminal penalties, damages, fines, exclusion from participation in government health care programs, such as Medicare and Medicaid, imprisonment, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

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

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

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

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

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

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

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

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

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

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

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

We have conducted in the past and are currently conducting clinical trials in the United States; Canada; Sydney, Australia; Ankara, Turkey; Hannover, Germany; Karachi, Pakistan; Auckland, New Zealand and Jerusalem and Beersheba, Israel, and accordingly, we are subject to risks associated with doing business globally, including commercial, political, and financial risks. Emerging regions, such as Eastern Europe, Latin America, Asia, and Africa, as well as more developed markets, such as the United Kingdom, France, Germany, and Australia, provide clinical study opportunities for us. In addition, we are subject to potential disruption caused by military conflicts; potentially unstable governments or legal systems; civil or political upheaval or unrest; local labor policies and conditions; possible expropriation, nationalization, or confiscation of assets; problems with repatriation of foreign earnings; economic or trade sanctions; closure of markets to imports; anti-American sentiment; terrorism or other types of violence in or outside the United States; health pandemics; and a significant reduction in global travel. For example, both Turkey and Pakistan are key regions for clinical activity relating to Hepatitis Delta, and further outbreaks of violence and political instability in the region could disrupt our clinical operations or otherwise limit our ability to access or conduct clinical studies in those regions. Our success will depend, in part, on our ability to overcome the challenges we encounter with respect to these risks and other factors affecting U.S. companies with global operations. If our global clinical trials were to experience significant disruption due to these risks or for other reasons, it could have a material adverse effect on our financial results.

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

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

Risks Related to Celladon's Historical Business Operations

We are the subject of securities class action lawsuits that were filed against Celladon in 2015, and additional securities litigation may be brought against us in the future.

In July 2015, following Celladon's announcements of the negative CUPID 2 data and the suspension of further research and development activities and the subsequent declines of the price of its common stock, three putative class actions were filed in the U.S. District Court for the Southern District of California against Celladon and certain of its current and former officers. The complaints generally alleged that the defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, by making materially false and misleading statements regarding the clinical trial program for MYDICAR, thereby artificially inflating the price of Celladon's common stock. The complaints sought unspecified monetary damages and other relief, including attorneys' fees. On December 9, 2015, the district court consolidated the three putative securities class actions and appointed a lead plaintiff to represent the putative class. The lead plaintiff filed a consolidated amended complaint on February 29, 2016.

On October 7, 2016, the district court granted defendants' motion to dismiss the consolidated amended complaint and granted leave to amend within 60 days from the date of the district court's order. The lead plaintiff subsequently filed a notice of intent not to amend the consolidated amended complaint and instead indicated that it intended to appeal the district court's decision. On December 9, 2016, the district court closed the case.

On December 28, 2016, the lead plaintiff filed a notice to the United States Court of Appeals for the Ninth Circuit appealing the district court's order dismissing the consolidated amended complaint. On May 5, 2017, the lead plaintiff filed his opening brief. On July 5, 2017, the defendants filed their appellate brief response. On August 18, 2017, the lead plaintiff filed his reply appellate brief. Oral arguments are scheduled to be heard on August 28, 2018 before the Ninth Circuit Court of Appeals.

It is possible that additional suits will be filed, or allegations made by stockholders, with respect to these same or other matters and also naming us and/or our former officers and directors as defendants. We believe that we have meritorious defenses and intend to defend these lawsuits vigorously. We are not able to predict or reasonably estimate the ultimate outcome or possible losses relating to these claims. While we and Celladon's former directors and officers have a separate liability insurance policy dedicated to any claims that may arise from premerger events, there is no assurance that the coverage will be sufficient. In addition, any such litigation could result in substantial costs and a diversion of our management's attention and resources, which could harm 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 or NDA 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.

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

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

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

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

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

If existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after legal restrictions on resale lapse, the trading price of our common stock could decline. Certain of our existing stockholders, including Vivo Ventures Fund VI, L.P. and Interwest Partners X, L.P., and their respective affiliated entities, own substantial ownership interest in our common stock and any decision to sell a significant number of shares may negatively impact the price of our common stock.

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

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

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

On December 22, 2017, President Trump signed into law new tax legislation, or the Tax Act, which significantly changes the Internal Revenue Code of 1986, as amended, or the Code. The Tax Act, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%; limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses); for net operating losses generated after 2017, limitation of the deduction to 80% of current year taxable income, indefinite carryforward of net operating losses and elimination of net operating loss carrybacks; changes in the treatment of offshore earnings regardless of whether they are repatriated; 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 impact of this tax reform on holders of our common stock is also uncertain and could be adverse. This annual report does not discuss any such tax legislation or the manner in which it might affect us or our stockholders in the future. We urge our stockholders to consult with their legal and tax advisors with respect to such legislation.

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 net operating loss 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. In addition, under the Code and similar state provisions, certain substantial changes in our ownership could result in an annual limitation on the amount of net operating loss carry-forwards that can be utilized in future years to offset future taxable income. The annual limitation may result in the expiration of net operating losses and credit carry-forwards before utilization. Moreover, if a corporation undergoes an “ownership change” within the meaning of Section 382 of the Code, or Section 382, the corporation’s net operating loss 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 an ownership change and, accordingly, Celladon’s and Eiger’s NOL carryforwards and certain other tax attributes will be subject to further limitations on their use. We assessed whether Eiger had an ownership change, as defined by Section 382 of the Code, that occurred from our formation through December 31, 2016. Based upon this assessment no reduction was made to the federal and state NOL carryforwards or federal and state tax credit carryforwards under these rules. Additional ownership changes in the future could result in additional limitations on the combined organization’s net operating loss carryforwards. Consequently, even if we achieve profitability, we may not be able to utilize a material portion of our NOL carryforwards and other tax attributes, which could have a material adverse effect on cash flow and results of operations. A full valuation allowance has been provided for the entire amount of our remaining net operating losses.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibit Number	Description of Document
3.1	Amended and Restated Certificate of Incorporation of Celladon Corporation (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K of Celladon Corporation, filed with the SEC on February 10, 2014).
3.2	Amended and Restated Bylaws of Celladon Corporation (incorporated by reference to Exhibit 3.2 to the Current Report on Form 8-K, filed with the SEC on February 10, 2014).
3.3	Certificate of Amendment of Amended and Restated Certificate of Incorporation of Celladon Corporation (incorporated by reference to Annex D to the Registration Statement on Form S-4, as amended (File No. 333-208521), originally filed with the SEC on December 14, 2015).
3.4	Certificate of Amendment of Amended and Restated Certificate of Incorporation of Celladon Corporation (incorporated by reference to Annex E to the Registration Statement on Form S-4, as amended (File No. 333-208521), originally filed with the SEC on December 14, 2015).
10.1	Master Services Agreement, dated April 26, 2018, by and between Eiger BioPharmaceuticals, Inc. and Clinigen Healthcare Ltd.
10.2#	Amendment No. 6 to License Agreement, dated September 2, 2010, by and between Eiger BioPharmaceuticals, Inc. and Merck Sharp & Dohme Corp.
10.3#	Collaboration and Supply Agreement, dated May 15, 2018, by and between Eiger BioPharmaceuticals, Inc. and The Progeria Research Foundation.
10.4	Second Amendment to Loan and Security Agreement, dated May 11, 2018, by and between Eiger BioPharmaceuticals, Inc. and Oxford Finance LLC.
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+	Certification 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.

Confidential treatment has been requested from the Securities and Exchange Commission for portions of this exhibit.

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: August 10, 2018

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

Eiger BioPharmaceuticals, Inc.

Date: August 10, 2018

By: /s/ James Welch
James Welch
Chief Financial Officer
(Principal Financial Officer)

Exhibit 10.1

Dated 26th April 2018

CLINIGEN HEALTHCARE LTD

and

EIGER BIOPHARMACEUTICALS, INC.

MASTER SERVICES AGREEMENT

Contents

This Agreement is made on 26th April 2018

Between

1) CLINIGEN HEALTHCARE LTD a company incorporated in England (registered number 06252720), whose registered office is at Pitcairn House, Crown Square, Centrum 100, Burton-on-Trent, Staffordshire DE14 2WW, United Kingdom (Clinigen):

2) Eiger BioPharmaceuticals, Inc., a Delaware company with its principal place of business located at 350 Cambridge Avenue, Suite 350, Palo Alto, CA 94306, USA (Client),

Individually a **Party** and collectively, the **Parties**.

Whereas

A. Clinigen has expertise in the provision and distribution of unlicensed pharmaceutical products and associated services prior to the grant of marketing authorisation and/or commercial launch in the country of supply, as permitted under applicable local laws and regulations.

B. Clinigen is also in the business of procuring and supplying certain pharmaceutical products for use in clinical trials and investigator initiated studies and providing associated services thereto.

C. Client wishes to engage Clinigen to provide certain pharmaceutical products and/or services, as described in the relevant Service Specific Terms and/or SOW/s.

It is agreed

1. Definitions and Interpretation

1.1. In this Agreement the following words have the following meanings:

Affiliate means in relation to either Party, any company, partnership or other person which directly or indirectly Controls, is Controlled by, or is under common Control with such Party from time to time.

Agreement means these Conditions and the Service Specific Terms;

Business Day means any day other than a Saturday or Sunday or a public or bank holiday in England or California.

Charges means the net charges and fees payable by Client as set out in a SOW;

Clinigen Background Intellectual Property means all report templates and formats flow chart templates and formats, know-how including but not limited to Unlicensed Supply processes and methodologies, regulatory strategies and solutions, regulatory feasibility reports, standard documents and templates, inventions, discoveries, procedures, Clinigen's Intellectual Property Rights, including Clinigen's Confidential Information and Clinigen's internet based data portal and reporting functionality, in each case as used by Clinigen and its Affiliates as of the

SOW Effective Date and any subsequent developments or improvements thereto during the SOW Term, but excluding Client New IP (as defined in Clause 11.5);

Client Trade Marks means the trademarks and trade names listed in the SOW and such other trademarks and trade names as Client notifies to Clinigen in writing from time to time after the SOW Effective Date;

Commercially Available means the date of commercial launch on a country by country basis in the Territory of the commercial Product pack specific to the country following grant of Marketing Authorisation and, where applicable, following the agreement of commercial pricing for the Product with the relevant health authority in that country;

Conditions means these terms and conditions excluding the Service Specific Terms;

Consignment Stock means stocks of Products which are held by Clinigen in its premises but which are owned by the Client until title passes to Clinigen in accordance with the terms of this Agreement;

Control means the beneficial ownership of more than 50 (fifty) percent of the issued share capital or the legal power to direct or cause the direction of the general management of the company, partnership or other person in question, and **Controlled** shall be construed accordingly;

Customer means a third party in the Territory to whom Clinigen supplies a Product pursuant to a Customer Order;

Customer Order means an order for a Product placed by a Customer which has been accepted by Clinigen;

Data Protection Legislation means any data protection legislation currently in force and that is applicable to the Services being provided under this Agreement, including but not limited to (i) unless and until the GDPR is no longer directly applicable in the UK, the General Data Protection Regulation (*(EU) 2016/679*) and any national implementing laws, regulations and secondary legislation, as amended or updated from time to time, in the UK and (ii) any successor legislation to the GDPR or the Data Protection Act 1998;

Data Subject means an individual who is the subject of Personal Data;

Effective Date means the date of this Agreement;

Force Majeure means any circumstances beyond the reasonable control of the relevant Party (including, without limitation, any strike, lock-out or other form of industrial action, acts of God, war or national emergency, an act of terrorism, riot, civil commotion, malicious damage, compliance with any law or government order, rule, regulation or direction, accident, fire, flood, or storm) which prevents that Party from complying with any or all of it obligations under this Agreement or a SOW;

Initial Term means the initial period of a SOW as may be specified in that SOW;

Intellectual Property Rights means all patents, rights to inventions, copyright, trademarks, business names and domain names, goodwill and the right to sue for passing off, database rights, rights to use, and protect the confidentiality of confidential information (including know-how and trade secrets) and all other intellectual property rights, in each case whether registered or unregistered and extension of, and rights to claim priority from, such rights and all similar or equivalent rights or forms of protection which subsist or will subsist now or in the future in any part of the world;

Marketing Authorisation means an authorisation for the sale and placing on the market of a Product within the Territory or a country within the Territory;

Personal Data has the meaning set out in the relevant Data Protection Legislation and relates only to personal data, or any part of such personal data of which the Client is the Data Controller and in relation to which the Supplier is providing services under this Agreement;

Process shall have the meaning set out in the relevant Data Protection Legislation, and “processing” and “processes” shall have a corresponding meaning;

Product means the pharmaceutical product/s specified in the relevant SOW;

Quality Technical Agreement means, where applicable, the separate Quality

Agreement to be entered into by the parties;

Regulatory Authorities means any competent regulatory authority in the Territory responsible for the regulation of the manufacture, sale and distribution of medicinal products;

Safety Data Exchange Agreement means, where applicable, the separate Safety

Data Exchange Agreement to be entered into by the parties;

Slavery and Human Trafficking has the meaning given to it in Section 54(12) of the Modern Slavery Act 2015;

Statement of Work or SOW means a schedule of terms relating to particular Products and/or Services;

Services means supplying or distributing Products or procuring their supply or distribution and/or other associated activities, as described in the applicable Service Specific Terms and each SOW;

Service Specific Terms means the terms set out in Exhibit A which apply when Clinigen is procuring unlicensed pharmaceutical products and providing associated services to the Client and/or the terms set out in Exhibit B which apply when Clinigen is procuring pharmaceutical products and providing associated services to the Client in respect of clinical trials or investigator initiated studies;

SOW Effective Date means the start date of any SOW as specified in that SOW;

SOW Terms means the period starting on the SOW Effective date and ending on the date specified in that SOW, subject to earlier termination of that SOW;

Term means the period of this Agreement which shall be five (5) Years, subject to (i) earlier termination of this Agreement; and/or (ii) any Initial Term;

Territory means the country/ies set out in the relevant SOW as varied by the Parties from time to time;

Third Party means a party other than Clinigen or the Client or any of their Affiliates;

Unlicensed Supply means the supply of Products which are not Commercially Available in the country of destination, or investigational drugs not registered in any country and which are lawfully supplied under any regulatory mechanism permitted in the Territory;

Year means the period of 12 (twelve) months beginning on the Effective Date (or SOW Effective Date) and each subsequent period of 12 (twelve) months commencing on the anniversary of the relevant effective date during the continuance of the relevant agreement (whether this Agreement, or a SOW).

1.2. Headings to the Clauses of any Exhibits to this Agreement are for convenience only and shall not affect its construction or interpretation.

1.3. References to Clauses are to the Clauses of these Conditions and references to Sections are to Sections of the Exhibits.

1.4. The word “indemnify” in this Agreement will mean to indemnify, keep indemnified and hold harmless the indemnified party from and against all costs (including the cost of enforcement), expenses, liabilities (including any tax liability), injuries, damages, claims, demands, proceedings or legal costs (on a full indemnity basis) and judgements which the indemnified party incurs or suffers and “indemnity”, indemnities and “indemnifies” have a corresponding meaning.

1.5. Any reference to “person” means a natural or legal person, firm or unincorporated association.

1.6. The terms “including”, “include”, “in particular” or any similar expression shall be construed as illustrative and shall not limit the sense of the words preceding those terms.

1.7. Words importing the singular the plural and vice versa.

2. Term

2.1. This Agreement will start on the Effective Date and will continue in force for the Term unless earlier terminated as provided herein.

2.2. A SOW will start on the SOW Effective Date and will continue in force for the SOW Term unless earlier terminated as provided herein.

3. Agreement Structure

3.1. This Agreement and any SOW entered into between the Parties are set up in a framework structure to allow the Client and its Affiliates to order various Products and/or Services from Clinigen and/or its Affiliates, from time to time which will be documented in an SOW.

3.2. Each SOW will constitute a separate agreement incorporating these Conditions and the relevant Service Specific Terms. Clinigen shall perform the Services in accordance with the applicable SOW, this Agreement and all applicable laws and regulations, and shall keep Client reasonable informed on the progress and results of the Services.

3.3. In the event of a conflict between any provision of these Conditions, the Service Specific Terms and/or any provision of a SOW;

a) the provisions of these Conditions shall take precedence over the Service Specific Terms; and

b) the Service Specific Terms shall take precedence over the provision of the SOW, in the event of any inconsistencies.

4. Confidentiality

4.1. Subject to Clause 4.3 each Party agrees that, during the Term of this Agreement and for a period of ten (10) years after the date of expiration or termination of this Agreement for any reason whatsoever, neither Party shall in any fashion, form or manner, either directly or indirectly, divulge, disclose or communicate to any individual or entity or utilise for such Party's own benefit or the benefit of any individual or entity in any manner whatsoever, any non-public information of any kind, nature or description disclosed by the other Party to such Party or obtained by such Party from the other Party under this Agreement, including such information concerning any matters affecting or relating to the business of the other Party of any kind, nature or description, which is by its nature confidential (regardless of whether the same has been marked "confidential") and any information obtained or resulting from the conduct of any audit which many be conducted in accordance with the provisions of this Agreement except with the express written consent of the other Party or as otherwise provided in this Agreement. The information described above shall be hereinafter collectively referred to as **Confidential Information**. For the purposes of this Agreement, a party divulging, disclosing or communicating Confidential Information shall be referred to as the **Disclosing Party** and the party receiving Confidential Information shall be referred to as the **Recipient**. Client New IP shall be deemed Confidential Information of Client and Clinigen shall be deemed the Recipient of such information, notwithstanding the fact that such information may be generated and disclosed by Clinigen to Client.

4.2. Notwithstanding any other provision of this Agreement, Confidential Information shall not include information that: (a) as shown by dated written or electronic records, the Recipient possessed prior to disclosure by the Disclosing Party free of any duty of confidence; (b) at the time of disclosure is or thereafter becomes known to or generally available to the public through no breach of this Agreement by the Recipient; (c) as shown by dated written or electronic records, is developed by the Recipient independent from any Confidential Information disclosed hereunder; (d) becomes available to the Recipient from a source, other than the Disclosing Party, which has represented to the Recipient (and which the Recipient has no reason to disbelieve after due inquiry and competent proof) that such source is not bound by a confidentiality agreement or any other obligation of confidentiality or fiduciary duty with the Disclosing Party; or (e) is explicitly, in writing, made exempt from the provisions of this Agreement by the Disclosing Party.

4.3. Notwithstanding any other agreement or any other provision of this Agreement, the Recipient may disclose Confidential Information which is required to be disclosed by law, rule, regulation, administrative or legal process or is requested to be disclosed by any governmental agency, including to the extent required to provide the Services (Compelled Request); provided, however, that the Recipient gives prompt prior written notice (if permitted by law) of any Compelled Request to the Disclosing Party and agrees to limit the scope of disclosure to the extent permitted by law and takes commercially reasonable measures to co-operate with the Recipient, if the Recipient seeks to challenge the Compelled Request.

4.4. Notwithstanding any other agreement or any other provision of this Agreement, the Parties may use and disclose Confidential Information to its Affiliates, employees, agents, subcontractors, professional advisers and auditors (or any of them) for the purposes of carrying out their respective obligations or exercising any of their respective rights under or in connection with under this Agreement and subject to each Party ensuring that the person in question complies with obligations of confidentiality no less onerous than those set out in this Clause 4.

4.5. Each Party recognises that the damages at law to the other Party may be an insufficient remedy to the other Party in the event that a Party breaches the terms of this Clause 4, and in the event a Party breaches or threatens to breach this Clause 4, the other Party shall be entitled to seek, upon application to a court of competent jurisdiction, a preliminary restraining order and permanent and temporary injunctions restraining the other Party from breaching this Clause 4, in addition to damages or any other relief the court may find appropriate.

5. Anti-Bribery and Corruption

5.1. Each Party shall not, and shall procure that its respective directors, employees, agents, representatives, contractors or sub-contractors shall not, engage in any activity, practice or conduct which would constitute an offence under any anti-bribery and anti-corruption laws, regulations and codes in any jurisdiction, including but not limited to the Bribery Act 2010 and, where applicable, the Foreign Corrupt Practices Act 1977.

5.2. Each Party shall have in place adequate procedures designed to prevent any person working for or engaged by that Party or any other Third Party in any way connected to this Agreement, any SOWs or Supply Orders, from engaging in any activity, practice or conduct which would infringe any anti-bribery and anti-corruption laws, regulations and codes in any jurisdiction, including but not limited to the Bribery Act 2010 and, where relevant, the Foreign Corrupt Practices Act 1977.

6. Modern Slavery

6.1. Clinigen shall and shall procure (where relevant) that all persons who are performing services or providing goods in connection with, or which will or may be used in performing or to support the performance of this Agreement or any SOW in any part of the world (collectively, its **Supply Chain**) shall at all relevant times:

a) comply with the provisions of the Modern Slavery Act 2015 and ensure that all of its relevant staff have received appropriate training on the same:

b) not engage in any activity, practice or conduct that would constitute an offence under the Modern Slavery Act 2015 if such activity, practice or conduct were carried out in the UK:

c) take all reasonable steps to ensure that Slavery and Human Trafficking are not taking place in its business or its Supply Chain:

d) immediately notify the Client if it has reason to believe that it or any person in its Supply Chain is engaged in Slavery and Human Trafficking or is in breach, or is likely to breach, the Modern Slavery Act 2015 or any provision of this Clause 6.1 (or would do so if it were a party to this Agreement), or if it receives a communication from any person alleging any of the foregoing.

7. Relationship of Parties

7.1. The Parties hereby agree and intend that the relationship of each to the other is that of independent contractors and that neither this Agreement nor any SOW or Supply Order shall be construed as an agreement of franchise, employment, partnership, joint venture or any other form of business entity. Neither Party shall exercise any direction or control over the methods by which the other Party (or such other Party's personnel) shall perform their work and duties while performing the obligations hereunder. The Parties agree that neither shall have the power or right to bind the other, nor shall either hold itself out as having such authority, nor shall a Party pledge the other Party's credit or extend credit to anyone in the other Party's name.

8. Data Protection

8.1. The provision of the Services may require Clinigen to Process Personal Data for and on behalf of the Client from time to time, acting as a Data Processor. Where such Processing of Personal Data takes place in the EEA or the UK, or otherwise involves the Processing of Personal Data of citizens in the EEA or the UK, the Parties acknowledge and agree that Clinigen shall:

i) process the Personal Data only on the documented instructions of the Client, except to the extent that any Processing of Personal Data is required by applicable laws to which Clinigen is subject;

ii) notify the Client where Clinigen believes any documented instructions from the Client in respect of the Processing of Personal Data infringe any Data Protection Legislation or any other applicable laws to which Clinigen is subject;

iii) ensure that its personnel who are authorised to Process the Personal Data have committed themselves to confidentiality;

iv) taking into account the nature of the Processing, assist the Client by appropriate technical and organisational measures, insofar as this is possible, for the fulfilment of the Client's obligation to respond to requests for exercising the Data Subject's rights under the Data Protection Legislation;

v) notify the Client without undue delay after becoming aware of any breach relating to the Personal Data;

vi) assist the Client in its compliance with Clause 8.6 below, insofar as it is able taking into account the nature of the Processing and the information available to Clinigen;

vii) at the Client's discretion, delete or return to the Client all of the Personal Data Processed under the applicable SOW at the end of the applicable SOW Term, and delete any copies of such Personal Data unless any applicable laws to which Clinigen is subject require that copies are kept; and

viii) make available to the Client all information, and submit to such audits (in each case to the extent reasonably necessary) as are required to demonstrate compliance with its obligations in this Clause 8.1.

8.2. Clinigen shall not sub-contract its Processing of Personal Data to a Third Party without the Client's prior specific or general written authorisation (not to be unreasonably withheld, conditioned or delayed). Clinigen shall inform the Client of any intended changes concerning the addition or replacement of any authorised sub-contractors, and the Client shall notify Clinigen of its approval or any objections it has to any such changes in writing within ten (10) Business Days, after which any such changes which the Client has not objected to in accordance with this Clause 8.2 shall be deemed to be accepted.

8.3. Where Clinigen sub-contracts its Processing of Personal Data to a Third Party in accordance with Clause 8.2 above, Clinigen shall ensure that the Third Party has necessary qualification and authorization to Process such Personal Data and is engaged on terms equivalent to those set out in this Clause 8, and Clinigen shall remain liable to the Client for any Processing of Personal Data by any such Third Party.

8.4. The Parties shall co-operate with any applicable regulator of the Data Protection Legislation on request in respect of the performance of its tasks under this Agreement and any SOW.

8.5. The Parties shall each implement appropriate technical and organisational measures to ensure a level of security appropriate to the risk of Processing in accordance with Article 32 of the GDPR.

8.6. To the extent required by the relevant Data Protection Legislation, Clinigen shall provide all reasonable assistance to the Client that is necessary to facilitate the Client's compliance with:

a) its breach notification requirements under the Data Protection Legislation; and

b) its obligations relating to conducting privacy impact assessments and (where applicable) liaising with the relevant regulator in relation to the same.

9. Audit Rights

9.1. Clinigen shall create and maintain complete and accurate records of all Services performed, including any data and information generated from such Services. If the Client gives at least 20 (twenty) Business Days' written notice (or in the event of a suspected material breach by Clinigen of the terms of this Agreement or a relevant SOW/s on 5 (five) Business Days' written notice), Clinigen will permit the Client or its representatives, no more than once in any

12 month period (excluding for cause audit) subject to Clause 9.2, access to the records maintained by Clinigen which specifically relate to the services provided, for the purposes of auditing, inspection or any other purpose required or permitted by applicable law, rule or regulation, at reasonable times during normal business hours provided always that Client undertakes to ensure that its representatives adhere to the confidentiality provisions contained in this Agreement.

9.2. Notwithstanding Clause 9.1 above, Clinigen may take reasonable measures to restrict Client, or its representatives, access to and inspection and audit of Clinigen's facilities in order to protect the confidentiality of Clinigen's other clients and their products and processes and Clinigen's books of accounts or financial records relating to its underlying costs.

9.3. Within twenty (20) Business Days of conducting an inspection requested pursuant to Clause 9.1, Client will provide Clinigen with a summary of its findings from such inspection**.**

9.4. Any information about Clinigen, Clinigen's facilities or otherwise obtained by Client as a result of inspections conducted by or on behalf of Client pursuant to Clause 9.1 above shall be treated as treated as the Confidential Information of Clinigen and shall be subject to the confidentiality obligations in Clause 4.

10. Invoicing and Taxation

10.1. All amounts set out in a SOW (and any Charges) are stated exclusive of any Value Added Tax (VAT) or similar tax, which if applicable, shall be payable in addition to the sum in question at the rate in force under the relevant law.

10.2. All customs duties, charges and/or taxes incurred by Clinigen in relation to Customer Order shipments which cannot be reclaimed by Clinigen or passed on to the relevant Customer will be charged by Clinigen to the Client and the Client will pay the same in accordance with the payment terms set out in this Clause 10.

10.3. Unless otherwise set out in the SOW, Clinigen shall invoice the Client on a monthly basis in relation to each SOW for the Charges in the amounts and at the times due in accordance with that SOW. Such Charges shall be paid by the Client to Clinigen within 30 (thirty) days' from the date of such invoice (unless otherwise set out in the SOW) by transfer to such bank account as Clinigen may from time to time notify in writing to the Client.

10.4. Each Party shall be entitled to set-off any outstanding Charges due to it against its payment due to the other Party under this Agreement.

10.5. If a Party disputes any invoices (or any part thereof), that Party shall provide the other Party with written notice of such dispute within seven (7) days of receipt of such invoice. The Parties shall negotiate in good faith to resolve any such dispute promptly. The Party disputing the invoice shall, however, pay that portion of the invoice not in dispute. Once the dispute is resolved, and if payment is due by a Party, the payment shall be made within thirty (30) days of the date of resolution.

10.6. If any undisputed sum payable under a SOW is not paid when due then, without prejudice to its other rights under a SOW, Clinigen shall have the right to charge interest from the date on which the relevant invoice is due for payment, until the date on which the payment is made in full, both before and after any judgment, at a rate of four per cent (4%) per annum over HSBC Bank plc UK base rate from time to time.

11. Intellectual Property Rights

11.1. Subject to the provisions of this Clause 11, nothing in this Agreement or any SOW shall operate to assign or transfer any title or interest in any Intellectual Property Rights existing prior to the Effective Date of this Agreement or any relevant SOW.

11.2. The Client grants Clinigen a royalty free licence to use the Client Trade Marks in the Territory in relation to the performance of the Services for the purposes only of exercising its rights and performing its obligations under this Agreement and any and all SOW/s (including, without limitation, supplying, distributing and selling the Products (as applicable)). Subject to the aforesaid licence, Clinigen shall have no rights in respect of any Client Trade Marks or of the goodwill associated therewith.

11.3. Clinigen shall not without the prior written consent of the Client alter, remove or tamper with any Client Trade Marks.

11.4. All Clinigen Background Intellectual Property (including all and any improvements and developments thereto during the term of this Agreement and all SOWs) shall belong to Clinigen exclusively.

11.5. Subject to Clause 11.4, all Intellectual Property created during the term of this Agreement and all SOWs shall belong to the Client exclusively ("Client New IP"). Clinigen shall promptly disclose all Client New IP to Client. Clinigen shall and hereby does assign to Client all right, title and interest in and to all Client New IP, and agrees to take (and procure its employees, agents and contractors to take) such further actions reasonably requested by Client to evidence such assignment and to obtain and maintain patent and other intellectual property protection for Client New IP.

12. Insurance

12.1. During the Term of this Agreement and for six (6) years thereafter, each Party shall maintain with insurers or underwriters of good repute, such insurance relating to its business as is normally maintained by comparable businesses sufficient to meet its obligations under this Agreement or any SOW (including, in the case of the Client, commercial general liability insurance and product liability insurance) for any occurrence or series of occurrences within a twelve (12) month period covering: (i) all legal liability for death, personal injury and damage to or loss of property arising directly or indirectly out of the use, possession or operation of the Products supplied to Clinigen pursuant to this Agreement or any SOW.

12.2. On the written request of a Party, the other Party shall have its insurers furnish and provide the requesting Party with insurance certificates specifying the types and amounts of coverage in effect and the expiration dates of each policy upon written request.

13. Warranties

13.1. Clinigen represents and warrants that:

i) It shall hold and maintain all relevant licences and regulatory authorisations and shall comply with all applicable legal and regulatory requirements in relation to the supply and distribution of Products and the provision of the Services (where applicable) in the relevant Territories:

ii) all Services will be performed in a professional, workmanlike and timely manner and in compliance with these Conditions, the Service Specific Terms, the SOW and all applicable laws and regulatory requirements, and it will not infringe or misappropriate any intellectual property rights of any third party during its performance of the Services:

iii) it will inform the Client on a timely basis of any Product complaints that it receives from Customers;

iv) unless otherwise provided for in a Safety Data Exchange Agreement between the Parties, it will inform the Client of any adverse reaction(s) to the Products reported to it by any person within one (1) Business Day of cognisance.

v) neither it nor any of its employees are presently debarred, suspended, proposed for debarment or declared ineligible for the award of contracts by any government authority; and

vi) It is under no obligation to any Third Party which would prevent Client from carrying out its duties and other obligations under this Agreement or any SOW or which is inconsistent with the provisions herein contained.

13.2. The Client represents and warrants that:

i) It shall hold and maintain all licences necessary, and is authorised, to manufacture, assemble, package and label, export from the country of manufacture (if applicable) and supply the Client Products to Clinigen for Clinigen to distribute within the Territory in accordance with the terms of this Agreement and all relevant SOWs;

ii) It will comply with all applicable laws and regulatory requirements including, but without prejudice to the generality of the foregoing, those in relation to the manufacture, assembly, packaging, packing, labelling, export from the country of manufacture (if applicable) and/or supply of each of the Client Products to Clinigen;

iii) To Client's knowledge, the Client's Products, their manufacture, assembly, packaging and labelling, export from the country of manufacture (if relevant), use, supply to Clinigen and sale, supply or distribution of the Products and the use by Clinigen of the Client's Trade Marks in the Territory by Clinigen will not infringe the Intellectual Property Rights of any third party;

iv) the Client's Products and their packaging and labelling shall conform to their description, specification and data sheet or summary of product characteristics;

v) it has title to the Client's Products;

vi) neither it nor any of its employees are presently debarred, suspended, proposed for debarment or declared ineligible for the award of contracts by any government authority; and

vii) it is under no obligation to any Third Party which would prevent Client from carrying out is duties and other obligations under this Agreement or any SOW or which is inconsistent with the provisions herein contained.

14. Limits of Liability

14.1. Nothing in this Agreement and/or any SOW shall limit or exclude the liability of a Party for:

i) personal injury or death caused by its negligence;

ii) indemnification obligations under Clause 15;

iii) breach of confidentiality obligations under Clause 4; or iv)fraud or fraudulent misrepresentation.

14.2. Except as otherwise provided in this Agreement and/or SOW, neither Party shall be liable to compensate the other Party whether in contract, tort (including negligence) breach of statutory duty, misrepresentation or otherwise for any

i) special, indirect or consequential loss or damage;

ii) loss of profit;

iii) loss of business; or

iv) loss of goodwill.

14.3. Subject to Clauses 14.1 and 14.2, the maximum aggregate liability of Clinigen and/or its Affiliates under or in connection with this Agreement and/or any SOW in respect of all acts and omissions whether in contract, tort (including, without limitation, negligence), under statute, breach of statutory duty or otherwise shall not exceed the sum set out in the relevant Service Specific Terms.

15. Indemnity

15.1 Clinigen shall indemnify the Client and/or its Affiliates and their respective officers, directors, employees, agents and subcontractors against and from all liabilities, in relation to Third Party claims that arise out of or in connection with the following:

15.1.1 fraud, wilful misconduct or negligence by Clinigen and/or its Affiliates and their respective officers, directors, employees, agents and subcontractors in relation to any SOW;

15.1.2 breach of the provisions of Clause 13.1 above.

15.2 Client shall indemnify Clinigen and and/or its Affiliates and their respective officers, directors, employees, agents and subcontractors against and from all liabilities including in relation to third party claims, that arise out of or in connection with any one or more of the following:

15.2.1 breach of the provisions of Clause 13.2 above;

15.2.2 fraud, wilful misconduct or negligence of the Client and/or its Affiliates and their respective officers, directors, employees, agents and subcontractors in relation to any SOW; and

15.2.3 any allegation or finding that the use of the Trade Marks or supply or sale of the Products by Clinigen in the Territory in accordance with this Agreement infringes the Intellectual Property Rights of any third party.

15.3 The process for claiming under an indemnity is set out in Clause 15.4 below.

15.4 Any indemnity given by a Party in the Service Specific Terms shall be conditional in each case upon the indemnified Party:

15.4.1 promptly giving written notice of any claim to be indemnified to the indemnifying Party;

15.4.2 providing the indemnifying Party with the absolute discretion to conduct, take or resist any proceedings as it sees fit at its own expense;

15.4.3 providing the indemnifying Party on request with such information and assistance in relation to such proceedings as it may reasonably require, subject to the indemnifying Party indemnifying the other Party against all costs reasonably incurred by it in the provision of such information or assistance; and

15.4.4 not making any settlement, compromise or prejudicial admission in relation to such claim without the prior consent of the indemnifying Party (such consent not to be unreasonably withheld or delayed).

16 Termination

16.1 Subject to any Initial Term, the Agreement or a SOW may be terminated by either Party at any time without cause by giving a minimum one hundred and eighty (180) day' written notice to the other Party of its intention to terminate the Agreement or a SOW (as the case may be).

16.2 Either Party shall have the right to terminate this Agreement or any SOW immediately (as applicable) by notice to the other if the other Party:

16.2.1 ceases, or threatens to cease to carry on business or suspends all or substantially all of its operations, or suspends payment of its debts; or

16.2.2 Is unable to pay its debts or becomes insolvent or an order is made or a resolution passed for the administration, winding-up or dissolution of the other Party (otherwise than for the purposes of a solvent amalgamation or reconstruction) or an administrative or other receiver, manager, liquidator, administrator, trustee or similar officer is appointed over all or any substantial part of the assets of the other Party or it enters into or proposes any composition or arrangement with its creditors generally or anything analogous to the foregoing occurs in any applicable jurisdiction;

16.2.3 commits any material breach of the Agreement or any SOW, or any Quality Technical Agreement or any Safety Data Exchange Agreement if, in the case of a breach capable of remedy, the other Party fails to remedy such breach within 30 (thirty) days after receipt of a notice giving full particulars of the breach and requiring it to be remedied.

16.3 The rights to terminate this Agreement given by Clauses 16.1 and 16.2 shall be without prejudice to any other right or remedy of either party in respect of the breach concerned (if any) or any other breach.

17 Consequences of Termination or Expiry

17.1 Termination or expiry of this Agreement will not affect a SOW unless such SOW is also terminated in accordance with the terms of that SOW.

17.2 Notwithstanding the expiry or the termination of this Agreement pursuant to Clause 16, the Parties agree that it shall remain in full force and effect in relation to any existing SOW/s until such time as all such SOWs are terminated or have expired.

17.3 Upon termination of this Agreement and/or a SOW for any reason at the written request of a Party and at that Party's expense, the other Party shall return or destroy any Confidential Information provided by the Disclosing Party under the Agreement and/or that SOW (whichever is terminated), save that each Party shall be entitled to retain copies of the other Party's Confidential Information to the extent necessary to comply with its regulatory or legal obligations (which copies shall remain subject to the confidentiality obligations set forth herein).

17.4 On expiry or the termination of this Agreement and all SOW/s for any reason the Quality Technical Agreement shall immediately terminate subject to any provisions therein which are expressly stated to remain in full force and effect on its expiry or termination.

17.5 Upon termination of a SOW Clinigen shall:

17.5.1 invoice Client for all outstanding Charges due for Services properly performed under the applicable SOW prior to and up to the date of termination;

17.5.2 be entitled to complete all Customer Orders in respect of Products held by Clinigen as Consignment Stock placed with Clinigen prior to the date of termination; and

17.5.3 in respect only of Consignment Stock of Products, at the request of the Client and subject to the Client paying the costs of transport and insurance in advance, return all or any part of the remaining Consignment Stock in relation to that SOW then held by Clinigen to the Client at the Client's risk. In such cases Clinigen will be responsible for arranging transportation and insurance. Alternatively, Clinigen will make available for collection by the Client all or any part of the remaining Consignment Stock in relation to that SOW then held by Clinigen. Any such Consignment Stock which the Client does not wish to be returned or collected may be destroyed by Clinigen on notice to the Client at the Client's expense.

17.6 Provisions in this Agreement which are either expressly stated to remain in force after the expiry or termination of this Agreement, or which should be deemed to do so by implication, shall continue to have full effect, including Clauses 1 (Definitions), 4 (Confidentiality), 8 (Data Protection), 10 (Invoicing and Taxation), 11 (Intellectual Property), 12 (Insurance), 13 (Warranties), 14 (Limits of Liability), 15 (Indemnities), 17 (Consequences of Termination), 19 (Notices), 21 (General), 22 (Dispute Resolution), 23 (Arbitration) and 24 (Governing Law).

18 Force Majeure

18.1 If either Party is affected by Force Majeure it shall forthwith notify the other Party of the nature and extent thereof.

18.2 Neither Party shall be deemed to be in breach of this Agreement and/or a SOW, or otherwise be liable to the other, by reason of any delay in performance, or non- performance, of any of its obligations under this Agreement and/or a SOW to the extent that such delay or non-performance is due to any Force Majeure of which it has notified the other Party, and the time for performance of that obligation shall be extended accordingly.

18.3 If the Force Majeure in question prevails for a continuous period in excess of 3 (three) months, the Parties shall enter into bona fide discussions with a view to alleviating its effects, or to agreeing upon such alternative arrangements as may be fair and reasonable in the circumstances.

19 Notice

19.1 All notices to be given to a party under this Agreement and/or a SOW shall be in writing in English and shall be marked for the attention of the person, and delivered by hand, sent by registered prepaid post to the registered office from time to time of the relevant party or to such other address in the United Kingdom as the relevant party may notify to the other party in accordance with this Clause or sent by electronic mail to the address specified below (or as otherwise agreed between the parties).

19.2 A notice shall be treated as having been received:

19.2.1 if delivered by hand between 9.00 am and 5.00 pm on a Business Day (which time period is referred to in this clause as **Business Hours**), when so delivered; and if delivered by hand outside Business Hours, at the start of the next Business Day;

19.2.2 if sent by registered prepaid post, at 9.00 am on the second Business Day after posting if posted on a Business Day and at 9.00 am on the third Business Day after posting if not posted on a Business Day; and

19.2.3 if sent by electronic mail between 9.00 am and 5.00 pm on a Business Day when so delivered; and if delivered by hand outside Business Hours, at the start of the next Business Day.

Clinigen:

Clinigen Healthcare Limited

Pitcairn House,

Crown Square,

Centrum 100,

Burton-on-Trent,

Staffordshire DE14 2WW,

United Kingdom

Attention: Head of Managed Access

Tel: +44 (0) 1932 824000

Email: john.lagus@clinigenhealthcare.com

With a copy to:-

General Counsel

Attention: Amanda Miller

Tel: 44 (0) 1932 824000

Email: amanda.miller@clinigengroup.com

Client:

Eiger Biopharmaceuticals, Inc.

2155 Park Boulevard,

Palo Alto, CA 94306

USA

Attention: Jim Welch

Phone: 1-877-899-2051

Fax: 650-618-1621

Email: jwelch@eigerbio.com

In proving service it shall be sufficient to prove that the envelope containing such notice was correctly addressed and delivered, or that the notice was sent by electronic mail to the notified electronic mail address and a successful electronic mail read receipt or other written receipt confirmation exists.

20 Quality Technical Agreement and Safety Data Exchange Agreement

20.1 Where applicable the Parties will enter into a separate Quality Technical Agreement and a separate Safety Data Exchange Agreement on such terms as the Parties shall agree. The terms of such agreements shall take precedence over all other rights and obligations of the Parties in this Agreement and related SOW/s in so far as such rights and obligations relate to quality or safety issues (as the case may be), but not otherwise.

21 General

21.1 A person who is not a party to this Agreement may not enforce any of its provisions under the Contracts (Rights of Third Parties) Act 1999.

21.2 Clinigen may not assign or transfer, or purport to assign or transfer to any other person any of its rights or obligations under this Agreement or a SOW (except to its Affiliates or successors to all or substantially all of Clinigen's business to which this Agreement relates) without the prior written consent of the Client save that this Agreement and any SOW will be binding upon and inure to any successor(s) to the business of Clinigen.

21.3 Client may assign this Agreement or a SOW upon prior written notice to Clinigen.

21.4 Either Party may subcontract the performance of any its obligations to any of its Affiliates or a third party without the consent of the other Party. Notwithstanding such subcontracting, the relevant Party shall at all times remain primarily liable for the full and proper performance of all of its obligations under this Agreement and/or any SOW including any obligations provided through any permitted subcontractor.

21.5 This Agreement (together with all other documents to be entered into pursuant to it) sets out the entire agreement and understanding between the Parties, and supersedes all proposals and prior agreements, arrangements and understandings between the Parties, relating to its subject matter.

21.6 Each Party acknowledges that in entering into this Agreement and/or a SOW it does not rely on any representation, warranty, collateral contract or other assurance of any person (whether party to this Agreement and/or a SOW or not) that is not set out in this Agreement and/or a SOW. Each party waives all rights and remedies which, but for this Clause, might otherwise be available to it in respect of any such representation, warranty, collateral contract or other assurance. The only remedy available to any party in respect of any representation, warranty, collateral contract or other assurance that is set out in this Agreement and/or a SOW is for breach of contract under the terms of this Agreement and/or a SOW.

21.7 This Agreement and/or a SOW may not be modified except in writing signed by the duly authorised representatives of each Party.

21.8 Neither Party shall use the name of the other Party in any announcements, press releases, marketing materials nor advertisements, except as may be required by law, judicial order or regulatory governance, without the prior written consent of the other Party.

21.9 If any term, covenant or condition contained in this Agreement and/or a SOW is deemed to be invalid, illegal or unenforceable, then the rights and obligations of the Parties hereto shall be construed and enforced with that term, covenant or condition limited so as to make it valid, legal or enforceable to the greatest extent allowed by law; or, if it is totally invalid, illegal or unenforceable, then as if this Agreement and/or a SOW did not contain that particular term, covenant or condition. In such event, the remaining provisions of this Agreement and/or a SOW shall be valid and enforceable to the extent permitted by law.

21.10 Delay in exercising, or failure to exercise, any right or remedy in connection with this Agreement and/or a SOW shall not operate as a waiver of that right or remedy. The waiver of a right to require compliance with any provision of this Agreement and/or a SOW in any instance shall not operate as a waiver of any further exercise or enforcement of that right and the waiver of any breach shall not operate as a waiver of any subsequent breach.

21.11 The rights and remedies of the Parties in connection with this Agreement and/or a SOW are cumulative and, except as expressly stated in this Agreement and/or a SOW, are not exclusive of any other rights or remedies provided by law or equity or otherwise. Except as expressly stated in this Agreement and/or a SOW (or at law or in equity in the case or rights and remedies provided by law or equity) any right or remedy may be exercised (wholly or partially) from time to time.

21.12 This Agreement and/or any SOW may be executed in any number of counterparts, each of which when executed shall be construed as an original, but together will constitute one agreement, in relation to this Agreement or a SOW. Signature transmitted by industry standard electronic signature software and/or by electronic mail in “portable document format” (“pdf”) shall have the same legal force and effect as physical delivery of the paper document bearing the original signature.

22 Dispute Resolution

22.1 If any dispute arises out of this Agreement and/or a SOW, in the first instance, the Parties’ account managers shall attempt to resolve the dispute amicably within thirty (30) days.

22.2 If a dispute cannot be resolved by the Parties’ account managers, the Parties shall promptly refer the matter to their respective Chief Executive Officer. If either Party refuses to make such referral or participate in good faith in this dispute resolution procedure and in any event, if the dispute is not resolved within thirty (30) days of such referral or the date such referral could have been made, then either Party may commence proceedings in accordance with Clause 23**.**

22.3 Where either Party reasonably believes that a dispute relates to a material breach or potential breach of this Agreement, that Party shall notify its and the other Party’s account managers and each Party shall then refer the dispute directly to their Chief Executive Officers and the provisions of Clause 22.2 shall apply.

23 Arbitration

23.1 Any dispute that cannot be settled amicably shall be resolved by arbitration before a sole arbitrator, which shall be the exclusive method of dispute resolution under this Agreement and/or any SOW. Such arbitration shall be held in New York City, New York, USA, and in accordance with the ICC Rules of Arbitration. Nothing herein shall, however, prohibit a Party from seeking temporary or preliminary injunctive relief in a court of competent jurisdiction. The parties expressly consent to arbitration and waive any right of appeal to any court from any arbitral award (which shall be final and binding upon the parties).

24 Governing Law

24.1 This Agreement and any SOW shall be governed by, and construed in all respects in accordance with the laws of the State of New York, USA.

24.2 Subject to Clause 23, the courts of New York City, New York, USA will have exclusive jurisdiction to settle any disputes which may arise out of or in connection with this Agreement and/or any SOW, save that either Party may seek injunctive relief in any court of competent jurisdiction.

The Parties have signed this Agreement on the date set out above.
SIGNED for and on behalf of:
Eiger Biopharmaceuticals, Inc.

/s/ John Ferraro
[signature]

John Ferraro
[printed name]

VP, Clinical Operations
[position in company]

27 Apr 2018
[date]

SIGNED for and on behalf of
CLINIGEN HEALTHCARE LIMITED

DocuSigned by:

John Lagus

Signer Name: John Lagus
Signing Reason: I approve this document
Signing Time: 26-Apr-2018

19F51008EB7A4EDB9F0A7E116ED422FB

[signature]

John Lagus
[Printed name]

Head of Managed Access
[position in company]

26-Apr-2018
[date]

DocuSigned by:

Lee Mainwaring

Signer Name: Lee Mainwaring
Signing Reason: I approve this document
Signing Time: 26-Apr-2018

01C6D73EA86348FFAD8417807CB5A5D5

[signature]

Lee Mainwaring
[Printed name]

Finance Director
[position in company]

26-Apr-2018
[date]

Exhibit A – Unlicensed Supply

1 Definitions

In this Exhibit, the following additional defined terms shall apply:

Latent Defect means a defect that causes a particular supply of one or more of the Products to fail to conform to their approved specifications, which defect is not discoverable upon inspection under Section 7 but is discovered at a later time;

Maximum Resale Price means the maximum Sale Price set out in the SOW;

Sale Price means the price or prices to be paid by the Customer to Clinigen for the Products;

Supply Order has the meaning set out in Section 5.1;

Supply Price means the price or prices to be paid by Clinigen to the Client for the Products as set out in the applicable SOW;

Territory means those countries set out in the SOW and any amendment to a SOW.

2 Nature of Services

2.1 The Client grants Clinigen the non-exclusive right to distribute the Products, and provide associated Services, where applicable, on an Unlicensed Supply basis within the Territory for the SOW Term.

2.2 Clinigen shall be entitled to describe itself as an authorised distributor of the Products (on an Unlicensed Supply basis) in the Territory in relation to the applicable SOW.

3 Products

3.1 The Client will supply the Products to Clinigen under a SOW in accordance with the terms of the Conditions, this Exhibit A and the relevant SOW/s to the exclusion of any other terms and conditions of sale submitted at any time (including at the point of acceptance of a Supply Order in accordance with Section 5.1 by the Client and whether printed or sent with any order form, delivery note, invoice or otherwise).

3.2 The Client will notify Clinigen in writing of any Product which becomes the subject of a Marketing Authorisation for an indication/s after the respective SOW Effective Date and will provide reasonable written notice to Clinigen of the date of the Product being Commercially Available in respect of each Product in each country in the Territory, to enable Clinigen to close down its distribution of Products and associated Services, where applicable, in that country/ies in an ethical and orderly fashion.

3.3 The Client will provide Clinigen with such up to date information concerning the Products as Clinigen may reasonably require to assist Clinigen with the distribution and sale or supply of the Products in the Territory.

4 Supply Pricing

4.1 Client will supply the Product to Clinigen on a Consignment Stock basis only at the Supply Price set out in the applicable SOW.

4.2 The Client may recommend in writing to Clinigen a selling price for each of the Products or impose a Maximum Resale Price (which is not to be below the Supply Price) at any time; provided that price does not amount to a minimum selling price or retail price maintenance.

5 Supply and Delivery of the Products

5.1 Clinigen will submit, from time to time, written supply orders ("**Supply Orders**") to the Client for the supply of the Products under a SOW.

5.2 The Client shall accept or reject any Supply Order within ten (10) Business Days of receipt.

5.3 The Client will not supply Clinigen with any Products with a remaining shelf life of less than twelve (12) months, unless otherwise agreed in the relevant SOW. If the Client is unable to comply with this Section 5.3 it will notify Clinigen immediately providing details of the remaining unexpired shelf lives of the available Products and, in such event, the Client shall not proceed with the Supply Order until it has received written confirmation from Clinigen that the Supply Order may proceed. The Parties acknowledge that under certain extraordinary circumstances, Products with remaining shelf life of six (6) months may be acceptable. The Client acknowledges that Customers may have particular minimum shelf-life requirements and accordingly that it may not be possible for Clinigen to deliver to Customers Product with less than a certain shelf-life remaining. Client shall use all reasonable efforts to provide Products with sufficient remaining shelf life for Customers having minimum shelf life requirements.

5.4 Before acceptance by the Client of a Supply Order, Clinigen may vary, add or omit any or all of the Products in a Supply Order by notice in writing to the Client. Neither party shall vary, add or omit any of the Products or any part of them from a Supply Order following acceptance of such Supply Order without the express written consent of the other Party.

5.5 Within five (5) Business Day of the acceptance of a Supply Order the Client will provide Clinigen with a date for delivery.

5.6 The Client will use all commercially reasonable endeavours to meet delivery dates and will:

(a) notify Clinigen as soon as reasonably practicable of any anticipated or actual delays it experiences or anticipates experiencing in meeting a delivery date;

(b) provide Clinigen with such details of the causes of such delays as Clinigen reasonably requires; and

(c) update Clinigen at least once a week until the causes of such delays are rectified or lapse.

5.7 Failure to meet the delivery date or any subsequently agreed date or notify Clinigen of any actual or anticipated delay shall entitle Clinigen to terminate the relevant Supply Order immediately on written notice to the Client.

5.8 The Client will deliver the Products to Clinigen as set out in the SOW. Delivery of the Products shall take place at the delivery address specified in the relevant Supply Order. The Client will reimburse Clinigen for any importation VAT (value added tax) that Clinigen or its Affiliate is unable to reclaim.

5.9 The Client shall:

(a) fax or email to Clinigen's key programme contact notified to the Client from time to time a copy of the delivery note for each delivery prior to such delivery;

(b) supply a copy of the delivery note with the delivered Products; and

(c) provide Clinigen with a written valuation of the Products prepared according to relevant approved customs valuation methods for use by Clinigen for customs valuation and taxation purposes for each delivery of Products.

6 Risk in the Product

6.1 Risk of damage to or loss of the Products shall pass to Clinigen upon delivery of the Products to Clinigen by the Client or its Affiliate. Client shall retain ownership and title in the Products until the shipment of the Product pursuant to a Customer Order by Clinigen to Customer.

7 Acceptance and Rejection

7.1 Notwithstanding any other provision of the Conditions and this Exhibit A, acceptance of Products under a SOW will not occur until Clinigen or its agent or representative has been given five (5) Business Days following delivery of the Products to Clinigen to:

(a) validate the quantity of Products received against the relevant Supply Order; and

(b) inspect visually the Products' outer packaging and labelling for damage, visual defects and compliance with the Agreement and any relevant SOW/s.

7.2 If there is a surplus quantity of Products received over that set out in the Supply Order, Clinigen may in its sole discretion accept or reject such surplus Products.

7.3 If there is a shortfall of Product from that set out in the Supply Order, the Client shall deliver the difference in quantity within ten (10) Business Days of its original delivery or within such other timescale as the Parties may agree.

7.4 If during the visual inspection Clinigen becomes aware of Product damage, defect, or non-compliance, Clinigen will reject such Products by notice to the Client specifying the nature and quantity of the defective Products and the Client will:

(a) forthwith replace the defective Products at the Client's cost and expense; and

(b) within thirty (30) days' of receipt of such notice the Client will either (i) collect the defective Products from Clinigen at the Client's expenses (including, without limitation, costs of carriage, insurance, export/import duties); or (ii) request Clinigen to destroy such defective Products at the Client's expense.

7.5 If any damage, defect or non-compliance not reasonably discoverable during such visual inspection of the Products' outer packaging and labelling, or a Latent Defect becomes apparent Clinigen may, within a reasonable time of becoming aware of the same and provided that the shelf-life of such Product has not expired yet, reject such Products by notice to the Client specifying the nature and quantity of the defective Products. The Client will:

(a) where such Products have not yet been distributed by Clinigen, forthwith replace the defective Products with Products at the Client's cost and expense; and within thirty (30) days' of receipt of such notice the Client will either (i) collect the defective Products from Clinigen at the Client's expenses (including, without limitation, costs of carriage, insurance, export/import duties); or (ii) request Clinigen to destroy such defective Products at the Client's expense; or

(b) where such Products have been distributed by Clinigen the Client will (i) deduct the relevant amount from the invoice to be raised for such distribution or credit to Clinigen's account the Supply Price invoiced and any applicable value added or other sales tax (where these have been paid) for such defective Products plus costs of carriage, insurance and other fees incurred by Clinigen (including, without limitation, export/import duties and any costs associated with arranging for Products to be returned from Customers); and

(ii) unless otherwise specified in the Quality Technical Agreement, either collect the defective Products from Clinigen at the Client's expenses (including, without limitation, costs of carriage, insurance, export/import duties); or request Clinigen to destroy such defective Products at the Client's expense.

(c) For the avoidance of doubt, the Client will remain responsible for paying Clinigen any Charges as may be applicable associated with the distribution of such defective Products.

7.6 If the Client fails to collect defective Products or requests the destruction of the same pursuant to **Section 7** within thirty (30) days, Clinigen may destroy the defective Products upon written notice to the Client at the Client's expense.

8 Compensation and Reimbursement

8.1 In respect of Consignment Stock of a Product:

(a) Clinigen shall make available Product sales data ("**Sales Data**") on a regular basis which shall set out the quantity of Products relevant to the applicable SOW sold by Clinigen to Customers and such other information as the Parties may reasonably agree in writing;

(b) Within the first ten (10) Business Days of each month the Client will invoice Clinigen, with reference to each applicable SOW, for the Supply Price of the Products sold by Clinigen to Customers for the just concluded month as stated in the Sales Data.

(c) Clinigen will not pay the Client the Supply Price in respect of the Client's invoice for any Customer Order until Clinigen has received payment from the Customer. Invoices issued by the Client for the Supply Price of Products sold by Clinigen shall be paid by Clinigen within thirty (30) days of the date of receipt of payment from the Customer by Clinigen. For the avoidance of doubt, all associated Charges for Customer Orders shall be due upon shipment of each such order and shall remain payable in accordance with the payment terms in the Conditions.

9 Limits of Liability

9.1 Except as otherwise provided in the Conditions, the maximum aggregate liability of Clinigen or its Affiliates for Services provided under an SOW in respect of all acts and omissions whether in contract, tort (including, without limitation, negligence) under statute, breach of statutory duty or otherwise shall not exceed:

9.1.1 a sum equivalent to the aggregate of the total Charges paid by the Client to Clinigen in respect of the relevant SOW where such Charges are paid by the Client to Clinigen

AND

9.2 in respect of Consignment Stock the lower of US $250,000 (two hundred and fifty thousand US$) and the value of the relevant Products based on the valuation thereof provided to Clinigen by the Client in accordance with Section 5.9 (c) above in respect of Product loss or damage or theft of Products while in Clinigen's control.

EXECUTION VERSION
Exhibit 10.2

AMENDMENT #6 TO LICENSE AGREEMENT

This Amendment #6 to License Agreement ("Amendment #6") is entered into as of the date of last signature below ("Amendment #6 Effective Date") by and between Merck Sharp & Dohme Corp. (formerly known as Schering Corporation), a New Jersey corporation having a place of business at 2000 Galloping Hill Road, Kenilworth, NJ 07033 ("Merck") and Eiger BioPharmaceuticals, Inc., a Delaware corporation having a place of business at 350 Cambridge Avenue, Suite 350, Palo Alto, CA 94306 ("Licensee") (each of Merck and Licensee, a "Party", and together, the "Parties") to amend that certain License Agreement between the Parties dated September 3, 2010, as amended on January 18, 2011 and subsequently first amended June 11, 2013, as second amended November 20, 2014, as third amended March 6, 2015, as fourth amended June 9, 2015, and as fifth amended December 15, 2015 (collectively, the "Agreement").

IN CONSIDERATION OF the mutual promises and covenants contained herein, the parties agree as follows:

1. Definitions.

(a) The following definition is hereby added to Article I of the Agreement:

> "Progeria" shall mean Hutchinson-Gilford Progeria Syndrome.

(b) Section 1.18 of the Agreement is hereby deleted and replaced with the following:

> "Field" means (i) the use of the Licensed Compound or Licensed Product for all human antiviral applications, except for the treatment of Hepatitis C virus, Hepatitis B virus, or HIV infections, provided, however, that the Field specifically includes, without limitation, the treatment of Hepatitis D virus infections, including the treatment of patients co-infected with Hepatitis D virus and either or both of Hepatitis C virus and Hepatitis B virus; and (ii) the Progeria Field.

(c) The definition of the term "Progeria Field", as set forth in Amendment #5 to the Agreement, is hereby deleted and replaced with the following:

> "Progeria Field" shall mean the use of any Licensed Product (including the Licensed Progeria Product) for purposes related to the treatment of Progeria in humans.

(d) The definition of the term "Licensed Progeria Product" as set forth in Amendment #5 to the Agreement, is hereby deleted and replaced with the following:

> "Licensed Progeria Product" shall mean a Licensed Product in finished capsule form containing the Licensed Compound as the sole active pharmaceutical ingredient for use in the Progeria Field"

(e) The definition of the term "First Indication", as set forth in Section 1.20 of the Agreement, is hereby deleted and replaced throughout the Agreement with the following:

"First Antiviral Indication" means treatment of the Hepatitis D virus infections in humans.

2. Section 2.1 of the Agreement is hereby deleted in its entirety and replaced with the following:

(a) License Grant. Subject to the terms and conditions of this Agreement, including Merck's retained rights under Section 2.3, Merck hereby grants to Licensee an exclusive (even as to Merck), sub-licensable (subject to the obligations and restrictions in Section 2.5), royalty-bearing license under the Merck Know-How, Compound Patent Rights, and Merck's interest in any solely or jointly owned Program IP to Develop, make, have made, use, import, export, Commercialize, sell, offer for sale, and market the Licensed Compound and Licensed Product in the Field in the Territory.

(b) License Expansion. In the event Licensee would like to expand the license granted in this Section 2.1 beyond the Field, it shall provide Merck with a reasonably detailed development plan including evidence of existing resources and capabilities, and proposed terms relating thereto. Merck will consider any such proposed requests from Licensee in good faith.

3. Section 2.3 of the Agreement is hereby deleted in its entirety and replaced with the following:

Retained Rights; Covenants. Merck retains any and all other rights under the Compound Patent Rights and Merck Know-How that are outside the scope of the license granted under Section 2.1, including, for the avoidance of doubt, the right to Develop the Licensed Compound and Licensed Product outside the Field. Notwithstanding the foregoing, Merck shall not Commercialize the Licensed Compound or Licensed Product or grant any Third Party any license or right under any Compound Patent Rights and/or Merck Know-How rights to Commercialize the Licensed Compound or the Licensed Product for any use whether in or outside of the Field. Licensee shall not grant any Third Party any license or right under any Compound Patent Rights and/or Merck Know-How, other than as expressly permitted by this Agreement. Any breach of this Section 2.3 shall be deemed a material breach of the Agreement.

4. Section 2.5(e) of the Agreement (as subsequently amended) is hereby deleted in its entirety and replaced with the following:

> (e) Licensee shall, in each agreement under which it grants a sublicense under the license set forth in Section 2.1 (each, a "Sublicense Agreement"), require the sublicensee to transfer to Merck, if Merck terminates this Agreement under Section 12.4, and to Licensee, if only such Sublicense Agreement terminates, (i) all regulatory filings and Regulatory Approvals held, possessed or Controlled by such sublicensee with respect to a Licensed Product and (ii) all patent rights and Know-How Controlled by such sublicensee with respect to a Licensed Product or its use, Manufacture, sale, or importation (which patent rights and Know-How shall be transferred either by assignment or by a freely sublicensable exclusive license). In the event that this Agreement terminates other than for breach by a sublicensee, Merck may, in its sole discretion, elect to enter in an agreement with each sublicensee on the same terms as the existing Sublicense Agreement. All Sublicense Agreements shall be consistent with the terms and conditions of this Agreement. Licensee shall (I) use reasonable efforts to procure the performance by any sublicensee of the terms of each applicable Sublicense Agreement and (II) be responsible to Merck for any material breach by a sublicensee of any terms and conditions of this Agreement or obligations of Licensee hereunder. Licensee hereby guarantees the performance of its sublicensees that are party to a Sublicense Agreement as permitted herein, and the grant of any such sublicense will not relieve Licensee of its obligations under this Agreement, except to the extent they are satisfactorily performed by such sublicensee. [*].

5. Section 3.2(b) is hereby deleted in its entirety and replaced with the following:

> Development Plan. Licensee shall provide Merck with a reasonably detailed report updating its Development activities and timelines with respect to the following Calendar Year in accordance with Section 3.2(c) (the "Development Plan"). [*]. At Merck's written request, the President of Merck's research division, or his designee, and the President of Licensee's research division or equivalent position, or his designee, shall meet to discuss such comments. Any revision of the clinical protocols shall be submitted to Merck promptly after their completion.

6. Section 3.7 is hereby deleted in its entirety and replaced with the following:

> Commercialization of Licensed Product in the Field. Licensee hereby covenants that it shall not, nor shall it authorize any Affiliate, permitted sublicensee or Third Party contractor to Commercialize Licensed Product in the Territory for any use outside the Field. Merck hereby covenants that neither it nor its Affiliates shall Commercialize the Licensed Compound or Licensed Product or grant any Third Party any license or right under any Compound Patent Rights and/or Merck Know-How rights to Commercialize the Licensed Compound or the Licensed Product for any use whether in or outside of the Field. [*]. To the extent either Party can prove the other Party materially breached this Section 3.7(a), such material breach shall permit such non-breaching Party to terminate this Agreement for cause under Section 12.4.

7. Sections 4.1(d) and 4.1(e) are each hereby deleted in their entirety and replaced with the following:

> (d) Licensee shall be solely responsible for (i) interfacing, corresponding and meeting with the FDA and other Regulatory Authorities throughout the Territory with respect to Licensed Product in the Field, including the Progeria Field and (ii) obtaining and maintaining Regulatory Approvals in the Territory with respect to Licensed Products in the Field, including the Progeria Field. Merck shall be under no obligation to provide Licensee with Regulatory assistance in fulfilling the necessary regulatory activities to achieve Regulatory Approval in the Field, including the Progeria Field, in the Territory other than providing copies of any available data in Merck's possession during the Term required to be submitted for obtaining and maintaining Regulatory Approvals in the Territory with respect to the Licensed Products in the Field, including the Progeria Field. Assistance shall include copies of material correspondence with FDA or other Regulatory Authorities in the United States, the Major European Countries and Japan relating to Regulatory Approval of Licensed Product, and responding to all reasonable inquiries by the other Party with respect thereto. Each Party shall also provide the other Party in a timely manner with meeting minutes from any material meetings with Regulatory Authorities in the United States, the Major European Countries and Japan concerning the Regulatory Approval of Licensed Product in the Field, including the Progeria Field. For mutual convenience, Licensee shall direct any such material correspondence with Regulatory Authorities, or any requests for data from Merck, via the following e-mail address [*].
>
> (e) Licensee shall provide Merck with a table report on an annual basis that contains the status of Regulatory Approvals for the Licensed Product in the Field in the Territory.

8. The following is added as Section 4.4 to the Agreement:

> Regulatory Approvals; Progeria Field. Licensee agrees to use Commercially Reasonable Efforts to achieve Regulatory Approval for a Licensed Product in the Progeria Field in the Territory.

9. Section 6.1 of the Agreement is hereby deleted in its entirety and replaced with the following:

> Manufacturing Responsibility. Licensee will be solely responsible for the Manufacture of Licensed Compound and Licensed Product for Development and Commercialization of Licensed Product by Licensee, its Affiliates and its sublicensees in the Field in the Territory.

10. The following sentence is added to the end of Section 6.2 of the Agreement:

> Notwithstanding the foregoing, as of the Amendment #6 Effective Date, [*].

11. Section 6.3 of the Agreement is hereby deleted in its entirety.

12. Section 6.5 is hereby deleted in its entirety and replaced with the following:

> 6.5 Licensee acknowledges receipt of Licensed Product, Licensed Compound, and Starting Material, as described in Amendment #5 from Merck. Licensee shall have sole responsibility for its supply of Licensed Compound and Licensed Product for purposes of the Agreement. In the event that Licensee requests any additional Starting Material, and to the extent such Starting Material is available, Merck shall employ good faith efforts to transfer such available Starting Material to Licensee's designated CMO as soon as practicable at a cost of [*] plus a reasonable cost of shipping.

13. Section 6.6 is hereby deleted in its entirety and replaced with the following:

> 6.6(a) Manufacture and Transfer. During the Term and subject to all applicable provisions of the Agreement, Licensee will be responsible for the Manufacture and supply of PRF's requirements for Licensed Progeria Product in [*], and/or [*] capsules as may be separately agreed with PRF under the supply agreement referenced in Section 6.6(b) as reasonably requested with respect to delivery dates and quantities for use by PRF in the Progeria Field in the Territory, at no cost to PRF or Merck. Licensee will be responsible for the Manufacture and supply of Licensed Compound and/or Licensed Product for Merck's use pursuant to Section 2.3 as reasonably requested by Merck from time to time during the Term of the Agreement solely for Merck to exercise its right to Develop the Licensed Compound and Licensed Product outside the Field pursuant to

Section 2.3; provided that Merck shall pay actual labelling and shipping and handling costs for delivery of Licensed Product to Merck for quantities delivered for such uses. For any requests exceeding [*] of Licensed Compound, Merck will compensate Eiger for the cost of such drug plus [*]. Licensee shall transfer to Merck such amounts of Licensed Compound and/or Licensed Product on such schedule as is mutually agreed based on reasonable requests by Merck for Merck's use pursuant to Section 2.3. Notwithstanding the foregoing, Licensee shall [*].

6.6(b) PRF Supply Agreement. Within ten (10) days of the Amendment #6 Effective Date, Licensee shall execute an agreement with PRF for the supply of Licensed Progeria Product needed by PRF, at no cost to PRF, to be used by PRF for (i) Development purposes in the Progeria Field and (ii) expanded access beyond clinical trials. [*].

6.6(c) Continuity of Supply to PRF. (A) Upon expiration or termination of this Agreement; and/or (B) [*]; or (C) at any time in the event that Licensee terminates (i) this Agreement pursuant to Article XII, (ii) Licensee's Development, Manufacture or Commercialization of Licensed Product under this Agreement, (iii) Licensee's supply agreement contemplated in Section 6.6(b); or (iv) Licensee's Sublicense Agreement(s) with its CMO(s) for the Manufacture of Licensed Product, Licensee hereby grants to Merck [*]. In the event that Merck does not [*], then Licensee shall use commercially reasonable efforts to [*]. Merck shall have the right, but not the obligation, at its sole discretion, to purchase any raw materials, in process materials and/or finished goods originally manufactured for Licensee in the amounts deemed desirable by Merck and at Licensee's cost of goods. Merck shall have no obligation to purchase remaining materials in inventory. [*].

14. The following shall be added as Section 7.2(d) to the Agreement:

No Progeria Milestone Payments. Licensee shall have no obligation to make any milestone payments to Merck in relation to any Licensed Product (including the Licensed Progeria Product) for use in the Progeria Field.

15. Section 7.3(b) to the Agreement is hereby deleted in its entirety and replaced with the following:

Term of Royalty Obligation. Royalties on the Licensed Product shall commence upon the First Commercial Sale of a Licensed Product in a particular country in the Territory and will continue, on a product-by-product and country-by-country basis, until the [*] of the date of First Commercial Sale of the Licensed Product for the First Antiviral Indication in such country ("Royalty Term"). For clarity, during the Royalty Term, the royalty payments pursuant to this Section 7.3 shall be payable regardless of whether it is Licensee, its Affiliate, or its sublicensee that is selling the Licensed Product.

16. The following shall be added as Section 7.3(c) to the Agreement.

> Licensed Progeria Product Royalty Exemption. It is understood and agreed by the Parties that it is Merck's intent that it shall receive no royalties for sales of Licensed Progeria Product. Subject to Regulatory Approval for Licensed Progeria Product, Merck shall receive no royalties on the sale of any Licensed Progeria Product for the [*] sold per Calendar Year (the approximate quantity needed to treat the currently estimated worldwide prevalence of patients with Progeria per year). The Parties shall amend the Agreement to adjust this amount in the future if there is a change in prevalence rates of Progeria or changes in the approved dosing regimen for Licensed Progeria Product in the Progeria Field. In order for the Parties to effectuate the intent of this Section 7.3(c), Licensee's Net Sales reports for Licensed Product (including the Licensed Progeria Product) as required by Section 7.4(a) shall include [*] in such Calendar Quarter. For clarity, Additional Indication shall not include the treatment or amelioration of Progeria.

17. Section 13.3 is hereby deleted in its entirety and replaced with the following:

> Equitable Relief. By agreeing to arbitration, the Parties do not intend to deprive any competent court of such court's jurisdiction to issue a pre-arbitral injunction, pre-arbitral attachment or other order in aid of the arbitration proceedings and the enforcement of any award or judgment. Without prejudice to such provisional remedies in aid of arbitration as may be available under the jurisdiction of a national court, the court of arbitration shall have full authority to grant provisional remedies and to award damages for failure of any Party to respect the court of arbitration's order to that effect. With respect to any pre-arbitral preliminary injunction sought under this Section 13.3, both Parties agree to waive any requirement that the other (i) post a bond or other security as a condition for obtaining any such relief or (b) show irreparable harm, balancing of harms, consideration of the public interest, or inadequacy of monetary damages as a remedy.

18. Except as set forth herein, all capitalized terms not defined in this Amendment #6 shall have the meanings given to them in the Agreement.

19. In the event of any inconsistency between the terms of this Amendment and the terms of the Agreement, the terms of this Amendment shall govern.

20. Except as expressly amended hereby, all of the terms and conditions of the Agreement remain in full force and effect.

IN WITNESS WHEREOF, the Parties have executed this Amendment #6 by their duly authorized representatives as of the Amendment #6 Effective Date.

Eiger BioPharmaceuticals, Inc.		**Merck Sharp & Dohme Corp.**	
By:	/s/ David Cory	By:	/s/ Bryan Rafalko
Title:	President, CEO	Title:	SVP, Director of Business Development and Licensing
Date:	5/15/18	Date:	5/15/18

[*] = Certain confidential information contained in this document, marked by brackets, is filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

EXECUTION VERSION
Exhibit 10.3

COLLABORATION AND SUPPLY AGREEMENT

This **Collaboration and Supply Agreement** ("**Agreement**") is made and entered into as of May 15, 2018 (the "**Effective Date**") by and between Eiger BioPharmaceuticals, Inc., a Delaware corporation having a place of business at 350 Cambridge Avenue, Suite 350, Palo Alto, CA 94306 ("**Eiger**"), and The Progeria Research Foundation, Inc., a 501(c)(3) not-for-profit organization currently located at 200 Lake St., Peabody MA 01960 ("**PRF**"). Eiger and PRF are individually referred to as a "**Party**" and collectively referred to as the "**Parties.**"

Whereas, PRF is engaged in research, development, investigation and testing activities for the treatment of Progeria (as defined below) and diseases related to Progeria;

Whereas, Eiger is engaged in the business of the research, development and commercialization of pharmaceutical products;

Whereas, Eiger and Merck Sharp & Dohme Corp. (successor-in-interest of Schering Corporation), a New Jersey corporation having a place of business at 2000 Galloping Hill Road, Kenilworth, NJ 07033 ("**Merck**") are parties to that certain License Agreement, dated September 3, 2010, as amended (the "**Merck License Agreement**"), under which Eiger obtained a license from Merck to develop, make, use and commercialize lonafarnib for certain uses;

Whereas, Eiger and Merck have agreed that Eiger will license and supply lonafarnib to PRF and that Eiger and Merck will execute an amendment to the Merck License Agreement ("**Merck Amendment**") expanding the license from Merck to Eiger for exclusive (even as to Merck) license rights to lonafarnib in certain specified indications, including Progeria, and, as between Merck and Eiger during the term of the Merck License Agreement and Merck Amendment, making Eiger solely responsible for granting a sublicense to PRF with respect to lonafarnib in the Field (as defined below) and supplying lonafarnib to PRF, in each case, on terms and conditions agreed upon by PRF and Eiger; and

Whereas, the Parties desire to collaborate to explore the use and commercialization of lonafarnib in the treatment of Progeria;

Now therefore, in consideration of the mutual promises and agreement set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

1. **Definitions**. The following terms shall have the following respective meanings when used in this Agreement:

(a) "**Additional Site**" shall have the meaning set forth in Section 9(e).

(b) "**Affiliate**" of a Party means any person or entity that at any time is controlling, controlled by, or under common control with such Party, where "control" (or any of its correlates) means beneficial ownership, directly or indirectly, of more than fifty percent (50%) of the equity or other interests entitled to vote for the election of directors or equivalent governing body of a person or entity.

(c) "**CoA**" shall have the meaning set forth in Section 9(c).

(d) "**Combination Drug**" means a co-formulated pharmaceutical product or product candidate containing the Licensed Compound and one or more active pharmaceutical ingredient(s) in a single vehicle. For the avoidance of doubt, a Combination Drug does not cover the simultaneous administration of the Licensed Compound and one or more active pharmaceutical ingredients using more than one (1) vehicle.

(e) "**Commercialize**" or "**Commercialization**" means all activities comprising or relating to the manufacture, promotion, marketing, advertising, sale, distribution, disposal and other exploitation of any Licensed Products, including any Research Activities and any activities necessary to maintain any regulatory approvals.

(f) "**Controlled**" means, with respect to any Intellectual Property, know-how or Data, a Party has the legal authority or right (whether by ownership, license or otherwise) to grant a license, sublicense, right of access or right to use (as applicable) with respect to such Intellectual Property, know-how or Data to the other Party on the terms and conditions set forth in this Agreement at the time of such grant, in each case without breaching the terms of any applicable agreement with a third party.

(g) "**Data**" means, in any form or format, all clinical and non-clinical data, natural history data, correspondence with all regulatory authorities, regulatory documents , orphan drug designation of lonafarnib for Progeria (pursuant to 21 CFR § 316.27) or other regulatory exclusivities owned or Controlled by a Party, including any data relating to any Licensed Product collected, compiled, reviewed or analyzed by Accenture PLC and any summaries, memoranda or analyses prepared by Accenture PLC with respect to any such data.

(h) "**Default**" shall have the meaning set forth in Section 9(h).

(i) "**Defense**" shall have the meaning set forth in Section 20(d).

(j) "**Eiger Indemnified Parties**" shall have the meaning set forth in Section 20(c).

(k) "**FDA**" means the U.S. Food and Drug Administration, an agency of the U.S. Department of Health and Human Services.

(l) "**Federal Arbitration Act**" shall have the meaning set forth in Section 27(b).

(m) "**Field**" means the treatment of Progeria.

(n) "**IND**" shall have the meaning set forth in Section 5(c).

(o) "**Indemnified Party**" shall have the meaning set forth in Section 20(d).

(p) "**Indemnifying Party**" shall have the meaning set forth in Section 20(d).

(q) "**Initial Term**" shall have the meaning set forth in Section 21.

(r) "**Intellectual Property**" means all patents, copyrights, trademarks, trade secrets and all other intellectual property and industrial property under the laws of any jurisdiction and all rights in, to and under each of the foregoing, together with all applications for registration or issuances with respect to any of the foregoing and all registrations and issuances with respect to any of the foregoing.

(s) "**JSC**" shall have the meaning set forth in Section 4.

(t) "**Licensed API**" means (i) prior to the filing of the Progeria NDA, the active pharmaceutical ingredient of the Licensed Compound in the form as previously supplied to PRF by Eiger prior to the Effective Date or (ii) following the filing of the Progeria NDA, the form of the active pharmaceutical ingredient of the Licensed Compound used for the Licensed Progeria Product under the Progeria NDA.

(u) "**Licensed Compound**" means that certain compound known as of the Effective Date as lonafarnib with the chemical structure described in Exhibit A, including any prodrug, metabolite, salt, ester, solvate, hydrate or crystalline form thereof.

(v) "**Licensed Product**" means any (i) pharmaceutical product or product candidate that contains the Licensed Compound, either alone or in combination with one or more other active pharmaceutical ingredients (including all formulations, line extensions and modes of administration thereof) and (ii) Licensed API.

(w) "**Licensed Progeria Product**" means any Licensed Product in finished capsule form containing lonafarnib as the sole active pharmaceutical ingredient (i) as manufactured and supplied by or on behalf of Eiger to Boston Children's Hospital pursuant to the Boston Children's Hospital Investigator Sponsored Clinical Trial Research Agreement, dated October 4, 2016, as amended on October 28, 2016, by and between Eiger and Boston Children's Hospital or (ii) following the filing of the Progeria NDA, as submitted to the FDA under the Progeria NDA.

(x) "**Losses**" shall have the meaning set forth in Section 20(b).

(y) "**Merck License Agreement Termination Notice**" shall have the meaning set forth in Section 22(b).

(z) "**NDA**" means any new drug application (as defined in Title 21 of the United States Code of Federal Regulations, as amended from time to time) filed with the FDA seeking regulatory approval to market and sell any Licensed Product in the United States for a particular indication.

(aa) "**Non-Conforming Product**" shall have the meaning set forth in Section 12(a).

(bb) "**Pre-existing Eiger IP**" shall have the meaning set forth in Section 15.

(cc) "**Pre-existing PRF IP**" shall have the meaning set forth in Section 15.

(dd) "**PRF IND**" shall have the meaning set forth in Section 5(c).

(ee) "**PRF Indemnified Parties**" shall have the meaning set forth in Section 20(b).

(ff) "**PRF Second Source**" shall have the meaning set forth in Section 9(g).

(gg) "**Progeria**" means Hutchinson-Gilford Progeria Syndrome and progeroid laminopathies.

(hh) "**Progeria NDA**" shall have the meaning set forth in Section 5(a).

(ii) "**Progeria PRV**" shall have the meaning set forth in Section 6(a).

(jj) "**PRV Sale**" shall have the meaning set forth in Section 6(a).

(kk) "**Publishing Party**" shall have the meaning set forth in Section 17(a).

(ll) "**Renewal Term**" shall have the meaning set forth in Section 21.

(mm) "**Research Activities**" means any research, development, investigation or testing activities (including any activities in connection with any pre-clinical research or clinical trials and any activities conducted under any PRF IND (as defined below)) using any Licensed Product conducted by, on behalf of, under the direction or supervision of, as instructed by, with funding from or in collaboration with PRF.

(nn) "**Right of Reference**" means any written and signed statement by a Party to the applicable regulatory authority that authorizes such regulatory authority to reference data and information submitted previously by such Party to such regulatory authority, as described in 21 CFR § 312.23(b), or the equivalent authorization in a jurisdiction other than the United States.

(oo) "**Term**" shall have the meaning set forth in Section 21.

2. License Grants; Certain Covenants.

(a) Subject to the terms and conditions of this Agreement, Eiger hereby grants to PRF a non-exclusive, world-wide, royalty-free, fully paid-up sub-licensable (i) license under and to all Intellectual Property, know-how and Data Controlled by Eiger or any of its Affiliates and (ii) sublicense under and to all Intellectual Property, know-how and Data licensed by Merck or any of its Affiliates to Eiger or any of its Affiliates, in each case (i) and (ii) solely to (A) conduct or perform, or have conducted or performed, any Research Activities using any Licensed Product in the Field and (B) prepare, file, own and maintain any Progeria IND.

(b) Subject to the terms and conditions of this Agreement, PRF hereby grants to Eiger a non-exclusive, world-wide, fully paid-up, sub-licensable license under and to all Intellectual Property, know-how and Data Controlled by PRF solely to prepare and file any NDA for the Licensed Product, including the Progeria NDA.

(c) Eiger shall not amend the Merck License Agreement to narrow or limit the scope of the Licensed Progeria Product or Eiger's rights with respect to the Licensed Progeria Product or any Intellectual Property, know-how or Data related thereto.

(d) After the Effective Date, Eiger shall not, without PRF's prior written consent, enter into any agreement or amend any agreement that would limit Eiger's ability to fulfill its obligations pursuant to this Agreement, provided that this Section 2(d) shall not be deemed to limit or restrict Eiger's ability, or require PRF's consent, to amend or terminate an existing manufacturing agreement, or enter into a new manufacturing agreement, for Licensed Progeria Product so long as (i) Eiger replaces any existing manufacturer with at least a comparable manufacturer and (ii) Eiger continues to fulfill its obligations pursuant to this Agreement.

(e) PRF shall not conduct or have conducted any clinical trial involving use in humans of the Licensed Progeria Product in the Field at any Additional Site if such Additional Site does not agree in a written agreement (to which Eiger is an express third party beneficiary) to indemnify the Eiger Indemnified Parties for any Losses resulting from any suit, action, claim, demand or proceeding of any kind or nature arising from any death of, or bodily injury to, any person enrolled in such clinical trial that is caused by the ingestion or use of the Licensed Progeria Product by such person in the conduct of such clinical trial (except to the extent arising from (i) Eiger's breach of any of its representations, warranties, covenants or agreements set forth in Section 18, (ii) any of Eiger's actions or failure to take action with respect to any Licensed Progeria Product in accordance with this Agreement or (iii) Eiger's negligence or willful misconduct).

3. **No Implied License**. Nothing herein shall be deemed to grant either Party or any third party acting on behalf of either Party any implied license or right under any Intellectual Property rights Controlled by the other Party except as expressly set forth in this Agreement.

4. **Management of Collaboration**. Within [*] after the execution of this Agreement, the Parties shall establish a Joint Steering Committee ("**JSC**") to oversee the preparation and filing of regulatory filings and collaboration activities of the Parties (including as further described in Section 4(c)) and to conduct or perform any other activities as the Parties may agree upon in writing.

[*] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

(a) The JSC will be comprised of [*] appointed by Eiger and [*] appointed by PRF. All JSC decisions will be made by unanimous vote, with the JSC representatives of Eiger collectively having one vote and the JSC representatives of PRF collectively having one vote. If the JSC is unable to decide or resolve unanimously: (i) when to file the Progeria NDA with the FDA; or (ii) any other matter subsequent to a change of control of Eiger, then in each case (i) and (ii), the Parties agree to resolve such dispute in accordance with the dispute resolution procedures set forth in Section 27. For all other matters that are within the scope of the JSC's responsibility as agreed upon by the Parties in writing, that are properly presented to the JSC for action and that the JSC is unable to decide or resolve unanimously, Eiger shall have final decision making authority with respect to such matter. For purposes of this Section 4(a), "change of control" means any transaction or series of transactions as a result of which all or a majority of Eiger's outstanding voting stock or all or a majority of the business or assets of Eiger are sold or otherwise transferred or disposed of and are no longer directly or indirectly owned by the persons owning a majority of the voting stock of Eiger prior to the first such transaction.

(b) The JSC shall meet in accordance with a schedule established by mutual written agreement of the Parties, but no less frequently than [*] per calendar year, unless the Parties mutually agree in writing to a different frequency, with the location for such meetings to be determined by the JSC. The JSC shall remain in effect as long as necessary to support regulatory preparation and filing for approval of the Licensed Progeria Product in all territories.

(c) The responsibilities of the JSC shall include (i) reviewing and providing input on current and proposed future Research Activities; however, the Parties acknowledge and agree that the JSC does not have any right to approve or veto any such Research Activities, (ii) discussing overall regulatory requirements for obtaining regulatory approval of any Licensed Progeria Product in the Field, (iii) determining when to submit applications for regulatory approval of any Licensed Progeria Product in the Field, (iv) discussing whether to make the Licensed Progeria Product available in the Field as an investigational drug for treatment use pursuant to Section 8(b) in a particular jurisdiction outside the United States if Eiger believes in good faith that doing so will subject Eiger to an unreasonable risk of liability, (v) discussing whether to make the Licensed Progeria Product available in the Field as an investigational drug for treatment use pursuant to Section 8(b), (vi) reviewing and commenting on correspondence and submissions to regulatory authorities, (vii) coordinating safety monitoring activities between the Parties with respect to the Licensed Progeria Product and any Licensed API supplied by or for Eiger under this Agreement, (viii) facilitating the flow of information between the Parties, (ix) discussing whether to seek regulatory approval of the Licensed Progeria Product in the Field in any country outside of the United States and (ix) performing such other functions as may be appropriate to further the purposes of this Agreement and that are agreed upon by the Parties in writing.

[*] = Certain confidential information contained in this document, marked by brackets, is filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

5. Regulatory.

(a) Promptly after the Effective Date and delivery to Eiger of Data and know-how Controlled by PRF in the Field, Eiger shall undertake a review of the regulatory and clinical Data and information provided by PRF and provide the JSC with its reasonable determination of the estimated time for filing of a NDA for a Licensed Progeria Product in [*] and [*] capsule formulations in the Field ("**Progeria NDA**") by Eiger. In the event that the JSC determines that such PRF Data and know-how and any other information Controlled or possessed by Eiger or any of its Affiliates supports the filing of the Progeria NDA by the first anniversary of the Effective Date, Eiger agrees to use commercially reasonable efforts to prepare and file the Progeria NDA [*]. Eiger agrees that if the JSC determines that filing the Progeria NDA [*] is impracticable, then Eiger will use commercially reasonable efforts to file the Progeria NDA as soon as practicable thereafter, as determined by the JSC. In any event, Eiger agrees to use commercially reasonable efforts to file the Progeria NDA [*] for the Licensed Product. The Parties agree that Eiger will submit a request to the FDA for a rare pediatric disease designation for the Licensed Progeria Product for the treatment of Progeria prior to submission of the Progeria NDA, and will use commercially reasonable efforts to submit such request (i) [*] it submits any request for expedited approval of the Progeria NDA under 21 USC § 356 or (ii) by the [*], whichever is earlier, unless the parties mutually agree upon an alternate submission date in writing after conferring with each other in good faith. Following the approval of the Progeria NDA, Eiger agrees to use commercially reasonable efforts to develop and register a [*] of the Licensed Progeria Product for use in the Field. The Parties further agree to use commercially reasonable efforts to prepare and file NDA equivalents outside of the United States for the Licensed Progeria Product for the treatment of Progeria as determined by the JSC.

(b) Eiger shall be the sole sponsor of the Progeria NDA or similar submission during the Term. During the Term, PRF shall, at Eiger's sole cost and expense, provide reasonable cooperation and assistance reasonably requested by Eiger with respect to obtaining and maintaining regulatory approvals for an NDA for any Licensed Progeria Product in the Field. Upon the reasonable written request of PRF, Eiger shall make available to PRF records of the Licensed Product reasonably necessary for PRF to fulfill its regulatory requirements with respect to its use of the Licensed Progeria Product in the Field.

(c) PRF shall have the right, but not the obligation, at its sole cost and expense, to own and maintain an Investigational New Drug ("**IND**") application under which Research Activities of PRF are conducted with respect to Licensed Product ("**PRF IND**"); provided that if PRF elects to exercise such right, then (i) Eiger shall be the exclusive (subject to Section 9(h)) provider of the Licensed Progeria Product under the PRF IND and shall supply the Licensed Progeria Product to PRF as set forth in Section 9; (ii) PRF shall grant Eiger a Right of Reference to Data included in or as part of the PRF IND; (iii) in connection with the PRF IND, Eiger shall grant PRF a Right of Reference to Data included in or as part of any IND or NDA submitted, sponsored or obtained by Eiger for any Licensed Product; and (iv) any material regulatory correspondence or material submission under a PRF IND shall be reviewed and discussed by the JSC prior to submission by PRF to the FDA. If PRF desires to pursue a study of a Combination Drug in the Field under the PRF IND, Eiger shall consider in good faith entering into a third party collaboration with another drug supplier to enable PRF to pursue such study with Licensed Product.

[*] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

(d) Eiger shall be solely responsible for any additional clinical or non-clinical studies necessary for obtaining and maintaining approval of the Progeria NDA. Eiger shall be solely responsible for the costs of such additional studies up to a cumulative total of [*]. The Parties will negotiate in good faith regarding the allocation of any costs in excess of this amount. Eiger agrees to maintain complete and accurate books and records relating to such additional studies. Eiger shall promptly notify PRF in writing when the costs of such additional studies total each of [*]. If the costs of such additional studies exceeds [*] and the Parties agree that PRF shall share the costs of any such additional studies in excess of such amount, PRF shall have the right to inspect such books and records (upon reasonable prior written notice to Eiger and during Eiger's normal business hours and no more than once per year), using an independent certified public accountant retained by PRF and reasonably acceptable to Eiger, for the sole purpose of verifying the costs of such additional studies. PRF shall bear the expense of any such inspection, except that if any such inspection reveals that the actual costs of such additional studies are less than [*] by [*] or more, then Eiger shall bear the expense of such investigation.

(e) The Parties shall reasonably cooperate in good faith with respect to the conduct of any inspections by any regulatory authority of a Party's site or facility (or, in the case of PRF, any clinical site conducting Research Activities with PRF as permitted under this Agreement) related to any Licensed Product. To the extent permitted by applicable law, Eiger shall be allowed to attend any such inspection relating to any Research Activities (other than any Research Activities using Licensed API and no other Licensed Product).

6. Priority Review Voucher.

(a) The Parties acknowledge that a Priority Review Voucher may be available and awarded to Eiger as the sponsor of the Progeria NDA ("**Progeria PRV**"). The Parties agree that, if awarded, Eiger will use commercially reasonable efforts to sell the Progeria PRV to a third party ("**PRV Sale**") on commercially reasonable terms within twelve (12) months of the issuance of such Progeria PRV. Eiger agrees not to retain the Progeria PRV for itself or any of its Affiliates. [*].

(b) PRF and Eiger shall share the proceeds of any PRV Sale [*]. For clarity, as used in this Section 6(b), "proceeds" means the gross amounts received by Eiger with respect to any PRV Sale, less applicable taxes on such amounts.

7. Commercialization Diligence; Patient Support Programs.

(a) Eiger shall use commercially reasonable efforts to Commercialize the Licensed Progeria Product in the Field in the United States within [*] of the Progeria NDA approval in the United States. In addition, Eiger shall use commercially reasonable efforts to obtain regulatory approval of and Commercialize the Licensed Progeria Product in the Field outside the United States.

(b) Eiger shall (i) establish a patient support program prior to the first commercial sale of the Licensed Progeria Product in the United States and (ii) use commercially reasonable efforts to [*] in which Eiger seeks regulatory approval of the Licensed Progeria Product to treat Progeria, in each case (i) and (ii), to [*] after the Licensed Progeria Product is approved by the applicable regulatory authority to treat Progeria in each applicable country. For the avoidance of doubt, Eiger's obligations under this Section 7 to provide the Licensed Progeria Product [*] means that Eiger will [*].

(c) Prior to seeking regulatory approval in any particular country outside the United States, if Eiger in good faith believes that (i) it will not be commercially reasonable to establish any such program described in Section 7(b)(ii) in such country and (ii) following regulatory approval of the Licensed Progeria Product in such country, [*], then the JSC shall discuss whether to seek regulatory approval of the Licensed Progeria Product for the Field in such country as set forth in Section 4(c).

8. Expanded Access. Eiger shall use commercially reasonable efforts to make the Licensed Progeria Product available in the Field as an investigational drug for treatment use (a) in the United States in a manner consistent with all applicable laws, rules and regulations, as each such law, rule or regulation is then in effect and (b) outside the United States, in accordance with "named patient" programs in countries where they are available and delivery by or for Eiger is permitted under applicable law without unreasonable cost, expense or risk of liability, in each case (a) and (b), [*]; provided that, with respect to (a) and (b), the aggregate net cost to Eiger for making the Licensed Progeria Product available as an investigational drug for treatment use under this Section 8 shall not in the aggregate exceed [*]. For the avoidance of doubt, such [*] excludes the costs of manufacturing the Licensed Progeria Product. Eiger shall notify PRF promptly in writing if the aggregate costs of making the Licensed Progeria Product available in the Field as an investigational drug for treatment use pursuant to the foregoing clauses (a) and (b) will exceed such [*]. If Eiger in good faith believes that (i) it is not commercially reasonable to make the Licensed Progeria Product available in the Field as an investigational drug for treatment use pursuant to the foregoing clauses (a) or (b) or (ii) making the Licensed Progeria Product available in the Field as an investigational drug for treatment use pursuant to the foregoing clause (b) will subject Eiger to an unreasonable cost, expense or risk of liability, then the Parties shall discuss in good faith potential alternatives. For purposes of this Section 8, "commercially reasonable efforts" shall be deemed met if Eiger spends, excluding the costs of manufacturing the Licensed Progeria Product, [*] to make the Licensed Progeria Product available as an investigational drug for treatment use in accordance with the foregoing clauses (a) and (b).

9. Supply of Licensed Progeria Product; Second Source.

(a) Eiger shall supply and deliver to PRF the Licensed Progeria Product requested by PRF for any Research Activities, by delivery dates reasonably agreed upon by the Parties, in the quantities and to the delivery locations as reasonably agreed upon by the Parties, at no cost or expense to PRF, provided that:

(i) each month, PRF shall provide Eiger in writing with a rolling non-binding estimate of its monthly requirement for the Licensed Progeria Product for Research Activities in each of the following [*], which PRF shall, if applicable, update such estimate before the beginning of each month;

(ii) the quantities set forth in the non-binding estimate are reasonably consistent with the quantities ordered and within a reasonable variance from the applicable forecast, provided that Eiger may request that the Parties mutually agree to specific minimum or maximum order variance limits to the extent quantities actually ordered deviate substantially from forecasted orders; and

(iii) PRF shall specify, on a best estimates basis, each estimated order and the related factors or contingencies for the delivery of the Licensed Progeria Product [*] before PRF's requested delivery date, unless otherwise mutually agreed upon by the Parties in writing, and the Parties shall regularly update and discuss the status and timing of delivery over the course of such period, provided that in any event any quantities originally estimated shall be within any maximum order variance set forth under Section 9(a)(ii).

(b) Eiger will package the Licensed Progeria Product in accordance with Eiger's IND application number [*] approved by the U.S. Food and Drug Administration on March 7, 2011 or Eiger's then-approved NDA for a Licensed Product.

(c) Eiger shall (i) retain a sample of each batch of the Licensed Progeria Product supplied under or pursuant to this Agreement and (ii) maintain and provide to PRF access to records of the Licensed Progeria Product in each shipment, including certificates of analysis that include the dates of manufacture (such certificates, "**CoAs**"). As reasonably requested by PRF, Eiger shall promptly provide PRF (A) a copy of such CoAs and (B) access to a copy of any such other records described in subclause (ii) of the foregoing sentence and any records of testing performed on such Licensed Progeria Product (as such testing records are required to be maintained by Eiger pursuant to any applicable law, statute, rule or regulation).

(d) PRF shall use the Licensed Progeria Product in the formulation supplied by Eiger and shall in no way modify, reverse-engineer, create derivatives of, reformulate or otherwise use a different form of such Licensed Progeria Product.

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(e) If PRF wishes to conduct (or have conducted) any Research Activities or clinical trials at a site other than Boston Children's Hospital ("**Additional Site**") for any Licensed Progeria Product in the Field, PRF shall notify Eiger and Eiger shall promptly and as soon as practicable enter into a material transfer agreement directly with such Additional Site to provide the Licensed Progeria Product for use in the Field. The JSC shall discuss in good faith plans and supply needs for the Licensed Progeria Product for any Additional Sites. Eiger acknowledges and agrees that PRF has the right to conduct, direct or sponsor any clinical trials at any Additional Sites using the Licensed Progeria Product, alone or in combination with other therapeutic or pharmaceutical agents, solely in the Field.

(f) Eiger shall (i) continue to supply the Licensed Progeria Product at no charge to Boston Children's Hospital pursuant to the Boston Children's Hospital Investigator Sponsored Clinical Trial Research Agreement, dated October 4, 2016, as amended on October 28, 2016, by and between Eiger and Boston Children's Hospital and (ii) supply any Additional Sites, in each case (i) and (ii), until [*] (or such longer period of time that PRF and Eiger may agree upon in writing) after regulatory approval of the Licensed Progeria Product in the Field in the territory in which Boston Children's Hospital or such Additional Site, as applicable, is located. If, however, any patient is enrolled in any PRF conducted, directed or sponsored clinical trial and receiving the Licensed Progeria Product from Eiger at the end of such [*], Eiger will continue to supply the Licensed Progeria Product at no charge to each such patient for the duration of the clinical trial. In the event that any Additional Site is located in a territory where a Licensed Progeria Product does not receive regulatory approval during the Term for commercial sale, Eiger will provide the Licensed Progeria Product [*] to such Additional Site for the Term.

(g) From time to time during the Term, PRF may identify a second source of supply for the Licensed Progeria Product or Licensed API reasonably acceptable to Eiger ("**PRF Second Source**"). Upon written request from PRF, Eiger agrees to: (i) work with such PRF Second Source in good faith; (ii) use commercially reasonable efforts to qualify such PRF Second Source for the manufacture of the Licensed Progeria Product and Licensed API; (iii) provide such PRF Second Source with all information and support necessary, and reasonable assistance, to enable such PRF Second Source to manufacture the Licensed Progeria Product and Licensed API for supply in accordance with this Agreement; and (iv) grant to such PRF Second Source a non-exclusive, world-wide, royalty-free, fully paid-up, non-sublicensable license under and to all Intellectual Property Controlled by Eiger necessary to manufacture the Licensed Progeria Product and Licensed API for supply in accordance with this Agreement. All costs and expenses with respect to the engagement, assessment, review and commitment of such PRF Second Source shall be the responsibility of PRF, provided that Eiger [*] from Eiger to such PRF Second Source.

(h) Eiger agrees that, if, for any reason, Eiger Defaults (as defined below) on any of its obligations to supply any Licensed Progeria Product to PRF in accordance with this Agreement, and fails to cure such Default within [*] after its receipt from PRF of a written notice describing such Default, PRF has the right to obtain such Licensed Progeria Product or Licensed API from such PRF Second Source. Commencing on the [*] anniversary of the Effective Date, Eiger shall, at all times during the remainder of the Term, maintain an existing inventory of Licensed Progeria Product in an amount equal to the total amount of Licensed Progeria Product set forth in PRF's then-current monthly orders for the subsequent [*]. If, at any time during the Term, Eiger engages a second source to supply the Licensed Progeria Product or Licensed API, then Eiger shall identify to PRF in writing such alternative manufacturer and, at PRF's request, Eiger shall use commercially reasonable efforts to facilitate the manufacture of the Licensed Progeria Product or Licensed API for PRF by such alternative manufacturer [*] as the terms and conditions pursuant to which such alternative manufacturer agrees to manufacture the Licensed Progeria Product or Licensed API for Eiger. For purposes of this Section 9(h), "**Default**" means that Eiger fails to deliver to PRF at least [*] of the quantities of Licensed Progeria Product ordered under Section 9(a) (excluding all Non-Conforming Product for purposes of determining such failure level) in any [*] orders.

(i) In the event of (i) expiration or any termination of this Agreement (other than Eiger's termination of this Agreement in accordance with Section 22(b)(i) for an uncured, material breach of this Agreement by PRF), (ii) expiration or any termination of the Merck License Agreement, or (iii) the termination of development (including efforts to seek regulatory approval) or commercialization of Licensed Product by Eiger for any reason, Eiger shall: (A) upon PRF's written request, to the extent practicable, assign to PRF all manufacturing agreements and supply agreements that Eiger has not assigned to Merck pursuant to the Merck License Agreement relating to the manufacture or supply of Licensed Product then Controlled by Eiger and, to the extent Eiger has such rights, provide the necessary regulatory licenses and any other rights to PRF to enable continuity of supply of the Licensed Product (which manufacturing agreements and supply agreements assigned to PRF (**"Assigned Manufacturing Agreements**") may require payment by PRF for supply of the Licensed Product, it being understood that, with respect to any Assigned Manufacturing Agreement: (1) after the assignment of such Assigned Manufacturing Agreement by Eiger to PRF becomes effective ("**Assignment Effective Time**"), PRF shall be responsible for all ongoing obligations of Eiger under such Assigned Manufacturing Agreement, but only to the extent that such obligations: (w) arise after the Assignment Effective Time; (x) do not arise from or relate to any breach by Eiger of any provision of such Assigned Manufacturing Agreement; (y) are not the result of any event, circumstance or condition occurring or existing on or prior to the Assignment Effective Time; and (z) are ascertainable solely by reference to the express terms of such Assigned Manufacturing Agreement; provided, however, that (I) PRF shall not be obligated to assume, discharge or perform any obligation or liability under such Assigned Manufacturing Agreement if there shall not have been obtained prior to the assignment of such Assigned Manufacturing Agreement by Eiger to PRF any consent required to be obtained from any third party with respect to the assignment or delegation to PRF of any rights or obligations under such Assigned Manufacturing Agreement and (II) in no event shall PRF assume or be deemed to assume, pursuant to this Agreement or otherwise, any obligation or liability arising under such Assigned

Manufacturing Agreement that accrued or arose prior to the Assignment Effective Time, unless expressly agreed upon by PRF and Eiger in the written assignment agreement effectuating such assignment; and (2) such Assigned Manufacturing Agreement shall, if agreed upon by the third party counter-party to such Assigned Manufacturing Agreement, be novated and assigned to PRF in its entirety (as may be modified by PRF and such counter-party)); (B) fulfill any outstanding orders for Licensed Progeria Product submitted by PRF pursuant to Section 22(c); and (C) except to the extent Eiger is obligated under the Merck License Agreement to deliver Eiger's remaining inventory of Licensed Progeria Product to Merck, deliver to PRF all of the safety stock maintained by Eiger pursuant to Section 9(h). With respect to any other remaining inventory of Licensed Progeria Product of Eiger, the Parties shall discuss in good faith Eiger (as may be permitted by Merck if Merck does not exercise its rights under the Merck License Agreement to the Licensed Progeria Product possessed by Eiger) making available any such remaining inventory of Licensed Progeria Product to PRF. For the avoidance of doubt, any such remaining inventory of Licensed Progeria Product assigned to PRF other than the safety stock maintained by Eiger pursuant to Section 9(h) shall be delivered on an "as is" basis without warranty of any kind, and PRF shall be responsible for requalification or other requirements for research use or use in humans under any applicable laws, rules and regulations with respect to such remaining inventory. In the event Eiger provides to PRF any such remaining inventory of Licensed Progeria Product other than such safety stock, Eiger shall provide to PRF [*].

10. Delivery. Eiger shall deliver the Licensed Progeria Product [*] to PRF or its designee (provided that all products in a single order will be delivered to a single place of destination in the U.S.) by PRF's requested delivery date, provided that with respect to Licensed Progeria Product, PRF supply orders are made in accordance with Section 9(a). Delivery of the Licensed Progeria Product intended to be used for Research Activities outside of the U.S. shall be [*] for PRF to undertake export, shipment and delivery outside of the U.S. For clarity, this Section 10 does not apply to, and Eiger remains solely responsible for, the delivery of all Licensed Progeria Product under the global patient support program described in Section 7 and the expanded access or other "named patient" programs described in Section 8.

11. Supply of Licensed API.

(a) Eiger shall supply and deliver to PRF an average quantity of [*] of Licensed API (or such higher quantity as reasonably agreed upon by the Parties) per calendar year (the "Applicable Calendar Year"), at no cost or expense to PRF, for inclusion in and distribution by PRF's Cell and Tissue Bank (information about which is located, as of the Effective Date, at https://www.progeriaresearch.org/cell-and-tissue-bank/). Eiger may supply and deliver such average quantity of Licensed API during such Applicable Calendar Year or the immediately subsequent calendar year (the "Subsequent Calendar Year"), but the supply and delivery of such average quantity of Licensed API for the Applicable Calendar Year during the Subsequent Calendar Year shall not decrease Eiger's obligation to supply and deliver such average quantity of Licensed API for the Subsequent Calendar Year. Eiger shall deliver such Licensed API to [*], unless the Parties otherwise agree in writing to an alternative delivery location, [*], by delivery dates reasonably agreed upon by the Parties in writing.

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(b) Eiger shall (i) retain a sample of each batch of the Licensed API supplied under or pursuant to this Agreement and (ii) maintain and provide to PRF reasonable access to records of the Licensed API in each shipment, including CoAs. As reasonably requested by PRF, Eiger shall promptly provide PRF (A) a copy of such CoAs and (B) access to a copy of any such other records described in subclause (ii) of the foregoing sentence and any records of testing performed on such Licensed API (as such testing records are required to be maintained by Eiger pursuant to any applicable law, statute, rule or regulation).

12. Rejection.

(a) For each shipment of the Licensed Progeria Product, Eiger shall provide PRF with a CoA no less than [*] days before shipping. PRF shall reasonably promptly review the CoA and notify Eiger in writing within [*] days after PRF's receipt of such CoA of any non-conformance PRF identifies in the CoA. If no notification is provided from PRF, then Eiger shall ship the Licensed Progeria Product as scheduled, and PRF (or its designee) shall inspect the Licensed Progeria Product upon its receipt thereof. Within ten [*] days after delivery of any Licensed Progeria Product, PRF may reject all or any portion of any shipment of the Licensed Progeria Product that (i) has been damaged or tampered with (or the container or packaging of which has been damaged or tampered with) prior to receipt of such Licensed Progeria Product by or on behalf of PRF or its designee, (ii) is not in conformance with the approved Eiger IND or NDA for such Licensed Progeria Product or (iii) is adulterated or misbranded within the meaning of such terms under the Federal Food, Drug and Cosmetic Act (each of such Licensed Progeria Product, a "**Non-Conforming Product**").

(b) In order to reject a shipment of the Licensed Progeria Product, PRF must provide Eiger with a written notice of rejection and the basis therefor within [*] days after PRF's receipt of such shipment, except that in the case of any Licensed Progeria Product having any latent defect which, upon reasonable examination by PRF or its designee, could not have been discovered within such [*] day period after receipt thereof, PRF must provide Eiger with a notice of rejection and the basis therefor within [*] days after PRF becomes aware of such defect. Any notice of rejection from PRF must contain reasonable documentation to allow Eiger to reasonably determine whether such rejected Licensed Progeria Product is a Non-Conforming Product. If no such notice of rejection is received by Eiger within the applicable [*] day period set forth above, PRF shall be deemed to have accepted such delivery of such Licensed Progeria Product, as the case may be.

(c) If in good faith Eiger does not accept PRF's basis for rejection of any Licensed Progeria Product, the Parties shall engage a mutually acceptable independent third party laboratory to test the putative Non-Conforming Product in question to determine if such Licensed Progeria Product is a Non-Conforming Product. The determination of such laboratory shall be binding upon the Parties, and the costs of such testing shall be shared equally by the Parties.

(d) If Eiger accepts PRF's basis for rejection of any Licensed Progeria Product or if any such independent third party laboratory determines that the Licensed Progeria Product in question is a Non-Conforming Product, promptly upon receipt of such notice of rejection or such determination, Eiger shall, at PRF's request, use commercially reasonable efforts to promptly provide PRF with replacement Licensed Progeria Product in the same quantity as the Non-Conforming Product. Unless Eiger requests the return of a rejected batch of the Licensed Progeria Product within [*] after the later of the receipt of PRF's notice of rejection or, if applicable, the independent third party laboratory's determination that such Licensed Progeria Product is a Non-Conforming Product, PRF shall destroy such rejected batch of the Licensed Progeria Product and provide Eiger with written certification of such destruction. Within [*] after PRF's receipt of a written request from Eiger for the return of a rejected batch of the Licensed Progeria Product, PRF shall return such rejected batch to Eiger, at Eiger's cost and expense.

13. **Recalls; Safety Reporting**. Eiger shall have sole decision-making authority with respect to, and shall bear all costs and expenses relating to, issuing any recall, market withdrawal or correction of any Licensed Progeria Product provided by Eiger or with respect to issuing any advisory letter or other safety related communication with respect to any Licensed Progeria Product provided by Eiger. Eiger shall notify PRF in writing promptly (and in any event within (a) [*] after Eiger's receipt of any written notice or other communication from a regulatory agency that could reasonably be expected to result in any recall, market withdrawal, correction or suspension of distribution of any Licensed Progeria Product or (b) [*] after Eiger's receipt of any written notice or other communication from a regulatory agency that could reasonably be expected to result in any clinical hold of any Licensed Progeria Product) if any Licensed Progeria Product, or any Licensed API contained therein, is alleged or proven to be the subject of any recall, market withdrawal, correction, clinical hold or suspension of distribution. PRF will make available to Eiger, upon Eiger's written request, all of PRF's pertinent records in its Control relating to such Licensed Progeria Product that Eiger may reasonably request to assist in effecting any such recall, market withdrawal or correction. If either Party becomes aware of any information that reasonably suggests that a death or serious adverse reaction or injury will impact the Commercialization or development of the Licensed Progeria Product, such Party will (i) furnish such information to the other Party within [*] after such Party becomes aware of such information and (ii) make, maintain and retain records of such information.

14. **Inventory Records**. PRF shall keep Eiger reasonably informed of its use of all Licensed Progeria Product and shall keep full and accurate records of its receipt, use and inventory of any Licensed Progeria Product. Within [*] after the end of each [*], PRF shall provide Eiger with a written inventory report for the Licensed Progeria Product, documenting amounts of the Licensed Progeria Product being allocated to Research Activities and amounts otherwise being held in the possession of PRF, if any.

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15. **Intellectual Property**. Except as specifically set forth in this Agreement, Eiger retains all right, title, and interest in and to all Intellectual Property, information, know-how, Data and inventions that Eiger Controls as of the Effective Date ("**Pre-existing Eiger IP**") and all enhancements, modifications, extensions, improvements and derivatives of any Pre-existing Eiger IP developed independently by or for Eiger (either solely or jointly with any third party) and without use of the Confidential Information of PRF. Except as specifically set forth in this Agreement, PRF retains all right, title and interest in and to all Intellectual Property, information, know-how, Data and inventions that PRF Controls as of the Effective Date ("**Pre-existing PRF IP**") and all enhancements, modifications, extensions, improvements and derivatives of any Pre-existing PRF IP developed independently by or for PRF (either solely or jointly with any third party) and without use of the Confidential Information of Eiger (other than use of any Licensed Product in the Field).

16. **Confidential Information**.

(a) Obligations. Each Party (the "**Receiving Party**") will maintain in strict trust and confidence, and will not (i) use for any purpose other than the performance of its obligations and exercise of its rights under this Agreement, any Confidential Information (as defined below) received from the other Party in connection with this Agreement (the "**Disclosing Party**") or (ii) disclose any Confidential Information of the Disclosing Party to any persons or entities (other than the Receiving Party's employees, clinical site staff, contractors, consultants, agents or, in the case PRF is the Receiving Party, any person or entity to whom it provides any Licensed Progeria Product or Licensed API for any Research Activities, in each case who require such access for the purpose of this Agreement (including for the Receiving Party to perform its obligations or exercise its rights under this Agreement) and are obligated to keep the Disclosing Party's Confidential Information in confidence). "**Confidential Information**" of the Disclosing Party means (i) any information disclosed, directly or indirectly, by the Disclosing Party to the Receiving Party pursuant to this Agreement that (A) is in written, graphic, electronic or other tangible form (including documents, samples, know-how, data, product plans, research and development) and is marked "Confidential" or in a similar manner to indicate its confidential nature, (B) is disclosed orally, provided that such information is designated as confidential at the time of initial disclosure, or (C) otherwise should reasonably be considered confidential by the Receiving Party based on the circumstances of disclosure or the nature of the information itself or (ii) any Data owned or Controlled by the Disclosing Party. Confidential Information may include information of a third party disclosed by the Disclosing Party to the Receiving Party under this Agreement.

(b) Exceptions to Confidential Information. Obligations of non-disclosure and non-use will not apply to any information which: (i) is in the public domain or comes into the public domain through no breach of the confidentiality obligations set forth herein; (ii) is disclosed to the Receiving Party without restriction on disclosure and use by an independent third party having a legal right to make such disclosure without making such disclosure subject to confidentiality obligations; (iii) is already rightfully known by the Receiving Party without any confidentiality obligations at the time of receiving such information from the Disclosing

Party, as evidenced by the Receiving Party's prior written records and other competent evidence; or (iv) is independently developed by the Receiving Party without any use of or reference to the Disclosing Party's Confidential Information, as evidenced by written records and other competent evidence. If the Receiving Party becomes legally compelled to disclose any Confidential Information, the Receiving Party shall provide the Disclosing Party prompt written notice, if legally permissible, and shall reasonably assist the Disclosing Party in seeking a protective order, confidential treatment or other appropriate restriction on disclosure or remedy. In any event, the Receiving Party shall disclose only that portion of such Confidential Information that the Receiving Party is legally required to disclose and shall maintain the confidentiality of such disclosed Confidential Information for all other purposes in accordance with this Agreement.

(c) Maintenance of Confidentiality. The Receiving Party shall protect the Disclosing Party's Confidential Information against unauthorized use and disclosure using at least the same degree of care and taking at least the same measures the Receiving Party uses and takes to protect its own confidential information of a similar nature, but in no event will the Receiving Party use or take less than reasonable care or reasonable measures. The Receiving Party shall promptly notify the Disclosing Party of any actual or suspected unauthorized use or disclosure of any of the Disclosing Party's Confidential Information, of which the Receiving Party becomes aware.

17. Publicity.

(a) Publications. If either Party desires to publish findings related to any Research Activities conducted after the Effective Date (such Party, the "**Publishing Party**"): (i) the Publishing Party shall provide a copy of the proposed publication to the other Party for review at least [*] prior to publication if reasonably possible and, if not, as soon as reasonably possible prior to submission for publication but in no event less than [*] prior to publication; (ii) such other Party shall provide the Publishing Party with any comments to such proposed publication at least [*] prior to the proposed publishing date; and (iii) the Publishing Party shall consider such comments in good faith. Upon such other Party's reasonable written request, the Publishing Party shall remove any Confidential Information of such other Party contained in such publication.

(b) Public Announcement. Other than as required by law or regulation, neither Party shall issue any press release or public announcement relating to this Agreement, or otherwise publicize the collaboration between the Parties under this Agreement, without the prior written approval of the other Party, which approval shall not be unreasonably withheld, conditioned or delayed, except that, once a press release or public announcement has been approved in writing by both Parties, a Party may make subsequent public disclosure of the information contained in such statement without any further approval of the other Party.

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18. Representations and Warranties.

(a) Eiger hereby represents, warrants, covenants and agrees that:

(i) as of the Effective Date, Eiger has all rights, approvals and authorities necessary to enter into, and perform all of its obligations under, this Agreement;

(ii) Eiger shall manufacture, package, handle, supply and ship the Licensed Progeria Product and Licensed API in compliance with (A) the approved Eiger IND, (B) all applicable laws, statutes, rules and regulations, and (C) all standards consistent with and necessary for products intended for use in humans;

(iii) Eiger shall manufacture the Licensed Progeria Product and Licensed API in compliance with the good manufacturing practices promulgated by the FDA and the quality assurance and quality control practices that are standard in the pharmaceutical industry;

(iv) neither the Licensed Progeria Product nor Licensed API will be adulterated or misbranded within the meaning of such terms under the Federal Food, Drug and Cosmetic Act;

(v) accompanying each shipment of the Licensed Progeria Product for use in humans, Eiger shall supply the CoA confirming that the Licensed Progeria Product meets all requirements and specifications set forth in the Eiger IND or NDA (including specifications of purity, stability, and composition), as applicable;

(vi) as of the Effective Date, Eiger has all rights necessary to grant to PRF all licenses, sublicenses, rights of access and rights of use (as applicable) to all Intellectual Property, know-how and Data pursuant to and accordance with the terms and conditions of this Agreement; and

(vii) Eiger has provided to PRF a true and complete copy of the Merck License Agreement in effect as of the Effective Date.

(b) PRF hereby represents, warrants, covenants and agrees that:

(i) as of the Effective Date, PRF has all rights, approvals and authorities necessary to enter into, and fulfill all of its obligations under, this Agreement;

(ii) PRF shall handle, store, and use the Licensed Progeria Product and Licensed API in accordance with all applicable laws and regulations and any written instructions provided by Eiger with respect to the proper handling, storage, and use of the Licensed Progeria Product and Licensed API;

(iii) PRF shall not take any action to adulterate or misbrand (within the meaning of such terms under the Federal Food, Drug and Cosmetic Act) the Licensed Progeria Product or Licensed API;

(iv) the provisions of this Agreement cover, in addition to other matters, all covenants and obligations of Merck to PRF as of the Effective Date with respect to the supply of Licensed Progeria Product and Licensed API to PRF and the use of the Licensed Progeria Product and Licensed API in the Field; and

19. Warranty Disclaimer. EXCEPT FOR THE REPRESENTATIONS AND WARRANTIES PROVIDED BY THE PARTIES IN SECTION 18, (a) THE LICENSED PROGERIA PRODUCT AND LICENSED API ARE SUPPLIED BY EIGER TO PRF WITH NO WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, AND (b) BOTH PARTIES HEREBY DISCLAIM ALL WARRANTIES, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

20. Insurance; Indemnification.

(a) Each Party shall obtain and maintain insurance, including product liability insurance, in commercially reasonable and appropriate amounts at all times during the Term. Within [*] after a Party's written request, the other Party shall provide to the requesting Party copies of certificates of such insurance of such other Party. Each such insurance policy shall entitle the other Party to receive at least [*] prior written notice of any cancellation (including for nonrenewal) or change of any such insurance policy. All such insurance policies of Eiger will include PRF as an additional insured with respect to the Licensed Product. [*].

(b) Eiger shall indemnify, defend and hold harmless PRF and each of its officers, directors, employees and agents (collectively, "**PRF Indemnified Parties**") from and against any and all third party claims, losses, liabilities, damages, settlements, costs and expenses of any kind, as incurred, including reasonable attorneys' fees (collectively, "**Losses**") resulting from any suit, action, claim, demand or proceeding of any kind or nature arising from (i) Eiger's breach of any of its representations, warranties, covenants or agreements set forth in Section 18, (ii) any of Eiger's actions or failure to take action with respect to any Licensed Product in accordance with this Agreement or (iii) Eiger's gross negligence or willful misconduct, except in each case (i), (ii) and (iii) to the extent resulting from PRF's gross negligence or willful misconduct or to the extent such Losses would otherwise be subject to indemnification by PRF pursuant to Section 20(c) if such Losses were incurred or suffered by Eiger.

(c) PRF shall indemnify, defend and hold harmless Eiger and each of its officers, directors, employees and agents (collectively, "**Eiger Indemnified Parties**") from and against any and all third party Losses resulting from any suit, action, claim, demand or proceeding of any kind or nature arising from (i) PRF's use, handling, transfer or storage of the Licensed Progeria Product and Licensed API, in each case other than Losses in connection with any clinical trial agreement between PRF and an Additional Site that conducts, on behalf of, under the direction or supervision of, as instructed by or in collaboration with PRF, any clinical trial involving use in humans of the Licensed Progeria Product in the Field, (ii) PRF's breach of any of its representations and warranties set forth in Section 18 or (iii) PRF's gross negligence or willful misconduct, except in each case (i), (ii) and (iii) to the extent resulting from Eiger's gross negligence or willful misconduct or to the extent such Losses would otherwise be subject to indemnification by Eiger pursuant to Section 20(b) if such Losses were incurred or suffered by PRF.

(d) With respect to the indemnification obligations of each Party ("**Indemnifying Party**") set forth above in this Section 20: (a) the indemnified Party ("**Indemnified Party**") shall reasonably promptly notify the Indemnifying Party in writing of any claim for which the Indemnified Party seeks indemnification under this Section 20, provided, however, that the failure to reasonably promptly provide such notice will not relieve the Indemnifying Party from its liability or obligations under this Section 20, except to the extent the Indemnifying Party's defense of such claim is materially prejudiced by such failure; (b) the Indemnifying Party shall have sole control of the defense, settlement and negotiations for settlement (collectively, "**Defense**") of such claim at the Indemnifying Party's expense, provided, however, that the Indemnifying Party shall not, without the Indemnified Party's prior written consent, settle any such claim if such settlement (i) requires that any of the PRF Indemnified Parties (in the case PRF is the Indemnified Party) or any of the Eiger Indemnified Parties (in the case Eiger is the Indemnified Party) makes any payment or bears any other obligations (beyond those required under this Agreement), (ii) includes any admission of wrongdoing, fault or liability on the part of any of the PRF Indemnified Parties (in the case PRF is the Indemnified Party) or any of the Eiger Indemnified Parties (in the case Eiger is the Indemnified Party), (iii) does not include a full release of all PRF Indemnified Parties (in the case PRF is the Indemnified Party) or all Eiger Indemnified Parties (in the case Eiger is the Indemnified Party) or (iv) includes any injunctive or other equitable relief; and (c) the Indemnified Party shall, as reasonably requested by the Indemnifying Party, reasonably cooperate and provide reasonable assistance in connection with the Defense of such claim. The Indemnified Party shall have the right to participate in (but not control) such Defense through its own counsel and at its own cost and expense to monitor such Defense. The Indemnifying Party shall in good faith consult with such counsel for the Indemnified Party and keep such counsel reasonably advised of the status of such Defense.

21. **Term**. Unless earlier terminated in accordance with Section 22, this Agreement shall commence as of the Effective Date and continue in effect for an initial term of [*] ("**Initial Term**"), and shall thereafter automatically renew for subsequent renewal terms of two (2) years each (each a "**Renewal Term**"), unless either Party notifies the other Party in writing no later than [*] prior to the end of the then existing Initial Term or Renewal Term (as the case may be) that it does not intend to renew this Agreement for a subsequent Renewal Term. The Initial Term together with all Renewal Terms are referred to in this Agreement as the "**Term**."

22. **Termination**.

(a) PRF Termination. PRF may terminate this Agreement: (i) for any reason upon [*] prior written notice to Eiger; or (ii) [*]. The Parties agree that any termination pursuant to the foregoing clause (ii) in this Section 22(a) shall be deemed a termination for convenience by Eiger.

(b) Eiger Termination. Eiger may terminate this Agreement: (i) immediately upon PRF's material breach of this Agreement if PRF fails to cure such breach within [*] after its receipt from Eiger of a written notice reasonably describing such breach; or (ii) immediately upon written notice to PRF of the rightful termination or expiration of the Merck License Agreement pursuant to the terms and conditions thereof, provided that Eiger has notified PRF in writing immediately upon Eiger's receipt from Merck, or Eiger's sending to Merck, any notice of termination of the Merck License Agreement ("**Merck License Agreement Termination Notice**").

(c) Orders Prior to Termination. In the event PRF terminates this Agreement for any reason or Eiger terminates this Agreement pursuant to Section 22(b)(ii), Eiger agrees that, subject to Eiger's obligation to continue to supply the Licensed Progeria Product as set forth in Section 9(f), PRF has the right (but not the obligation) to submit to Eiger prior to the effective date of termination, and Eiger will fulfill, any final orders in accordance with Section 9(a) for any Licensed Progeria Product in quantities specified by PRF (such quantities to be reasonable based on the then-current estimates pursuant to Section 9(a)(iii) as finally agreed upon by the Parties after conferring with each other in good faith), notwithstanding any prior forecasts by PRF for such Licensed Progeria Product.

(d) Effects of Termination. In the event of expiration or termination of this Agreement for any reason (other than (1) Eiger's termination of this Agreement in accordance with Section 22(b)(i) for PRF's uncured material breach or (2) PRF's termination of this Agreement in accordance with Section 22(a)(i) for convenience and not due to any breach of this Agreement by Eiger), Eiger shall, to the extent Eiger has rights or is permitted under the Merck License Agreement or Merck (or any successor of Merck or of Merck's rights in the Licensed Compound) otherwise agrees or permits in writing:

(i) [*] (A) [*] (B) *];

(ii) [*] (A) [*] and (B) [*];

(iii) provide PRF with complete and unredacted copies of all Data and all draft regulatory filings (it being understood that "draft" means documents reasonably available and in the possession or control of Eiger (or any of its Affiliates) as of the date of such expiration or termination), in each case to the extent Controlled by Eiger that may be necessary to (A) Commercialize the Licensed Product in the Field and (B) prepare, file or maintain any Progeria NDA, it being understood that with respect to access to Data and information regarding chemistry, manufacturing and controls such information may be provided solely by Right of Reference granted by Eiger to PRF (or its designee);

(iv) (A) [*] (B) [*];

(v) [*] (A) [*]; (B) [* ; and (C) [*]; and

(vi) [*] (A) [*] or (B) [*].

(e) Return or Destruction of Confidential Information. Upon the expiration or termination of all licenses granted by a Party ("Granting Party") to the other Party under or pursuant to this Agreement ("Former Licensee"), such Former Licensee shall (a) reasonably promptly return to such Granting Party or destroy all of such Granting Party's Confidential Information, and all copies, notes or extracts thereof, in the possession or control of such Former Licensee and (b) in the case of destruction, provide such Granting Party with written certification of such destruction signed by an officer of such Former Licensee.

[*] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

(f) Survival. Upon the expiration or any termination of this Agreement, the following provisions shall survive: Sections 1, 3, 6, the last sentence of 9(c), 9(f), 9(i), 10, the last sentence of 11(b), 13, 15, 16, 17(a), 18, 19, 20(b), 20(c), 20(d), 22(c), 22(d), 22(e), 22(f), and 23 through and including 31. In addition, upon the expiration or termination of this Agreement for any reason (other than for Eiger's termination of this Agreement in accordance with Section 22(b) or PRF's termination of this Agreement in accordance with Section 22(a)(i) for convenience and not due to any breach of this Agreement by Eiger), Sections 2(c) and 2(d) shall survive so long as the Merck License Agreement is in effect.

23. **Assignment**. Neither Party may assign this Agreement, including by operation of law, without the prior written consent of the other Party, which consent will not be unreasonably withheld or delayed, except that either Party may assign this Agreement (i) to an Affiliate of such Party or (ii) as part of a merger, consolidation, corporate reorganization or sale of all or substantially all of such Party's assets, in each case (i) and (ii), without the prior written consent of the other Party provided that (A) the permitted assignee assumes in writing the performance of all of the assigning Party's obligations under this Agreement and (B) in the case Eiger is the assigning Party, Eiger simultaneously assigns the Merck License Agreement to the permitted assignee. Any attempted assignment in violation of the foregoing restriction will be void. Subject to the foregoing restriction, this Agreement will be binding upon, enforceable by, and inure to the benefit of the Parties and their respective successors and permitted assigns.

24. **Entire Agreement**. This Agreement sets forth the complete and final agreement of the Parties with respect to the subject matter hereof and supersedes and terminates all prior agreements and understandings, written or oral, between the Parties with respect to such subject matter, including the Non-Binding Term Sheet, dated July 14, 2017, by and between the Parties. This Agreement may be amended, and the observance of any provision of this Agreement may be waived, only by a writing signed by both Parties. The failure by either Party to enforce any provision of this Agreement will not constitute a waiver of future enforcement of that or any other provision.

25. **Relationship of the Parties**. PRF and Eiger are independent contractors, and nothing in this Agreement will be construed as making them partners or as creating the relationships of employer and employee, master and servant, or principal and agent between them, for any purpose whatsoever. Neither Party will make any contracts, warranties or representations or assume or create any other obligations, express or implied, in the other Party's name or on its behalf.

26. **Governing Law**. The validity, performance, construction, and effect of this Agreement shall be governed by and construed under the substantive laws of the State of New York, without regard to conflicts of law rules that would cause the application of the laws of another jurisdiction.

[*] = Certain confidential information contained in this document, marked by brackets, is filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

27. Dispute Resolution.

(a) Resolution by Executives. If any unresolved dispute as to matters arising under or relating to this Agreement or either Party's rights or obligations hereunder arises, either Party may refer such dispute to the Executive Director (if referring the dispute to PRF) or the Chief Executive Officer (if referring the dispute to Eiger), who shall meet in person or by telephone within [*] after such referral to attempt in good faith to resolve such dispute. If such matter cannot be resolved by discussion of such officers within such [*] period (as may be extended by mutual written agreement of the Parties), such dispute shall be resolved in accordance with Section 27(b). The Parties acknowledge that discussions between the Parties in an attempt to resolve any disputes are settlement discussions under applicable rules of evidence and without prejudice to either Party's legal position.

(b) Arbitration. Any dispute that is not resolved pursuant to Section 27(a), except for any dispute, claim or controversy subject to Section 27(b)(vi), shall be settled by binding arbitration administered by federal arbitration before a single arbitrator having substantial experience with commercial transactions in the pharmaceutical industry. Such arbitration shall be governed by the U.S. Federal Arbitration Act, 9 U.S.C. §§ 1-16 (the "**Federal Arbitration Act**"), to the exclusion of any inconsistent state laws and conducted in accordance with the Arbitration Rules and Procedures of the Judicial Arbitration and Mediation Service, Inc. ("**JAMS**") then in effect. The arbitration will be conducted promptly in Boston, Massachusetts, and the Parties consent to the personal jurisdiction of the Federal District Court in the District of Massachusetts for any case arising out of or otherwise related to the arbitration, its conduct or its enforcement. Each Party shall have [*] to present its case, and the Parties shall jointly request that the arbitrator render a final decision within [*] following completion of each Party's presentation or as soon thereafter as is practicable.

(i) Any award shall be promptly paid free of any tax, deduction or offset, and any costs, fees or taxes incident to enforcing the award shall, to the maximum extent permitted by law, be charged against the Party resisting enforcement. The prevailing Party in the arbitration shall be entitled to receive reimbursement of its reasonable expenses (including reasonable attorneys' fees, expert witness fees and all other expenses) incurred in connection with such arbitration. Each Party agrees (A) to abide by the award rendered in any arbitration conducted pursuant to this Section 27(b) and (B) that, subject to the Federal Arbitration Act, judgment may be entered upon the final award in the Federal District Court in the District of Massachusetts and that other courts may award full faith and credit to such judgment in order to enforce such award. The award shall include interest from the date of any damages incurred for breach of this Agreement, and from the date of the award until paid in full, at a rate fixed by the arbitrator.

(ii) Except as set forth in Section 27(b)(i), each Party shall bear its own legal fees. The arbitrators shall have the authority to grant specific performance or to allocate between the Parties the costs of arbitration (including service fees, arbitrator fees and all other fees related to the arbitration) in such equitable manner as the arbitrator may determine.

(iii) Provided a Party has made a sufficient showing under the rules and standards set forth in the U.S. Federal Rules of Civil Procedure and applicable case law, the arbitrator shall have the freedom to invoke, and the Parties agree to abide by, injunctive

measures after either Party submits in writing for arbitration claims requiring immediate relief. Additionally, nothing in this Section 27 will preclude either Party from seeking any injunctive relief from a court of competent jurisdiction, including a temporary restraining order, preliminary injunction, permanent injunction or other equitable relief, concerning a dispute either prior to, during or after any arbitration if necessary to protect the interests of such Party or to preserve the status quo pending the arbitration proceeding.

(iv) The arbitration proceeding will be confidential and the arbitrator shall issue appropriate protective orders to safeguard each Party's Confidential Information.

(v) Any duty to arbitrate under this Agreement shall remain in effect and be enforceable after expiration or termination of this Agreement for any reason.

(vi) Any dispute, controversy or claim relating to the scope, validity, enforceability, infringement, violation, ownership, license or other rights of or with respect to any patents, trademarks or other intellectual property shall be submitted to a court of competent jurisdiction.

28. **Notices**. All notices required or permitted to be given under this Agreement will be in writing and will be sent by an overnight courier service with package tracking capabilities and costs prepaid, by registered or certified airmail, return receipt requested and postage prepaid, to the other Party at the addresses set forth in the preamble of this Agreement and to the attention of President and Executive Director (in the case of PRF) or the President and CEO (in the case of Eiger). Such notices will be deemed to have been given when received by the addressee. Any Party may give written notice of a change of address in accordance with this Section 28, whereupon any notice or request will thereafter be given to such Party as above provided at such changed address.

29. **Severability**. If any provision of this Agreement is held to be illegal or unenforceable, such provision will be limited or eliminated to the minimum extent necessary so that the remainder of this Agreement will continue in full force and effect and be enforceable, and the validity, legality and enforceability of the remaining provisions will not in any way be affected or impaired thereby. The Parties agree to negotiate in good faith an enforceable substitute provision for any invalid or unenforceable provision that most nearly achieves the Parties' intent of such provision.

30. **Construction; Headings**. No rule of construction that disfavors the drafting party will apply to this Agreement. As used in this Agreement, "including" and words of similar import mean "including but not limited to." The use of "or" will not be deemed to be exclusive. Headings and titles used in this Agreement are for convenience of reference only and shall not be used in interpreting this Agreement.

31. **Counterparts**. This Agreement may be executed in counterparts (including by facsimile or electronic transmission), each of which shall be deemed to be an original copy of this Agreement and all of which taken together shall be regarded as one and the same instrument.

[*SIGNATURE PAGE FOLLOWS.*]

[*] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

In Witness Whereof, the Parties have executed this Agreement in duplicate originals by their respective authorized officers as of the Effective Date.

Eiger BioPharmaceuticals, Inc.		**The Progeria Research Foundation, Inc.**	
By:	/s/ David Cory	By:	/s/ Meryl Fink
Name:	David Cory	Name:	Meryl Fink
Title:	President, CEO	Title:	Executive Director, President

[Signature Page to Collaboration and Supply Agreement]

[*] = Certain confidential information contained in this document, marked by brackets, is filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

EXECUTION VERSION

Exhibit A

[*]

[*] = Certain confidential information contained in this document, marked by brackets, is filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

SECOND AMENDMENT TO
LOAN AND SECURITY AGREEMENT

THIS **SECOND AMENDMENT** to Loan and Security Agreement (this "**Amendment**") is entered into as of May 11, 2018, by and between **OXFORD FINANCE LLC**, a Delaware limited liability company with an office located at 133 North Fairfax Street, Alexandria, Virginia 22314 ("**Oxford**"), as collateral agent (in such capacity, "**Collateral Agent**"), the Lenders listed on Schedule 1.1 of the Loan Agreement (as defined below) or otherwise party thereto from time to time including Oxford in its capacity as a Lender (each a "**Lender**" and collectively, the "**Lenders**"), and EIGER BIOPHARMACEUTICALS, INC., a Delaware corporation ("**Parent**"), EB Pharma, LLC, a Delaware limited liability company ("**EB Pharma**") and EBPI Merger, Inc., a Delaware corporation ("**EBPI**"), each with offices located at 2155 Park Blvd., Palo Alto, CA 94306 (Parent, EB Pharma and EBPI, individually and collectively, jointly and severally, "**Borrower**").

RECITALS

A. Collateral Agent, Lenders and Borrower have entered into that certain Loan and Security Agreement dated as of December 30, 2016 (as amended from time to time, the "**Loan Agreement**").

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

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

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

AGREEMENT

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

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

2. Amendments to Loan Agreement.

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

"(a) Availability.

(i) Subject to the terms and conditions of this Agreement, on the Effective Date, the Lenders, severally and not jointly, made term loans to Borrower in an aggregate amount of Fifteen Million Dollars ($15,000,000.00) according to each Lender's Term A Loan Commitment as set forth on Schedule 1.1 hereto (as in effect prior to the Second Amendment Effective Date) (such term loans are hereinafter referred to singly as a "**Term A Loan**", and collectively as the "**Term A Loans**"). After repayment, no Term A Loan may be re-borrowed.

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

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

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

"(b) Repayment. Borrower shall make monthly payments of interest only commencing on the first (1st) Payment Date following the Funding Date of each Term Loan, and continuing on the Payment Date of each successive month thereafter through and including the Payment Date immediately preceding the Amortization Date. Borrower agrees to pay, on the Funding Date of each Term Loan, any initial partial monthly interest payment otherwise due for the period between the Funding Date of such Term Loan and the first Payment Date thereof. Commencing on the Amortization Date, and continuing on the Payment Date of each month thereafter, Borrower shall make consecutive equal monthly payments of principal, together with applicable interest, in arrears, to each Lender, as calculated by Collateral Agent (which calculations shall be deemed correct absent manifest error) based upon: (1) the amount of such Lender's Term Loan then outstanding, (2) the effective rate of interest, as determined in Section 2.3(a), and (3) a repayment schedule equal to thirty (30) months. All unpaid principal and accrued and unpaid interest with respect to each Term Loan is due and payable in full on the Maturity Date. Each Term Loan may only be prepaid in accordance with Sections 2.2(c) and 2.2(d)."

2.3 Section 2.5 (Fees). Section 2.2(b) of the Loan Agreement hereby is amended and restated in its entirety to read as follows:

"**2.5 Fees.** Borrower shall pay to Collateral Agent:

(a) Facility Fee. A fully earned, non-refundable facility fee of One Hundred Twenty-Five Thousand Dollars ($125,000.00) to be shared between the Lenders pursuant to their respective Commitment Percentages payable as follows: (i) Seventy-Five Thousand Dollars ($75,000.00) of the facility fee shall be due and payable on the Effective Date, (ii) Twenty-Five Thousand Dollars ($25,000.00) of the facility fee shall be due and payable on the Second Amendment Effective Date, and (iii) the remaining Twenty-Five Thousand Dollars ($25,000.00) of the facility fee shall be due and payable on the Funding Date of the Term C Loan;

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

(c) Prepayment Fee. The Prepayment Fee, when due hereunder, to be shared between the Lenders in accordance with their respective Pro Rata Shares;

(d) Second Amendment Fee. The Second Amendment Fee, when due hereunder, to be shared between the Lenders in accordance with their respective Pro Rata Shares; and

(e) Lenders' Expenses. All Lenders' Expenses (including reasonable attorneys' fees and expenses for documentation and negotiation of this Agreement) incurred through and after the Effective Date, when due."

2.4 **Section 10 (Notices).** The notice information for Borrower in Section 10 of the Loan Agreement hereby is amended and restated as follows:

If to Borrower:	EIGER BIOPHARMACEUTICALS, INC. 2155 Park Blvd. Palo Alto, CA 94306 Attn: Chief Financial Officer Fax: (650) 618-1621 Email: jwelch@eigerbio.com
with a copy (which shall not constitute notice) to:	Cooley LLP 3175 Hanover Street Palo Alto, CA 94304-1130 Attn: Glen Sato Fax: (650) 849-7400 Email: gsato@cooley.com”

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

“**Amortization Date**” is February 1, 2019.

“**Draw Period**” is the period commencing on the date of the occurrence of a Term C Milestone and ending on the earliest of (i) sixty (60) days from the occurrence of a Term C Milestone, (ii) December 31, 2018, and (iii) the occurrence of any Event of Default; provided, however, that the Draw Period shall not commence if on the date of the occurrence of a Term C Milestone an Event of Default has occurred and is continuing.

“**Second Amendment Effective Date**” is May 11, 2018.

“**Second Amendment Fee**” is a non-refundable amendment fee, fully-earned as of the Second Amendment Effective Date, in the amount of Eighty-Five Thousand Dollars ($85,000.00) due on the earlier to occur of (i) the Maturity Date or (ii) the prepayment of the Term Loans pursuant to Section 2.2(c) or (d).

“**Term C Loan(s)**” is defined in Section 2.2(a)(iii) hereof.

“**Term C Milestone**” means Borrower has achieved positive final Phase 2 data from at least one of the following three programs: (i) pegylated interferon-lambda LIMT-HDV Phase 2 trial in hepatitis delta virus, (ii) the Exendin Prevent Phase 2 trial in post-bariatric surgery associated hypoglycemia, or (iii) the Ubenimex ULTRA Phase 2 trial in lymphedema; in each case, provided that Borrower has provided to Collateral Agent written evidence of the same, in form and content acceptable to Collateral Agent in its sole discretion.

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

2.6 **Section 13.1 (Definitions).** The defined terms “Second Draw Period” and “Term B Milestones” and their respective definitions are deleted in their entirety from Section 13.1 of the Loan Agreement.

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

3. Limitation of Amendment.

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

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

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

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

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

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

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

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

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

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

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

6. Effectiveness. This Amendment shall be deemed effective upon (a) the due execution and delivery to Collateral Agent and Lenders of (i) this Amendment by each party hereto, (ii) the Disbursement Letter attached hereto, (iii) a Secured Promissory Note in favor of Oxford in respect of the Term B Loan attached hereto, and (iv) the Corporate Borrowing Certificate for each Borrower, the form of which is attached hereto, (b) Borrower's payment of Twenty-Five Thousand Dollars ($25,000.00) of the facility fee due as specified in Section 2.5 of the Loan Agreement (as revised by this Amendment), and (c) Borrower's payment of all Lenders' Expenses incurred through the date of this Amendment.

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

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

BORROWER:

EIGER BIOPHARMACEUTICALS, INC.

By: /s/ Jim Welch
Name: Jim Welch
Title: CFO

EB PHARMA, LLC

By: _____
Its: _____

By: _____
Name: _____
Title: _____

EBPI MERGER, INC.

By: /s/ Jim Welch
Name: Jim Welch
Title: CFO

COLLATERAL AGENT AND LENDER:

OXFORD FINANCE LLC

By: _____
Name: _____
Title: _____

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

BORROWER:

EIGER BIOPHARMACEUTICALS, INC.

By: _____
Name: _____
Title: _____

EB PHARMA, LLC

By: /s/ James P. Shaffer
Its: Chief Business Officer

By: /s/ James P. Shaffer
Name: _____
Title: _____

EBPI MERGER, INC.

By: _____
Name: _____
Title: _____

COLLATERAL AGENT AND LENDER:

OXFORD FINANCE LLC

By: _____
Name: _____
Title: _____

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

BORROWER:

EIGER BIOPHARMACEUTICALS, INC.

By: _____
Name: _____
Title: _____

EB PHARMA, LLC

By: _____
Its: _____

By: _____
Name: _____
Title: _____

EBPI MERGER, INC.

By: _____
Name: _____
Title: _____

COLLATERAL AGENT AND LENDER:

OXFORD FINANCE LLC

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

SCHEDULE 1.1

Lenders and Commitments

Term A Loans

Lender	Term Loan Commitment	Commitment Percentage
OXFORD FINANCE LLC	$15,000,000.00	100.00%
TOTAL	**$15,000,000.00**	**100.00%**

Term B Loans

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

Term C Loans

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

Aggregate (all Term Loans)

Lender	Term Loan Commitment	Commitment Percentage
OXFORD FINANCE LLC	$25,000,000.00	100.00%
TOTAL	**$25,000,000.00**	**100.00%**

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: August 10, 2018

/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, James Welch, 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: August 10, 2018

/s/ James Welch
James Welch
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 James Welch, 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 June 30, 2018, 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: August 10, 2018

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

/s/ James Welch
James Welch
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."