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

Form 10-Q

(Mark One)

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

For the quarterly period ended September 30, 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, every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☒		

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

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

As of November 5, 2018, the number of outstanding shares of the registrant's common stock, par value $0.001 per share, was 19,095,526.

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

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	September 30, 2018 (Unaudited)	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 16,927	$ 32,035
Debt securities, available-for-sale	48,013	9,744
Prepaid expenses and other current assets	1,864	712
Total current assets	66,804	42,491
Property and equipment, net	185	79
Other assets	389	312
Total assets	$ 67,378	$ 42,882
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 6,517	$ 3,183
Accrued liabilities	1,459	2,084
Current portion of long term debt	6,565	2,002
Total current liabilities	14,541	7,269
Long term debt, net	18,856	13,091
Other long term liabilities	214	—
Total liabilities	33,611	20,360
Stockholders' equity:		
Common stock	14	11
Additional paid-in capital	188,455	141,320
Accumulated other comprehensive loss	(6)	(3)
Accumulated deficit	(154,696)	(118,806)
Total stockholders' equity	33,767	22,522
Total liabilities and stockholders' equity	$ 67,378	$ 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 September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Operating expenses:				
Research and development	$ 13,196	$ 6,145	$ 25,080	$ 21,740
General and administrative	3,643	2,727	9,874	9,195
Total operating expenses	16,839	8,872	34,954	30,935
Loss from operations	(16,839)	(8,872)	(34,954)	(30,935)
Interest expense	(681)	(388)	(1,574)	(1,129)
Interest income	371	98	654	321
Other income (expense), net	5	(8)	(16)	188
Net loss	$ (17,144)	$ (9,170)	$ (35,890)	$ (31,555)
Net loss per common share, basic and diluted	$ (1.20)	$ (1.10)	$ (2.92)	$ (3.77)
Weighted-average common shares outstanding, basic and diluted	14,255,843	8,372,934	12,290,500	8,366,880

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Net loss	$ (17,144)	$ (9,170)	$ (35,890)	$ (31,555)
Other comprehensive loss:				
Unrealized gain (loss) on available-for-sale debt securities	8	4	(3)	13
Comprehensive loss	$ (17,136)	$ (9,166)	$ (35,893)	$ (31,542)

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

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

	Nine Months Ended September 30,	
	2018	**2017**
Operating activities		
Net loss	$ (35,890)	$ (31,555)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	34	30
Amortization of debt securities discounts	(257)	(63)
Non-cash interest expense	393	266
Common stock issued under Product Development Agreement	361	—
Stock-based compensation	3,496	3,223
Gain on intellectual property sale	—	(200)
Change in operating assets and liabilities:		
Prepaid expenses and other current assets	(1,152)	(202)
Other non-current assets	(77)	77
Accounts payable	3,334	1,528
Accrued and other liabilities	(625)	(1,083)
Other long term liabilities	214	—
Net cash used in operating activities	(30,169)	(27,979)
Investing activities		
Purchase of debt securities available-for-sale	(52,265)	(22,533)
Proceeds from maturities of debt securities available-for-sale	14,250	35,525
Proceeds from intellectual property sale	—	200
Purchase of property and equipment	(140)	(44)
Net cash (used in) provided by investing activities	(38,155)	13,148
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	9,935	—
Proceeds from issuance of common stock upon stock option exercises	295	11
Proceeds from issuance of common stock upon ESPP purchase	96	142
Net cash provided by financing activities	53,216	153
Net decrease in cash and cash equivalents	(15,108)	(14,678)
Cash and cash equivalents at beginning of period	32,035	27,756
Cash and cash equivalents at end of period	$ 16,927	$ 13,078

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. Lonafarnib is the Company's lead compound advancing into 1) Phase 3 in a single, pivotal trial to treat Hepatitis Delta Virus ("HDV") infection by the end of the year, and 2) NDA for the treatment of Hutchinson-Gilford Progeria Syndrome (HGPS or Progeria) in 2019. The Company's principal operations are based in Palo Alto, California, and it operates in one segment.

Liquidity

As of September 30, 2018, the Company had $16.9 million of cash and cash equivalents, $48.0 million of debt securities available-for-sale, an accumulated deficit of $154.7 million and negative cash flows from operating activities. The Company expects to continue to incur losses for the next several years.

In October 2018, the Company completed an underwritten public offering of 4,830,918 shares of common stock, including 630,120 shares of common stock purchased to the underwriter's option to purchase additional shares, at an offering price of $10.35 per share. The Company received net proceeds of approximately $48.0 million, after deducting underwriting discounts and commissions. See Note 11.

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 September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Options to purchase common stock	2,079,497	1,530,394	2,079,497	1,530,394
Warrants to purchase common stock	10,180	10,180	10,180	10,180
Total	2,089,677	1,540,574	2,089,677	1,540,574

Recent Accounting Pronouncements

In January 2016, the FASB issued ASU No. 2016-01, *Recognition and Measurement of Financial Assets and Financial Liabilities*. ASU No. 2016-01 supersedes and amends the guidance to classify equity securities with readily determinable fair values into different categories (that is, trading or available-for-sale) and require equity securities to be measured at fair value with changes in the fair value recognized through net income. The amendments allow equity investments that do not have readily determinable fair values to be remeasured at fair value either upon the occurrence of an observable price change or upon identification of an impairment. The amendments also require enhanced disclosures about those investments. ASU No. 2016-01 is effective for annual reporting beginning after December 15, 2017, including interim periods within the year of adoption, and calls for prospective application. The Company has adopted this guidance during the quarter ended March 31, 2018. The adoption of this guidance did not have a significant impact on the operating results when adopted.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*, which requires lessees to recognize most leases on their balance sheet. The new standard will be effective for fiscal years beginning after December 15, 2018. Early adoption is permitted. Originally, entities were required to adopt ASU 2016-02 using a modified retrospective transition method. However, in July 2018, the FASB issued ASU No. 2018-11, *Targeted Improvements to Leases (Topic 842)*, which provides entities with an additional transition method. Under ASU No. 2018-11, entities have the option of recognizing the cumulative effect of applying the new standard as an adjustment to beginning retained earnings in the year of adoption while continuing to present all prior periods under previous lease accounting guidance. Additionally, in July 2018, the FASB issued ASU No. 2018-10, *Codification Improvements to Leases (Topic 842)*, which clarifies how to apply certain aspects of ASU 2016-02. 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 August 2016, the FASB issued ASU No. 2016-15, *"Statement of Cash Flows (Topic 230)*: *Classification of Certain Cash Receipts and Cash Payments.* ASU 2016-15 identifies how certain cash receipts and cash payments are presented and classified in the Statement of Cash Flows. The standard is effective for fiscal years and interim periods beginning after December 15, 2017. The standard should be applied retrospectively and early adoption is permitted, including adoption in an interim period. The Company has adopted this guidance during the quarter ended March 31, 2018. The adoption of this guidance did not have a significant impact on the statement of cash flows when adopted.

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.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820)*. The standard eliminates, modifies and adds disclosure requirements for fair value measurements. The pronouncement is effective for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2019, with early adoption permitted. The Company is currently in the process of evaluating the impact the standard will have on its consolidated financial statements.

3. Fair Value Measurements

Fair value accounting is applied for all financial assets and liabilities that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually). At September 30, 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 September 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):

	September 30, 2018			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Money market fund	$ 6,681	$ —	$ —	$ 6,681
Corporate debt securities	—	21,722	—	21,722
Commercial paper	—	28,537	—	28,537
Total	$ 6,681	$ 50,259	$ —	$ 56,940

	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 September 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):

	September 30, 2018			
	Amortized cost	Unrealized gain	Unrealized loss	Estimated Fair Value
Cash equivalents:				
Money market funds	$ 6,681	$ —	$ —	$ 6,681
Corporate debt securities	—	—	—	—
Commercial paper	2,246	—	—	2,246
Total cash equivalents	$ 8,927	$ —	$ —	$ 8,927
Debt securities:				
Corporate debt securities	$ 21,726	$ 1	$ (5)	$ 21,722
Commercial paper	26,293	1	(3)	26,291
Total debt securities	$ 48,019	$ 2	$ (8)	$ 48,013

	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 nine months ended September 30, 2018, the Company did not recognize any other-than-temporary impairment losses.

4. Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	September 30, 2018	December 31, 2017
Compensation and related benefits	$ 1,049	$ 1,262
Contract research costs	196	634
Consulting costs	184	87
Franchise tax	30	56
Contract manufacturing costs	—	4
Other	—	41
Total accrued liabilities	$ 1,459	$ 2,084

5. License, Collaboration and Product Development Agreements

Product Development Agreement

On August 11, 2018, the Company entered into a Product Development Agreement and a First Project Agreement (the "Product Agreements"), pursuant to which the Company will receive development program support services for its hepatitis Delta virus ("HDV") program. The services are to be provided from July 1, 2018 through the completion of the Phase 3 Clinical Study Reports and the subsequent NDA filing. As consideration, the Company has committed to pay fees of approximately $10.0 million in cash and stock over four years, including approximately $0.8 million for expert consultant fees and pass through costs to vendors, plus certain incentive-based regulatory milestone fees up to $1.0 million. As part of the aggregate payment, the Company issued 115,526 shares of common stock subject to quarterly vesting requirements related to successful performance of the services and achievement of budget timeline set forth in the Product Agreements. The Product Agreements can be terminated by either party due to material breach or by the Company without cause with 90 days prior written notice. As of September 30, 2018, the Company recognized research and development expense of $0.4 million related to the shares issued under the Product 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 or any royalty payments for sales of a specified quantity of lonafarnib to treat the currently estimated progeria and progeroid laminopathies patient population worldwide.

Progeria Research Foundation (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 and progeroid laminopathies 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 and progeroid laminopathies at the Company's expense, (ii) prepare and be the sponsor of any NDA submission for lonafarnib for the treatment of progeria and progeroid laminopathies to the FDA, (iii) use commercially reasonable efforts to file a NDA for progeria and progeroid laminopathies 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 providing 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.

6. Debt

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

The Oxford Loan bears interest at a floating rate per annum equal to the greater of either the 30-day U.S. Dollar LIBOR reported in the Wall Street Journal plus 6.41% or 6.95%. 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, $0.4 million for Amended Tranche B and $0.4 million for Amended Tranche C. 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 $0.4 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 September 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 $0.7 million and $1.6 million for the three and nine months ended September 30, 2018. Long-term debt and unamortized discount balances are as follows (in thousands):

	September 30, 2018	December 31, 2017
Face value of long term debt	$ 25,000	$ 15,000
Exit fee	1,960	1,125
Unamortized debt discount associated with exit fee, debt issuance costs and loan origination fees	(1,539)	(1,032)
Total long term debt	25,421	15,093
Less: current portion of long term debt	(6,565)	(2,002)
Long term debt, net	$ 18,856	$ 13,091

7. Stock-Based Compensation

The following table summarizes stock option activity under the Company's stock-based compensation plan during the nine months ended September 30, 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		(39,780)	$ 7.45		
Canceled and forfeited	215,274	(215,274)	$ 13.36		
Outstanding as of September 30, 2018	673,479	2,079,497	$ 11.75	8.33	$ 4,243
Vested and exercisable as of September 30, 2018		842,968	$ 12.62	7.66	$ 2,080

During the three and nine months ended September 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 $7.50 for the nine months ended September 30, 2018. During the three and nine months ended September 30, 2017, the Company granted employees stock options for 56,000 and 579,700 shares, respectively. The weighted-average grant date fair value of these options was $7.45 and $7.66 for the three and nine months ended September 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 September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Expected term (in years)	—	5.77-6.08	5.27-6.08	5.27-6.08
Volatility	—	79.0%	84.0%-84.5%	79.0%-80.0%
Risk free interest rate	—	1.93%-2.01%	2.35%-2.68%	1.63%-2.23%
Dividend yield	—	—	—	—

Stock-Based Compensation Expense

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Research and development	$ 344	$ 273	$ 1,138	$ 771
General and administrative	828	680	2,358	2,452
Total	$ 1,172	$ 953	$ 3,496	$ 3,223

As of September 30, 2018, the total unrecognized compensation expense related to unvested options was $9.7 million, which the Company expects to recognize over an estimated weighted average period of 2.8 years.

8. Income Taxes

The tax expense for the three and nine months ended September 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 nine months ended September 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 were heard on August 28, 2018 before the Ninth Circuit Court of Appeals, and on September 17, 2018, the court ruled that the lower court ruling was re-affirmed. The plaintiff had two weeks to file a petition for a rehearing and such filing was not made within the allowed time, effectively terminating the shareholder lawsuit.

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 nine months ended September 30, 2018.

11. Subsequent Events

In October 2018, the Company completed an underwritten public offering of 4,830,918 shares of common stock, including 630,120 shares of common stock purchased to the underwriter's option to purchase additional shares, at an offering price of $10.35 per share. The Company received net proceeds of approximately $48.0 million, after deducting underwriting discounts and commissions.

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 Boston Children's Hospital and have evaluated a number of well-characterized development candidates, previously in development at other pharmaceutical companies, to comprise a pipeline of novel product candidates for rare diseases.

Lonafarnib is our lead compound that we expect to advance into Phase 3 with a single pivotal trial to treat Hepatitis Delta Virus, or HDV, infection and for which we expect to file an NDA for the treatment of Hutchinson-Gilford Progeria Syndrome, known as HGPS or progeria, and progeroid laminopathies in 2019. In addition, we recently announced positive Phase 2 data with pegylated interferon lambda for HDV infection and avexitide for post-bariatric hypoglycemia. All our programs address distinct rare diseases.

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

Recent Developments

Rare Pediatric Disease Designation for Lonafarnib in the Treatment of Progeria and Progeroid Laminopathies

On October 22, 2018, we announced that the U.S. Food and Drug Administration, or FDA, granted Rare Pediatric Disease, or RPD, designation to lonafarnib in the treatment of progeria and progeroid laminopathies. RPD designation enables priority review voucher, or PRV, eligibility upon U.S. market approval of lonafarnib for these ultra-rare and fatal genetic conditions characterized by accelerated aging in children. We are collaborating with The Progeria Research Foundation, or PRF, and we plan to submit a new drug application, or NDA, in 2019. There is currently no approved treatment for progeria or progeroid laminopathies.

The Priority Review Voucher Program is focused on encouraging development of therapies to prevent and treat rare pediatric diseases. If lonafarnib is approved by the FDA for progeria and progeroid laminopathies, the RPD designation qualifies Eiger, as the therapeutic

sponsor, for the PRV upon marketing approval. The voucher, which can be sold or transferred to another entity, can be used by the holder to receive priority review for a future NDA or biologics license application submission, which reduces the FDA submission review time from ten to six months. Pursuant to our collaboration and Supply Agreement with PRF, we will equally share with PRF any proceeds from the monetization of any PRV that we may receive for lonafarnib for the treatment of progeria and progeroid laminopathies to support future progeria research.

Phase 2 LIMT Study

On October 17, 2018, we announced positive data with Pegylated Interferon Lambda, or Lambda, in our Phase 2 LIMT HDV (Lambda Interferon MonoTherapy in Hepatitis Delta Virus) Study. LIMT HDV enrolled a total of 33 patients, randomized to Lambda 180 µg (N=16) or Lambda 120 µg (N=17), respectively, with weekly subcutaneous injections for 48 weeks in patients with chronic HDV. Lambda is a first in class, type III interferon, in development for the treatment of HDV.

At Week 48, patients in the 180 µg Lambda treated group experienced a -2.4 $\log_{10}$ mean decline in HDV-RNA, with 6 of 10 (60%) experiencing 2log10 decline, 4 of 10 (40%) patients were HDV-RNA negative at end of treatment. At Week 48, patients in the 120 µg Lambda treated group experienced a -1.5 $\log_{10}$ mean decline in HDV RNA, with 6 of 14 (42.9%) experiencing 2log10 decline, 2 of 14 (14.3%) patients were HDV-RNAnegative at end of treatment. The most common adverse events included mild to moderate flu-like symptoms and elevated transaminase levels.

Phase 2 PREVENT Study

On October 16, 2018, we announced positive results from our Phase 2 PREVENT study, which is a multi-center, placebo-controlled study investigating the safety and durability of effect of 28-day dosing of subcutaneous, or SC, avexitide (formerly known as exendin 9-39) in post-bariatric surgical patients who experience dangerously low, postprandial blood glucose levels known as post-bariatric hypoglycemia, or PBH. Avexitide is a first in class glucagon-like peptide-1, or GLP-1, antagonist in development for PBH as a convenient, novel liquid formulation for SC administration. PBH is an orphan disease with a high unmet medical need and no approved pharmacologic therapy.

Eighteen patients with refractory, severe PBH were enrolled across five U.S. academic centers and dosed as outpatients in the PREVENT study. All patients received placebo subcutaneous injections for 14 days in a single-blinded manner followed by avexitide subcutaneous injections of 30 mg twice daily, or BID, injections for 14 days and 60 mg once daily, or QD, injections for 14 days, for a total of 28 days active dosing, in a double-blinded to dose, cross-over design.

The primary efficacy endpoint of improved postprandial glucose nadir during mixed meal tolerance testing, or MMTT, was achieved with statistical significance with avexitide 30 mg BID (57.1 vs 47.1 mg/dL; $p = 0.001$) and 60 mg QD (59.2 vs 47.1 mg/dL; $p = 0.0002$), and with fewer participants requiring glycemic rescue during each of the active dosing regimens than during placebo dosing. The secondary endpoint of reduced postprandial insulin peak during MMTT was also statistically significant with avexitide 30 mg BID (349.5 vs 454.5 µIU/mL; $p < 0.03$) and 60 mg QD (357.2 vs 454.5 µIU/mL; $p = 0.04$).

Metabolic and clinical improvements were also monitored during each patients' daily routine in the outpatient setting and assessed by electronic diary and continuous glucose monitoring, or CGM. Patients experienced fewer episodes of hypoglycemia (hypoglycemia symptoms confirmed by self-blood glucose monitor, or SBGM, concentrations of <70 mg/dL) and severe hypoglycemia (neuroglycopenic symptoms confirmed by SBGM concentrations <55 mg/dL) during both dosing regimens of avexitide as compared to placebo. These results were corroborated by CGM data.

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

Phase 2 ULTRA Study

On October 16, 2018, we also announced results from our Phase 2 ULTRA study in primary and secondary lymphedema of the lower limb, which demonstrated no improvement of ubenimex over placebo in the primary endpoint of skin thickness and secondary endpoints of limb volume and bioimpedance. No safety signals attributed to ubenimex were identified.

Topline analysis suggests select, individual patient responses, which clinical investigators believe warrant further exploration. We currently plan no additional clinical work for ubenimex but will support any additional investigator analyses and will reevaluate if future findings suggest any potential pathway forward. We expect that we would only pursue such an option through a strategic partnership.

Notice of Allowance for Lonafarnib Patent Claims in HDV

On July 31, 2018, we announced the receipt of the Notice of Allowance from the United States Patent and Trademark Office for U.S. patent application number 15/335,327, entitled “Treatment of Hepatitis Delta Virus Infection.” The allowed claims cover a broad range of doses and durations of lonafarnib boosted with ritonavir. Lonafarnib is an oral, small molecule farnesyl transferase inhibitor in development for the treatment of HDV infection.

This Notice of Allowance concludes substantive examination of the patent application and after administrative processes are completed, is expected to result in the issuance of a U.S. patent with a term extending to 2035. We are pursuing additional claims with continuation applications.

In January 2018, we announced that Phase 2 LIBERTY study results in pulmonary arterial hypertension or PAH demonstrated no improvement overall or in key subgroups. On October 16, 2018, we announced results from our Phase 2 ULTRA study in primary and secondary lymphedema of the lower limb, demonstrated no improvement of ubenimex over placebo in the primary endpoint of skin thickness and secondary endpoints of limb volume and bioimpedance. The company discontinued development of ubenimex in both PAH and lymphedema 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 $35.9 million and $31.6 million for the nine months ended September 30, 2018 and 2017, respectively. As of September 30, 2018, we had an accumulated deficit of $154.7 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 nine months ended September 30, 2018 and 2017 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Product candidates:				
Lonafarnib HDV	$ 6,857	$ 715	$ 10,663	$ 3,105
Ubenimex Lymphedema (terminated in October 2018)	1,563	500	2,356	1,359
Avexitide PBH	939	721	2,282	2,540
Lambda HDV	666	719	1,755	2,141
Ubenimex PAH (terminated in January 2018)	225	1,994	1,653	7,633
Progeria	1,375	—	1,419	—
Internal research and development costs	1,571	1,496	4,952	4,962
Total research and development expense	$ 13,196	$ 6,145	$ 25,080	$ 21,740

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 nine months ended September 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 September 30, 2018 and 2017

	Three Months Ended September 30,		$	%
	2018	2017	Change	Change
Operating expenses:				
Research and development	$ 13,196	$ 6,145	$ 7,051	115%
General and administrative	3,643	2,727	916	34%
Total operating expenses	16,839	8,872	7,967	90%
Loss from operations	(16,839)	(8,872)	(7,967)	
Interest expense	(681)	(388)	(293)	76%
Interest income	371	98	273	279%
Other income (expense), net	5	(8)	13	*
Net loss	$ (17,144)	$ (9,170)	$ (7,974)	87%

*Percentage not meaningful

Research and development expenses

Research and development expenses increased by $7.1 million to $13.2 million for the three months ended September 30, 2018, from $6.1 million for the same period in 2017. The increase was primarily due to a $7.2 million increase in consulting fees and clinical expenditures related to an increase in program activity, and a $0.1 million increase in stock-based compensation expense due to a higher level of stock-based compensation expense in the third quarter of 2018, which was partially offset by a $0.2 million decrease in milestone payments to Stanford University inventors as there were no such payments in the third quarter of 2018.

General and administrative expenses

General and administrative expenses increased by $0.9 million to $3.6 million for the three months ended September 30, 2018, from $2.7 million for the same period in 2017. The increase was primarily due to a $0.5 million increase in legal, consulting, advisory and accounting services, a $0.2 million increase in stock-based compensation expense and a $0.1 million increase in compensation and personnel related expenses due to changes in head count and a higher level of stock-based compensation expense in the third quarter of 2018, and a $0.1 million increase in facility and insurance expenses related to the new office lease.

Interest expense

Interest expense increased by $0.3 million to $0.7 million for the three months ended September 30, 2018 from $0.4 million for the same period in 2017. Interest expense primarily increased due to the draw of additional $10.0 million under the Oxford Loan in the second and third quarters of 2018.

Interest income

Interest income increased by $0.3 million to $0.4 million for the three months ended September 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.

Comparison of the Nine Months Ended September 30, 2018 and 2017

	Nine Months Ended September 30,		$	%
	2018	2017	Change	Change
Operating expenses:				
Research and development	$ 25,080	$ 21,740	$ 3,340	15%
General and administrative	9,874	9,195	679	7%
Total operating expenses	34,954	30,935	4,019	13%
Loss from operations	(34,954)	(30,935)	(4,019)	
Interest expense	(1,574)	(1,129)	(445)	39%
Interest income	654	321	333	104%
Other (expense) income, net	(16)	188	(204)	*
Net loss	$ (35,890)	$ (31,555)	$ (4,335)	14%

*Percentage not meaningful

Research and development expenses

Research and development expenses increased by $3.4 million to $25.1 million for the nine months ended September 30, 2018 from $21.7 million compared the same period in 2017. The increase was primarily due to a $3.8 million increase in clinical expenditures related to an increase in program activity, and a $0.4 million increase in stock-based compensation expense due to options granted in 2018. The increase was partially offset by a $0.3 million decrease in consulting fees, a $0.3 million decrease in compensation and personnel related expenses due to changes in headcount, and a $0.2 million decrease in milestone payments as there were no payments to Stanford University inventors.

General and administrative expenses

General and administrative expenses increased by $0.7 million to $9.9 million for the nine months ended September 30, 2018 from $9.2 million for the same period in 2017. The increase was primarily due to a $0.3 million increase in facility and insurance expenses related to the new office lease, a $0.2 million increase in compensation and related expenses due to higher salaries and benefits in 2018, and a $0.2 million increase in legal, consulting, advisory and accounting services.

Interest expense

Interest expense increased by $0.5 million to $1.6 million for the nine months ended September 30, 2018 from $1.1 million for the same period in 2017. Interest expense primarily increased due to the draw of additional $10.0 million under the Oxford Loan in the second and third quarters of 2018.

Interest income

Interest income increased by $0.3 million to $0.6 million for the nine months ended September 30, 2018 from $0.3 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 nine months ended September 30, 2018.

Liquidity and Capital Resources

Sources of Liquidity

As of September 30, 2018, we had $16.9 million of cash and cash equivalents, $48.0 million of debt securities available-for-sale and an accumulated deficit of $154.7 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.

In October 2018, we completed an underwritten public offering of 4,830,918 shares of common stock, including 630,120 shares of common stock purchased to the underwriter's option to purchase additional shares, at an offering price of $10.35 per share. We received net proceeds of approximately $48.0 million, after deducting underwriting discounts and commissions.

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

Future Funding Requirements

We have not generated any revenue from product sales. We do not know when, or if, we will generate any revenue from product sales. We do not expect to generate any revenue from product sales unless and until we obtain regulatory approval for and commercialize any of our product candidates. At the same time, we expect our expenses to increase in connection with our ongoing development and manufacturing activities, particularly as we continue the research, development, manufacture and clinical trials of, and seek regulatory approval for, our product candidates.

Our primary uses of capital are, and we expect will continue to be, funding research efforts and the development of our product candidates, compensation and related expenses, hiring additional staff, including clinical, scientific, operational, financial, and management personnel, and costs associated with operating as a public company. We expect to incur substantial expenditures in the foreseeable future for the development and potential commercialization of our product candidates.

We plan to continue to fund losses from operations and capital funding needs through future equity and/or debt financings, as well as potential additional collaborations or strategic partnerships with other companies. The sale of additional equity or convertible debt could result in additional dilution to our stockholders. The incurrence of indebtedness would result in debt service obligations and could result in operating and financing covenants that would restrict our operations. We can provide no assurance that financing will be available in the amounts we need or on terms acceptable to us, if at all. If we are not able to secure adequate additional funding we may be forced to delay, make reductions in spending, extend payment terms with suppliers, liquidate assets where possible, and/or suspend or curtail planned programs. Any of these actions could materially harm our business.

Cash Flows

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

	Nine Months Ended September 30,	
	2018	2017
Net cash used in operating activities	$ (30,169)	$ (27,979)
Net cash (used in) provided by investing activities	(38,155)	13,148
Net cash provided by financing activities	53,216	153
Net decrease in cash and cash equivalents	$ (15,108)	$ (14,678)

Cash flows from operating activities

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

Cash used in operating activities for the nine months ended September 30, 2017 was $28.0 million, consisting of a net loss of $31.6 million, which was partially offset by stock-based compensation expense of $3.2 million. Additionally, cash used in operating activities reflected changes in operating assets and liabilities primarily due to an increase of $1.5 million in accounts payable. The increase was partially offset by $1.1 million decrease in accrued and other liabilities associated with the timing of payments.

Cash flows from investing activities

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

Cash provided by investing activities was $13.1 million for the nine months ended September 30, 2017, and primarily consisted of $35.5 million proceeds from maturities of debt securities and $0.2 million proceeds from MYDICAR sale, which was partially offset by $22.5 million purchase of debt securities.

Cash flows from financing activities

Cash provided by financing activities for the nine months ended September 30, 2018 consisted of $42.9 million of net proceeds from the issuance of common stock upon public offering, $9.9 million of net proceeds from borrowings in connection with the Oxford Loan, $0.3 million of proceeds from the issuance of common stock upon stock option exercises, and $0.1 million of proceeds from the purchases of common stock under our ESPP.

Cash provided by financing activities for the nine months ended September 30, 2017 primarily consisted of proceeds from the purchase of common stock under our ESPP.

Contractual Obligations and Other Commitments

Our contractual obligations as of September 30, 2018 are the same as of December 31, 2017, except for the following additional obligations:

- 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.
- 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. The term loan debt and interest amounts above do not reflect our future payments under the amended 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 September 30, 2018, we had market risk exposure related to our cash and cash equivalents. We had cash and cash equivalents of $16.9 million and $48.0 million of debt securities available-for-sale. Such interest-earning instruments carry a degree of interest rate risk; however, historical fluctuations of interest income have not been significant. We have not been exposed nor do we anticipate being exposed to material risks due to changes in interest rates. A hypothetical 10% change in interest rates during any of the periods presented would not have had a material impact on our unaudited condensed consolidated financial statements.

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

We carry out some of our clinical development and supportive activities in foreign countries and payments may be due in foreign currencies. We do not participate in any foreign currency hedging activities and we do not have any other derivative financial instruments. We did not recognize any significant exchange rate losses during the three and nine months ended September 30, 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 nine months ended September 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 nine months ended September 30, 2018 and 2017, we reported a net loss of $35.9 million and $31.6 million, respectively. As of September 30, 2018, we had an accumulated deficit of $154.7 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 meetings with the FDA throughout 2018, the FDA confirmed that a single, 400 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, lonafarnib for the treatment of progeria and progeroid lamnipathies, Lambda for HDV, and avexitide for PBH;
- seek regulatory and marketing approvals and reimbursement for our product candidates;
- establish a sales, marketing, and distribution infrastructure to commercialize any products for which we may obtain marketing approval and market ourselves;
- seek to identify, assess, acquire, and/or develop other product candidates;
- make milestone, royalty or other payments under third-party license agreements;
- seek to maintain, protect, and expand our intellectual property portfolio;
- seek to attract and retain skilled personnel;
- create additional infrastructure to support our operations as a public company and our product development and planned future commercialization efforts; and
- experience any delays or encounter issues with the development and potential for regulatory approval of our clinical candidates such as safety issues, clinical trial accrual delays, longer follow-up for planned studies, additional major studies, or supportive studies necessary to support marketing approval.

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

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

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

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

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

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

To the extent that we raise additional capital through the sale of equity, debt or other securities convertible into equity, your ownership interest will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect your rights as a common stockholder such as the Loan and Security Agreement we entered into with Oxford Finance LLC, or Oxford Finance, in December 2016, or the Oxford Loan. 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. In August 2018, we drew the final $5.0 million upon achievement of certain clinical milestones. 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 two Phase 2 development programs focused on two 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 in pulmonary arterial hypertension (PAH) demonstrated no improvement overall or in key subgroups. On October 16, 2018, we announced results from our Phase 2 ULTRA study in primary and secondary lymphedema of the lower limb, demonstrated no improvement of ubenimex over placebo in the primary endpoint of skin thickness and secondary endpoints of limb volume and bioimpedance. The company discontinued development of ubenimex in both PAH and lymphedema 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, only one of our product candidates has advanced into a pivotal study for our proposed indications. However, it may be years before such studies are initiated and completed, if at all. In October 2018, the FDA granted Rare Pediatric Disease, or RPD, designation to lonafarnib in the treatment of progeria and progeroid laminopathies. RPD designation enables priority review voucher, or PRV, eligibility upon U.S. market approval of lonafarnib for these ultra-rare and fatal genetic conditions characterized by accelerated aging in children. We are collaborating with The Progeria Research Foundation, or PRF, and we plan to submit a new drug application, or NDA, in 2019.

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 some of our product candidates in multiple targeted indications, failure to demonstrate significant benefit over existing approved drugs in pivotal clinical trials may lead to marketing approval but without qualifying for orphan drug protection in some regions, such as in Europe.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable, typically takes many years following the commencement of clinical studies and depends upon numerous factors. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate’s clinical development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application. We have not obtained regulatory approval for any product candidate, and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

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

- the FDA or comparable foreign regulatory authorities may disagree with the design, size or implementation of our clinical studies;
- the population studied in the clinical program may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from our development efforts;

- the data collected from clinical studies of our product candidates may not be sufficient or complete or meet the regulatory requirements to support the submission of a new drug application, or NDA, or other submission or to obtain regulatory approval in the United States or foreign jurisdictions;
- the FDA or comparable foreign regulatory authorities may find failures in our manufacturing processes, validation procedures and specifications, or facilities of our third-party manufacturers with which we contract for clinical and commercial supplies that may delay or limit our ability to obtain regulatory approval for our product candidates; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our NDA or other submission insufficient for approval.

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

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

Clinical testing is expensive and generally takes many years to complete, and the outcome is inherently uncertain. Failure can occur at any time during the clinical study process. The results of preclinical studies and early clinical studies of our product candidates may not be predictive of the results of larger, later-stage controlled clinical studies. Product candidates that have shown promising results in early-stage clinical studies may still suffer significant setbacks in subsequent clinical studies. Our clinical studies to date have been conducted on a small number of patients in limited numbers of clinical sites and in academic settings or for other indications. We will have to conduct larger, well-controlled studies in our proposed indications to verify the results obtained to date and to support any regulatory submissions for further clinical development. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical studies due to lack of efficacy or adverse safety profiles despite promising results in earlier, smaller clinical studies. Moreover, clinical data are often susceptible to varying interpretations and analyses. We do not know whether any Phase 2, Phase 3, or other clinical studies we have conducted or may conduct will demonstrate consistent or adequate efficacy and safety with respect to the proposed indication for use sufficient to obtain regulatory approval to receive regulatory approval or market our drug candidates.

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. 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 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. We will be required to report certain adverse reactions and production problems, if any, to the FDA and comparable foreign regulatory authorities.

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

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

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

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

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

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

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

In addition, we do not currently have, nor do we plan to establish the capability to manufacture product candidates for use in the conduct of our clinical studies, 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. In 2017, we transferred the manufacturing technology to our third-party vendors.

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

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

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

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

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 lonafarnib, Lambda and avexitide, a substantial portion of the potential commercial opportunity will likely rely on patent term extensions, and we cannot provide any assurances that any such patent term extensions will be obtained and, if so, for how long. As a result, we may not be able to maintain exclusivity for our products for an extended period after regulatory approval, which would negatively impact our business and results of operations. If we do not have sufficient patent terms or regulatory exclusivity to protect our products, our business and results of operations will be adversely affected.

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

Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. We therefore cannot be certain that it or our licensors were the first to make the invention claimed in our owned and licensed patents or pending applications, or that we or our licensor were the first to file for patent protection of such inventions. Assuming the other requirements for patentability are met, in the United States prior to March 15, 2013, the first to make the claimed invention is

entitled to the patent, while outside the United States, the first to file a patent application is entitled to the patent. After March 15, 2013, under the Leahy-Smith America Invents Act, or the Leahy-Smith Act, enacted on September 16, 2011, the United States has moved to a first to file system. The Leahy-Smith Act also includes a number of significant changes that affect the way patent applications will be prosecuted and may also affect patent litigation. The effects of these changes are currently unclear as the USPTO must still implement various regulations, the courts have yet to address any of these provisions and the applicability of the act and new regulations on specific patents discussed herein have not been determined and would need to be reviewed. In general, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

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

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

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

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

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There have been many lawsuits and other proceedings involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions, and reexamination proceedings before the USPTO and corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.

Third parties may assert that we are using or exploiting their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture, or methods for treatment related to the use or manufacture of our product candidates. Even if we conduct freedom to operate analyses, we would expect to do so only with respect to certain of our product candidates as they move through development. Accordingly, there may be third-party patents that would impair our ability to commercialize product candidates and we cannot assure you that we could obtain a license, or even if available, whether such license might be obtained on commercially reasonable terms. Even in those situations where we conduct a freedom to operate analysis, there can be no assurance that we would identify all relevant or necessary patents and patent applications that may apply to the manufacture and commercialization of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe, and if patents issue with respect to any such application and we become aware of such issuance, we would have to determine its impact on our efforts to develop and commercialize our product candidates and the strategy for obtaining a license or contesting any such issued patent.

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

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

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

We currently have rights to the intellectual property, through licenses from third parties and under patents that we do not own, to develop and commercialize our product candidates. Because our programs may require the use of proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to maintain in effect these proprietary rights. For example, we have certain specified diligence obligations under our Stanford license 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 September 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 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#	Product Development Agreement, dated July 1, 2018, by and between Eiger BioPharmaceuticals, Inc. and RRD International, LLC.
10.2	Common Stock Purchase Agreement, dated September 19, 2018, by and between Eiger BioPharmaceuticals, Inc. and RRD International, LLC.
10.3#	Product Assignment 1, dated July 1, 2018, by and between Eiger BioPharmaceuticals, Inc. and RRD International, 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: November 9, 2018

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

Eiger BioPharmaceuticals, Inc.

Date: November 9, 2018

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

EXHIBIT 10.1

PRODUCT DEVELOPMENT AGREEMENT

This Product Development Agreement (this "Agreement") is effective July 1, 2018 (the "Effective Date") and is between RRD International, LLC, a Delaware limited liability company with offices at 7361 Calhoun Place, Suite 510, Rockville, MD 20855 (hereinafter "RRD") and Eiger BioPharmaceuticals, Inc., a Delaware corporation with executive offices at 2155 Park Boulevard., Palo Alto, CA 94306 (hereinafter "Eiger"). Each of RRD and Eiger is a "Party" and together they are the "Parties." When signed by both Parties, this Agreement will set forth the terms and conditions under which RRD agrees to provide certain product development services to Eiger as set forth herein.

Recitals:

WHEREAS, Eiger is engaged in the development and commercialization of novel pharmaceutical products.

WHEREAS, RRD provides strategic product development services for the development of pharmaceutical products by utilizing a Product Development Team ("PDT") structure that functions similarly to a biopharma's PDT and includes senior-level experts who are fully engaged in product development strategy and planning.

WHEREAS, RRD's model is specifically structured to create a strong alignment of interests between RRD and its clients, while accelerating and streamlining the development process. Within this framework, the RRD team will function as the part of the Eiger PDT and will provide engagement, oversight, and management of third-party Clinical Research Organizations ("CROs") and vendors, in each case, to the extent requested by Eiger.

WHEREAS, Eiger desires to engage the services of RRD for the development of certain products, with such services to be described and agreed upon by the Parties within the Project Agreements (as defined below).

NOW THEREFORE, in consideration of the premises and the mutual covenants contained herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

1. Project Agreements.

A. As a "master" form of contract, this Agreement allows the Parties to contract for multiple projects through multiple Project Agreements, without having to renegotiate the basic terms and conditions herein.

B. The specific details of each assignment or task for the development of each individual Eiger product will be separately negotiated and specified in a written project agreement (each, a "Project Agreement") on terms acceptable to the Parties.

C. Upon execution by RRD and Eiger, each Project Agreement shall constitute an integral part of this Agreement. Each Project Agreement will include substantially all of the information relating to the specific services to be conducted by RRD (as related to each Project Agreement, the "Services") including the items listed in Section 1.D, below. No Services shall be commenced or performed by RRD, and neither Party shall be obligated with respect to any assignment or task, until an applicable Project Agreement is executed by both Parties, nor shall either Party be obligated to enter into any Project Agreement hereunder. Each Project Agreement shall be subject to all of the terms and conditions of this Agreement, in addition to the specific details set forth in the Project Agreement. In the event of any inconsistency between this Agreement and

any Project Agreement, this Agreement shall control. Any changes to a Project Agreement must be made in writing and signed by the Parties. RRD shall perform all Services under any Project Agreement in a diligent, professional and timely manner in accordance with the terms of this Agreement, such applicable Project Agreement and all applicable laws and regulations.

D. Each Project Agreement shall contain the following exhibits as listed below as more specifically described herein:

- Initial Protocol Assumptions
- RRD Product Development Team
- Development Advisory Committee Charter
- Clinical Development Plan
- Development Budget
- Payment Terms
- Description of Services

2. Overview of Development.

A. Generally.

(1) RRD and Eiger shall enter into a separate Project Agreement for each Eiger product/indication that shall be developed pursuant to this Product Development Agreement.

(2) Each Project Agreement shall contain all of the information, available as of the date of execution thereof, that is necessary to describe the goals and objectives (including cost) of the applicable product development program (the "Program"). During the initial [***] of the term of each Project Agreement, the Parties will work diligently and in good faith to refine (including amending, to the extent necessary) the initial Clinical Development Plan and Development Budget. Approximately [***] following commencement of the applicable Project Agreement, or upon the next meeting of the Development Advisory Committee (as defined in Section 2(B)(3)), the Development Advisory Committee shall review and formally approve (pursuant to the approval procedures described in the Development Advisory Committee Charter (as defined in Section 2(B)(3)) attached to the respective Project Agreement) the most recently submitted Clinical Development Plan and Development Budget, or shall request specific changes thereto (pursuant to the procedures described in the Development Advisory Committee Charter attached to the respective Project Agreement) which, when incorporated into the Clinical Development Plan and/or Development Budget, will render such documents approved without further action by the Development Advisory Committee. Thereafter, the Clinical Development Plan and Development Budget shall continue to be developed, refined and amended (pursuant to the approval procedures described in the Development Advisory Committee Charter attached to the respective Project Agreement), as necessary by the Development Advisory Committee, in accordance with this Agreement and the applicable Project Agreement, throughout the term of the Project Agreement.

(3) Utilizing the RRD Product Development Team (as defined in Section 2(B)(2)), RRD shall conduct the Services for each Program in accordance with the joint decision-making process, as set forth in the Development Advisory Committee Charter for that particular Program.

(4) RRD shall have responsibility for the conduct of the Services and for all matters designated to RRD in this Agreement and in the Project Agreement (including the Clinical Development Plan) and, to the extent included in the Project Agreement, may engage Development Vendors (as defined below), consultants, contractors and agents external to the RRD Product Development Team ("RRD Consultants and Subcontractors"), as deemed necessary by the Parties, with the prior agreement of Eiger, to carry out such assigned duties set forth therein and herein consistent with the Section 4 (RRD Responsibilities). Eiger hereby acknowledges that while RRD may provide advice and guidance in the negotiation of vendor contracts between Eiger and one or more third parties with respect to the Program, and RRD and RRD-contracted attorneys may be part of the PDT, under no circumstances will RRD be expected by Eiger to provide legal advice or legal services and no attorney-client relationship is created or shall exist between the Parties under this Agreement.

(5) The consideration to be paid by Eiger to RRD for the Services will be based upon: (a) the PDT service fees; and (b) the RRD Consultants and Subcontractors and pass-through costs, to the extent such service fees and pass-through costs are included in the Development Budget for the particular Project Agreement.

B. Project Specific Exhibits to the Project Agreements.

(1) **Initial Protocol Assumptions.** The Initial Protocol Assumptions exhibit to each Project Agreement shall represent the understanding of the Parties as to the requirements of the Program as of the date of the Project Agreement.

(2) **RRD Product Development Team.**

The RRD Product Development Team exhibit for each Project Agreement shall list the staff and personnel intended to be retained or used by RRD in providing the Services (the "RRD Product Development Team"). RRD shall not change key staff and personnel on RRD Product Development Team without consulting with Eiger. If any staff or personnel on RRD Product Development Team is no longer employed by RRD or otherwise no longer available, RRD shall promptly notify Eiger and shall use diligent efforts to find a suitable replacement. Per the specific Project Agreement, RRD will assume both responsibility and accountability for the Project. The model provides for a fully-integrated, multi-functional PDT deployed on a fractional FTE basis with the flexibility of scaling up or down based upon the Clinical Development Plan and the Development Budget.

(3) **Development Advisory Committee Charter.**

The Parties shall establish and maintain a separate committee (the "Development Advisory Committee") to oversee the development of each of the Programs (including the ongoing development and refinement of the Clinical Development Plan and the Development Budget). The Development Advisory Committee shall be established, operated and governed in accordance with the policies and procedures set forth in the "Development Advisory Committee Charter", attached to each Project Agreement. The Development Advisory Committee Charter may be amended only with the unanimous approval of the Development

Advisory Committee Members. In no event shall the Development Advisory Committee have the power to amend the terms of this Agreement or the applicable Project Agreement.

(4) **Clinical Development Plan.**

An initial version of a Clinical Development Plan shall be prepared by the PDT and formally approved by the Development Advisory Committee ("DAC"), according to a time line agreed to by the DAC, which is generally expected to be within [***] after the execution of the Project Agreement. The Clinical Development Plan shall describe the Services to be conducted under the Project Agreement (specifically excluding IP work) including: preclinical pharmacology and toxicology, regulatory, CMC (Chemistry, Manufacturing and Controls), and clinical (including clinical pharmacology). The Clinical Development Plan will also include project timeline and budget information. The exact level of detail to be included in the initial version of the Clinical Development Plan will be proposed by the PDT and agreed to by the DAC. The Plan is generally prepared using PowerPoint and will have appendices containing appropriate supportive information.

The Clinical Development Plan is intended to be updated periodically to reflect changes. The PDT shall, on an ongoing basis, evaluate if changes to the Clinical Development Plan are necessary and will propose such changes to the DAC in accordance with the approval procedures described in the Development Advisory Committee Charter.

(5) **Development Budget.**

The "Development Budget" directly associated with each Project Agreement shall consist of two (2) components: (i) PDT service fees, and (ii) RRD Consultant and Subcontractor costs and other pass-through costs, in a format and level of detail to be agreed upon by the DAC.

The DAC shall formally approve (in accordance with the approval procedures described in the Development Advisory Committee Charter) a draft Development Budget (which shall include RRD Consultants and Subcontractors and pass-through cost estimates ([***])) approximately [***] after the execution of the related Project Agreement based upon the initial Development Budget/estimate, as well as information gathered during the [***] following execution of the Project Agreement, and such draft Development Budget will be proposed to, and approved by, Eiger. The DAC may propose and submit to Eiger for its approval changes to the Development Budget from time to time in accordance with this Agreement. All anticipated expenditures under the Project Agreement shall be included in the Development Budget.

Separate budgets for the Development Vendors (as defined below) will be reviewed with the Development Budget by the DAC, in context of the overall program budget.

(6) **Payment Terms.** Any specific payment terms, if any, that are applicable to a Project shall be included in the exhibit to the respective Project Agreement.

(7) **Description of Services.** All Services to be conducted by RRD in connection with each Product shall be included and described in the exhibit to the Project Agreement.

C. Amendments to the Clinical Development Plan and Budget.

(1) Any amendments to, and all material deviations from, the Clinical Development Plan and/or the Development Budget (including amendments or deviations made at the request of RRD

or Eiger) shall be made in accordance with the procedures described herein and the approval procedures described in the Development Advisory Committee Charter attached to the respective Project Agreement. Notwithstanding the foregoing, all amendments to, and all material deviations from the Clinical Development Plan and/or the Development Budget shall require the prior written approval of Eiger, subject to RRD's rights to terminate herein and in any relevant Project Agreement.

(2) The DAC shall perform a comprehensive review of the Clinical Development Plan and Development Budget, at a minimum, on a semi-annual basis to determine whether any changes are required, and shall comply with all procedures required to amend the Clinical Development Plan or Development Budget and to implement such changes as described above. The DAC shall, on an ongoing basis, continue to refine the Clinical Development Plan and Development Budget, including, without limitation, in response to requests, proposals or reports from Eiger and RRD to the DAC. The DAC shall review and recommend such change(s) for approval by Eiger within the next [***] period, or shall request specific changes thereto.

(3) The Clinical Development Plan shall not be amended in any manner that would require Eiger or RRD (or any person acting on behalf of Eiger or RRD) to perform any assignments or tasks in a manner that would violate any applicable law or regulation. In the event of a change in any applicable law or regulation that materially affects the conduct of the Clinical Development Plan, the DAC shall consider amending the Clinical Development Plan to enable Eiger or RRD (or any person acting on behalf of Eiger or RRD), as the case may be, to comply fully with such law or regulation. If such amendment is not approved, the affected Party shall be excused from performing any activity specified herein or in the Clinical Development Plan that would violate or result in a violation of the applicable law or regulation.

(4) All changes to the Clinical Development Plan and/or Development Budget (including any components thereof) made pursuant to this Agreement and the Development Advisory Committee Charter shall have the effect of an amendment to the applicable Project Agreement as it applies to the Clinical Development Plan and/or Development Budget contained therein.

3. Compensation. The consideration to be paid by Eiger to RRD for its conduct of the Services will consist of (a) a fixed fee to be paid for the Services conducted by the PDT, (b) Expert Consultant Fees, and (c) pass through costs to be paid for the RRD Consultants and Subcontractors engaged by RRD to conduct Services, in each case to the extent identified in the Development Budget for the particular Project Agreement. Payment Terms shall be attached to each relevant Project Agreement. RRD is solely responsible for filing all tax returns and submitting all tax payments as required by any federal, state, local, or foreign tax authority arising from the payment received by RRD under this Agreement, and agrees to do so in a timely manner. If applicable, Eiger will report the payments to RRD under this Agreement by filing Form 1099-MISC with the Internal Revenue Service as required by law.

4. RRD Obligations.

A. Generally.

(1) RRD shall have primary, but not sole, responsibility for implementing the Clinical Development Plan. Without limiting the foregoing, except as subcontracted to third parties as agreed upon by Eiger and RRD, RRD shall be responsible for (i) performing all non-clinical and clinical development for each Program in accordance with the Clinical Development Plan,

and (ii) undertaking such other activities as are set forth in the Clinical Development Plan that are assigned to RRD by the DAC pursuant to the Clinical Development Plan (collectively, the "RRD Obligations").

(2) The Parties anticipate and agree that RRD and Eiger will enter into 3way agreements with the vendors necessary to execute the Development Plan ("Development Vendors") solely for the purpose of providing RRD with the authority to manage such Development Vendors (including providing oversight and direction to such Development Vendors, reviewing and approving invoices, etc.) and for purposes of avoiding conflicting instructions to such Development Vendors, RRD shall be the main point of contact on such contracts. Although RRD will be a party to such contracts, provided that in the management of such contract and Development Vendors, RRD complies with the terms and conditions of the applicable Clinical Development Plan, Project Agreement, this Agreement, Eiger's reasonable instructions (in compliance with this Agreement) and applicable laws and regulations, then Eiger shall be solely responsible for: (x) [***]; (y) payment obligations; or (z) [***].

(3) With respect to staff and personnel retained or used by RRD in providing Services under this Agreement, RRD shall cause such staff and personnel to exercise the same standard of care, skill, prudence, diligence and commitment of time and effort as is customary in its industry. RRD shall ensure that all such staff and personnel comply with the terms and conditions of this Agreement, including without limitation confidentiality and intellectual property provisions. RRD shall be responsible for the actions of such staff and personnel performed under this Agreement.

B. Subcontracting by RRD.

(1) **Generally**. Except as noted above, RRD may engage third parties for commodity services that are not otherwise a part of the PDT (RRD Consultants and Subcontractors), subject to the prior written consent of Eiger (including without limitation CROs), to perform any of RRD's obligations under this Agreement; provided, however, that RRD shall remain responsible for all of RRD's obligations hereunder. RRD shall be responsible for the direction and coordination of the services of all RRD Consultants and Subcontractors, shall ensure their compliance with the terms and conditions of this Agreement and the relevant Project Agreement and shall be responsible for the compliance by any RRD Consultant or Subcontractor with the terms and conditions of this Agreement and/or the relevant Project Agreement.

(2) **Payments to RRD Subcontractors and Consultants**. RRD shall enter into contracts (and change orders thereto) with RRD Consultants and Subcontractors only with the prior consent and approval of Eiger (each, an "Approved Contract"). RRD hereby agrees that (a) it will enter into Approved Contract on terms and conditions that are consistent with those set forth herein, including without limitation confidentiality, records, intellectual property and termination provisions, (b) it will promptly apply all advance payments made by Eiger for use in paying third parties under the appropriate Approved Contract and (c) it will provide Eiger with monthly reconciliation statements confirming the application of all such advances made by Eiger. By providing such prior consent and approval, Eiger agrees [***]; provided, that, RRD will provide Eiger with prior written notice if any such fee is reasonably expected to become due and payable under any Approved Contract.

(3) **Clinical Investigators**. The Parties acknowledge and agree that Clinical Investigators shall not be considered the employees, agents or subcontractors of RRD or Eiger, and that Clinical Investigators shall exercise their own independent medical judgment. As used herein, "Clinical Investigator" means any third party medical and/or research professional acting as the lead investigator in a study under the applicable Project Agreement.

C. Reports and Correspondence.

(1) **Records.** RRD will keep complete and accurate records of the status and progress of each Program ("Records"), including Records of all data and results generated from the Program, as set forth in the Project Agreement. Upon reasonable advance notice, Eiger shall have the right to inspect and copy all such Records.

(2) **Report.** RRD shall keep the DAC informed of its activities under the Clinical Development Plan, as set forth in this Section, through regular reports, not less than once per calendar quarter ("Reports"). All Reports will be prepared in the standard format of RRD unless otherwise specified in the Project Agreement or as otherwise agreed to by the DAC. At each scheduled meeting of the DAC, or according to a schedule agreed to by the DAC, RRD shall, to the extent reasonably required by the DAC, provide a summary of the technical and financial information related to each Program in a format, and to a level of detail, as reasonably required by the DAC.

(3) **Event Resulting in a Material Effect**. RRD shall notify at least one (1) of the DAC Members designated by Eiger as soon as possible, but no later than [***], following RRD's knowledge of the occurrence of any event that has, or could reasonably be expected to have, in RRD's judgment and in light of the circumstances existing at the time, a material effect on the Clinical Development Plan or the Development Budget and shall keep the DAC regularly updated and informed with respect to any such event.

D. Staffing. RRD shall provide sufficient and competent staff and personnel (including, without limitation, such employees or agents of RRD Consultants and Subcontractors retained by RRD) that have the skill and expertise necessary to perform RRD's obligations under this Agreement and the applicable Project Agreement.

E. QA Audit. During the term of this Agreement, RRD will permit Eiger Representatives to examine and audit, during regular business hours, the Services conducted by RRD hereunder and the facilities at which such Services are conducted to determine that RRD's obligations are being conducted in accordance with the terms of this Agreement, the Project Agreement, and the Clinical Development Plan ("QA Audits"). Eiger shall give RRD reasonable advance notice of any such QA Audit specifying the proposed scope of the QA Audit. For QA audits conducted more than [***] per [***] period (other than for cause or follow up audits), Eiger shall reimburse RRD for its time associated in participating in such QA Audit. As used herein, "Eiger Representatives" shall mean representatives identified by Eiger in advance and reasonably acceptable to RRD, each of which shall enter into a confidentiality agreement with RRD (if not already covered by an existing CDA) obligating them to keep confidential any Confidential Information of RRD disclosed in connection with the conduct of any such QA Audit.

F. Financial Audit of RRD Pass-Through Costs. RRD shall keep and maintain for [***] after the effective date of termination of any applicable Project Agreement complete and accurate records of all external costs and expenses incurred by it in connection with the conduct of the Services as

part of such Project Agreement in sufficient detail to allow confirmation of same and to allow confirmation that all advance payments made by Eiger were properly allocated by RRD to Approved Contracts. During the Term and [***] thereafter, RRD will permit an independent certified public accounting firm reasonably acceptable to RRD to audit and verify such costs and expenses (each, a "Financial Audit"), which audit shall be conducted during regular business hours and will take place upon Eiger' request, unless otherwise agreed to by the Parties. Eiger shall give RRD reasonable advance notice of such Financial Audits specifying the proposed scope of the Financial Audit, which shall not include the records for any period that has previously undergone a Financial Audit. For Financial Audits conducted more than [***] per [***] period (other than for cause or follow up audit), Eiger shall reimburse RRD for its time associated with participating in such Financial Audits.

5. Eiger Obligations.

A. Insurance. [***]. Such insurance shall carry a minimum [***] of coverage. Upon RRD's request, Eiger shall instruct its insurance carrier(s) to promptly furnish to RRD certificates reflecting such coverage and a covenant of Eiger confirming that such coverage shall not be canceled or otherwise terminated during the Term without [***] prior written notice to RRD. Notwithstanding anything to the contrary herein, this Section shall survive for a period of [***] following termination or expiration of this Agreement. Such insurance coverage, with regard to coverage for specific clinical trials, shall remain in place for a period of [***] after the conclusion of the respective clinical trial. The foregoing obligations of Eiger for any of the above [***] periods may be satisfied by Eiger through any combination of renewal policies or extended reporting period endorsements.

B. Cooperation; Delays; Disclosure of Hazards.

Eiger shall forward to RRD, in a timely manner, all data and information in Eiger' possession or control necessary for RRD to conduct the Services ("Eiger Information"). RRD shall not be liable for, nor be deemed to have breached this Agreement for, any delays in the conduct of the Services that arise from Eiger' failure to provide Eiger Information in a timely manner or Eiger' failure to otherwise cooperate with RRD to the extent required by the applicable Project Agreement. Eiger shall promptly provide RRD with all any information of which Eiger is aware regarding known or potential hazards associated with the use of any substances supplied by Eiger, and Eiger shall comply with applicable laws and regulations concerning the shipment of such substances to RRD.

C. Eiger agrees to provide any new safety information related to a Program as soon as reasonably practical.

6. Mutual Covenants. Each of Eiger and RRD covenants and agrees that, with respect to the Programs and any other rights and obligations set forth herein, it shall:

A. perform all of its obligations pursuant to this Agreement in material compliance with: (i) all applicable international, federal and state laws, statutes, rules, regulations and orders (including all applicable approval and qualification requirements thereunder), including, without limitation, the Federal Food, Drug and Cosmetic Act and the regulations promulgated pursuant thereto; (ii) all applicable good clinical practices and guidelines; (iii) all applicable standard operating procedures; (iv) all applicable protocols; (v) the provisions of this Agreement and Project Agreements and (vi) with respect to RRD, RRD shall perform the Services in a professional manner;

B. not employ (and shall not use any contractor or consultant who is or that employs) any individual or entity debarred by the Food and Drug Administration ("FDA") (or subject to a similar sanction of any other regulatory authority), or, to the best of its knowledge, any individual who or entity which is the subject of an FDA debarment investigation or proceeding (or similar proceeding of any other regulatory authority), in the conduct of the Programs; and with respect to RRD, RRD shall promptly notify Eiger in the event any RRD employee, contractor or consultant is under or threated to be under investigation by the FDA or is subject to debarment by the FDA during the term of this Agreement;

C. promptly deliver to the other, upon receipt thereof, notice of all actions, suits, investigations, litigation and proceedings before any governmental authority, which would reasonably be expected to affect such Party's ability to perform its obligations under this Agreement.

Upon its acquiring knowledge of (i) any possible breach by it of any representation, warranty, covenant or any other term or condition of this Agreement or (ii) any other event or development, in each case that may, or may be reasonably expected to be, materially adverse to the other Party with respect to any Program, such Party shall promptly notify the other Party in writing within [***] of acquiring such knowledge; provided, that the failure to provide such notice shall not impair or otherwise be deemed a waiver of any rights any Party may have arising from such breach, event or development and that notice under this Section shall not be deemed an admission by the Party providing such notice of any breach of this Agreement.

7. Representations and Warranties.

A. RRD Representations and Warranties. RRD hereby represents and warrants to Eiger that, as of the Effective Date:

(1) **Organization**. RRD is a limited liability company, duly organized, validly existing and in good standing under the laws of the State of Delaware.

(2) **Authority and Validity**. RRD has all requisite corporate power and authority to execute, deliver and perform its obligations under this Agreement and to consummate the transactions contemplated thereby. The execution, delivery and performance by RRD of this Agreement and the consummation of the transactions contemplated thereby have been duly and validly authorized by all necessary action required on the part of RRD, and no other proceedings on the part of RRD are necessary to authorize this Agreement or for RRD to perform its obligations under this Agreement. This Agreement constitutes the lawful, valid and legally binding obligations of RRD, enforceable in accordance with its terms, except as the same may be limited by applicable bankruptcy, insolvency, reorganization, moratorium or similar laws affecting the enforcement of creditors' rights generally and general equitable principles regardless of whether such enforceability is considered in a proceeding at law or in equity.

(3) **No Violation or Conflict**. The execution, delivery and performance of this Agreement and the transactions contemplated thereby do not and will not (i) violate, conflict with or result in the breach of any provision of the organizational documents of RRD, (ii) conflict with or violate any law or governmental order applicable to RRD or any of its assets, properties or businesses to the extent that such conflicts, breaches, defaults or other matters would not, individually or in the aggregate, reasonably be expected to have a material adverse effect on RRD or a material adverse effect on the Programs, or (iii) conflict with any terms of any other

contractual obligations with third parties, and will not enter into any contractual obligations with any third party that would create a conflict with the terms of this Agreement.

(4) **No Litigation**. There are no actions by or against RRD pending before any governmental authority or, to the knowledge of RRD, threatened to be brought by or before any governmental authority, which would, individually or in the aggregate, reasonably be expected to have a material adverse effect on RRD's ability to fulfill its obligations under this Agreement. There are no pending or, to the knowledge of RRD, threatened actions, to which RRD is a party (or is threatened to be named as a party) to set aside, restrain, enjoin or prevent the execution, delivery or performance of this Agreement or the consummation of the transactions contemplated hereby or thereby by any party hereto or thereto. RRD is not subject to any governmental order (nor, to the knowledge of RRD, is there any such governmental order threatened to be imposed by any governmental authority) that would, individually or in the aggregate, reasonably be expected to have a material adverse effect on RRD's ability to fulfill its obligations under this Agreement or a material adverse effect on any of the Programs.

B. Eiger Representations and Warranties. Eiger hereby represents and warrants to RRD that, as of the Effective Date:

(1) **Organization**. Eiger is a Delaware corporation, duly organized, validly existing and in good standing under the laws of Delaware.

(2) **Authority and Validity**. Eiger has all requisite corporate power and authority to execute, deliver and perform its obligations under this Agreement and to consummate the transactions contemplated thereby. The execution, delivery and performance by Eiger of this Agreement and the consummation of the transactions contemplated thereby have been duly and validly authorized by all necessary action required on the part of Eiger, and no other proceedings on the part of Eiger are necessary to authorize this Agreement or for Eiger to perform its obligations under this Agreement. This Agreement constitutes the lawful, valid and legally binding obligations of Eiger, enforceable in accordance with its terms, except as the same may be limited by applicable bankruptcy, insolvency, reorganization, moratorium or similar laws affecting the enforcement of creditors' rights generally and general equitable principles regardless of whether such enforceability is considered in a proceeding at law or in equity.

(3) **No Violation or Conflict**. The execution, delivery and performance of this Agreement and the transactions contemplated thereby do not and will not (i) violate, conflict with or result in the breach of any provision of the organizational documents of Eiger, (ii) conflict with or violate any law or governmental order applicable to Eiger or any of its assets, properties or businesses to the extent that such conflicts, breaches, defaults or other matters would not, individually or in the aggregate, reasonably be expected to have a material adverse effect on Eiger or a material adverse effect on the Programs, or (iii) conflict with any terms of any other contractual obligations with third parties, and will not enter into any contractual obligations with any third party that would create a conflict with the terms of this Agreement.

(4) **No Litigation**. There are no actions by or against Eiger pending before any governmental authority or, to the knowledge of Eiger, threatened to be brought by or before any governmental authority that would, individually or in the aggregate, reasonably be expected to have a material adverse effect on Eiger' ability to fulfill its obligations under this

Agreement. There are no pending or, to the knowledge of Eiger, threatened actions to which Eiger is a party (or is threatened to be named as a party) to set aside, restrain, enjoin or prevent the execution, delivery or performance of this Agreement or the consummation of the transactions contemplated hereby by any party hereto. Eiger is not subject to any governmental order (nor, to the knowledge of Eiger, is there any such governmental order threatened to be imposed by any governmental authority) that would, individually or in the aggregate, reasonably be expected to have a material adverse effect on Eiger' ability to fulfill its obligations under this Agreement or a material adverse effect on the Programs.

8. Regulatory Matters.

A. Investigational New Drug ("IND") Sponsor. Eiger shall be the sponsor for any IND filed in relation to the Program(s) unless otherwise stated in the relevant Project Agreement.

B. Transfer of Regulatory Responsibilities. RRD and Eiger, where appropriate and included in a Project Agreement, shall cooperate in the completion of a Transfer of Regulatory Obligations Form ("TORO") in conjunction with the relevant Project Agreement. The TORO will be filed with the FDA by Eiger, where appropriate, or as required by law or regulation. Any regulatory responsibilities not specifically transferred in the TORO shall remain the responsibility of Eiger. Nothing in this Agreement shall be construed to transfer from Eiger to RRD any FDA or regulatory record-keeping requirements unless such transfer is specifically provided for in the applicable `TORO. [***]. In all cases, RRD shall [***] ensure that any transfer of regulatory responsibilities will be managed in such a way as to avoid disrupting the Project or presenting unreasonable risk or inconvenience to patients and investigators.

C. Correspondence. Each Party hereto acknowledges that Eiger, in its capacity as IND Sponsor (except as otherwise stated in the relevant Project Agreement or any relevant TORO), shall be solely responsible for responding to any regulatory correspondence or inquiry regarding, or which would reasonably be expected to affect, any of the Programs. Each Party shall, within [***] of receipt of any FDA or other governmental or regulatory correspondence: (a) notify at least one (1) of the DAC Members designated by RRD of any FDA or other governmental or regulatory correspondence, inspection or inquiry regarding, or reasonably expected to impact, any of the Programs; and (b) forward to the DAC copies of any correspondence sent to or received from any regulatory or governmental agency, including, but not limited to, FDA Form 483 notices and FDA refusal to file, action or warning letters, to the extent they are relevant to any Program or this Agreement, even if they do not specifically mention Eiger or RRD. To the extent practicable, Eiger shall [***], but Eiger shall not be obligated to do so if such action would require a delay beyond any time period permitted by applicable law or regulations. [***]. In the event that RRD receives a request or notification from a governmental authority with respect to the Programs, RRD shall: (i) notify Eiger within twenty-four (24) hours of receipt of such request or communication and (ii) to the extent practicable, submit any proposed response to Eiger for review and approval; provided, that such approval shall not be unreasonably withheld and shall not prevent RRD from complying with any legal requirements or acting to avoid any civil or criminal liability. In the event that a response to such request or notification should be filed by the IND Sponsor, Eiger shall have such responsibility unless RRD has been designated as IND Sponsor, or the responsibility has been delegated to RRD, pursuant to the terms of the relevant Project Agreement.

D. Inspections and Meetings. Each Party agrees that, during an inspection by the FDA or other regulatory authority concerning the Programs ("Inspections"), it (the "Inspected Party") will not

disclose to such agency any Confidential Information of the other Party without first obtaining the consent of the other Party (which consent shall not be unreasonably withheld or delayed), except to the extent that such Party may be required by law to disclose such information and materials.

The Inspected Party shall be the primary Party responsible for arranging (unless otherwise stated in writing by the other) and will allow the other Party to reasonably participate, to the extent permitted, in any meetings with any regulatory authority concerning any of the Programs. The Inspected Party shall consult with the DAC prior to any such meetings and provide to the DAC for review all relevant correspondence to date. During the Inspected Party's consultation with the DAC, the Inspected Party and the DAC shall discuss and agree upon issues including, but not limited to, overall regulatory strategy, proposed agendas, goals and objectives, preparation and attendees. The Inspected Party shall provide prompt and reasonable prior notice of any such meetings to at least one (1) of the DAC Members designated by the other Party, and shall, upon a request from the other Party, and to the extent reasonably possible, facilitate the attendance of at least one (1) of the DAC Members designated by the other Party at any such meeting reasonably anticipated to pertain in a material way to a Program. Following any meeting that pertains to a Program, but that was not attended for any reason by at least one (1) of the DAC Members designated by the other Party, the Inspected Party shall provide at least one (1) of the DAC Members designated by the other Party with an oral summary of that portion of the meeting relevant to such Program within [***] of such meeting and a written summary of that portion within [***] of such meeting.

9. Confidentiality.

A. It is understood that during the course of this Agreement, RRD and Eiger may each receive from the other Party data and information (including, without limitation, computer programs, technical drawings, algorithms, know-how, formulas, processes, ideas, inventions (whether patentable or not), schematics and other technical, business, financial, customer and product development plans, forecasts, strategies and information) that is either confidential or proprietary to the disclosing Party. All such data and information, whether written or verbal, tangible or intangible, made available, disclosed or otherwise made known by a Party to the recipient Party (including its employees) pursuant to this Agreement (including in connection with activities with respect to any Project Agreement) shall (except as otherwise provided below) be considered confidential and shall be considered the sole property of the disclosing Party and shall hereinafter be referred to as "Confidential Information." For clarity, all Eiger Information, Records, Reports, data and results generated from the Program shall be Confidential Information of Eiger for purposes of this Agreement and RRD shall be deemed the recipient Party of such information that it actually receives or generates (notwithstanding the fact that such information is generated and disclosed by RRD to Eiger).

B. Confidential Information of the disclosing Party shall be used by the receiving Party only for purposes of performing the receiving Party's obligations or exercising its rights hereunder. Each Party agrees that it will not reveal, publish or otherwise disclose the Confidential Information of the other Party to any third party without the prior written consent of the disclosing Party; provided, however, that each of RRD and Eiger may disclose the other Party's Confidential Information to persons within their respective organizations and to their respective contractors, consultants, attorneys, advisors and collaborators that have a need to receive such Confidential Information in order to further the purposes of this Agreement or any particular Project

Agreement and that are bound to protect the confidentiality of such Confidential information pursuant to terms no less stringent than those described herein. RRD and Eiger have or shall obtain agreements that impose at least comparable confidentiality obligations as those contained in this Agreement with all parties who are permitted access to the other Party's Confidential Information under this Agreement or any Project Agreement.

C. The foregoing obligations shall not apply to Confidential Information to the extent that it:

(1) is, at the time of disclosure by the disclosing Party hereunder, or thereafter becomes, generally available to the public other than as a result of a disclosure by the receiving Party;

(2) becomes available to the receiving Party on a non-confidential basis from a third party source that is not prohibited from disclosing such information; or

(3) was developed independently of any disclosure by the disclosing Party and without access or reference to the disclosing Party's Confidential Information or was known to the receiving Party prior to its receipt from the disclosing Party, in each case as shown by contemporaneous written evidence.

Notwithstanding the foregoing, a receiving Party may disclose specific Confidential Information of the other Party to the extent that such disclosure is required by law, regulation or valid court order to be disclosed; provided, however, in the event that receiving Party or receiving Party's representatives become legally compelled to disclose any Confidential Information of the disclosing Party, such receiving Party (a) will provide disclosing Party with reasonable notice so that disclosing Party may seek a protective order or other appropriate remedy or waive compliance with the provisions of the Agreement and (b) will disclose only that portion of the Confidential Information that it is advised by opinion of counsel (reasonably acceptable to disclosing Party) is legally required (in accordance with any applicable protective order or other order) and will endeavor to obtain assurance that confidential treatment will be accorded the Confidential Information so furnished.

D. These obligations of confidentiality, nondisclosure and non-use shall remain in effect until [***] after the date of termination or expiration of this Agreement.

10. Ownership and Inventions.

A. All data and information generated or derived by RRD as the result of Services performed by RRD under this Agreement shall be and remain the exclusive property of Eiger. Any inventions (whether patentable or not) and/or related patents that may arise from or relate to such data and information described above or the Services shall belong solely to Eiger. RRD hereby assigns and shall assign its rights in all such data, information, inventions and/or related patents and other intellectual property rights (collectively, "Eiger Program IP") to Eiger without compensation except for RRD's reasonable time and expenses related to any additional time or expenses required above and beyond the general assignment provided in this paragraph. RRD shall notify Eiger in writing of any and all Eiger Program IP promptly after its conception, identification, development or reduction to practice. RRD agrees to take, and to cause its employees, agents, consultants and permitted subcontractors to take, at Eiger's reasonable request and reasonable expense, all further acts reasonably required to evidence, effect or perfect such assignment and transfer to Eiger and to obtain intellectual property right protection for the Eiger Program IP.

B. RRD acknowledges that Eiger possesses certain inventions, processes, know-how, trade secrets, improvements, other intellectual properties and other assets, including, but not limited to, standard operating procedures (and related documents), analytical methods, procedures and techniques, procedure manuals, personnel data**,** financial information, computer technical expertise and software, that have been developed by Eiger independently and outside the scope of this Agreement, and that relate to Eiger's business or operations and/or any proprietary product or material of Eiger (collectively "Eiger's Property"). Eiger and RRD agree that any of Eiger' Property shall be and remain the exclusive property of Eiger.

C. Eiger acknowledges that RRD possesses certain inventions, processes, know-how, trade secrets, improvements, other intellectual properties and other assets, including, but not limited to, standard operating procedures (and related documents), analytical methods, procedures and techniques, procedure manuals, personnel data**,** financial information, computer technical expertise and software, that have been developed by RRD independently and outside the scope of this Agreement, and that relate to RRD's business or operations (collectively "RRD's Property"). Eiger and RRD agree that any of (i) RRD's Property, (ii) any improvements thereto that are used, improved, modified or developed by RRD during the term of this Agreement outside of the conduct of the Services and (iii) any RRD Improvements (as defined below) shall be and remain the exclusive property of RRD. As used herein, "RRD Improvements" shall mean any inventions, processes, know-how, trade secrets, or improvements that (a) are conceived or reduced to practice solely by RRD during the Term without the use of any Eiger's Property, (b) does not relate in any respect to any Eiger's Property or any proprietary product or material of Eiger, and (c) relate solely and specifically to RRD's Property.

D. Notwithstanding the foregoing, if any RRD's Property or RRD Improvement is employed by, is embodies within, or otherwise materially useful or necessary to use or to practice, use or otherwise exploit any Eiger Program IP, RRD shall be deemed to have granted, and hereby grants, to Eiger a non-exclusive, worldwide, royalty-free, fully-paid, sublicensable, perpetual license under such RRD's Property or RRD Invention solely to the extent necessary to practice, use or exploit such Eiger Program IP.

11. Publication. Project results may not be published or referred to, in whole or in part, by RRD without the prior express written consent of Eiger. Neither Party will use the other Party's name in connection with any publication or promotion without the other Party's prior written consent. Notwithstanding the above, neither Party will be restricted from using the other Party's name in filings or communications with the FDA, or other governmental or regulatory agencies, when required to do so by such agencies or by applicable law or regulation. In the event that such disclosure is required as aforesaid, the disclosing Party shall provide the other Party with notice beforehand and coordinate with the other Party with respect to the wording and timing of any such disclosure.

12. Independent Contractor Relationship. For the purposes of this Agreement, the Parties are independent contractors and nothing contained in this Agreement shall be construed to create any joint venture, principal and agent, employer/employee or partnership relationship between RRD and Eiger, and the Parties acknowledge and agree that RRD is acting as an independent contractor in the performance of its obligations under this Agreement. Each Party agrees that it shall have no power or right to bind or obligate the other Party, other than through the express terms of this Agreement that grant such power or right, and neither Party shall hold itself out as having such authority.

13. Indemnification.

A. To the greatest extent permitted by applicable law:

(1) Eiger shall indemnify, defend and hold harmless RRD and its affiliates and each of their respective LLC members, officers, directors, employees, contractors, agents, managers, successors and assigns (each, an "RRD Indemnified Party"), from and against any and all claims, losses, costs, interest, awards, judgments, fees (including reasonable fees for attorneys and other professionals), court costs, liabilities, damages and expenses of any kind (including arising out of physical injury) incurred by any RRD Indemnified Party (irrespective of whether any such Indemnified Party is a party to the action for which indemnification hereunder is sought) (hereinafter, "RRD Losses") to the extent resulting from or arising out of any third party suits, claims, actions, proceedings, investigations, litigation or demands arising from or in connection with: (a) [***]; (b) [***]; or (c) [***] (i) [***] or (ii) [***].

(2) RRD shall indemnify, defend and hold harmless Eiger and its affiliates and each of their respective officers, directors, employees, contractors, agents, successors and assigns (each, an "Eiger Indemnified Party"), from and against any and all claims, losses, costs, interest, awards, judgments, fees (including reasonable fees for attorneys), court costs, liabilities, damages and expenses (collectively, "Eiger Losses") to the extent resulting from, or arising out of any third party suits, claims, actions, proceedings, investigations, litigation or demands arising from or in connection with this Agreement, any Project Agreement or the Services contemplated herein relating to, arising from or in connection with: (a) [***] or (b) [***] (i) [***] or (ii) [***]. Notwithstanding the foregoing, RRD shall not be responsible for or provide any indemnification for any Eiger Losses arising out of [***].

(3) To the extent that the foregoing undertaking by RRD or Eiger may be unenforceable for any reason, such Indemnifying Party shall make the maximum contribution to the payment and satisfaction of any Loss that is permissible under applicable law

(4) To the extent that the foregoing undertaking by RRD or Eiger may be duplicated by any other undertaking by RRD or Eiger under any other agreement, the Eiger Indemnified Parties or RRD Indemnified Parties, as the case may be, shall be entitled to only one recovery for the relevant Losses (and not entitled to any duplicative recovery for the same Losses).

B. **Notice of Claims**. Any Eiger Indemnified Party or RRD Indemnified Party (each an "Indemnified Party") that proposes to assert a right to be indemnified under this Section shall notify RRD or Eiger, as applicable (the "Indemnifying Party"), promptly after receipt of notice of commencement of any action, suit or proceeding against such Indemnified Party (an "Indemnified Proceeding") in respect of which a claim is to be made under this Section, or the incurrence or realization of any Loss in respect of which a claim is to be made under this Section, of the commencement of such Indemnified Proceeding or of such incurrence or realization, enclosing a copy of all relevant documents, including all papers served and claims made, but the omission to notify the applicable Indemnifying Party promptly of any such Indemnified Proceeding or incurrence or realization shall not relieve such Indemnifying Party from any liability that it may have to such Indemnified Party under this Section or otherwise, except, as to such Indemnifying Party's liability under this Section, to the extent, but only to the extent, that such Indemnifying Party shall have been prejudiced by such omission or delay in the defense of such claim.

C. **Procedure**. The Indemnifying Party shall be entitled to participate in and assume the defense of any Indemnified Proceeding, with counsel reasonably satisfactory to the Indemnified Party, and, after notice to the Indemnified Party from the Indemnifying Party of its election to assume the defense thereof, the Indemnifying Party shall be responsible for all legal and other expenses incurred by it in connection therewith; provided, that, if the Indemnified Party shall have reasonably concluded that there may be one or more legal defenses available to it which are different from or are in addition to those available to the Indemnifying Party, or that such claim or litigation involves or could have an effect upon matters beyond the scope of the indemnity agreement provided in this Section 13, the Indemnifying Party shall not have the right to assume the defense of such action on behalf of the Indemnified Party, and the Indemnifying Party shall reimburse the Indemnified Party for the fees and expenses of a single counsel retained by the Indemnified Party which are reasonably related to the matters covered by the indemnity agreement in this Section 13. The Indemnified Party shall fully cooperate with the Indemnifying Party and its representatives in the investigation of any claim or lawsuit related to the Services provided in this Agreement.

D. **Settlement**. Without the prior written consent of such Indemnified Party, such consent not to be unreasonably withheld, such Indemnifying Party shall not settle or compromise, or consent to the entry of any judgment in, any pending or threatened Indemnified Proceeding, unless such settlement, compromise, consent or related judgment (i) includes an unconditional release of such Indemnified Party from all liability for Losses arising out of such claim, action, investigation, suit or other legal proceeding, (ii) provides for the payment of money damages as the sole relief for the claimant (whether at law or in equity), (iii) involves no admission of fact adverse to the Indemnified Party or finding or admission of any violation of law or the rights of any person by the Indemnified Party, and (iv) is not in the nature of a criminal or regulatory action. No Indemnified Party shall settle or compromise, or consent to the entry of any judgment in, any pending or threatened Indemnified Proceeding (A) in respect of which any payment would result hereunder, (B) which includes an injunction that will adversely affect any Indemnifying Party, (C) which involves an admission of fact adverse to the Indemnifying Party or a finding or admission of any violation of law or the rights of any person by the Indemnifying Party, or (D) which is in the nature of a criminal or regulatory action, without the prior written consent of the Indemnifying Party, such consent not to be unreasonably conditioned, withheld or delayed.

14. Limitation of Liabilities.

A. NEITHER PARTY NOR ANY OF THEIR RESPECTIVE DIRECTORS, OFFICERS, MEMBERS, MANAGERS, EMPLOYEES, CONTRACTORS OR AGENTS SHALL HAVE ANY LIABILITY OF ANY TYPE (INCLUDING, BUT NOT LIMITED TO, CONTRACT, NEGLIGENCE AND TORT LIABILITY) TO THE OTHER PARTY FOR ANY SPECIAL, INCIDENTAL, INDIRECT, PUNITIVE OR CONSEQUENTIAL DAMAGES, INCLUDING, BUT NOT LIMITED TO, THE LOSS OF OPPORTUNITY, LOSS OF USE OR LOSS OF REVENUE OR PROFIT IN CONNECTION WITH OR ARISING OUT OF THIS AGREEMENT OR THE SERVICES PERFORMED HEREUNDER, EVEN IF SUCH DAMAGES MAY HAVE BEEN FORESEEABLE.

B. RRD EXPRESSLY DISCLAIMS ANY AND ALL LIABILITY TO EIGER FOR OR IN RESPECT OF ANY CLAIM ARISING OUT OF ANY CONDITION CAUSED BY OR ALLEGEDLY CAUSED BY ANY PHARMACEUTICAL OR BIOTECHNOLOGY PRODUCT OR DEVICE WHICH IS THE SUBJECT OF A PROJECT AGREEMENT IN ACCORDANCE WITH THE PROVISIONS OF ANY PROJECT AGREEMENT.

C. IN NO EVENT SHALL THE LIABILITY (INCLUDING, BUT NOT LIMITED TO, CONTRACT, NEGLIGENCE AND TORT LIABILITY) OF RRD AND ITS DIRECTORS, OFFICERS, MEMBERS, MANAGERS, EMPLOYEES, CONTRACTORS AND AGENTS UNDER THIS AGREEMENT EXCEED AN AMOUNT EQUAL TO [***].

D. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 14 IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER SECTION 13, OR DAMAGES AVAILABLE FOR A PARTY'S BREACH OF CONFIDENTIALITY OBLIGATIONS IN ARTICLE 9 THAT ARE THE RESULT OF THE NON-INDEMNIFYING PARTY OR BREACHING PARTY'S GROSS NEGLIGENCE OR INTENTIONAL MISCONDUCT.

15. Term and Termination.

A. Termination of this Agreement.

(1) **Manner of Termination.** The term of this Agreement shall commence on the Effective Date and shall continue until terminated in any of the following manners:

(a) this Agreement (or any individual Project Agreement) may be terminated by Eiger without cause on [***]' prior written notice to RRD (and such notice shall begin the notice period for any Project Agreement then in effect);

(b) this Agreement (or the applicable Project Agreement)may be terminated by either Party for material breach by the non-terminating Party upon [***]' written notice specifying the nature of the breach, if such breach has not been substantially cured within the [***] period (and such notice shall begin the notice period for any Project Agreement then in effect);

(c) in the event a Party makes an assignment for the benefit of creditors, appoints or suffers appointment of a receiver or trustee over all or substantially all of its property, files a petition under any bankruptcy or insolvency act or has any such petition filed against it which is not discharged within [***] of the filing thereof, then the other Party may terminate this Agreement effective immediately upon written notice to such Party;

(d) this Agreement (or the applicable Project Agreement)may be immediately terminated by either Party upon written notice to the other Party in the event that such Party has a good faith belief, after consultation with the other Party, that : (1) the other Party has committed (or such Party has a good faith belief that the other Party will commit) any significant action or inaction that is in direct violation of any statute or regulation, FDA guideline, or GCP which puts patient safety at risk; or (2) the continuation of any particular program that is the subject of a Project Agreement currently in place raises significant medical, scientific or safety concerns for patient safety; or

(e) this Agreement (or the applicable Project Agreement) may be immediately terminated by either Party upon written notice to the other Party in the event that FDA or other regulatory authority takes any action to suspend or terminate or withdraw approval of the clinical study under the Program subject to the consequences of termination as described in this Agreement or any relevant Project Agreement.

(2) Effect on Project Agreements. Unless otherwise agreed by the Parties, the termination of this Agreement will result in the concurrent termination of all Project Agreements hereunder, subject to any termination clauses contained therein.

B. Termination of Project Agreement.

(1) The term of each Project Agreement shall be set forth in each applicable Project Agreement and shall continue until terminated in accordance with the terms and conditions contained herein or the specific termination provisions contained in a particular Project Agreement. No termination of any Project Agreement shall have any effect upon continuation of this Agreement or any other Project Agreement except as otherwise agreed to by the Parties. Any written termination notice shall identify the specific Project Agreement or Project Agreements that are being terminated.

(2) Upon the termination of any specific Project Agreement, RRD shall cease performing any work not necessary for the orderly close out of the affected Services or for the fulfillment of regulatory requirements in connection with such orderly close out. Using commercially reasonable efforts, RRD shall wind down the affected Services as efficiently as possible with the intent of mitigating any costs related to the wind down, the transfer of regulatory responsibilities and the transfer of third-party contracts to Eiger or a third party of Eiger' choice. RRD shall cooperate with Eiger in the orderly transition of the Services to Eiger or a third party designated by Eiger [***]. [***].

(3) RRD shall, upon request or as required by applicable laws, deliver to Eiger as soon as reasonably possible, all data and materials provided by Eiger to RRD for the conduct of the Services under the terminated Project Agreement(s), and all data and information generated or derived by or on behalf of RRD, including, without limitation, statistical data, all statistical reports, all data entries and any other documentation produced as the result of Services performed by RRD under the terminated Project Agreement(s), shall be delivered to Eiger upon payment (not subject to a good faith dispute) to RRD for all Services completed through the date of termination in accordance with the applicable Project Agreement and the terms of this Agreement. RRD reserves the right to retain, at its own cost and subject to the confidentiality provisions herein, one copy of such materials and any Eiger Confidential Information ("RRD Retained Documents"), for archival purposes solely to be used to satisfy regulatory requirements relating to the Services performed by RRD for Eiger or to resolve disputes regarding the Services. Eiger agrees that the RRD Retained Documents, if any, are not intended to serve as archives for Eiger and Eiger shall have no expectation of access to such RRD Retained Documents. RRD is under no obligation to retain said documents for any specific period of time, except as required by law.

(4) Eiger shall, as soon as reasonably possible, deliver to RRD all RRD Confidential Information provided by RRD to Eiger in connection with the Services under the terminated Project Agreement(s). Eiger reserves the right to retain, at its own cost and subject to the confidentiality provisions herein, (i) such RRD Confidential Information as is subject to the license granted to Eiger under Section 11(D) and (ii) one copy of such materials and any RRD Confidential Information ("Eiger Retained Documents"), for archival purposes solely to be used to satisfy regulatory requirements or to resolve disputes regarding the Services. RRD agrees that the Eiger Retained Documents, if any, are not intended to serve as archives for RRD and RRD shall have no expectation of access to such Eiger Retained Documents. Eiger is

under no obligation to retain said documents for any specific period of time, except as required by law.

(5) Notwithstanding the foregoing, Confidential Information contained in system back up files (e.g., computer backup tapes) need not be returned or destroyed so long as they were created during the normal course of automatic system back up and are maintained in confidence and not readily accessible to users.

(6) Eiger shall [***], incurred to complete activities associated with the termination, close out of the project or Services, and fulfillment of regulatory obligations through the date of termination, unless otherwise agreed to by the Parties in writing, but in all events, consistent with the payment terms agreed to in each Project Agreement. In addition, Eiger will pay RRD for any reasonable, non-cancelable out-of-pocket costs and expenses incurred in providing the Services (including, without limitation, RRD pass-through costs and expenses and third party termination fees), any reasonable out-of-pocket costs and expenses directly incurred by RRD to close out the project, and any amounts due and owing for Services conducted at the time of the termination notice is received. If Eiger has pre-paid to RRD more than the amount due RRD in the final invoice, then RRD agrees to refund such excess amount to Eiger.

C. Consequences of Project Agreement Termination. Additional consequences of termination (if any) for each Project Agreement shall be addressed separately in each individual Project Agreement.

16. Transition Following Termination.

A. In the Event RRD Acts as IND Sponsor. In the event RRD acts as IND Sponsor, both Parties agree to make commercially reasonable efforts to, by the [***] after the termination of this Agreement or any individual Project Agreement, take all actions necessary to effect the transfer back to Eiger (or a third party designated by Eiger) of, (i) the IND or that portion of the IND related to the terminated Program, (ii) the regulatory files related to such terminated Programs, and (iii) any and all documents or materials related to the terminated Programs.

B. In the Event RRD Has Contracted for Third-Party Services on Eiger' Behalf. RRD shall assign to Eiger or its designee, at Eiger' expense and as of the termination date of such Program, all of the Approved Contracts then in effect, to the extent they relate solely to the terminated Program. Both Parties shall use commercially reasonable efforts to cause the assignment of any non-assignable subcontracting agreement or portion thereof relating to the terminated Programs. If it is not successful in causing such assignment, RRD shall act as Eiger' agent, at Eiger' request and reasonable expense, in procuring all goods and services under such agreements until such time as Eiger enters into alternative arrangements to procure such services, provided that Eiger uses commercially reasonable efforts to enter into such alternative arrangements as soon as possible. RRD shall provide copies of all such subcontracting agreements to Eiger, at Eiger' reasonable expense, in connection with such transfer. RRD agrees to take such commercially reasonable actions as Eiger may request in furtherance of the foregoing, at the expense of Eiger. Such efforts shall not include any obligation for RRD to incur any out-of-pocket costs that are not reimbursable by Eiger.

17. Miscellaneous.

A. Force Majeure. No delay by either Party to carry out or observe any of such Party's obligations under this Agreement (other than any payment obligation) shall give rise to any claim against such Party or be deemed a breach of this Agreement for the period of delay if such delay arises from an act of God, an act of Government, or any other circumstance beyond the reasonable control of the Party affected by the event of force majeure; provided that such Party gives the other Party reasonable notice of such reason or cause and the obligation affected, and uses good faith reasonable efforts to seek to perform the obligation as soon as practicable.

B. No Restrictions. Nothing in this Agreement shall limit or restrict the right of any RRD member, director, officer or employee of RRD or any member, director, officer, or employee of any of its subsidiaries or its affiliates to engage in any other business or to devote his or her time and attention to the management or other aspects of any other business, whether of a similar or dissimilar nature, nor limit or restrict the right of RRD or any of its affiliates to engage in any other business or to render services of any kind to any other entity; provided however that RRD and such member, director, officers and employee complies with the confidentiality and non-use obligations set forth herein.

C. Non-Solicitation. During the term of this Agreement and for [***] thereafter, neither Party will solicit or hire any employee or affiliate of the other Party (or former employee or affiliate of the other Party) who has performed or is performing Services under this Agreement.

D. Notices. Any notice, request, demand, waiver, consent, approval or other communication which is required or permitted to be given to any Party shall be in writing addressed to the Party at its address set forth below (provided that each Party may change its address for receipt of notice by giving notice of such change to the other Party) and shall be deemed given (i) when delivered to the Party personally, (ii) when delivered by next business day delivery by a nationally recognized courier service, or (iii) if sent by registered or certified mail when received, provided postage and registration or certification fees are prepaid and delivery is confirmed by a return receipt:

If to RRD:
J. Scott Tarrant
President
RRD International, LLC
7361 Calhoun Place, Suite 510
Rockville, MD 20855
Fax: [***]

With a copy to:
Raymond V. Lee, Esq.
Vice President, Legal Affairs

If to Eiger:
David Cory
Chief Executive Officer
Eiger BioPharmaceuticals, Inc.
2155 Park Boulevard
Palo Alto, CA 94306

E. **Arbitration.** Any controversy or claim arising out of, or relating to, this Agreement or the breach thereof shall be finally settled by arbitration administered by the American Arbitration Association ("AAA") under its Commercial Arbitration Rules ("AAA Rules") and judgment on the award rendered by the arbitrator shall be binding and may be entered in any court having jurisdiction thereof. [***] Notwithstanding the foregoing, either Party may seek injunctive relief before any court of competent jurisdiction for a breach of the confidentiality provisions of this Agreement or to preserve the status quo pending arbitration.

F. **Governing Law.** This Agreement shall be governed by, and construed in accordance with, the laws of the State of Delaware, excluding its conflicts of law provisions that may require the application of the laws of a different jurisdiction.

G. **Amendment**. The terms of this Agreement shall not be modified, amended, waived or supplemented in any manner whatsoever except by a written instrument signed by each of the Parties.

H. **Successors**. Nothing expressed or implied herein is intended or shall be construed to confer upon or to give to any person, other than the Parties, any right, remedy or claim under or by reason of this Agreement or of any term, covenant or condition hereof, and all the terms, covenants, conditions, promises and agreements contained herein shall be for the sole and exclusive benefit of the Parties and their successors and permitted assigns.

I. **Assignment**. Neither Party may assign this Agreement or any of its rights or obligations under this Agreement to any third party without the express, written consent of the other Party, which consent shall not be unreasonably withheld or delayed; provided, however, that either Party may assign this Agreement without such consent to its successor or the acquirer of all or substantially all of its assets or the assets to which this Agreement relates except in the event such assignment would cause a conflict that would prevent the non-assigning Party from entering into this Agreement.

J. **Counterparts**. This Agreement may be executed in one or more counterparts, each of which, when executed, shall be deemed an original but all of which taken together shall constitute one and the same Agreement.

K. **Severability**. If any term or other provision of this Agreement is invalid, illegal or incapable of being enforced by any rule of law or public policy, all other conditions and provisions of this Agreement shall nevertheless remain in full force and effect so long as the economic or legal substance of the transactions contemplated hereby is not affected in a manner materially adverse to either Party. Upon such determination that any term or other provision is invalid, illegal or incapable of being enforced, the parties hereto shall negotiate in good faith to modify this Agreement so as to effect the original intent of the parties as closely as possible in an acceptable manner to the end that the transactions contemplated hereby are fulfilled to the extent possible.

L. **Survival.** The rights and obligations of Eiger and RRD which expressly survive beyond the effective date of termination (including, but not limited to, Sections 4(C)(1), 4(F), 5(A), 9, 10, 11, 13, 14, 15(B), 16, 17(C), (D), (E) and (F) shall survive the termination of this Agreement.

M. **Entire Agreement**. This Agreement (including any attachments hereto and as may be amended from time to time) and any Project Agreement contains the entire understandings of the Parties

with respect to the subject matter herein, and supersedes all previous agreements (oral and written), negotiations and discussions.

N. Press Releases. Neither Party to this agreement shall issue any press release or make any other public announcement concerning the terms of this Agreement, the activities hereunder or the transaction between the Parties, without prior review and written approval by the other party, except in the case of a press release or governmental filing required by laws or regulations.

O. Previous Agreements. Concurrently upon the execution of this Agreement, the following agreements shall be automatically terminated and any obligations between the Parties thereunder shall be subsumed into this Agreement or relevant Project Agreement (including payment obligations thereunder which shall be reconciled with payment obligations hereunder), provided however, that any confidential information disclosed by Eiger under any of the following agreements shall be deemed Confidential Information pursuant to Section 9 of this Agreement:

Agreement	**Effective Date**
Master Services Agreement	[***]
Work Order 2	[***]
Work Order 3	[***]
Work Order 4	[***]
Work Order 5	[***]
Change Order 1	[***]
Change Order 2	[***]
Change Order 2 - Amended and Restated	[***]
Change Order 3	[***]
Work Order 6	[***]
Change Order 1	[***]
Work Order 7	[***]
Work Order 8	[***]
Change Order 1	[***]
Change Order 2	[***]
Work Order 9	[***]
Change Order 1	[***]
Change Order 2	[***]
Work Order 10	[***]
Change Order 1	[***]
Work Order 11	
LOA	[***]
LOA – Extension to 3/9/18	[***]
Amended and Restated WO 11	[***]

Amended and Restated WO 11 – Amend 1	[***]
Amended and Restated WO 11 – Amend 2	[***]
Amended and Restated WO 11 – Amend 3	[***]

Notwithstanding anything herein to the contrary, the MSA shall remain in effect for Work Order 1 and the following change orders, only For the purposes of RRD continuing to provide ad-hoc, hourly consulting services for projects not related to this PDA and any Project Agreements hereunder.

Work Order 1	[***]
Change Order 1	[***]
Change Order 2	[***]
Change Order 3	[***]

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

ACKNOWLEDGED, ACCEPTED AND AGREED TO:

RRD INTERNATIONAL, LLC		**EIGER BIOPHARMACEUTICALS, INC.**	
By:	/s/ J. Scott Tarrant	By:	/s/ David Cory
Name:	J. Scott Tarrant	Name:	David Cory
Title:	President	Title:	Chief Executive Officer
Date:	8/11/18	Date:	8/11/18

EIGER BIOPHARMACEUTICALS, INC.

COMMON STOCK PURCHASE AGREEMENT

THIS COMMON STOCK PURCHASE AGREEMENT (the "***Agreement***") is made as of September 19, 2018, by and between Eiger BioPharmaceuticals, Inc., a Delaware corporation (the "***Company***"), and RRD International, LLC, a Delaware limited liability company (the "***Purchaser***").

RECITALS

WHEREAS, in connection with the Product Development Agreement and Project Agreement 1 ("***Project Agreement 1***") by and between the Company and Purchaser effective July 1, 2018 and any amendments thereto (collectively, the "***RRD Agreements***") and pursuant to terms set forth in this Agreement the Company desires to sell to the Purchaser, and the Purchaser desires to purchase from the Company, shares of the Company's common stock, par value $0.001 per share ("***Common Stock***");

NOW, THEREFORE, in consideration of the premises and mutual covenants herein contained, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

SECTION 1

Purchase and Sale of Shares

1.1 ***Sale of Shares***. Subject to the RRD Agreements and the terms and conditions hereof, the Company will issue and sell to the Purchaser, and the Purchaser will purchase from the Company, at the Closing, 115,526 shares of Common Stock (the "***Shares***") in partial consideration of the Purchaser entering into the RRD Agreements.

1.2 ***Closing***. The purchase and sale of the Shares shall take place remotely via the exchange of documents concurrently with the signature hereof (such date is hereinafter referred to as the "***Closing***"). As soon as commercially practicable but in no event more than three (3) business days from the Closing, Company shall instruct its transfer agent issue to Purchaser the Shares in book entry per Section 2, below.

SECTION 2

Restrictions on Shares; Legend

2.1 ***Vesting.*** All of the Shares purchased herein (the "***Unvested Shares***") shall be subject to vesting. The Shares shall vest per the vesting schedule attached hereto as **Exhibit A** (the "***Vesting Provisions***") and once vested, shall be deemed fully paid and non-assessable and shall not be subject to cancellation or repurchase without the agreement of Purchaser.

2.2 ***Adjustments to Unvested Shares***. If, from time to time, during the term of this Agreement there is any change affecting the Company's outstanding Common Stock as a class

that is effected without the receipt of consideration by the Company (through merger, consolidation, reorganization, reincorporation, stock dividend, dividend in property other than cash, stock split, liquidating dividend, combination of shares, change in corporation structure or other transaction not involving the receipt of consideration by the Company), then any and all new, substituted or additional securities or other property to which Purchaser is entitled by reason of Purchaser's ownership of Unvested Shares shall be immediately be included in the meaning of "Unvested Shares" for all purposes of this Agreement with the same force and effect as the Unvested Shares.

2.3 ***Cancellation of Unvested Shares.*** Upon the termination of the Project Agreement 1, the Company shall have an irrevocable option for a period of 120 days after said default or termination, to cancel the number of Unvested Shares that have not vested in accordance with the Vesting Provisions as of such termination date. Purchaser agrees and acknowledges that in the event of cancellation in accordance with this Section 2.3, Company will exercise its cancellation option by instructing its transfer agent to cancel any Unvested Shares in its books.

2.4 ***Corporate Transaction.*** If Project Agreement 1 is terminated within 6 months of and in connection with (a) an Acquisition (as defined below); or (b) an Asset Transfer (as defined below) ((a) and (b) being collectively referred to in the Agreement as a "***Corporate Transaction***"), 100% of all Unvested Shares then-outstanding shall immediately become vested. If Project Agreement 1 is not terminated in connection with a Corporate Transaction, this Agreement shall be assigned by the Company to any successor of the Company (or the successor's parent) in connection with such Corporate Transaction. To the extent this Agreement remains in effect following such a Corporate Transaction, it shall apply to the new capital stock or other property received in exchange for the Unvested Shares in consummation of the Corporate Transaction, but only to the extent the Unvested Shares are at the time covered by such right. For the purposes of this Section 2.4: (i) "***Acquisition***" shall mean (A) any consolidation or merger of the Company with or into any other corporation or other entity or person, or any other corporate reorganization; or (B) any transaction or series of related transactions to which the Company is a party in which in excess of 50% of the Company's voting power is transferred; and (ii) "***Asset Transfer***" shall mean a sale, lease, exclusive license or other disposition of all or substantially all of the assets of the Company or which are the subject of Project Agreement 1.

2.5 ***Rights of Purchaser in Unvested Shares.*** Subject to Sections 2.6, 2.7, 2.8 and 2.10 in this Agreement, Purchaser shall exercise all rights and privileges of a stockholder of the Company with respect to the Unvested Shares held in book entry by the Company's transfer agent. Purchaser shall be deemed to be the holder for purposes of receiving any dividends that may be paid with respect to such Unvested Shares and for the purpose of exercising any voting rights relating to such Unvested Shares, even if some or all of such Unvested Shares have not yet vested.

2.6 ***Limitations on Transfer.*** In addition to any other limitation on transfer created by applicable securities laws, Purchaser shall not assign, hypothecate, donate, encumber or otherwise dispose of any interest in the Unvested Shares. Further, Purchaser shall not assign, hypothecate, donate, encumber or otherwise dispose of any interest in the Shares except in compliance with the

provisions herein, in the Company's Amended and Restated Bylaws (the "***Bylaws***"), and applicable securities laws. During the period of time during which the Purchaser holds the Common Stock, the value of the Common Stock may increase or decrease, and any risk associated with such Common Stock and such fluctuation in value shall be borne by the Purchaser.

2.7 ***Refusal to Transfer.*** The Company shall not be required (i) to transfer on its books any Unvested Shares of the Company that shall have been transferred in violation of any of the provisions set forth in this Agreement or (ii) to treat as owner of such shares or to accord the right to vote as such owner or to pay dividends to any transferee to whom such shares shall have been so transferred.

2.8 ***Legends.*** Purchaser authorizes the Company and its agents to place on each certificate for shares which Purchaser may acquire pursuant to this Agreement any legends required under the Bylaws and/or federal and state securities laws. Each certificate, if any, of Shares issued pursuant to this Agreement will be imprinted with the following legends (or a legend or legends substantially similar thereto):

(a) "THE SHARES REPRESENTED BY THIS CERTIFICATE ARE SUBJECT TO CANCELLATION SET FORTH IN AN AGREEMENT BETWEEN THE CORPORATION AND THE REGISTERED HOLDER, OR SUCH HOLDER'S PREDECESSOR IN INTEREST, A COPY OF WHICH IS ON FILE AT THE PRINCIPAL OFFICE OF THE CORPORATION. ANY TRANSFER OR ATTEMPTED TRANSFER OF ANY SHARES SUBJECT TO SUCH CANCELLATION IS VOID WITHOUT THE PRIOR EXPRESS WRITTEN CONSENT OF THE COMPANY."

(b) "THE SHARES REPRESENTED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), OR APPLICABLE STATE SECURITIES LAWS AND ARE SUBJECT TO CERTAIN TRANSFER AND VESTING RESTRICTIONS SET FORTH IN THE SECURITIES PURCHASE AGREEMENT, DATED EFFECTIVE AS OF JULY 1, 2018. THE SECURITIES MAY NOT BE OFFERED FOR SALE, SOLD, TRANSFERRED OR ASSIGNED (I) IN THE ABSENCE OF (A) AN EFFECTIVE REGISTRATION STATEMENT FOR THE SECURITIES UNDER THE SECURITIES ACT OR (B) AN AVAILABLE EXEMPTION FROM, OR IN A TRANSACTION NOT SUBJECT TO, THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT AND IN ACCORDANCE WITH APPLICABLE STATE SECURITIES LAWS OR BLUE SKY LAWS AS EVIDENCED BY A LEGAL OPINION OF COUNSEL REASONABLY SATISFACTORY TO THE COMPANY AND ITS TRANSFER AGENT OR (II) UNLESS SOLD PURSUANT TO RULE 144 UNDER THE SECURITIES ACT."

2.9 ***Registration Requirements.***

(a) If at any time when it is eligible to use Form S-3 registration statement or similar after the termination or expiration of Project Agreement 1, the Company receives a written request from the Purchaser, the Company shall, as soon as reasonably practicable, and in any event within sixty (60) days after receipt of such request from Purchaser, prepare and file a registration statement on a Form S-3 or such other form as is available with the SEC under the Securities Act (the "***Registration Statement***") for the sale of the Shares from time to time through the automated quotation system of the NASDAQ National Market System or in privately negotiated transactions, and thereafter shall use commercially reasonable efforts to secure the effectiveness of such Registration Statement within sixty (60) days after such Registration Statement is filed.

(b) The Company shall use commercially reasonable efforts to prepare and file with the SEC such amendments and supplements to the Registration Statement and the prospectus used in connection therewith as may be necessary to keep the Registration Statement effective until all the Shares have been sold pursuant thereto, or until the Purchaser is able to dispose of the Purchaser's entire remaining ownership interest in the Shares in a single transaction pursuant to Rule 144 promulgated under the Securities Act ("***Rule 144***") without exceeding the volume limitations under subsection (e) of Rule 144 or would be able to so dispose of its remaining ownership interest but for the fact that the Purchaser is an "affiliate" of the issuer as such term is defined in Rule 144. For purposes of this Agreement, references to Rule 144 shall include the provisions of any successor or similar rule adopted under the Securities Act.

(c) The Company shall furnish to the Purchaser with respect to the Shares registered under the Registration Statement such number of copies of prospectuses and preliminary prospectuses in conformity with the requirements of the Securities Act and such other documents as the Purchaser may reasonably request, in order to facilitate the public sale or other disposition of all or any of the Shares by the Purchaser.

(d) The Company shall file the documents required of the Company for blue sky clearance in states specified in writing by the Purchaser, provided, however, that the Company shall not be required to qualify to do business or consent to service of process in any jurisdiction in which it is not now so qualified or has not so consented.

(e) With a view to making available to the Purchaser the benefits of Rule 144 promulgated under the Securities Act and any other rule or regulation of the SEC that may at any time permit the Purchaser to sell the Shares to the public without registration, the Company hereby covenants and agrees, so long as the Purchaser owns any Shares, to: (i) make and keep public information available, as those terms are understood and defined in Rule 144; (ii) file with the SEC in a timely manner all reports and other documents required of the Company under the Securities Act and Exchange Act; and (iii) furnish to the Purchaser (A) a copy of the most recent annual or quarterly report of the Company and (B) such other information as may be reasonably requested in order to avail the Purchaser of any rule or regulation of the SEC that permits the selling of the Shares without registration.

(f) Notwithstanding the foregoing, the Company shall not be obligated to effect, or action to effect, any Registration Statement pursuant to this Section 2.9 during the period that is sixty (60) days before the Company's good faith estimate of the date of filing of, and ending on a date that is one hundred eighty (180) days after the effective date of, a Company-initiated registration, provided that the Company is actively employing in good faith commercially reasonable efforts to cause such registration statement to become effective or after the Company has effected one registration pursuant to Subsection 2.9(a) or if the Company has effected one registration within the twelve (12) month period immediately preceding the date of such request.

(g) The Company shall bear all expenses in connection with the procedures in paragraphs (a) through (f) of this Section 2.9 and the registration of the Shares pursuant to the Registration Statement, except for all underwriting discounts, selling commissions, fees and expenses, if any, of counsel or other advisors to the Purchaser.

(h) The right of the Purchaser to request registration pursuant to this Section 2.9 shall terminate upon the earlier of:

(i) the closing of a Corporate Transaction; and

(j) such time as Rule 144 or another similar exemption under the Securities Act is available for the sale of all of the Shares by the Purchaser without limitation during a three-month period without registration.

SECTION 3

Representations and Warranties of the Company

The Company hereby represents and warrants as of Closing (except for the representations and warranties that speak as of a specific date, which shall be made as of such date), that, except as otherwise disclosed to the Purchaser or as disclosed in the Company's filings with the United States Securities and Exchange Commission, including, but not limited to, the Company's registration statements, prospectuses, forms, reports and definitive proxy statements (the "***SEC***" and such filings the "***SEC Filings***"):

3.1 ***Organization and Good Standing and Qualifications***. The Company is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware and has full corporate power and authority to conduct its business as presently conducted and as proposed to be conducted by it. The Company is duly qualified to do business as a foreign corporation in the State of California and is in good standing under the laws of such state.

3.2 The Company has filed with the SEC as exhibits to its Annual Report on Form 10-K complete and accurate copies of its Amended and Restated Certificate of Incorporation (the "***Certificate of Incorporation***") and Bylaws, each as amended to date and presently in effect. The Company has at all times complied with all provisions of its Certificate of Incorporation and

Bylaws and is not in default under, or in violation of, any such provision. The Company is not, and has never been, a "shell company," as described in paragraphs (i)(1)(i) and (ii) of Rule 144 promulgated under the Securities Act of 1933, as amended (the "***Securities Act***").

3.3 ***Authorization***. The execution, delivery and performance by the Company of this Agreement, and the consummation by the Company of the transactions contemplated hereby, have been duly authorized by all necessary corporate action. This Agreement has been (or upon delivery will have been) duly executed and delivered by the Company and constitutes a valid and binding obligation of the Company enforceable against the Company in accordance with its respective terms. The execution and delivery of this Agreement, the consummation of the transactions contemplated hereby and the compliance with the provisions of this Agreement by the Company will not (a) conflict with or violate any provision of the Certificate of Incorporation or Bylaws, (b) conflict with, result in a breach of, constitute (with or without due notice or lapse of time or both) a default under, result in the acceleration of obligations under, create in any party the right to accelerate, terminate, modify or cancel, or require any notice, consent or waiver under, any contract, lease, sublease, license, sublicense, franchise, permit, indenture, agreement or mortgage for borrowed money, instrument of indebtedness, Security Interest (as defined below) or other arrangement to which the Company is a party or by which the Company is bound or to which its assets are subject, (c) result in the imposition of any Security Interest (as defined below) upon any assets of the Company or (d) violate any order, writ, injunction, decree, statute, rule or regulation applicable to the Company or any of its properties or assets. For purposes of this Agreement, "***Security Interest***" means any mortgage, pledge, security interest, encumbrance, charge or other lien (whether arising by contract or by operation of law).

3.4 ***Valid Issuance of Shares***. The Shares have been duly and validly authorized and when issued and paid for in accordance with the terms of the Agreement, will be duly and validly issued, fully paid and non-assessable free and clear of all liens and restrictions other than restrictions imposed or created under this Agreement, by applicable law, or by the Purchaser. Assuming the accuracy of the representations and warranties of the Purchaser in this Agreement, will be issued in compliance with all applicable federal and state securities laws.

3.5 ***SEC Filings; Financial Statements.***

(a) The Company has timely filed with or furnished to the SEC all SEC Filings required to be filed by it under the Securities Act or the Exchange Act for the two years preceding the date hereof. Each SEC Filing, as amended or supplemented, if applicable, (i) as of its date, or, if amended, as of the date of the last such amendment, complied in all material respects with the applicable requirements of the Securities Act and the Exchange Act, as the case may be, and the rules and regulations of the SEC thereunder, applicable to such SEC Filing, and (ii) did not, at the time it was filed (or at the time it became effective in the case of registration statements), or, if amended, as of the date of the last such amendment, contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary in order to make the statements made therein, in the light of the circumstances under which they were made, not misleading.

(b) Each of the consolidated financial statements (including, in each case, any notes thereto) contained in the SEC Filings, as amended, supplemented or restated, if applicable, was prepared in accordance with United States generally accepted accounting principles applied on a consistent basis during the periods involved ("***GAAP***"), subject, in the case of unaudited statements, to normal, immaterial, year-end audit adjustments, (except as may be indicated in financial statements and the notes thereto and, in the case of unaudited quarterly financial statements, as permitted by the Form 10-Q under the Exchange Act) applied on a consistent basis throughout the periods indicated (except as may be indicated in such financial statements or the notes thereto), and each presented fairly, in all material respects, the consolidated financial position, results of operations and cash flows of the Company and the consolidated subsidiaries of the Company as of the respective dates thereof and for the respective periods indicated therein (subject, in the case of unaudited quarterly financial statements, to normal year-end adjustments).

(c) The Company and its subsidiaries have implemented and maintain a system of internal control over financial reporting (as required by Rule 13a-15(a) under the Exchange Act) that is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements in accordance with GAAP for external purposes and includes policies and procedures that (i) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the Company, (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP and to maintain accountability of assets, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company, and (iii) provide reasonable assurance regarding the prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on its financial statements, and such system of internal control over financial reporting is reasonably effective.

(d) The Company has implemented and maintains disclosure controls and procedures (as defined in Rule 13a-15(d) of the Exchange Act) that are designed to ensure that information required to be disclosed by the Company in the reports it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time frames specified by the SEC's rules and forms (and such disclosure controls and procedures are reasonably effective), and has disclosed, based on its most recent evaluation of its system of internal control over financial reporting prior to the date of this Agreement, to the Company's independent registered accountant and the audit committee of the Board of Directors (A) any significant deficiencies and material weaknesses to the Company's knowledge in the design or operation of its internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) and (B) to the Company's knowledge any fraud that involves management or other employees who have a significant role in the Company's internal control over financial reporting.

3.6 ***Governmental Consents***. No consent, approval, order or authorization of, or registration, qualification, designation, declaration or filing with, any court, arbitrational tribunal, administrative agency or commission or other governmental or regulatory authority or agency (each of the foregoing is hereafter referred to as a "***Governmental Entity***") is required on the part

of the Company in connection with the offer, issuance, sale and delivery of the Shares, as contemplated by this Agreement, except such filings as shall have been made prior to and shall be effective on and as of the Closing and such filings required to be made after the Closing under applicable federal and state securities laws.

3.7 ***Actions Pending***. There is no action, suit or proceeding, or governmental inquiry or investigation, pending, or, to the best of the Company's knowledge, any basis therefor or threat thereof, against the Company or any officer, director of the Company, which questions the validity of this Agreement or the right of the Company to enter into such agreement or to consummate the transactions contemplated hereby. Other than as disclosed in the SEC Filings, there is no litigation pending, or, to the best of the Company's knowledge, any basis therefor or threat thereof, against the Company or any of its employees by reason of the past employment relationships of any of the employees, the proposed activities of the Company, or negotiations by the Company with possible investors in the Company. The Company is not subject to any outstanding judgment, order or decree.

3.8 ***Compliance with Law***. The Company has, in all material respects, complied with all laws, regulations and orders applicable to its present and proposed business and has all material permits and licenses required thereby. There is no term or provision of any mortgage, indenture, contract, agreement or instrument to which the Company is a party or by which it is bound, or, to the best of the Company's knowledge, of any provision of any state or federal judgment, decree, order, statute, rule or regulation applicable to or binding upon the Company, which materially adversely affects or, so far as the Company may now foresee, in the future is reasonably likely to hhave a Company Material Adverse Effect. To the best of the Company's knowledge, no employee of the Company is in violation of any term of any contract or covenant (either with the Company or with another entity) relating to employment, patents, assignment of inventions, proprietary information disclosure, non-competition or non-solicitation.

3.9 ***Exemption from Registration, Valid Issuance***. Subject to, and in reliance on, the representations, warranties and covenants made herein by the Purchaser, the issuance and sale of the Shares in accordance with the terms and on the bases of the representations and warranties set forth in this Agreement, may and shall be properly issued pursuant to Section 4(a)(2) of the Securities Act, Regulation D promulgated pursuant to the Securities Act ("***Regulation D***") and/or any other applicable federal and state securities laws. The sale and issuance of the Shares pursuant to, and the Company's performance of its obligations under, this Agreement will not (i) result in the creation or imposition of any liens, charges, claims or other encumbrances upon the Shares or any of the assets of the Company, or (ii) entitle the holders of any outstanding shares of capital stock of the Company to preemptive or other rights to subscribe to or acquire the Shares or other securities of the Company.

3.10 ***Investment Company***. The Company is not an investment company within the meaning of the Investment Company Act of 1940, as amended.

3.11 ***Shell Company***. The Company is not, and has never been, an issuer identified in Rule 144(i)(1) promulgated under the Securities Act

3.12 ***Brokers***. No brokers, finders or financial advisory fees or commissions will be payable by the Company or its subsidiary in respect of the transactions contemplated by this Agreement.

3.13 ***Property and Assets***. The Company has good title to, or a valid leasehold interest in, all of its material properties and assets, including all properties and assets reflected in the Financial Statements, except those disposed of since the date thereof in the ordinary course of business, and none of such properties or assets is subject to any Security Interest other than those the material terms of which are described in the Financial Statements.

3.14 ***Bad Actors Matters***. Neither the Company nor, to the Company's knowledge, any of its officers, directors or other affiliates covered under Rule 506(d)(1) promulgated under the Securities Act (excluding for such purposes the Purchaser) meet any of the disqualifying criteria described in Rule 506(d)(1)(i) through (viii) promulgated under the Securities Act.

SECTION 4

Representations and Warranties of the Purchaser

The Purchaser hereby represents and warrants the following as of the date hereof and as of the Closing:

4.1 ***Experience***. The Purchaser has carefully reviewed the representations concerning the Company contained in this Agreement and has sufficient knowledge and experience in finance and business that it is capable of evaluating the risks and merits of its investment in the Company and the Purchaser is able financially to bear the risks thereof.

4.2 ***Investment***. The Purchaser is acquiring the Shares for investment for the Purchaser's own account and not with the view to, or for resale in connection with, any distribution thereof. The Purchaser understands that the Shares are being issued in a transaction that has not been and will not be registered under the Securities Act by reason of a specific exemption from the registration provisions of the Securities Act which depends upon, among other things, the bona fide nature of the investment intent as expressed herein. The Purchaser further represents that it does not have any contract, undertaking, agreement or arrangement with any person to sell, transfer or grant participation to any third person with respect to any of the Shares.

4.3 ***Rule 144***. The Purchaser acknowledges that the Shares must be held indefinitely unless subsequently registered under the Securities Act or an exemption from such registration is available. The Purchaser is aware of the provisions of Rule 144 which permit limited resale of shares purchased in a private placement subject to the satisfaction of certain conditions. In connection therewith, the Purchaser acknowledges that the Company will make a notation on its

stock books regarding the restrictions on transfers set forth in Section 2 and will transfer the Shares on the books of the Company only to the extent not inconsistent therewith.

4.4 ***Access to Information***. The Purchaser has received and reviewed information about the Company and has had an opportunity to discuss the Company's business, management and financial affairs with its management and to review the Company's facilities. The Purchaser has had a full opportunity to ask questions of and receive answers from the Company, or any person or persons acting on behalf of the Company, concerning the terms and conditions of an investment in the Shares. In connection with the purchase of the Shares hereunder, the Purchaser is not relying upon, and has not relied upon, any statement, representation or warranty made by any person, except for the statements, representations and warranties contained in this Agreement.

4.5 ***Authorization***. The Purchaser has full power and authority to enter into and to perform this Agreement in accordance with its terms. The Purchaser represents that it has not been organized, reorganized or recapitalized specifically for the purpose of investing in the Company. This Agreement has been duly executed and delivered by the Purchaser and constitutes a valid and binding obligation of the Purchaser enforceable against the Purchaser in accordance with their respective terms.

4.6 ***Purchaser Status***. The Purchaser acknowledges that it is either (i) an institutional "accredited investor" as defined in Rule 501(a) of Regulation D of the Securities Act or (ii) a "qualified institutional buyer" as defined in Rule 144A of the Securities Act and the Purchaser shall submit to the Company such further assurances of such status as may be reasonably requested by the Company.

4.7 ***No Inducement***. The Purchaser was not induced to participate in the offer and sale of the Shares by the filing of any registration statement in connection with any public offering of the Company's securities, and the Purchaser's decision to purchase the Shares hereunder was not influenced by the information contained in any such registration statement.

SECTION 5

Covenants and Other Rights

5.1 ***Limitation on Purchases.*** The Purchaser agrees that the Purchaser and its agents, representatives and affiliates shall not in any manner whatsoever enter into or effect, directly or indirectly, any purchase or sale of any Common Stock or derivative securities of the Common Stock or take any action designed to cause or to result in the stabilization or manipulation of the price of any security of the Company.

5.2 ***Integration.*** From and after the date of this Agreement, neither the Company, nor any of its affiliates will, and the Company shall use its reasonable best efforts to ensure that no person acting on their behalf will, directly or indirectly, make any offers or sales of any security or solicit any offers to buy any security, under circumstances that would (i) require registration of

the offer and sale by the Company to the Purchaser of any of the Shares under the Securities Act, or (ii) cause this offering of the Shares by the Company to the Purchaser to be integrated with other offerings of securities by the Company in a manner that would require stockholder approval pursuant to the rules and regulations of the Nasdaq on which any of the securities of the Company are listed or designated, unless in the case of this clause (ii), stockholder approval is obtained before the closing of such subsequent transaction in accordance with the rules of the Nasdaq.

SECTION 6

Miscellaneous

6.1 ***Governing Law***. This Agreement shall be governed in all respects by the laws of the State of Delaware (without reference to the conflicts of law provisions thereof).

6.2 ***Survival***. The representations, warranties, covenants and agreements made herein shall survive any investigation made by the Purchaser and the Closing.

6.3 ***Successors, Assigns***. Except as otherwise provided herein, the provisions hereof shall inure to the benefit of, and be binding upon, the successors, assigns, heirs, executors and administrators of the parties hereto. This Agreement may not be assigned by either party without the prior written consent of the other; except that either party may assign this Agreement to an affiliate (as defined in Series E Preferred Stock Purchase Agreement) of such party or to any third party that acquires all or substantially all of such party's business, whether by merger, sale of assets or otherwise.

6.4 ***Notices***. All notices and other communications required or permitted hereunder shall be in writing and shall be sent by facsimile (receipt confirmed) or mailed by registered or certified mail, postage prepaid, return receipt requested, or otherwise delivered by hand or by messenger, addressed

if to the Purchaser, at the following address:

J. Scott Tarrant
President
RRD International, LLC
7361 Calhoun Place, Suite 510
Rockville, MD 20855
Fax: (301) 762-6154

with a copy to:

Raymond V. Lee, Esq.
Vice President, Legal Affairs

if to the Company, at the following address:

David Cory
Chief Executive Officer
Eiger BioPharmaceuticals, Inc.
2155 Park Boulevard
Palo Alto, CA 94306

with a copy (which shall not constitute notice) to:

Cooley LLP
3175 Hanover Street
Palo Alto, California 94304
Attention: Glen Sato
Facsimile: (650) 849-7400

or at such other address as one party shall have furnished to the other party in writing. If notice is provided by facsimile, it shall be deemed to be given one (1) business day after transmission (with receipt of appropriate confirmation). If notice is provided by U.S. mail, notice shall be deemed to be given four (4) days after proper deposit in a U.S. mailbox, postage prepaid, and properly addressed. If notice is provided by a messenger service that guarantees "next business day" delivery, it shall be deemed effective one (1) business day after deposit with such messenger service.

6.5 ***Expenses***. Except as expressly set forth herein in relation to Registration Rights in Section 2.9, each of the Company and the Purchaser shall bear its own expenses and legal fees incurred on its behalf with respect to this Agreement and the transactions contemplated hereby.

6.6 ***Confidentiality***.

(a) Subject to the other provisions of this Section 6.6, the existence of this Agreement and the terms and conditions of this Agreement (collectively, the "***Confidential Information***") will be maintained in confidence and otherwise safeguarded by the parties to this Agreement. Subject to the other provisions of this Section 6.6, each party shall hold as confidential such Confidential Information in the same manner and with the same protection as such party maintains its own confidential information. Subject to the other provisions of this Section 6.6, a party may only disclose Confidential Information to its employees, representatives, agents, sublicensees, subcontractors, consultants and advisers and its affiliates to the extent reasonably necessary for the purposes of, and for those matters undertaken pursuant to, this Agreement; provided that such persons are bound to maintain the confidentiality of the Confidential Information in a manner consistent with the confidentiality provisions of this Agreement.

(b) The obligations under this Section 6.6 shall not apply to any information to the extent the disclosing party can demonstrate by competent evidence that such information is (at

the time of disclosure) or becomes (after the time of disclosure) known to the public or part of the public domain through no breach of this Agreement by such party or its affiliates.

(c) In addition to disclosures allowed under Section 6.6(b), each party may disclose Confidential Information solely to the extent such disclosure is necessary in the following instances: (i) complying with applicable law, court orders or governmental regulations, including rules of self-regulatory organizations and SEC filing and disclosure requirements or (ii) to potential or actual investors or acquirers as may be necessary in connection with their evaluation of a potential or actual investment or acquisition; provided that such persons shall be subject to obligations of confidentiality and non-use at least as protective as those set forth in this Section 6.6.

(d) In the event a party is required to disclose Confidential Information by law, applicable court order or governmental regulation or in connection with bona fide legal process, such disclosure shall not be a breach of this Agreement; provided that such party (i) informs the other party as soon as reasonably practicable of the required disclosure; (ii) limits the disclosure to that which is legally required to be disclosed; and (iii) at the other party's request and expense, assists in an attempt to object to or limit the required disclosure.

(e) Either party may disclose the existence and terms of this Agreement in confidence to its attorneys and advisors, and to potential acquirers (and their respective professional attorneys and advisors), in connection with a potential merger, acquisition or reorganization and to existing and potential investors or lenders of such party, as part of their due diligence investigations, or to existing and potential licensees or sublicensees or to permitted assignees, in each case under an agreement to keep the terms of confidentiality and non-use substantially no less rigorous than the terms contained in this Agreement and to use such information solely for the purpose permitted pursuant to this Section 6.6(e).

6.7 ***Finder's Fees***. Each of the Company and the Purchaser shall indemnify and hold the other harmless from any liability for any commission or compensation in the nature of a finder's fee, placement fee or underwriter's discount (including the costs, expenses and legal fees of defending against such liability) for which the Company or the Purchaser, or any of its respective partners, employees, or representatives, as the case may be, is responsible.

6.8 ***Counterparts***. This Agreement may be executed in any number of counterparts, each of which shall be an original, but all of which together shall constitute one instrument. Counterparts may be delivered via facsimile, electronic mail (including pdf or any electronic signature complying with the U.S. federal ESIGN Act of 2000, *e.g.*, www.docusign.com) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.

6.9 ***Severability***. In the event that any provision of this Agreement becomes or is declared by a court of competent jurisdiction to be illegal, unenforceable or void, this Agreement

shall continue in full force and effect without said provision; provided that no such severability shall be effective if it materially changes the economic benefit of this Agreement to any party.

6.10 ***Entire Agreement***. This Agreement, including the exhibits and schedule attached hereto, and the RRD Agreements constitute the full and entire understanding and agreement among the parties with regard to the subjects hereof and thereof. No party shall be liable or bound to any other party in any manner with regard to the subjects hereof or thereof by any warranties, representations or covenants except as specifically set forth herein or therein.

6.11 ***Waiver***. The failure of either party to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement shall not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition by the other party. None of the terms, covenants and conditions of this Agreement can be waived except by the written consent of the party waiving compliance.

6.12 ***California Corporate Securities Law***. THE SALE OF THE SECURITIES WHICH ARE THE SUBJECT OF THIS AGREEMENT HAS NOT BEEN QUALIFIED WITH THE COMMISSIONER OF CORPORATIONS OF THE STATE OF CALIFORNIA AND THE ISSUANCE OF SUCH SECURITIES OR THE PAYMENT OR RECEIPT OF ANY PART OF THE CONSIDERATION THEREFOR PRIOR TO SUCH QUALIFICATION OR IN THE ABSENCE OF AN EXEMPTION FROM SUCH QUALIFICATION IS UNLAWFUL. PRIOR TO ACCEPTANCE OF SUCH CONSIDERATION BY THE COMPANY, THE RIGHTS OF ALL PARTIES TO THIS AGREEMENT ARE EXPRESSLY CONDITIONED UPON SUCH QUALIFICATION BEING OBTAINED OR AN EXEMPTION FROM SUCH QUALIFICATION BEING AVAILABLE.

IN WITNESS WHEREOF, the parties have executed this Common Stock Purchase Agreement as of the date first set forth above.

COMPANY:

EIGER BIOPHARMACEUTICALS, INC.

/s/ David Cory
By: David Cory
President and Chief Executive Officer

SIGNATURE PAGE TO EIGER BIOPHARMACEUTICALS, INC.
COMMON STOCK PURCHASE AGREEMENT

IN WITNESS WHEREOF, the parties have executed this Common Stock Purchase Agreement as of the date first set forth above.

PURCHASER:

RRD INTERNATIONAL, LLC

/s/ J. Scott Tarrant
By: J. Scott Tarrant
President

SIGNATURE PAGE TO EIGER BIOPHARMACEUTICALS, INC.
COMMON STOCK PURCHASE AGREEMENT

EXHIBIT A

VESTING SCHEDULE

Date of Vesting Milestone	Number of Shares Vested
Project Agreement Execution	29,000
10/1/2018	9,288
1/1/2019	6,404
4/1/2019	5,884
7/1/2019	5,684
10/1/2019	6,141
1/1/2020	5,854
4/1/2020	5,536
7/1/2020	5,724
10/1/2020	5,864
1/1/2021	5,494
4/1/2021	5,527
7/1/2021	5,416
10/1/2021	6,457
1/1/2022	5,355
4/1/2022	1,898
Total:	**115,526**

EXHIBIT 10.3

PROJECT AGREEMENT 1 TO THE PRODUCT DEVELOPMENT AGREEMENT BETWEEN RRD INTERNATIONAL, LLC AND EIGER BIOPHARMACEUTICALS, INC.

Product Development of Eiger's HDV Program

This Project Agreement 1 (this "Project Agreement"), effective July 1, 2018 (the "Project Agreement Effective Date"), is between Eiger BioPharmaceuticals, Inc. ("Eiger") and RRD International, LLC ("RRD") and relates to the Product Development Agreement dated July 1, 2018 (the "Agreement"). Pursuant to the Agreement, RRD has agreed to perform certain services in accordance with written Project Agreements, such as this one, entered into from time-to-time describing such services. Capitalized terms used herein, and not otherwise defined, shall have the meanings given such terms in the Agreement.

WHEREAS, upon the Project Agreement Effective Date, the Parties have executed this Project Agreement to describe the terms and conditions under which RRD shall provide certain services related to Eiger's Hepatitis D Virus (HDV) Program.

NOW THEREFORE, RRD and Eiger, in consideration of the premises and the mutual covenants and agreements contained herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, hereby agree as follows:

1. **Project Agreement**. This document constitutes a Project Agreement under the Agreement, and the services contemplated herein are subject to the terms and provisions of the Agreement.

2. **Overview of Services**. This Project Agreement, along with the Agreement, describes the terms under which RRD will provide development services to Eiger for its HDV product(s) (the "Product").

The services to be conducted under the current scope of this Project Agreement cover the Eiger HDV program supporting activities from [***]. It is anticipated that support of this program will be expanded by amendment, to include – among other potential activities – [***], and through completion of the NDA supporting activities when those details and timing are understood. The current scope includes advancing the Product through the conduct of the following [***]:

[***]

In addition, the following corresponding services will be conducted in support of protocol preparation, CSR completion, IND Maintenance, Ex-US regulatory planning, NDA planning, clinical operations and study management activities:

a. Senior Management and Strategic Oversight
b. Program Management
c. Regulatory Affairs and Medical Writing
d. Clinical Pharmacology Strategy and Phase 1 Study Management
e. Phase 3 Clinical Study Management
f. Quality Assurance

The services provided under this Project Agreement are further described herein and in Exhibit G (Scope of Services) attached hereto (the "Services").

Under this Project Agreement, RRD will assume primary responsibility for the Program, subject to oversight and guidance by a Development Advisory Committee, in the same manner as an internal biopharma product development team and operations staff. The RRD Product Development Team (PDT) will also provide operational oversight and management of RRD Consultants and Subcontractors.

3. **Study Protocols**. Protocols for the studies are attached hereto as Exhibit A.

4. **Eiger - RRD Product Development Team.** The initial Eiger - RRD Product Development Team, as described in Section 2.B(2) of the Agreement, is attached hereto as Exhibit B.

5. **Development Advisory Committee Charter.** The Development Advisory Committee Charter, as described in 2.B(3) of the Agreement, is attached hereto as Exhibit C.

6. **Clinical Development Plan.** The initial Clinical Development Plan, as described in Section 2.B(4) of the Agreement, shall be attached hereto as Exhibit D when approved by the Development Advisory Committee.

7. **Development Budget and Timeline.** The Development Budget for this Project Agreement (including the budget for the conduct of the [***] and the additional activities including strategic and operational development planning / oversight by RRD's senior management team), as described in Section 2.B(5) of the Agreement, is attached hereto as Exhibit E. RRD will invoice Eiger per the Payment Terms based upon the Development Budget, as such Development Budget is amended from time to time by the Development Advisory Committee.

   It is anticipated that the budget and timeline will be adjusted by amendment to include – among other potential activities – the [***], and completion of the NDA supporting activities when those details and timing are understood.

8. **Payment Terms.** The Payment Terms, as described in Section 2.B(6) of the Agreement, are attached hereto as Exhibit F.

9. **Scope of Services.** A description of the roles and responsibilities of the Parties, as described in Section 2.B(7) of the Agreement, is attached hereto as Exhibit G.

10. **Consequence of Major Project Delays.** In the event of a Major Project Delay ([***]), the Development Advisory Committee shall revise the Clinical Development Plan and Development Budget pursuant to the Agreement and the Development Advisory Committee Charter. During the first [***] of a Major Project Delay, [***]. Thereafter, unless such Major Project Delay is [***].

11. **Project Agreement Term; Termination.**

    A. **Term**. The term of this Project Agreement shall commence on the Project Agreement Effective Date and shall continue per the agreed upon Services, Budget and Timeline (the "Project Agreement Term").

B. **Termination Due to Default, Breach or Termination Without Cause by Eiger**.

(1) Each Party may terminate this Project Agreement at any time, upon written notice to the other Party, if the other Party is in material default or breach of the Agreement or this Project Agreement or if the other Party commits a non-material default or breach of the Agreement or this Project Agreement which has resulted in, or would reasonably be expected to result in, a material adverse effect on the non-breaching Party's rights under the Agreement or this Project Agreement and such material or non-material default or breach continues un-remedied for a period of [***] after written notice thereof is delivered to the breaching or defaulting Party. If the breaching or defaulting Party fails to remedy the default or breach within the applicable cure period, such non-breaching Party may, by notice of termination to the other Party, immediately terminate this Agreement.

(2) Eiger may terminate this Project Agreement without cause with [***] prior written notice, subject to the consequences of such termination as outlined herein.

(3) Upon termination of this Project Agreement by Eiger pursuant to Section 11.B(2) or termination by RRD pursuant to Section 11.B(1) herein or Section 15(A)(1)(d) of the PDA, Eiger shall [***]. In the event a [***] is applicable, the following shall apply: (a) [***], and (b) [***]. In the event that the aggregate amount of Service Fees and Wind-down Fees paid by Eiger as provided in the foregoing sentence exceeds the amount of [***], RRD shall promptly reimburse the excess amount to Eiger.

C. **Termination Due to: (1) Medical, Scientific/Regulatory or Safety Reasons Related to the Drug Product and/or the Administration Thereof; or (2) Termination by RRD Based on the Parties' Inability to Agree Upon an Amendment to the Development Budget or Clinical Development Plan**.

(1) The Development Advisory Committee has the authority, upon the unanimous agreement in good faith by all members, to terminate this Project Agreement in the event that medical, scientific/regulatory or safety reason(s) related to the drug product(s) that is the subject of this Project Agreement and/or the administration thereof justify such termination, in its sole and absolute discretion. In such event, this Agreement will be deemed to have been mutually terminated by the Parties.

(2) RRD may terminate this Project Agreement with [***] prior written notice in the event of RRD and Eiger's inability to materially agree in good faith on a Material Amendment to the Development Budget or Clinical Development Plan. As used herein, a "Material Amendment" means an amendment proposed by either Party that (a) is material to the conduct of this Project Agreement and (b) is not attributable to any act or failure to act by RRD (including any material default or breach of the Agreement or this Project Agreement by RRD).

[***]

D. Upon termination of this Project Agreement for any reason, a transition plan will be developed to wind down the Services (which transition plan may cover a period that is shorter than the applicable notice period), and such transition plan will be submitted for approval to the Development Advisory Committee outlining the fees, expenses and timing of such transition plan

(the "Wind-down Fees"). RRD shall implement such transition plan only upon approval thereof by the Development Advisory Committee, including the budget therefore. Once approved by the Development Advisory Committee, the transition plan shall become part of the Clinical Development Plan (as amended) hereunder, and the transition budget, including "Wind-down Fees", shall become part of the Development Budget (as amended) hereunder.

E. Upon the termination of this Project Agreement for any reason, RRD shall immediately return to Eiger any unused portion of the Deposit advanced by Eiger to RRD as described in the Payment Terms.

12. **Amendments.** No modification, amendment, or waiver of this Project Agreement shall be effective unless in writing and duly executed and delivered by each Party.

ACKNOWLEDGED, ACCEPTED, AND AGREED TO:

RRD INTERNATIONAL, LLC		**EIGER BIOPHARMACEUTICALS, INC.**	
By:	/s/ J. Scott Tarrant	By:	/s/ David Cory
Name:	J. Scott Tarrant	Name:	David Cory
Title:	President	Title:	Chief Executive Officer
Date:	8/11/18	Date:	8/11/18

Exhibit A – Study Protocols
Exhibit B – Eiger – RRD Product Development Team
Exhibit C – Development Advisory Committee Charter
Exhibit D – Clinical Development Plan
Exhibit E – Development and Budget Timeline
Exhibit F – Payment Terms
Exhibit G – Scope of Services
Exhibit H – General Approach and Outline of Anticipated NDA Supporting Activities

EXHIBIT A
STUDY PROTOCOLS

The services to be conducted under this Project Agreement include advancing the Product through the conduct of the [***] listed below.

[***]

Note that it is anticipated that support of this program will be expanded by amendment, to include – among other potential activities – [***], and through completion of the NDA supporting activities, when those details and timing are understood.

EXHIBIT B
EIGER - RRD PRODUCT DEVELOPMENT TEAM

[***]

The PDT outlined above may be amended from time to time for the most effective use of resources to develop the Program.

EXHIBIT C
DEVELOPMENT ADVISORY COMMITTEE CHARTER

1. **Purpose.** The Development Advisory Committee is established by Eiger and RRD to oversee the Clinical Development Plan and the Development Budget for the Programs.

2. **Authority and Duties.**

   A. Generally. The role of the Development Advisory Committee will be to provide oversight and direction for the program, review critical issues as they arise and to make recommendations to Eiger's management. In addition, the Development Advisory Committee shall decide on any other matters relating to the Clinical Development Plan and the Development Budget that may arise, including (i) responding to requests from RRD or Eiger for amendments to the Clinical Development Plan and/or the Development Budget, and (ii) addressing all other matters that are identified in the Agreement as requiring the input or approval of the Development Advisory Committee. The foregoing list of duties is not exhaustive, and the Development Advisory Committee may, in addition, perform such other functions as may be necessary or appropriate for the performance of its duties and the furtherance of the development of Programs, including as may be required under the Agreement.

   B. Clinical Development Plan and Development Budget Approvals. Approximately [***] after the execution of this Project Agreement, the Development Advisory Committee shall meet and approve (pursuant to the approval procedures described in Section 5 of this Charter) the Clinical Development Plan and the Development Budget. Thereafter, the Development Advisory Committee shall continue to develop and refine the Clinical Development Plan and Development Budget and shall approve any revisions to the Clinical Development Plan and Development Budget (pursuant to the approval procedures described in Section 5 of this Charter). Notwithstanding the foregoing, the Development Advisory Committee shall review the Clinical Development Plan and Development Budget no less frequently than on a semi-annual basis. Any approval or non-approval of the Clinical Development Plan and Development Budget by the Development Advisory Committee shall be recorded in the minutes of such meeting.

   C. Ongoing Review of the Program. The Development Advisory Committee shall be the primary means by which Eiger shall provide oversight and input to the Services provided by RRD. In the event the Services do not conform to the Clinical Development Plan, the Development Budget or Eiger's reasonable expectations, the Development Advisory Committee members shall work together in good faith to resolve such non-conformities and any impact this may have to the Clinical Development Plan or Development Budget. If the Development Advisory Committee members are unable to resolve such issues at the Development Advisory Committee level, the chief executive officers/presidents of each Party shall meet in person (or, with the consent of both parties, via teleconference) to negotiate a resolution. If the Parties are unable to achieve a resolution following the meeting of the chief executive officers/presidents, the matter shall be resolved by Eiger, subject to RRD's rights to terminate the Agreement and/or the Project Agreement pursuant to Section 15 of the Agreement and/or Section 11 of the Project Agreement.

3. Composition.

A. The Development Advisory Committee shall consist [***] representation from RRD and Eiger with a minimum of [***] appointed by Eiger and a minimum of [***] appointed by RRD. Each Party may bring additional employees or representatives to each meeting as observers, but only if such employees or representatives are bound by confidentiality obligations at least as stringent as those previously defined in the Agreement.

B. Each Development Advisory Committee Member shall have the requisite background, experience and training to carry out the duties and obligations of the Development Advisory Committee. Development Advisory Committee Members need not be members, directors or employees of either Party.

C. The Chair of the Development Advisory Committee shall be appointed by Eiger and shall initially be [***].

D. By written notice to Eiger, RRD may remove or replace one or more Development Advisory Committee Members designated by RRD. By written notice to RRD, Eiger may remove or replace one or more Development Advisory Committee Members, including the Chair, designated by Eiger.

4. Operations.

A. The Development Advisory Committee shall meet at least twice per year during the Term, unless and until the Development Advisory Committee determines that such meetings should occur at a greater or lesser frequency (in either case, each a "Scheduled Meeting"). Scheduled Meetings may be held in person or by teleconference when appropriate. Eiger shall be solely responsible for RRD's reasonable out-of-pocket costs associated with Development Advisory Committee attendance and participation in any such Meetings that are held in person, but may direct RRD to pay such costs from the Development Budget. In addition, any Development Advisory Committee Member may call for an ad hoc meeting of the Development Advisory Committee to be held by teleconference at any time, by giving at least [***]' notice to the other members of the Development Advisory Committee unless such notice is waived by all of the members. An Ad Hoc Meeting may be called to address any time-sensitive matter, including changes to the Clinical Development Plan and/or Development Budget.

B. The Chair, or such person as the Chair may designate, shall, in consultation with other Development Advisory Committee Members, develop and set the Development Advisory Committee's agenda for each Scheduled Meeting. The agenda and information concerning the business to be conducted at each Scheduled Meeting shall be communicated in writing to the Development Advisory Committee Members at least one (1) week in advance of such Scheduled Meeting to permit meaningful review. Such an agenda shall not be required for an Ad Hoc Meeting; however, the purpose of the meeting shall be stated in the notice thereof.

C. The Chair, or such person as the Chair may designate, shall prepare and distribute to all Development Advisory Committee Members, draft committee minutes within a reasonable period of time following each Scheduled Meeting and Ad Hoc Meeting, but in any case, in sufficient time to be included as part of the agenda for the next Scheduled Meeting. As part

of the agenda of the first Scheduled Meeting, the Development Advisory Committee Members shall agree upon a standard procedure for review and approval of such draft committee minutes by the Development Advisory Committee Members.

5. Approval Procedures.

Approval of any matter by the Development Advisory Committee may be affected in either of the two following ways:

A. Approval at a Meeting of the Development Advisory Committee. [***].

B. Approval by Unanimous Written Consent. Notwithstanding anything to the contrary, the Development Advisory Committee may approve any matter via unanimous written consent signed by all members of the Development Advisory Committee.

C. If the Parties are unable to approve any matter as provided in subsection (A) or (B) above, the matter shall be resolved by Eiger, subject to RRD's rights to terminate the Agreement and/or the Project Agreement pursuant to Section 15 of the Agreement and/or Section 11 of the Project Agreement.

EXHIBIT D
CLINICAL DEVELOPMENT PLAN

To Be Incorporated Herein Once Approved by the Development Advisory Committee

EXHIBIT E
DEVELOPMENT BUDGET AND TIMELINE

The Development Budget shall be drafted and agreed upon pursuant to the terms of the Agreement and the Development Advisory Committee Charter. It shall be amended from time to time as described herein and shall constitute this Exhibit E and become part of the Agreement.

1. General

The timeline and budget phasing for the Program Development Budget is shown below. The timeline reflects [***]. [***], which will include the expanded program scope, timeline, budget, and payment terms, when these details are understood. The budgeting process is an iterative process that will be revised and updated over the course of the program. The budget will be revisited for performance and reforecasting purposes at each DAC Meeting. Specific to this program, the following are additional milestones which, upon completion, the budget will be revisited and updated:

[***]

RRD currently anticipates the following budget updates:

A. Version 1.0: July 2018: Initial budget estimate covering [***].

B. Version 2.0: Q1 2019: Revised budget estimate to capture [***].

C. Additional and/or subsequent budget revisions: Material budget changes outside of RRD's control (i.e., actual cost of negotiated third-party contracts, enrollment issues, safety issues, a truncated or extended clinical study, etc.) may only be made upon the recommendation of the Development Advisory Committee and with Eiger management's prior approval.

2. Program Timeline (July 1, 2018 – August 31, 2022)

[***]

3. Economic Structure

For the Program, [***]. RRD will work closely with Eiger to further define the development program and finalize the study protocols and timelines before completing the final budget.

Based upon the current timeline, project scope, assumptions and discussions between RRD and Eiger, the average monthly PDT FTE utilization rate is approximately [***] FTEs over the next [***]. The chart below reflects the total monthly FTE utilization throughout the program and coincides with work effort as described in the timeline above.

4. PDT FTE Utilization

[***]

5. PDT Fixed Fee Program Budget

A. Cash Compensation.

[***] shall be paid to RRD [***] per [***] budget below and the payment terms attached hereto as Exhibit F.

[***]

B. Equity Compensation.

The remaining [***] of the RRD Fixed Service Fees (cash value of [***]) shall be paid to RRD in the form of shares of Eiger common stock (NASDAQ Capital Market Ticker Symbol EIGR) (the "Common Shares"). The Common Shares shall be priced at $12.50 per share. The Common Shares shall be issued subject to a separate Stock Purchase Agreement to be mutually agreed upon and executed between the parties, and such Common Shares will vest as invoiced per the budget above. If this Project Agreement 1 terminates, for any reason, all of the Common Shares that are unvested as of the termination date shall be forfeited immediately and automatically to Eiger, without payment to RRD and any termination or wind-down fees shall be paid in cash.

Eiger shall issue to RRD a single share certificate for the full amount of the Common Shares, subject to vesting (the "Share Certificate").

6. Estimated Expert Consultant and Pass-Through Budget[1]

[***]

[1] [***].

7. Total Budget Estimates

[***]

8. Payment Schedule for RRD PDT Fixed Fees - Cash Component and Equity Vesting Schedule [***][2]

[***]

9. Incentive Fees.

Eiger shall pay to RRD cash incentive fees (in addition to the amounts above) in the amounts described below within [***] of the corresponding milestone's date. These amounts shall be due to RRD regardless of whether such milestone occurs during or after the term of the Product Development Agreement so long as RRD provides services to Eiger related to Eiger's HDV Program within twelve months of the U.S. NDA submission.

Milestone	Amount
[***]	[***]

EXHIBIT F
PAYMENT TERMS

With respect to the development activities and services provided by RRD pursuant to this Project Agreement No. 1, and in accordance with the terms of Project Agreement No. 1, the Clinical Development Plan and the Development Budget, RRD will invoice Eiger in accordance with this Payment Terms Exhibit.

1. Generally. In regard to the budgeted service fees for RRD's Senior Development Management and Core Development Team, RRD shall invoice Eiger per the payment schedule detailed in Section 8 of Exhibit F. In addition, costs incurred for RRD Expert Consultants and Subcontractors and amounts paid for actual travel and other associated pass-through expenses shall be invoiced monthly, in arrears, subject to the deposit described below.

2. Initial Payments.

A. Initial Cash Payment. Immediately upon execution of Project Agreement No. 1, Eiger shall make a cash payment to RRD in the amount of [***] which represents: (a) [***]; and (b) [***].

Initial Cash Payment Due Upon Execution of this Project Agreement	Amount
[***]	[***]
Total Amount of Initial Cash Payment	[***]

[1]Credit of [***] is transferred from Eiger WO 11.

[2] The number of Common Shares shall be determined based on a stock price of $12.50 per share.

B. **Equity**. Eiger shall issue to RRD the Share Certificate within [***] after execution of Project Agreement No. 1 as described in Exhibit E.

3. **Subsequent Payments**. Subsequent to the Initial Payment, RRD shall invoice Eiger, and Eiger shall pay to RRD:

A. As scheduled, per Section 8 of Exhibit F. In the event of a modification of the Development Budget, upon approval of the Development Advisory Committee, RRD and Eiger will negotiate an amendment to the payment schedule in good faith consistent with the revised Development Budget over the remainder of the term; and

B. On a [***] basis, RRD shall invoice Eiger for the RRD Expert Consultant fees and actual amount of pass-through expenses (including RRD Subcontractors) incurred during the most recently completed month, [***]. RRD shall promptly (i) pay all invoices for RRD Expert Consultant fees and pass-through expenses (including RRD Subcontractors) for Services contemplated under this Project Agreement No. 1 in accordance with the payment terms of the applicable agreement between such RRD Expert Consultant or RRD Subcontractor and RRD and (ii) provide Eiger with reasonable evidence of such payment when made by RRD. In the event the aggregate net amount of such costs paid by RRD at any one time is equal to or greater than the amount of the Deposit, Eiger shall either be responsible for paying such further payments directly to the respective vendors or reasonably increasing the amount of the Deposit to RRD to cover such net payments going forward.

C. RRD reserves [***].

D. Upon termination of this Project Agreement, RRD will reconcile unpaid service fees earned (including wind-down fees, if any), unreimbursed RRD Expert Consultant fees and pass-through expenses (including RRD Subcontractors), and all other unreimbursed pass-through expenses against the balance of funds previously advanced by Eiger. Any excess of unapplied Eiger deposits over unpaid fees, costs and expenses will be offset against (i.e., deducted from) the final billing due to Eiger. If such excess is not able to be completely offset in this manner, the difference will be promptly refunded by RRD to Eiger, or alternatively, Eiger can in its sole discretion offset it against any payments still due to RRD under previous invoices.

4. **Miscellaneous.**

A. RRD shall invoice Eiger for RRD Expert Consultants and Subcontractors and pass-through expenses (i.e., travel, postage / delivery, phone charges, etc.) in arrears, on a monthly basis.

B. All pass-through expenses, as identified in the Development Budget, shall be billed to Eiger without mark-up.

C. All fees, costs, and expenses invoiced by RRD to Eiger, will be payable in US Dollars and are due within [***] of the receipt of the invoice. If Eiger disputes in good faith any portion of an invoice, then Eiger shall pay the undisputed portion of the invoice, and the parties shall use good faith efforts to reconcile the disputed amount as soon as practicable. RRD shall not be required to pay, nor be liable for its failure (or delay) to pay, any fees to RRD Expert Consultants and

Subcontractors or any pass-through expenses if the balance of the payments made by Eiger pursuant to Section 2 and Section 3B above is insufficient to cover any such payment due by RRD, and provided that such insufficiency is solely the result of Eiger's delayed payment of, under-payment of, or failure to pay any billing by RRD for such expenses or advances therefor.

D. RRD shall transmit invoices to Eiger at the following email addresses:
Eiger BioPharmaceuticals, Inc.
Please send invoices to Eiger at: [***]
With copy to [***]
[***]

All payments to RRD shall be sent to RRD as follows:
RRD Wire and ACH Instructions (ACH preferred):
[***]

For questions related to invoicing, please contact [***] at:
[***]

EXHIBIT G
SCOPE OF SERVICES

Clinical Pharmacology (Phase 1) Services, Phase 3 Services, IND Maintenance, and NDA Planning

[***]

DESCRIPTION OF SERVICES

In addition to the Services described below, this Project Agreement will continue the services commenced under Amended and Restated Work Order 11, effective as of February 15, 2018, which was terminated upon execution of the Product Development Agreement and this Project Agreement per the terms of section 17(N) of the Product Development Agreement.

A. **SERVICES.** RRD will provide the following Services in support of the Phase 1 and Phase 3 HDV Program:

1. Senior Management and Strategic Oversight
2. Program Management
3. Regulatory Affairs and Medical Writing
4. Clinical Pharmacology Strategy and Study Management
5. Phase 3 Clinical Operations and Study Management
6. Quality Assurance

B. **DESCRIPTION OF SERVICES.**

1. Senior Management and Strategic Oversight

[***]

2. Program Management

[***]

3. Regulatory Affairs and Medical Writing

[***]

4. Clinical Pharmacology Strategy and Study Management

[***]

5. Phase 3 Clinical Operations and Study Management

[***]

6. Quality Assurance

[***]

C. LIST OF TASKS AND RESPONSIBILITIES.

[***]

EXHIBIT H
General Approach and Outline of Anticipated NDA Supporting Activities

A. Summary

The services to be conducted under the current scope of this PDA Project Agreement 1 (PDA PA1) cover the Eiger HDV program supporting activities from [***]. Support of this program will be expanded, by amendment, through filing of the NDA and the requisite supporting activities when those details are understood. The following outlines RRD's high-level approach and plan to conduct these NDA supporting activities, including [***]. The detailed scope, budget, and timeline of Stages 2 – 4, outlined below are not included in this PA1; these will be prepared and included in a subsequent amendment.

B. NDA Strategy and Planning, NDA Application Preparation/Submission, and Key Meetings with FDA

Pre-NDA and NDA activities will be implemented in a staged approach as described below. Throughout the process, the RRD team will meet regularly, via telephone or in person with Eiger to report progress and resolve issues on a cross-functional and cross-operational basis. Program management for tasks related to the strategic development of the CTD sections of the NDA includes the following: coordinating communication and timeline for deliverables with internal and external team members/vendors for transition of information and review of NDA sections.

Stage 1: (included in PDA PA 1): RRD will work with Eiger to develop [***]

Stage 2 (to be included in PDA PA1 Amendment): Activities related to [***]

Stage 3 (to be included in PDA PA1 Amendment): Activities related to [***]

Stage 4 (to be included in PDA PA1 Amendment): After [***]

C. Reference Timeline - NDA Strategy and Planning, NDA Application Preparation/Submission, and Key Meetings with FDA

The following reference timeline, in the light blue shaded section surrounded by the red dashed line, illustrates the potential timing for the key activities in the aforementioned Stages 2 – 4 through NDA filing and FDA review/decision of the application. The timeline activities will be firmed up and detailed in the amendment which will include [***]

Exhibit 31.1

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

I, David A. Cory, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 9, 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: November 9, 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 September 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: November 9, 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."