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

Form 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2020

OR

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

For the transition period from _____ to _____

Commission file number: 001-36183

Eiger BioPharmaceuticals, Inc.

(Exact Name of Registrant as Specified in its Charter)

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

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

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

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

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

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

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

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

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

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

As of August 3, 2020, the number of outstanding shares of the registrant's common stock, par value $0.001 per share, was 29,242,967.

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.

ITEM 1. FINANCIAL STATEMENTS

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

	June 30, 2020 (Unaudited)	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 62,813	$ 39,373
Debt securities, available-for-sale	27,962	55,621
Prepaid expenses and other current assets	6,564	5,390
Total current assets	97,339	100,384
Property and equipment, net	616	590
Operating lease right-of-use assets	1,421	1,654
Other assets	3,781	2,511
Total assets	$ 103,157	$ 105,139
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 5,180	$ 6,414
Accrued liabilities	7,136	10,001
Current portion of operating lease liabilities	548	534
Current portion of long-term debt, net	3,283	—
Total current liabilities	16,147	16,949
Long-term debt, net	27,495	30,390
Operating lease liabilities	1,024	1,320
Total liabilities	44,666	48,659
Stockholders' equity:		
Common stock	27	24
Additional paid-in capital	330,433	297,863
Accumulated other comprehensive income	45	42
Accumulated deficit	(272,014)	(241,449)
Total stockholders' equity	58,491	56,480
Total liabilities and stockholders' equity	$ 103,157	$ 105,139

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	$ 9,754	$ 12,936	$ 19,235	$ 25,804
General and administrative	4,873	4,225	10,114	8,282
Total operating expenses	14,627	17,161	29,349	34,086
Loss from operations	(14,627)	(17,161)	(29,349)	(34,086)
Interest expense	(891)	(869)	(1,775)	(1,634)
Interest income	186	502	553	1,013
Other income (expense), net	6	1	6	(9)
Net loss	$ (15,326)	$ (17,527)	$ (30,565)	$ (34,716)
Net loss per common share, basic and diluted	$ (0.60)	$ (0.75)	$ (1.22)	$ (1.63)
Weighted-average common shares outstanding, basic and diluted	25,501,514	23,408,652	25,001,432	21,338,551

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Net loss	$ (15,326)	$ (17,527)	$ (30,565)	$ (34,716)
Other comprehensive gain:				
Unrealized gain on available-for-sale debt securities, net	9	—	3	30
Comprehensive loss	$ (15,317)	$ (17,527)	$ (30,562)	$ (34,686)

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

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

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2019	24,523,381	$ 24	$ 297,863	$ 42	$ (241,449)	$ 56,480
Issuance of common stock upon exercise of stock options	2,895	—	30	—	—	30
Vesting of common stock issued under Product Development Agreement	—	—	53	—	—	53
Issuance of common stock upon ESPP purchase	11,332	—	83	—	—	83
Issuance of common stock upon offering at-the-market, net of issuance costs of $221	32,751	—	191	—	—	191
Stock-based compensation expense	—	—	1,629	—	—	1,629
Unrealized loss on debt securities, net	—	—	—	(6)	—	(6)
Net loss	—	—	—	—	(15,239)	(15,239)
Balance at March 31, 2020	24,570,359	24	299,849	36	(256,688)	43,221
Issuance of common stock upon offering at-the-market, net of issuance costs of $786	2,612,476	3	28,577	—	—	28,580
Issuance of common stock upon exercise of stock options	58,805	—	490	—	—	490
Vesting of common stock issued under Product Development Agreement	—	—	55	—	—	55
Stock-based compensation expense	—	—	1,462	—	—	1,462
Unrealized gain on debt securities, net	—	—	—	9	—	9
Net loss	—	—	—	—	(15,326)	(15,326)
Balance at June 30, 2020	27,241,640	$ 27	$ 330,433	$ 45	$ (272,014)	$ 58,491

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

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

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

	Six Months Ended June 30,	
	2020	2019
Operating activities		
Net loss	$ (30,565)	$ (34,716)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	72	27
Amortization of debt securities discounts	(45)	(192)
Non-cash interest expense	388	352
Amortization of operating lease right-of-use assets	233	197
Common stock issued under Product Development Agreement	108	111
Stock-based compensation	3,091	2,682
Change in operating assets and liabilities:		
Prepaid expenses and other current assets	(1,374)	(1,541)
Other assets	(1,270)	(2,162)
Accounts payable	(1,234)	1,323
Accrued liabilities	(2,684)	73
Operating lease liabilities	(282)	(206)
Net cash used in operating activities	(33,562)	(34,052)
Investing activities		
Purchase of debt securities available-for-sale	(32,930)	(60,247)
Proceeds from maturities of debt securities available-for-sale	60,637	34,050
Purchase of property and equipment	(98)	(19)
Net cash provided by (used in) investing activities	27,609	(26,216)
Financing activities		
Issuance of common stock upon offering at-the-market, net of issuance costs	28,790	—
Proceeds from issuance of common stock upon stock option exercises	520	127
Proceeds from issuance of common stock upon ESPP purchase	83	59
Proceeds from issuance of common stock upon public offering, net of issuance costs	—	53,194
Proceeds from borrowings in connection with term loan, net of issuance costs	—	6,627
Repayment of accrued exit fee and second amendment fee	—	(913)
Repayment of term loan	—	(1,667)
Net cash provided by financing activities	29,393	57,427
Net increase (decrease) in cash and cash equivalents	23,440	(2,841)
Cash and cash equivalents at beginning of period	39,373	61,262
Cash and cash equivalents at end of period	$ 62,813	$ 58,421
Supplemental disclosure of cash flow information:		
Interest paid	$ 1,395	$ 1,242
Non-cash investing activities:		
Costs of available-for-sale securities in accrued liabilities	$ —	$ 1,404

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

1. Description of Business

Eiger BioPharmaceuticals, Inc. (the Company or Eiger) was incorporated in the State of Delaware on November 6, 2008. Eiger is a late-stage biopharmaceutical company focused on the development and commercialization of well-characterized drugs for life-threatening, rare and ultra-rare diseases with high unmet medical needs. Eiger has reported positive proof-of-concept clinical results across five programs: lonafarnib monotherapy in Hutchinson-Gilford Progeria Syndrome (HGPS or Progeria) and Progeroid Laminopathies, lonafarnib boosted with ritonavir in Hepatitis Delta Virus (HDV), peginterferon lambda (lambda) in HDV, and avexitide in both post-bariatric hypoglycemia (PBH) and congenital hyperinsulinism (CHI), all with first-in-class drugs, now under review for regulatory approvals, in Phase 3 clinical development, or advancing into Phase 3 development.

Eiger's lead clinical program is in Phase 3, developing lonafarnib, a first-in-class prenylation inhibitor, boosted with ritonavir, for the treatment of HDV infection, the most severe form of human viral hepatitis. The Company is also advancing lonafarnib monotherapy for treatment of Progeria and Progeroid Laminopathies, with a New Drug Application (NDA) and Marketing Authorization Application (MAA) under review by the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA), respectively. Progeria and Progeroid Laminopathies are ultra-rare and rapidly fatal genetic conditions of accelerated aging in children. Lambda is the Company's second program treating HDV and is Phase 3 ready. Lambda is a well-characterized, late-stage, first-in-class, type III interferon. The Company is also developing avexitide, a well-characterized peptide, as a treatment for PBH, a debilitating and potentially life-threatening condition for which there is currently no approved therapy, and as a treatment CHI, an ultra-rare pediatric metabolic disorder.

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

Liquidity

As of June 30, 2020, the Company had $90.8 million of cash, cash equivalents and investments, comprised of $62.8 million of cash and cash equivalents and $28.0 million of debt securities available-for-sale. The Company had an accumulated deficit of $272.0 million and negative cash flows from operating activities as of June 30, 2020. The Company expects to continue to incur losses for the next several years.

During the six months ended June 30, 2020, the Company completed at-the-market (ATM) offerings for a total of 2,645,227 shares of its common stock. The offerings were made under Eiger's effective shelf registration statement and resulted in net proceeds to the Company of $29.0 million, after deducting commissions.

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

2. Summary of Significant Accounting Policies

Basis of Presentation

The unaudited condensed consolidated financial statements include the accounts of Eiger BioPharmaceuticals, Inc. and its wholly owned subsidiaries, EBPI Merger Inc., EB Pharma LLC, Eiger BioPharmaceuticals Europe Limited, and EigerBio Europe Limited have been prepared in accordance with accounting principles generally accepted in the United States of America, (U.S. GAAP) and following the requirements of the Securities and Exchange Commission (the SEC) for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by U.S. GAAP can be condensed or omitted. These financial statements have been prepared on the same basis as the Company's annual financial statements and, in the opinion of management, reflect all adjustments, consisting only of normal recurring adjustments, which are necessary for a fair statement of the Company's financial information. These interim results are not necessarily indicative of the results to be expected for the six months ended June 30, 2020 or for any other interim period or for any other future year. The balance sheet as of December 31, 2019, 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, 2019, filed with the Securities and Exchange Commission on March 13, 2020.

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, operating lease liabilities and income taxes. The Company bases its estimates on historical experience and on various other market-specific and relevant assumptions that the Company believes to be reasonable under the circumstances. Actual results could differ from those estimates.

Debt Securities

Short-term securities consist of debt securities classified as available-for-sale and have maturities greater than 90 days, but less than 365 days from the date of acquisition. All short-term securities are carried at fair value based upon quoted market prices. Unrealized gains and losses on available-for-sale securities are excluded from earnings and are reported as a component of accumulated other comprehensive income (loss). The cost of available-for-sale securities sold is based on the specific-identification method. Realized gains and losses on the sale of debt securities are determined using the specific-identification method and recorded in other income (expense), net on the accompanying unaudited condensed consolidated statements of operations.

Accrued Research and Development Costs

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

Leases

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

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

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

Net Loss per Share

Basic net loss per share of common stock is calculated by dividing the net loss by the weighted average number of shares of common stock outstanding during the period, without consideration for potentially dilutive securities. Since the Company was in a loss position for all periods presented, diluted net loss per share is the same as basic net loss per share for all periods as the inclusion of all potential common shares outstanding would have been anti-dilutive.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Options to purchase common stock	3,696,242	2,758,556	3,696,242	2,758,556
Restricted stock units (unvested)	37,500	—	37,500	—
Total	3,733,742	2,758,556	3,733,742	2,758,556

Recently Adopted Accounting Pronouncements

In August 2018, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (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 adopted this guidance on January 1, 2020. The adoption did not have a material impact on the Company's unaudited condensed consolidated financial statements.

Accounting Pronouncements Not Yet Adopted

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments—Credit Losses (Topic 326)*. The standard changes how entities will measure credit losses for most financial assets and certain other instruments that are not measured at fair value through net income. Financial assets measured at amortized cost will be presented at the net amount expected to be collected by using an allowance for credit losses. In April 2019, the FASB issued ASU No. 2019-04, *Codification Improvements to Topic 326, Financial Instruments – Credit Losses, Topic 815, Derivatives and Hedging, and Topic 825, Financial Instruments*, which clarifies and corrects certain unintended applications of the guidance contained in each of the amended Topics. Additionally, in May 2019, the FASB issued ASU No. 2019-05, *Financial Instruments – Credit Losses (Topic 326)*, which provides an option to irrevocably elect to measure certain individual financial assets at fair value instead of amortized cost. In November 2019, the FASB issued ASU No. 2019-10, *Financial Instruments – Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842)*, which defers the effective date for ASU No. 2016-13 for smaller reporting companies to fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. The Company is evaluating the impact of the guidance on its consolidated financial statements.

In March 2020, the FASB issued ASU No. 2020-4, *Reference Rate Reform (Topic 848)*. The standard provides optional expedients for facilitating the effects of the reference rate reform on financial reporting. For the Company, there are two applicable optional expedients for contract modifications permitted for contracts that are modified because of the reference rate reform and meet the scope guidance. The modifications of contracts within the scope of ASC Topic 470 should be accounted for prospectively adjusting the effective interest rate. The modifications of contracts within the scope of ASC Topic 842 should be accounted for as a continuation of the existing contracts with no reassessments of the lease classification and the discount rate or remeasurements of lease payments that otherwise would be required under ASC Topic 842 for modifications not accounted for as separate contracts. The pronouncement is effective for all entities as of March 12, 2020 through December 31, 2022. The Company plans to adopt upon the occurrence of such contract modification, but not later than December 31, 2022. The Company engaged in early-stage discussions with its lender and will assess the impact of the adoption once the contract is modified.

3. Fair Value Measurements

Fair value accounting is applied for all financial assets and liabilities that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually). As of June 30, 2020 and December 31, 2019, the carrying amount of prepaid expenses and other current assets, accounts payable and accrued liabilities approximated their estimate fair value due to their relatively short maturities. Management believes the terms of its long-term debt reflect current market conditions for an instrument with similar terms and maturity, therefore the carrying value of the Company's debt approximated its fair value.

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

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

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

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

The Company's money market funds are classified as Level 1 because they are valued using quoted market prices. The Company's debt securities consist of available-for-sale securities and are classified as Level 2 because their value is based on valuations using significant inputs derived from or corroborated by observable market data. There were no assets or liabilities classified as Level 3 as of June 30, 2020 and December 31, 2019.

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

The following tables present the fair value hierarchy for assets and liabilities measured at fair value (in thousands):

	June 30, 2020			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Money market funds	$ 60,687	$ —	$ —	$ 60,687
Corporate debt securities	—	8,968	—	8,968
U.S. treasury bills	—	18,994	—	18,994
Total	$ 60,687	$ 27,962	$ —	$ 88,649

	December 31, 2019			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Money market funds	$ 35,854	$ —	$ —	$ 35,854
Corporate debt securities	—	16,644	—	16,644
Commercial paper	—	7,457	—	7,457
U.S. government Bonds	—	31,520	—	31,520
Total	$ 35,854	$ 55,621	$ —	$ 91,475

There were no financial liabilities as of June 30, 2020 and December 31, 2019.

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

	June 30, 2020			
	Amortized cost	Unrealized gain	Unrealized loss	Estimated Fair Value
Cash equivalents:				
Money market funds	$ 60,687	$ —	$ —	$ 60,687
Total cash equivalents	$ 60,687	$ —	$ —	$ 60,687
Debt securities:				
Corporate debt securities	$ 8,936	$ 32	$ —	$ 8,968
U.S. treasury bills	18,981	13	—	18,994
Total debt securities	$ 27,917	$ 45	$ —	$ 27,962

	December 31, 2019			
	Amortized cost	Unrealized gain	Unrealized loss	Estimated Fair Value
Cash equivalents:				
Money market funds	$ 35,854	$ —	$ —	$ 35,854
Total cash equivalents	$ 35,854	$ —	$ —	$ 35,854
Debt securities:				
Corporate debt securities	$ 16,633	$ 11	$ —	$ 16,644
Commercial paper	7,457	—	—	7,457
U.S. government bonds	31,489	31	—	31,520
Total debt securities	$ 55,579	$ 42	$ —	$ 55,621

As of June 30, 2020 and December 31, 2019, the contractual maturity of the available-for-sale debt securities is less than one year. The Company periodically reviews the available-for-sale investments for other-than-temporary impairment loss. The Company considers factors such as the duration, severity and the reason for the decline in value, the potential recovery period and its intent to sell. For debt securities, it also considers whether (i) it is more likely than not that the Company will be required to sell the debt securities before recovery of their amortized cost basis, and (ii) the amortized cost basis cannot be recovered as a result of credit losses. During the six months ended June 30, 2020, the Company did not recognize any other-than-temporary impairment losses. All debt securities with unrealized losses have been in a loss position for less than 12 months.

4. Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	June 30, 2020	December 31, 2019
Contract research costs	$ 3,358	$ 5,288
Compensation and related benefits	1,908	1,707
Contract manufacturing costs	1,240	2,510
Other	630	496
Total accrued liabilities	$ 7,136	$ 10,001

5. Product Development Agreement

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 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 new drug application (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. For the three and six months ended June 30, 2020, the Company recognized research and development expense of $0.1 million and $0.1 million, respectively, related to the shares issued under the Product Agreements. Additionally, as of June 30, 2020, the total unrecognized compensation expense related to unvested restricted shares was $0.3 million, which the Company expects to recognize over an estimated weighted-average period of 1.8 years.

6. Debt

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

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

On March 5, 2019, the Company entered into the third amendment to the Oxford Loan (the Amended Oxford Loan) to refinance the Oxford Loan. The Amended Oxford Loan increased the aggregate amount available to be borrowed to $35.0 million and extended the maturity date to March 1, 2024. On March 5, 2019, prior to entering into the Amended Oxford Loan, the outstanding balance of the Oxford Loan was $23.3 million. At the time of entering into the Amended Oxford Loan, the Company borrowed an additional $6.7 million in principal under the Amended Oxford Loan, which increased the total amount borrowed to $30.0 million (Amended Tranche A). The remaining $5.0 million (Amended Tranche B) is available to the Company provided that certain milestones are achieved by February 2021. The Company does not currently expect to draw down Amended Tranche B.

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

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

The refinancing of the term loan did not have a material impact on terms, conditions, representations, warranties, covenants or agreements set forth in the Oxford Loan. The loan is secured by the perfected first priority liens on the Company's assets, including a commitment by the Company to not allow any liens to be placed upon the Company's intellectual property. The loan includes customary events of default, including failure to pay amounts due, breaches of covenants and warranties, material adverse effect events, certain cross defaults and judgments, and insolvency. If the Company is unable to comply with these covenants or if the Company defaults on any portion of the outstanding borrowings, the lenders can also impose a 5.0% penalty, restrict access to additional borrowings under the loan and security agreement, and accelerate the maturity of the debt.

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

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

	June 30, 2020	December 31, 2019
Face value of long-term debt	$ 30,000	$ 30,000
Exit fee	3,277	3,277
Unamortized debt discount associated with exit fee, debt issuance costs and loan origination fees	(2,499)	(2,887)
Total long-term debt	30,778	30,390
Less: current portion of long-term debt, net	(3,283)	—
Long-term debt, net	$ 27,495	$ 30,390

7. Stock-Based Compensation

The following table summarizes stock option activity under the Company's stock-based compensation plan during the six months ended June 30, 2020 (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, 2019	823,598	2,767,617	$ 12.14	7.94	$ 8,218
Additional options authorized	1,226,169	—			
Granted	(1,064,750)	1,064,750	$ 7.13		
Restricted stock units granted	(37,500)	—			
Exercised	—	(61,700)	$ 8.41		
Canceled and forfeited	74,425	(74,425)	$ 11.06		
Outstanding as of June 30, 2020	1,021,942	3,696,242	$ 10.78	8.05	$ 4,425
Vested and exercisable as of June 30, 2020		1,683,700	$ 11.89	6.93	$ 1,484

During the three and six months ended June 30, 2020, the Company granted stock options for the purchase of 50,600 and 1,064,750 shares of the Company's common stock with a weighted-average grant date fair value of $5.69 and $4.59 per share, respectively. During the three and six months ended June 30, 2019, the Company granted stock options for the purchase of 81,000 and 862,750 shares of the Company's common stock with a weighted-average grant date fair value of $7.77 and $9.48 per share, respectively.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Expected term (in years)	6.02-6.08	5.77-6.08	5.27-6.08	5.27-6.08
Contractual term (in years)	—	10.00	10.00	10.00
Volatility	76.00%-77.00%	80.69%-81.25%	73.00%-77.00%	79.62%-83.19%
Risk free interest rate	0.39%-0.45%	2.23%-2.42%	0.39%-1.37%	2.23%-2.57%
Dividend yield	—	—	—	—

Stock-Based Compensation Expense

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Research and development	$ 398	$ 442	$ 787	$ 807
General and administrative	1,064	1,045	2,304	1,875
Total	$ 1,462	$ 1,487	$ 3,091	$ 2,682

As of June 30, 2020, the total unrecognized compensation expense related to unvested options was $12.8 million, which the Company expects to recognize over an estimated weighted average period of 2.8 years.

Restricted Stock Units

In the first quarter of 2020, the Company revised its non-employee director compensation policy to approve the granting of restricted stock units (RSUs) in accordance with the Restated 2013 Equity Incentive Plan (the Restated 2013 Plan). Each eligible director who has served for less than six months during the prior calendar year and continues to serve as a non-employee member of the board is granted RSUs, which are pro-rated for the period served during the prior calendar year.

The RSUs granted to non-employee directors will vest on the one-year anniversary of the grant date, subject to the eligible director's continuous services through the vesting date, and will vest in full upon a change in control, as defined under the Restated 2013 Plan. For RSU's granted to employees during the six months ended June 30, 2020, the vesting will begin on the one-year anniversary through the two-year anniversary of the grant date. The fair value of all RSUs are measured at the grant date based on the closing market price of the Company's common stock and is recognized as stock-based compensation expense on a straight-line basis over the vesting period.

There were no RSUs granted during the three months ended June 30, 2020. For the six months ended June 30, 2020, the Company granted 37,500 RSUs with a weighted-average grant date fair value of $6.95 per share. The Company recognized $0.1 million and $0.1 million in stock-based compensation expense for the three and six months ended June 30, 2020, respectively, which is included in general and administrative expenses. As of June 30, 2020, the total unrecognized compensation expense related to unvested RSUs was $0.2 million, which the Company expects to recognize over an estimated weighted-average period of 0.9 years.

8. Income Taxes

The Company did not record tax expense for the three and six months ended June 30, 2020 and 2019 due to the Company's loss position and full valuation allowance.

9. Commitments and Contingencies

Lease Agreements

In October 2017, the Company entered into a non-cancelable operating facility lease agreement for 8,029 square feet of office space located at 2155 Park Blvd. in Palo Alto, California 94306. The lease commenced on March 1, 2018 and expires in February 2023. The lease has a three-year renewal option prior to expiration; however, the Company is not reasonably assured to exercise this option. The lease includes rent escalation clauses throughout the lease term. In October 2017, the Company provided a security deposit of $0.3 million. The Company also has three additional operating leases that are included in its lease accounting but are not considered significant for disclosure.

The maturity of the Company's operating lease liabilities were as follows (in thousands):

Undiscounted lease payments	June 30, 2020
Remaining in 2020	$ 317
2021	674
2022	662
2023	113
Total undiscounted payments	1,766
Less: imputed interest	194
Present value of future lease payments	1,572
Less: current portion of operating lease liabilities	548
Operating lease liabilities	$ 1,024

Rent expense recognized for the Company's operating leases was $0.1 million and $0.2 million for the three months ended June 30, 2020 and 2019, respectively, and $0.3 million and $0.3 million for the six months ended June 30, 2020 and 2019, respectively. Under the terms of the lease agreements, the Company is also responsible for certain variable lease payments that are not included in the measurement of the lease liability. Variable lease payments for the operating leases were $23,000 and $27,000 for the three months ended June 30, 2020 and 2019, respectively, and $46,000 and $0.1 million for the six months ended June 30, 2020 and 2019.

The operating cash outflows for the operating lease liabilities were $0.4 million and $0.3 million for the six months ended June 30, 2020 and 2019, respectively. As of June 30, 2020 and December 31, 2019, the weighted-average remaining lease terms were 2.7 years and 3.1 years, and weighted-average discount rates were 9.15% and 9.15%, respectively.

10. Subsequent Events

As of July 31, 2020, the Company completed the sale of all common stock subject to its $50.0 million ATM financing facility with Jefferies LLC (Jefferies) under the effective shelf statement filed on December 20, 2019 (the 2019 ATM Facility), resulting in the total offering of 4,646,554 shares of common stock and net proceeds to the Company of $48.6 million, after deducting commissions. These amounts include ATM offerings during the six months ended June 30, 2020 of 2,645,227 shares and $29.0 million in net proceeds, after deducting commissions.

On August 6, 2020, the Company entered into a new sales agreement (the 2020 ATM Facility) with Jefferies, under which the Company may offer and sell, from time to time at the Company's sole discretion, shares of its common stock with an aggregate offering price of up to $50.0 million through Jefferies, as sales agent. The issuance and sale of these shares by the Company pursuant to the 2020 ATM Facility are deemed "at-the-market" offerings defined in Rule 415 under the Securities Act of 1933, as amended (the Securities Act), and are registered under the Securities Act. The Company is not obligated to make any sales of common stock under the 2020 ATM Facility. The offering of shares of common stock pursuant to the 2020 ATM Facility will terminate upon the earlier of (i) the sale of all common stock subject to the 2020 ATM Facility or (ii) termination of the 2020 ATM Facility in accordance with its terms. The Company will pay Jefferies a commission of up to 3.0% of the gross sales proceeds of any common stock sold through Jefferies under the 2020 ATM Facility.

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

You should read the following discussion and analysis of Eiger's financial condition and results of operations together with our unaudited condensed consolidated financial statements and related notes thereto included in Part I, Item 1 of this Quarterly Report on Form 10-Q, and our consolidated financial statements and related notes thereto for the year ended December 31, 2019, included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission ("SEC") on March 13, 2020. This discussion and other parts of this report contain forward-looking statements that involve risks and uncertainties, such as our plans, objectives, expectations, intentions and beliefs. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified below and those discussed in the section entitled "Risk Factors" included elsewhere in this report.

Forward-Looking Statements

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

Overview

We are a late-stage biopharmaceutical company focused on the development and commercialization of well-characterized drugs for serious, rare and ultra-rare diseases with high unmet medical needs. We have reported positive proof-of-concept clinical results across all our programs, now under review for regulatory approvals, in Phase 3 clinical development, or advancing into Phase 3 development. Four of our five programs have Breakthrough Therapy designation.

Our programs have several aspects in common: the disease targets represent conditions of high unmet medical need; the therapeutic approaches are supported by an understanding of disease biology and mechanism as elucidated by our academic research relationships; prior clinical experience with the product candidates guides an understanding of safety; and the development paths leverage the experience and capabilities of our experienced, commercially-focused management team.

Our lead clinical program is in Phase 3, developing lonafarnib, a first-in-class prenylation inhibitor, boosted with ritonavir, for the treatment of Hepatitis Delta Virus (HDV) infection, the most severe form of human viral hepatitis. The pivotal Phase 3 D-LIVR study (n=400) is ongoing and enrolling patients. The study spans approximately twenty-two countries and one hundred sites and has potential to generate data for two lonafarnib-based ritonavir-boosted regimens for approval. An all-oral arm of lonafarnib boosted with ritonavir and a combination arm of lonafarnib boosted with ritonavir combined with pegylated interferon-alfa-2a will each be compared to placebo. We are also developing lonafarnib monotherapy for treatment of Progeria and Progeroid Laminopathies. In March 2020, we submitted a New Drug Application (NDA) to the Food & Drug Administration (FDA) and a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA). The NDA was accepted for filing by the FDA in May 2020 with priority review, and the MAA has been validated by the EMA and is under a standard review timeline. Progeria and Progeroid Laminopathies are ultra-rare and rapidly fatal genetic conditions of accelerated aging in children.

Peginterferon lambda (lambda) is our second program treating HDV and is Phase 3 ready. We have agreement from FDA and EMA on a single pivotal phase 3 study design and endpoints. Lambda is a well-characterized, late-stage, first in class, type III interferon. We previously reported Phase 2 LIMT (lambda monotherapy) study results (n=33) that demonstrated a 36% durable virologic response (DVR), or below the limit of quantification (BLQ), at 24 weeks post-treatment. In the Phase 2 LIFT study, HDV patients were treated with a combination of our two proprietary products, lambda and lonafarnib boosted by ritonavir. The interim end-of-study results reported in November 2019 showed that >50% of patients were HDV RNA undetectable or BLQ at Week 24 and 95% of patients achieved the primary end point of >2 log decline in HDV RNA at Week 24. Adverse events were mostly mild to moderate.

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

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

We have no products approved for commercial sale and have not generated any revenue from product sales. We have never been profitable and have incurred operating losses in each year since inception, and we do not anticipate that we will achieve profitability in the near term. Our net losses were $30.6 million and $34.7 million for the six months ended June 30, 2020 and 2019, respectively. As of June 30, 2020, we had an accumulated deficit of $272.0 million. Substantially all of our operating losses resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations.

We expect to incur significant expenses and increasing operating losses for at least the next several years as we initiate and continue the clinical development of, and seek regulatory approval for, and potentially commercialize our product candidates and add personnel necessary to operate as a public company with an advanced clinical candidate pipeline of products. In addition, we will incur costs for additional personnel and upgrades to our information technology systems as we transition from an emerging growth company. We expect that our operating losses will fluctuate significantly from quarter to quarter and year to year due to timing of clinical development programs and efforts to achieve regulatory approval.

Recent Developments

Update on Impact of COVID-19 Pandemic on Clinical Development Activities and Business Operations

We have taken proactive steps to ensure the safety of patients and the integrity of our HDV Phase 3 D-LIVR trial. We anticipate that the COVID-19 pandemic will shift the completion of D-LIVR enrollment into 2021. We have adequate clinical drug product supply for the D-LIVR study and do not anticipate any interruption in availability of study drug to patients.

We do not anticipate that the FDA reviews of our NDA for lonafarnib for Progeria and Progeroid Laminopathies will be impacted by COVID-19. We also do not anticipate any impact to our planned U.S. commercial launch, including availability of commercial drug supply. The EMA review of our MAA is impacted by COVID-19. EMA's request for inspections in addition to travel restrictions due to COVID-19 will delay the review of our MAA from being completed within the framework of accelerated assessment. We now expect the EMA review to follow a standard review timeline.

We have put into place remote operations and new policies, which are in-line with local, state and federal guidelines, to maintain the safety and well-being of our employees, while working to maintain business continuity as this unprecedented global situation continues to evolve. We continue to monitor the situation closely, including its potential effect on our clinical development plans and timelines.

First COVID-19 Patients Dosed with Peginterferon Lambda (lambda) in Investigator Sponsored Studies

On April 30, 2020, we announced that the first patients were dosed in a Phase 2 study of lambda in outpatients with mild COVID-19 at the Stanford University School of Medicine. The Stanford study is one of multiple international, investigator sponsored studies evaluating lambda in COVID-19. Eiger has been involved in protocol development, regulatory interactions and is providing lambda clinical drug supply. Collectively, over 500 patients are expected to be enrolled and dosed across sites. These studies will assess lambda's ability to reduce COVID-19 replication and limit virus transmission.

Lonafarnib for Treatment of Progeria and Progeroid Laminopathies

On May 19, 2020, we announced the FDA acceptance of our NDA of Zokinvy™ (lonafarnib) for the treatment of Progeria and Progeroid Laminopathies. The FDA granted Priority Review with a Prescription Drug User Fee Act (PDUFA) target action date of November 20, 2020. The FDA is not currently planning to hold an advisory committee meeting to discuss the application.

Financial Operations Overview

Research and Development Expenses

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

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

The largest component of our operating expenses has historically been the investment in clinical trials, including contract manufacturing arrangements, clinical trial material related costs and other research and development activities. However, we do not allocate internal research and development costs, such as salaries, benefits, stock-based compensation expense and indirect costs to product candidates on a program-specific basis. The following table shows our research and development expenses for the three and six months ended June 30, 2020 and 2019 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Product candidates:				
Lonafarnib	$ 6,347	$ 9,452	$ 12,915	$ 19,967
Avexitide	495	1,198	1,201	1,365
Lambda	569	322	1,177	542
Internal research and development costs	2,343	1,964	3,942	3,930
Total research and development expense	$ 9,754	$ 12,936	$ 19,235	$ 25,804

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

The process of conducting clinical trials necessary to obtain regulatory approval is costly and time consuming. We may never succeed in timely developing and achieving regulatory approval for our product candidates. The probability of success of our product candidates may be affected by numerous factors, including clinical data, competition, intellectual property rights, manufacturing capability and commercial viability. As a result, we are unable to determine the duration and completion costs of our development projects or when and to what extent we will generate revenue from the commercialization and sale of any of our product candidates. The COVID-19 pandemic presents additional risks and uncertainties associated with developing drugs, including:

- delays in trial activities and patient enrollment or diversion of healthcare resources as a result of the evolving effects of the COVID-19 pandemic or otherwise;
- production shortages or other supply interruptions in clinical trial materials resulting from the evolving effects of the COVID-19 pandemic or otherwise;
- our ability to hire and retain key research and development personnel;

- the scope, rate of progress, results and expense of our ongoing, as well as any additional, clinical trials and other research and development activities; and
- the timing and receipt of any regulatory approvals.

General and Administrative Expenses

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

Interest Expense

Interest expense consists of interest and amortization of the debt discount related to the Oxford Loan.

Interest Income

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

Critical Accounting Policies and Estimates

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

Accrued Research and Development Costs

We record accrued expenses for estimated costs of research and development activities conducted by external service providers, which include the conduct of clinical research and contract formulation and manufacturing activities. We record the estimated costs of development activities based upon the estimated amount of services provided but not yet invoiced and include these costs in accrued liabilities in the unaudited condensed consolidated balance sheet and within research and development expense in the unaudited condensed consolidated statements of operations. We record accrued expenses for these costs based on the estimated amount of work completed and in accordance with agreements established with these external service providers.

We estimate the amount of work completed through discussions with internal personnel and external service providers as to the progress or stage of completion of the services and the agreed-upon fee to be paid for such services. We make judgments and estimates in determining the accrued balance in each reporting period. As actual costs become known, we adjust our accrued estimates.

Stock-Based Compensation

We recognize compensation costs related to stock options and restricted stock units based on the estimated fair value of the awards on the date of grant. We estimate the grant date fair value of stock options, and the resulting stock-based compensation expense, using the Black-Scholes option-pricing model. The grant date fair value of the stock-based awards is generally recognized on a straight-line basis over the requisite service period, which is generally the vesting period of the respective awards. We record forfeitures when they occur.

The Black-Scholes option-pricing model includes the following assumptions:

Expected Term. Our expected term represents the period that our stock-based awards are expected to be outstanding and is determined using the simplified method (based on the mid-point between the vesting date and the end of the contractual term).

Expected Volatility. Since we have only been publicly traded for a short period and do not have adequate trading history for our common stock, the expected volatility was estimated based on the average volatility for comparable publicly traded biopharmaceutical companies over a period equal to the expected term of the stock option grants. The comparable companies were chosen based on their similar size, stage in the life cycle, or area of specialty. Beginning in the third quarter of 2019, as we had been publicly traded for four and a half years, we began to layer in our historical volatility in the calculation of expected volatility.

Risk-Free Interest Rate. The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of option.

Expected Dividend. We have never paid dividends on our common stock and have no plans to pay dividends on our common stock. Therefore, we used an expected dividend yield of zero.

We use the contractual term to determine the non-employee awards' fair value at the grant date. The contractual term of options granted under the Plan is 10 years. Our Board of Directors determined the fair value of each share of underlying common stock based on the closing price of our common stock as reported by the Nasdaq Global Market on the date of grant.

We estimate the fair value of restricted stock units based on the closing market price of our common stock on the date of grant and the resulting stock-based compensation expense is recognized on a straight-line basis over the requisite service period, which is generally the vesting period of the awards.

Results of Operations

Comparison of the Three Months Ended June 30, 2020 and 2019

	Three Months Ended June 30,		$	%
	2020	2019	Change	Change
Operating expenses:				
Research and development	$ 9,754	$ 12,936	$ (3,182)	(25%)
General and administrative	4,873	4,225	648	15%
Total operating expenses	14,627	17,161	(2,534)	(15%)
Loss from operations	(14,627)	(17,161)	2,534	
Interest expense	(891)	(869)	(22)	3%
Interest income	186	502	(316)	(63%)
Other income, net	6	1	5	*
Net loss	$ (15,326)	$ (17,527)	$ 2,201	(13%)

*Percentage not meaningful.

Research and development expenses

Research and development expenses decreased by $3.1 million to $9.8 million for the three months ended June 30, 2020, from $12.9 million for the same period in 2019. The decrease was primarily due to a $2.2 million decrease in contract manufacturing and clinical expenditures due to a decrease in program activities and a $1.2 million decrease in regulatory expenses. The decrease was partially offset by a $0.2 million increase in compensation and personnel related expenses.

General and administrative expenses

General and administrative expenses increased by $0.7 million to $4.9 million for the three months ended June 30, 2020, from $4.2 million for the same period in 2019. The increase was primarily due to a $0.5 million increase in outside legal, consulting, advisory and accounting services and a $0.2 million increase in compensation and personnel related expenses, including stock-based compensation expense due to an increase in headcount.

Interest expense

Interest expense increased by $22,000 to $0.9 million for the three months ended June 30, 2020 from $0.9 million for the same period in 2019.

Interest income

Interest income decreased by $0.3 million to $0.2 million for the three months ended June 30, 2020 from $0.5 million for the same period in 2019. The decrease was primarily due to a decrease in interest rate on money market funds.

Comparison of the Six Months Ended June 30, 2020 and 2019

	Six Months Ended June 30,		$	%
	2020	2019	Change	Change
Operating expenses:				
Research and development	$ 19,235	$ 25,804	$ (6,569)	(25%)
General and administrative	10,114	8,282	1,832	22%
Total operating expenses	29,349	34,086	(4,737)	(14%)
Loss from operations	(29,349)	(34,086)	4,737	
Interest expense	(1,775)	(1,634)	(141)	9%
Interest income	553	1,013	(460)	(45%)
Other income (expense), net	6	(9)	15	*
Net loss	$ (30,565)	$ (34,716)	$ 4,151	(12%)

*Percentage not meaningful.

Research and development expenses

Research and development expenses decreased by $6.6 million to $19.2 million for the six months ended June 30, 2020, from $25.8 million for the same period in 2019. The decrease was primarily due to a $5.5 million decrease in contract manufacturing and clinical expenditures due to a decrease in program activities and a $1.4 million decrease in regulatory expenses. The decrease was partially offset by a $0.2 million increase in compensation and personnel related expenses.

General and administrative expenses

General and administrative expenses increased by $1.8 million to $10.1 million for the six months ended June 30, 2020, from $8.3 million for the same period in 2019. The increase was primarily due to a $1.1 million increase in compensation and personnel related expenses, including stock-based compensation expense due to an increase in headcount, and a $0.6 million increase in outside legal, consulting, advisory and accounting services.

Interest expense

Interest expense increased by $0.2 million to $1.8 million for the six months ended June 30, 2020 from $1.6 million for the same period in 2019. Interest expense primarily increased due to the additional funds borrowed under the Oxford Loan in March 2019.

Interest income

Interest income decreased by $0.4 million to $0.6 million for the six months ended June 30, 2020 from $1.0 million for the same period in 2019. The decrease was primarily due to a decrease in interest rate on money market funds.

Liquidity and Capital Resources

Sources of Liquidity

As of June 30, 2020, we had $90.8 million of cash, cash equivalents and investments, comprised of $62.8 million of cash and cash equivalents and $28.0 million of debt securities available-for-sale, and an accumulated deficit of $272.0 million.

In December 2019, we filed a shelf registration statement on Form S-3 (File No. 333-235655) with the Securities and Exchange Commission, which permits the offering, issuance and sale by us of up to a maximum aggregate offering price of $150.0 million of

our common stock, preferred stock, debt securities and warrants. Up to a maximum of $50.0 million of the maximum aggregate offering price of $150.0 million may be issued and sold pursuant to an at-the-market (ATM) financing facility (2019 ATM Facility) under a sales agreement with Jefferies LLC (Jefferies).

In the second quarter of 2020, we completed ATM offerings for a total of 2,612,476 shares of our common stock, resulting in net proceeds to us of $28.6 million, after deducting commissions.

As of July 31, 2020, we completed the sale of all common stock subject to the 2019 ATM Facility, resulting in the total offering of 4,646,554 shares of our common stock and $48.6 million in net proceeds to us, after deducting commissions. These amounts include ATM offerings during the six months ended June 30, 2020 of 2,645,227 and $29.0 million in net proceeds, after deducting commissions.

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. Additionally, our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic.

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 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. As a result of economic conditions, general global economic uncertainty, political change and other factors, including the ongoing COVID-19 pandemic, we do not know whether additional capital will be available when needed, or that, if available, we will be able to obtain additional capital on reasonable terms. If we are unable to raise additional capital due to the volatile global financial markets, general economic uncertainty or other factors, we may need to curtail planned development or commercialization activities. The sale of additional equity or convertible debt could result in additional dilution to our stockholders. The incurrence of indebtedness would result in debt service obligations and could result in operating and financing covenants that would restrict our operations. We can provide no assurance that financing will be available in the amounts we need or on terms acceptable to us, if at all. If we are not able to secure adequate additional funding we may be forced to delay, make reductions in spending, extend payment terms with suppliers, liquidate assets where possible, and/or suspend or curtail planned programs. Any of these actions could materially harm our business.

Cash Flows

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

	Six Months Ended June 30,	
	2020	2019
Net cash used in operating activities	$ (33,562)	$ (34,052)
Net cash provided by (used in) investing activities	27,609	(26,216)
Net cash provided by financing activities	29,393	57,427
Net increase (decrease) in cash and cash equivalents	$ 23,440	$ (2,841)

Cash flows from operating activities

Cash used in operating activities for the six months ended June 30, 2020 was $33.6 million, which primarily consisted of a net loss of $30.6 million, which was partially offset by stock-based compensation expense of $3.1 million, non-cash interest expense of $0.4 million and amortization of operating lease right-of-use assets of $0.2 million. Additionally, cash used in operating activities reflected changes in net operating assets due to a decrease of $3.9 million in accounts payable and accrued liabilities due to timing of payments, an increase of $1.4 million in prepaid expenses and other current assets primarily due to the timing of payments and an increase of $1.3 million in other assets primarily related to long term deposits with clinical research organizations.

Cash used in operating activities for the six months ended June 30, 2019 was $34.1 million, which primarily consisted of a net loss of $34.7 million and amortization of the debt securities discount of $0.2 million, partially offset by stock-based compensation expense of $2.7 million, non-cash interest expense of $0.4 million and amortization of operating lease right-of-use assets of $0.2 million. Additionally, cash used in operating activities reflected changes in net operating assets of $2.5 million mainly due to an increase of $2.2 million in other assets primarily related to long term deposits with IQVIA, an increase of $1.5 million in prepaid expenses and other current assets primarily due to the timing of payments, partially offset by an increase of $1.4 million in accounts payable and accrued liabilities due to the timing of payments.

Cash flows from investing activities

Cash provided by investing activities was $27.6 million for the six months ended June 30, 2020, which primarily consisted of $60.6 million of proceeds from maturities of debt securities, which was partially offset by $32.9 million of purchases of debt securities.

Cash used in investing activities was $26.2 million for the six months ended June 30, 2019 consisted of $60.2 million purchases of debt securities, which was partially offset by $34.1 million proceeds from maturities of debt securities.

Cash flows from financing activities

Cash provided by financing activities for the six months ended June 30, 2020 consisted of $28.8 million of net proceeds from the issuance of common stock upon offering at-the-market and $0.6 million of proceeds from the issuance of common stock upon stock option exercises and ESPP purchase.

Cash provided by financing activities for the six months ended June 30, 2019 consisted of $53.2 million of net proceeds from the issuance of common stock upon public offering, $6.6 million of net proceeds from additional borrowings in connection with the Amended Oxford Loan and $0.2 million of proceeds from the issuance of common stock upon stock option exercises and ESPP purchase, partially offset by $2.6 million in payments of principal and fees associated with the Oxford Loan.

Contractual Obligations and Other Commitments

Our contractual obligations as of June 30, 2020 have not materially changed from what we presented in our Annual Report on Form 10-K for the year ended December 31, 2019 filed with the SEC on March 13, 2020.

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

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

ITEM 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We are responsible for maintaining disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Disclosure controls and procedures are controls and other procedures designed to ensure that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and our principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Based on our management's evaluation (with the participation of our principal executive officer and our principal financial officer) of our disclosure controls and procedures as required by Rule 13a-15 under the Exchange Act, our principal executive officer and our principal financial officer have concluded that our disclosure controls and procedures were effective to achieve their stated purpose as of June 30, 2020, the end of the period covered by this report.

Management's Report on Internal Control over Financial Reporting.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as such term is defined in Exchange Act Rule 13a-15(f). Internal control over financial reporting is a process designed under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, to provide reasonable assurance, not absolute assurance, regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America.

There are inherent limitations to the effectiveness of any system of internal control over financial reporting. These limitations include the possibility of human error, the circumvention or overriding of the system and reasonable resource constraints. Because of its inherent limitations, our internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework *Internal Control - Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

As of June 30, 2020, our management assessed the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework (2013 Framework). Based on this assessment, our management concluded that, as of June 30, 2020, our internal control over financial reporting was effective based on those criteria.

Changes in Internal Control over Financial Reporting

Except as otherwise described above under Management's Report on Internal Control over Financial Reporting, there were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the fiscal quarter ended June 30, 2020, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

ITEM 1A. RISK FACTORS

You should carefully consider the following risk factors, as well as the other information in this Quarterly Report on Form 10Q, 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 10Q and those we may make from time to time. You should consider all of the risk factors described when evaluating our business.

Risks Related to our Financial Condition, Integration and Capital Requirements

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

We are a clinical development-stage biopharmaceutical company with a limited operating history. We have incurred net losses in each year since our inception. For the six months ended June 30, 2020 and 2019, we reported a net loss of $30.6 million and $34.7 million, respectively. As of June 30, 2020, we had an accumulated deficit of $272.0 million. Our prior losses, combined with expected future losses, have had and may continue to have an adverse effect on our stockholders' equity and working capital.

We believe that our currently available resources will be sufficient to fund our planned operations for at least the next 12 months following the issuance date of these unaudited condensed consolidated financial statements. We will continue to require substantial additional capital to continue our clinical development, manufacturing and regulatory approval efforts and potential commercialization activities. Accordingly, we will need to raise substantial additional capital to continue to fund our operations. The amounts and timing of our future funding requirements will depend on many factors, including our ability to achieve regulatory approval and the pace and results of our clinical development efforts. Failure to raise capital as and when needed, on favorable terms or at all, would have a negative impact on our financial condition and our ability to develop our product candidates.

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

If we obtain regulatory approval to market a product candidate, our future revenue will depend upon the size of any markets in which our product candidates may receive approval, and our ability to achieve sufficient market acceptance, pricing, reimbursement from third-party payors, and adequate market share for our product candidates in those markets. Even if we obtain adequate market share for our product candidates, because the potential markets in which our product candidates may ultimately receive regulatory approval could be very small, we may never become profitable despite obtaining such market share and acceptance of our products. We have also agreed with The Progeria Research Foundation to make lonafarnib available to Hutchinson-Gilford Progeria Syndrome (HGPS or Progeria) and Progeroid Laminopathies patients under an Expanded Access Program that may not result in payment to us.

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

- continue the clinical development of our product 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 and develop potential commercial opportunities, such as lonafarnib boosted with ritonavir, lonafarnib for the treatment of Progeria and Progeroid Laminopathies, lambda for HDV, and avexitide for PBH and CHI;
- seek regulatory and marketing approvals and reimbursement for our product candidates;
- establish a sales, marketing, and distribution infrastructure to commercialize any products for which we may obtain marketing approval and market ourselves;
- seek to identify, assess, acquire, and/or develop other product candidates;
- make milestone, royalty or other payments under third-party license agreements;
- develop and educate HDV markets;
- seek to maintain, protect, and expand our intellectual property portfolio;
- seek to attract and retain skilled personnel;
- create additional infrastructure to support our operations as a public company and our product development and planned future commercialization efforts; and
- experience any delays or encounter issues with the development and potential for regulatory approval of our clinical candidates such as safety issues, clinical trial accrual delays, longer follow-up for planned studies, additional major studies, or supportive studies necessary to support marketing approval.

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

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

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

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

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

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

To the extent that we raise additional capital through the sale of equity, debt or other securities convertible into equity, your ownership interest will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect your rights as a common stockholder such as the Loan and Security Agreement we entered into with Oxford Finance LLC (Oxford Finance) in December 2016 (the Oxford Loan). The Oxford Loan was a $25.0 million debt financing arrangement with Oxford Finance wherein we borrowed the first tranche of $15.0 million upon closing of the debt financing in December 2016. In May 2018, we entered into an amendment to the Oxford Loan and borrowed $5.0 million. In August 2018, we drew the final $5.0 million upon achievement of certain clinical milestones. In March 2019, we entered into the third amendment to the Oxford Loan to refinance our outstanding principal balance of $23.3 million. Upon refinancing, the Oxford Loan was increased to $35.0 million in aggregate commitments, of which $30.0 million in principal is outstanding. The Oxford Loan is secured by perfected first priority liens on our assets, excluding intellectual property but including a commitment by us to not allow any liens to be placed upon such intellectual property. The Oxford Loan includes customary events of default, including failure to pay amounts due, breaches of covenants and warranties, material adverse effect events, certain cross defaults and judgments, and insolvency.

If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates or future revenue streams or grant licenses on terms that are not favorable to us. Our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic. We cannot assure you that we will be able to obtain additional funding if and when necessary to fund our entire portfolio of product candidates to meet our projected plans. If we are unable to obtain funding on a timely basis, we may be required to delay or discontinue one or more of our development programs or the commercialization of any product candidates or be unable to expand our operations or otherwise capitalize on potential business opportunities, which could materially affect our business, financial condition, and results of operations.

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

The Oxford Loan provides for up to $35.0 million in term loans due on March 1, 2024, of which $30.0 million in principal is outstanding. All of our current and future assets, except for intellectual property, secure our borrowings under the Oxford Loan. The Oxford Loan requires that we comply with certain covenants applicable to us, including among other things, covenants restricting dispositions, changes in business, management, ownership or business locations, mergers or acquisitions, indebtedness, encumbrances, distributions, investments, transactions with affiliates and subordinated debt, any of which could restrict our business and operations, particularly our ability to respond to changes in our business or to take specified actions to take advantage of certain business opportunities that may be presented to us. Our failure to comply with any of the covenants could result in a default under the Oxford Loan, which could permit the lenders to declare all or part of any outstanding borrowings to be immediately due and payable. If we are unable to repay those amounts, the lenders under the Oxford Loan could proceed against the collateral granted to them to secure that debt, and our inability to use or dispose of those assets would seriously harm our business. In addition, should we be unable to comply with these covenants or if we default on any portion of our outstanding borrowings, the lenders can also impose a 5.0% penalty, restrict access to additional borrowings under the loan and security agreement, and accelerate the maturity of the debt. Any default under the Oxford Loan would materially affect our liquidity and ability to fund our operations and complete our planned clinical trials and regulatory filings would be substantially impaired.

If the London Inter-Bank Offered Rate, or LIBOR, is discontinued, interest payments under the Oxford Loan may be calculated using another reference rate.

In July 2017, the Chief Executive of the United Kingdom Financial Conduct Authority (FCA), which regulates LIBOR, announced that the FCA intends to phase out the use of LIBOR by the end of 2021. In addition, the U.S. Federal Reserve, in conjunction with the Alternative Reference Rates Committee, a steering committee comprised of large U.S. financial institutions, is considering replacing U.S. dollar LIBOR with the Secured Overnight Financing Rate, or SOFR, a new index calculated by short-term repurchase agreements, backed by Treasury securities. Although there have been certain issuances utilizing SOFR, it is unknown whether this or any other alternative reference rate will attain market acceptance as a replacement for LIBOR. LIBOR is used as a benchmark rate throughout the Oxford Loan, and our credit agreement does not provide fallback language for all circumstances in which LIBOR ceases to be published. There remains uncertainty regarding the future utilization of LIBOR and the nature of any replacement rate, and any potential effects of the transition away from LIBOR on us are not known. The transition process may involve, among other things, increased volatility and illiquidity in markets for instruments that currently rely on LIBOR and may result in increased borrowing costs, the effectiveness of related transactions such as hedges, uncertainty under applicable documentation, including the Oxford Loan, or difficult and costly processes to amend such documentation. As a result, our ability to refinance our credit agreement or other indebtedness or to hedge our exposure to floating rate instruments may be impaired, which would adversely affect the operations of our business.

Risks Related to the Development of our Product Candidates

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

To date, we have invested substantially all of our efforts and financial resources to identify, acquire, and develop our portfolio of product candidates. Our future success is dependent on our ability to successfully further develop, obtain regulatory approval for, and commercialize one or more of these product candidates. In May 2020, the FDA accepted our NDA for lonafarnib for treatment of Progeria and Progeroid Laminopathies with Priority Review and a PDUFA target action date of November 20, 2020. Our MAA is currently under standard review with the EMA as well. We currently generate no revenue from sales of any drugs, and we may never be able to develop or commercialize a product candidate. In addition, to the extent that we receive regulatory approval for lonafarnib in Progeria and Progeroid Laminopathies, we expect our commitment to provide access for patients with Progeria and Progeroid Laminopathies for no or minimal cost to those patients to result in a loss to us.

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

We provide our geographically diverse clinical sites with good clinical practice protocols. We review and monitor the execution of our protocols at our various sites in an effort to understand those protocols are being followed. There can be no assurance that the data we develop for our product candidates in our planned indications will be sufficient or complete enough to obtain regulatory approval.

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

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

The clinical development, manufacturing, labeling, packaging, storage, recordkeeping, advertising, promotion, export, import, marketing and distribution and other possible activities relating to lonafarnib, lambda, avexitide and any other product candidate that we may develop in the future are subject to extensive regulation in the United States. Prior to the recent filing of our NDA for lonafarnib for the treatment of Progeria and Progeroid Laminopathies, we had not submitted an application for approval or obtained FDA approval for any product. This lack of experience may impede our ability to obtain FDA approval in a timely manner. We may receive requests for additional information during FDA's review of the NDA. The FDA may extend or be unable to meet its PDUFA goal date for the NDA, and may issue a complete response letter, rather than an approval.

Approval of an NDA is not guaranteed, and the approval process is an expensive and uncertain process that may take several years. The FDA and foreign regulatory entities also have substantial discretion in the approval process. The number and types of preclinical studies and clinical trials that will be required for approval varies depending on the product candidate, the disease or the condition that the product candidate is designed to target and the regulations applicable to any particular product candidate. Data are subject to varying interpretation and the FDA may not agree that our clinical data support that any of our product candidates are safe and effective for the proposed therapeutic use. Despite the time and expense associated with preclinical studies and clinical trials, failure can occur at any stage, and we could encounter problems that require us to repeat or perform additional preclinical studies or clinical trials or generate additional chemistry, manufacturing and controls data, including drug product stability data. HGPS and PL patients have accelerated or extensive cardiovascular disease. In previous studies, ECG abnormalities were reported, and were also observed in our lonafarnib program. We do not believe this will impact the approval, but we expect it to be reflected in the product labeling for HGPS and PL. We do not expect that this will impact the conduct of the D-LIVR HDV study. The FDA and similar foreign authorities could delay, limit or deny approval of a product candidate, and may ultimately approve the product for narrower indications or with unfavorable labeling that would impede our commercialization of the drug.

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

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

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

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

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

- the FDA or comparable foreign regulatory authorities may disagree with the design, size or implementation of our clinical studies;
- the population studied in the clinical program may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from our development efforts;
- the data collected from clinical studies of our product candidates may not be sufficient or complete or meet the regulatory requirements to support the submission of a new drug application (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 five of our development programs 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.

Although the FDA has granted Rare Pediatric Disease designation to lonafarnib for the treatment of Progeria and Progeroid Laminopathies and to avexitide for the treatment of congenital hyperinsulinism, NDA approvals for these programs may not meet the eligibility criteria for a priority review voucher.

Our lonafarnib and avexitide compounds have received Rare Pediatric Disease (RPD) designation from the FDA for the treatment of Progeria and Progeroid Laminopathies and Congenital Hyperinsulinism (CHI), respectively. The FDA defines a "rare pediatric disease" as a disease that affects fewer than 200,000 individuals in the United States primarily under the age of 18 years. Specifically, under this program, a sponsor who receives an approval for a drug or biologic for a "rare pediatric disease" may qualify for a voucher that can be redeemed to receive a priority review of a subsequent marketing application for a different product. The sponsor of a rare pediatric disease drug product receiving a priority review voucher may transfer (including by sale) the voucher to another sponsor. The voucher may be further transferred any number of times before the voucher is used, as long as the sponsor making the transfer has not yet submitted the application. The FDA may also revoke any priority review voucher if the rare pediatric disease drug for which the voucher was awarded is not marketed in the U.S. within one year following the date of approval. In addition, the priority review voucher is only awarded to an NCE, thus if a compound is approved first for an indication that is not a rare pediatric disease the compound may not be eligible to receive the voucher.

Congress has only authorized the Rare Pediatric Disease Priority Review Voucher program until September 30, 2020. However, if a drug candidate receives Rare Pediatric Disease designation before October 1, 2020, it is eligible to receive a voucher if it is approved before October 1, 2022. Lonafarnib or avexitide may not be approved by that date, or at all, and, therefore, we may not be in a position to obtain a priority review voucher prior to expiration of the program, unless Congress further reauthorizes the program.

There is no assurance we will receive a Rare Pediatric Disease Priority Review Voucher. Also, although Priority Review Vouchers may be sold or transferred to third parties, there is no guarantee that we will be able to realize any value if we were to sell a Priority Review Voucher.

Although we have received Breakthrough Therapy designation for four of our development programs, this may not lead to a faster development, regulatory review or approval process, and it does not increase the likelihood that any of our product candidates will receive marketing approval in the United States.

We have received Breakthrough Therapy designation for lonafarnib and lambda for the treatment of HDV, lonafarnib for the treatment of Progeria and Progeroid Laminopathies and for avexitide for the treatment of post-bariatric hypoglycemia. A breakthrough therapy is defined as a therapy that is intended, alone or in combination with one or more other therapies, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the therapy may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For therapies that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Therapies designated as breakthrough therapies by the FDA may also be eligible for priority review and accelerated approval. The Breakthrough Therapy designations we have obtained may not result in faster development processes, reviews or approvals compared to therapies considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, the FDA may later decide that any of our development programs no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

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

Clinical testing is expensive and generally takes many years to complete, and the outcome is inherently uncertain. Failure can occur at any time during the clinical study process. The results of preclinical studies and early clinical studies of our product candidates may not be predictive of the results of larger, later-stage controlled clinical studies. Product candidates that have shown promising results in early-stage clinical studies may still suffer significant setbacks in subsequent clinical studies. Our clinical studies to date have been conducted on a small number of patients in limited numbers of clinical sites and in academic settings or for other indications. We will have to conduct larger, well-controlled studies in our proposed indications to verify the results obtained to date and to support any regulatory submissions for further clinical development. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical studies due to lack of efficacy or adverse safety profiles despite promising results in earlier, smaller clinical studies. Moreover, clinical data are often susceptible to varying interpretations and analyses. We do not know whether any Phase 2, Phase 3, or other clinical studies we have conducted or may conduct will demonstrate consistent or adequate efficacy and safety with respect to the proposed indication for use sufficient to obtain regulatory approval to receive regulatory approval or market our drug candidates. For example, in 2018 we announced negative results from two of our Phase 2 clinical trials of ubenimex in two different indications and as a result we have terminated further development of ubenimex.

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

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

The eligibility criteria of our planned clinical studies may further limit the available eligible study participants as we expect to require that patients have specific characteristics that we can measure or meet the criteria to assure their conditions are appropriate for inclusion in our clinical studies. We may not be able to identify, recruit, and enroll a sufficient number of patients to complete our clinical studies in a timely manner because of the perceived risks and benefits of the product candidate under study, the availability and efficacy of competing therapies and clinical studies, and the willingness of physicians to participate in our planned clinical studies. Additionally, we may experience delays in patient enrollment for our clinical trials as a result of the evolving COVID-19 global pandemic and competition for patients at our European clinical trial sites due to the recent conditional approval of Hepcludex in Europe. For example, certain clinical study sites that were scheduled to open have been delayed in activating and other sites have suspended randomization of subjects and if this continues longer than anticipated, the D-LIVR trial may be delayed further than anticipated. 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 (CROs) and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical study sites;
- delays in obtaining required Institutional Review Board (IRB) approval at each clinical study site;
- failure to permit the conduct of a study by regulatory authorities, after review of an investigational new drug (IND) or equivalent foreign application or amendment;

- delays in recruiting qualified patients, or patients dropping out of, in our clinical studies, including as a result of the evolving COVID-19 global pandemic;
- 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;
- occurrence of adverse events associated with our product candidates;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- the cost of clinical studies of our product candidates;
- negative or inconclusive results from our clinical trials which may result in our deciding, or regulators requiring us, to conduct additional clinical studies or abandon development programs in other ongoing or planned indications for a product candidate; and
- delays in reaching agreement on acceptable terms with third-party manufacturers and the time for manufacture of sufficient quantities of our product candidates for use in clinical studies.

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

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

Our lonafarnib product candidate has been studied in thousands of oncology patients and the most common non-hematologic adverse events of any grade were gastrointestinal system disorders (nausea, anorexia, diarrhea and vomiting), weight loss, fatigue and rash. Our lonafarnib product candidate for HGPS and PL has been reported to cause ECG abnormalities, but these ECG abnormalities have not resulted in a risk of mortality for these patients. There is no guarantee that additional or more severe side effects or other properties will not be identified through ongoing clinical studies by other uses of lonafarnib for other indications or our own clinical trials. Our lambda product candidate is well-characterized and has been studied in thousands of HBV and HCV patients and the most common adverse events seen are moderate headache, pyrexia, fatigue, and myalgia. ALT flares that were seen result from vigorous antiviral immunological response to treatment, not due to direct hepatotoxicity. There is no guarantee that additional or more severe side effects will not be identified through ongoing clinical studies for other uses of lambda. Undesirable side effects, other properties, and negative results for other indications may negatively impact the development and potential for approval of our product candidates for our proposed indications. For example, the ECG abnormalities seen with lonafarnib in HGPS and PL patients has the potential to impact the labeling for lonafarnib boosted with ritonavir for HDV. Our avexitide product candidate has been studied in 54 PBH patients and 39 CHI patients and the most common adverse events are injection site bruising, nausea, and headache. There is no guarantee that additional or more severe side effects will not be identified through ongoing clinical studies for other uses of avexitide in clinical trials.

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

- regulatory authorities may withdraw approvals of such products;
- regulatory authorities may require additional warnings on the label;
- we may be required to create a Risk Evaluation and Mitigation Strategy (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 (cGMP) regulations and corresponding foreign regulatory manufacturing requirements. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any NDA or MAA.

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product candidate may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. We will be required to report certain adverse reactions and production problems, if any, to the FDA and comparable foreign regulatory authorities.

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

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

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

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

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

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

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

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

In addition, we do not currently have, nor do we plan to establish, the capability to manufacture product candidates for use in the conduct of our clinical studies or in support of our commercialization of potential products, and we lack the resources and the capability to manufacture any of our product candidates on a clinical or commercial scale without the use of third-party manufacturers. We plan to rely on third-party manufacturers and their responsibilities will include purchasing from third-party suppliers the materials necessary to produce our product candidates for our clinical studies and regulatory approval. There are expected to be a limited number of suppliers for the active ingredients and other materials that we expect to use to manufacture our product candidates, and we may not be able to identify alternative suppliers to prevent a possible disruption of the manufacture of our product candidates for our clinical studies, and, if approved, ultimately for commercial sale. Although we generally do not expect to begin a clinical study unless we believe we have a sufficient supply of a product candidate to complete the study, any significant delay or discontinuity in the supply of a product candidate, or the active ingredient or other material components in the manufacture of the product candidate, could delay completion of our clinical studies and potential timing for regulatory approval of our product candidates, which would harm our business and results of operations.

With respect to our lonafarnib program, we procured an inventory of product from Merck to supply our initial clinical study needs. In 2016, we transferred the manufacturing of drug substance and drug product to our third-party contractors. The material used for lonafarnib HDV pivotal trials and Progeria clinical studies are sourced from Eiger-controlled CMOs. These same vendors are currently under development for commercial qualification. Materials used for our avexitide clinical trials are also sourced from CMOs. Our vendors have successfully made GMP batches for our clinical studies. If these CMOs are not able to provide us with sufficient quantities of drug substance and drug product for our clinical trials or in support of our commercialization of potential products on a timely basis, or at all, whether due to production shortages or other supply interruptions resulting from the ongoing COVID-19 pandemic or otherwise, our clinical trials or regulatory approval may be delayed, or could impair our ability to generate revenue from the sale of such product candidate.

We rely and expect to continue to rely on third parties to manufacture our clinical product supplies, and if those third parties fail to obtain approval of government regulators, fail to provide us with sufficient quantities of 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 will be subject to pre-approval inspection by the FDA that will be conducted after we submit our marketing applications to the FDA or comparable foreign regulatory authorities. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements, known as cGMPs, for manufacture of our product candidates. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, our NDA and MAA for lonafarnib and future applications may not be approved by regulatory authorities, which would significantly delay our commercialization plans and increase our costs. We have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

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

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

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

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

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

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

We focus our product development principally on treatments for rare and ultra-rare diseases. Given the small number of patients who have the diseases that we are targeting, our eligible patient population and pricing estimates may differ significantly from the actual market addressable by our product candidate. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including the scientific literature, patient foundations, or market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. The number of patients may turn out to be lower than expected. For example, for lonafarnib and lambda, HDV is associated with hepatitis B virus infection, which is a pre-requisite for the replication of HDV. Although we believe that the data are supportive of antiviral activity against HDV, there can be no assurance that our clinical trials will successfully address this condition. Likewise, the potentially addressable patient population for each of our product candidates may be limited or may not be amenable to treatment with our product candidates, and new patients may become increasingly difficult to identify or gain access to, which would adversely affect our results of operations and our business. Moreover, if lonafarnib receives regulatory approval for use in Progeria and Progeroid Laminopathies, we expect that the sales of lonafarnib to patients with Progeria and Progeroid Laminopathies will have limited profits.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

In the United States, Orphan Drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. In addition, if a product receives the first FDA approval for the indication for which it has Orphan Drug designation, the product is entitled to Orphan Drug exclusivity, which means the FDA may not approve any other application to market the same 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 designations for each of our development programs in the United States and Europe, we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing pharmaceutical products. Further, even if we obtain Orphan Drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition. Even after an Orphan Drug is approved, the FDA or EMA can subsequently approve the same drug with the same active moiety for the same condition if the FDA or EMA concludes that the later drug is safer, more effective, or makes a major contribution to patient care. Orphan Drug designation neither shortens the development time or regulatory review time of a product candidate nor gives the product candidate any advantage in the regulatory review or approval process.

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

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

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

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

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

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

Patents have a limited term. In the United States, the statutory expiration of a patent is generally 20 years after it is filed. Although various extensions may be available, the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from generic medications. In addition, upon issuance in the United States any patent term can be adjusted based on certain delays caused by the applicant(s) or the United States Patent and Trademark Office (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 (the Leahy-Smith Act) enacted on September 16, 2011, the United States has moved to a first to file system. The Leahy-Smith Act also includes a number of significant changes that affect the way patent applications will be prosecuted and may also affect patent litigation. The effects of these changes are currently unclear as the USPTO must still implement various regulations, the courts have yet to address any of these provisions and the applicability of the act and new regulations on specific patents discussed herein have not been determined and would need to be reviewed. In general, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

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

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

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

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

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

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

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

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

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

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

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

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

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

Our product candidates may be subject to generic competition.

Under the Hatch-Waxman Act, a pharmaceutical manufacturer may file an abbreviated new drug application (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 products in the Orange Book after approval by FDA, ANDAs and 505(b)(2) NDAs with respect to those products would be required to include a certification as to each listed patent indicating whether the ANDA applicant does or does not intend to challenge the patent. We cannot predict whether any patents issuing from our pending patent applications will be eligible for listing in the Orange Book, how any generic competitor would address such patents, whether we would sue on any such patents, or the outcome of any such suit.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to our Business Operations

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

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

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

As of June 30, 2020, we had 28 full-time employees. As our development and commercialization plans and strategies develop, we expect to need additional managerial, operational, manufacturing, sales, marketing, financial, legal, and other resources. Our management may need to divert a disproportionate amount of their attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, operational mistakes, loss of business opportunities, loss of employees, and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth.

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

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

In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our partners. In addition, we may receive unintended health information in error from third parties (including research institutions from which we may obtain clinical trial data) that are subject to privacy and security requirements under the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH). Depending on the facts and circumstances, we could be subject to criminal penalties, including if we knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

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

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

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

In addition, in June 2018, California enacted the California Consumer Privacy Act (CCPA), which went into effect on January 1, 2020. The CCPA gives California residents expanded rights to access and require deletion of their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that may increase data breach litigation. Although the CCPA includes exemptions for certain clinical trials data, and HIPAA protected health information, the law may increase our compliance costs and potential liability with respect to other personal information we collect about California residents.

The CCPA has prompted a number of proposals for new federal and state privacy legislation that, if passed, could increase our potential liability, increase our compliance costs and adversely affect our business.

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

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

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

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

Specifically, data security breaches, whether inadvertent or intentional, by employees or others, may expose proprietary information, trade secrets, personal information, clinical trial data or other sensitive data to unauthorized persons, impact the integrity, availability or confidentiality of our IT systems or data (including, but not limited to, data loss), or disrupt or interrupt our IT systems or operations. Our partners and vendors face similar risks and any security breach of their systems could adversely affect our security posture. Malicious attacks by third parties are of ever-increasing sophistication and can be made by groups and individuals with a wide range of motives (including, but not limited to, industrial espionage) and expertise, including organized criminal groups, "hacktivists," nation states and others. Foreign, federal, and state laws or regulations allows for the imposition of civil liability, fines and/or corrective action on entities that improperly use or disclose the personal information of individuals, including through a data security breach. Accordingly, data security breaches experienced by us, our collaborators or contractors could lead to significant fines, required corrective action, loss of trade secrets or other intellectual property, or could lead to the public exposure of personally identifiable information (including sensitive personal information) of our employees, collaborators, clinical trial patients, and others. A data security breach or privacy violation that leads to disclosure or modification of or prevents access to personal information, including personally identifiable information, patient information or protected health information, could result in civil liability, harm our reputation, compel us to comply with federal and/or state breach notification laws, subject us to mandatory corrective action, require us to verify the correctness of database contents and otherwise subject us to liability under laws and regulations that protect personal data, resulting in increased costs or loss of revenue. If we are unable to prevent data security breaches or privacy violations, respond appropriately or implement satisfactory remedial measures, our operations could be disrupted, and we may suffer civil liability to our customers or individuals, loss of reputation, financial loss and other regulatory penalties because of lost or misappropriated information, including sensitive patient data. In addition, these breaches and other inappropriate access events can be difficult to detect, and any delay in identifying and responding to them may lead to increased harm of the type described above. Moreover, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information, trade secrets or other intellectual property. While we have implemented security measures designed to protect our data security and information technology systems, no set of security measures is infallible, and these measures may not prevent such events.

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

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

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

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

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

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

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (ACA) was passed, which substantially changed the way health care is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. There remains judicial and Congressional challenges to numerous provisions of the ACA, as well as efforts by the Trump administration to repeal or replace certain aspects of the ACA. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the ACA such as removing penalties, starting January 1, 2019, for not complying with the ACA's individual mandate to carry health insurance and delaying the implementation of certain ACA-mandated fees. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act of 2017. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. It is unclear how this decision, future decisions, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA and our business. In addition, since January 2017, President Trump has signed two Executive Orders designed to delay the implementation of any certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. 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." In addition, the 2020 federal spending package permanently eliminates, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. Also, there has been heightened governmental scrutiny recently over pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between

pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products For example, the Trump administration released a "Blueprint" to lower drug prices and reduce out-of-pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out-of-pocket costs of drug products paid by consumers. In addition, the Trump administration's budget proposal for fiscal year 2021 includes a $135.0 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. The Department of Health and Human Services, or HHS, has solicited feedback on some of these measures and, at the same, has implemented others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage plans the option to use step therapy for Part B drugs beginning January 1, 2020.This final rule codified CMS's policy change that was effective January 1, 2019. While some of these and other measures may require additional authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Any repeal and replace legislation may have the effect of limiting the amounts that government agencies will pay for healthcare products and services. Policy changes, including potential modification or repeal of all or parts of the ACA or the implementation of new health care legislation, could result in significant changes to the health care system, which may prevent us from being able to generate revenue, attain profitability or commercialize our drugs. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand or lower pricing for our product candidates, or additional pricing pressures.

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

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

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

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;
- HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;
- HIPAA and its implementing regulations impose certain requirements on certain covered entity healthcare providers, health plans, and healthcare clearinghouse as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, relating to the privacy, security, and transmission of individually identifiable health information;

- The Physician Payments Sunshine Act, which requires manufacturers of drugs, devices, biologics, and medical supplies to report annually to the U.S. Department of Health and Human Services information related to payments and other transfers of value to physicians, as defined by such law, and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members and applicable group purchasing organizations;
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payors, including commercial insurers, state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; state and local laws requiring the registration of pharmaceutical sales representatives; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts; and
- the GDPR and other EU member state data protection legislation, which require data controllers and processors, to adopt administrative, physical and technical safeguards to protect personal data, including health-related data, including mandatory contractual terms with third-party providers, requirements for establishing an appropriate legal basis for processing personal data, transparency requirements related to communications with data subjects regarding the processing their personal data, standards for obtaining consent from individuals to process their personal data, notification requirements to individuals about the processing of their personal data, an individual data rights regime, mandatory data breach notifications, limitations on the retention of personal data, increased requirements pertaining to health data, as well as strict rules and restrictions on the transfer of personal data outside of the EU, including to the United States.

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

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply, we may be subject to penalties, including significant civil, criminal and administrative penalties, damages, disgorgement, fines, sanctions, exclusion from participation in government health care programs, such as Medicare and Medicaid, imprisonment, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

The withdrawal of the United Kingdom from the EU, commonly referred to as "Brexit," may adversely impact our ability to obtain regulatory approvals of our product candidates in the EU, result in restrictions or imposition of taxes and duties for importing our product candidates into the EU, and may require us to incur additional expenses in order to develop, manufacture and commercialize our product candidates in the EU.

On June 23, 2016, the U.K. held a referendum in which a majority of the eligible members of the electorate voted for the U.K. to leave the EU. The U.K's withdrawal from the EU is commonly referred to as Brexit. The U.K. and the EU agreed to a withdrawal agreement (the ***Withdrawal Agreement***) pursuant to which the U.K. formally left the EU on January 31, 2020. Under the Withdrawal Agreement, the U.K. is subject to a transition period until December 31, 2020 (the ***Transition Period***), during which EU rules will continue to apply. Due to the current COVID-19 global pandemic, negotiations between the U.K. and the EU. scheduled for March are either being postponed or occurring in a reduced forum via video conference. There is, therefore, an increased likelihood that the Transition Period may need to be extended beyond December 31, 2020 (although it remains the position of the U.K. government that it will not be extended).

Since a significant proportion of the regulatory framework in the U.K. applicable to our business and our product candidates is derived from EU directives and regulations, Brexit, following the Transition Period, could materially impact the regulatory regime with respect to the development, manufacture, importation, approval and commercialization of our product candidates in the U.K. or the EU. For example, as a result of the uncertainty surrounding Brexit, the European Medicines Agency (EMA) relocated to Amsterdam from London. Following the Transition Period, the U.K. will no longer be covered by the centralized procedures for obtaining EU-wide marketing authorization from the EMA and, unless a specific agreement is entered into, a separate process for authorization of drug products, including our product candidates, will be required in the U.K., the potential process for which is currently unclear. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would prevent us from commercializing our product candidates in the U.K. or the EU and restrict our ability to generate revenue and achieve and sustain profitability. In addition, we may be required to pay taxes or duties or be subjected to other hurdles in connection with the importation of our product candidates into the EU, or we may incur expenses in establishing a manufacturing facility in the EU in order to circumvent such hurdles. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the U.K. or the EU for our product candidates, or incur significant additional expenses to operate our business, which could significantly and materially harm or delay our ability to generate revenues or achieve profitability of our business. Any further changes in international trade, tariff and import/export regulations as a result of Brexit or otherwise may impose unexpected duty costs or other non-tariff barriers on us. These developments, or the perception that any of them could occur, may significantly reduce global trade and, in particular, trade between the impacted nations and the U.K. It is also possible that Brexit may negatively affect our ability to attract and retain employees, particularly those from the EU.

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

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

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

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

- impairment of our business reputation;
- initiation of investigations by regulators;
- withdrawal of clinical trial participants;
- costs due to related litigation;
- distraction of management’s attention from our primary business;
- substantial monetary awards to patients or other claimants;
- the inability to commercialize our product candidates;
- product recalls, withdrawals or labeling, marketing or promotional restrictions; and
- decreased demand for our product candidates, if approved for commercial sale.

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

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

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

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

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

We have conducted in the past and are currently conducting clinical trials in the United States, Canada, Australia, Turkey, Germany, Pakistan, New Zealand, Mongolia, Spain, France, Bulgaria, Romania, Taiwan, Sweden, Italy, Belgium, Switzerland, United Kingdom, Greece, Moldova, Ukraine, Russia, and Israel, and accordingly, we are subject to risks associated with doing business globally, including commercial, political, and financial risks. Emerging regions, such as Eastern Europe, Latin America, Asia, and Africa, as well as more developed markets, such as the United Kingdom, France, Germany, and Australia, provide clinical study opportunities for us. In addition, we are subject to potential disruption caused by military conflicts; potentially unstable governments or legal systems; civil or political upheaval or unrest; local labor policies and conditions; possible expropriation, nationalization, or confiscation of assets; problems with repatriation of foreign earnings; economic or trade sanctions; closure of markets to imports; anti-American sentiment; terrorism or other types of violence in or outside the United States; health pandemics; and a significant reduction in global travel. For example, both Turkey and Pakistan are key regions for clinical activity relating to Hepatitis Delta Virus, 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. Certain countries have closed their borders due to COVID-19 preventing activation of clinical sites. 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, natural epidemics or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

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

Our business is currently adversely affected by and could be materially adversely affected in the future by the effects of disease outbreaks, epidemics and pandemics including the evolving effects of the COVID-19 outbreak, We have a significant number of clinical trial sites in countries that have been directly affected by COVID-19 and depend manufacturing operations in countries that have been directly affected by COVID-19 for various stages of our supply chain. COVID-19 continues to adversely affect our business and could materially and adversely affect our operations and those of our manufacturers and other third parties with whom we conduct business.

Our business has been adversely affected by COVID-19 and could be materially and adversely impacted by COVID-19 or other health epidemics in regions where we have significant manufacturing facilities, concentrations of clinical trial sites or other business operations.

The COVID-19 pandemic has presented a substantial public health and economic challenge around the world and is affecting employees, patients, community and business operations, as well as the U.S. economy and financial markets. The effects of the shelter-in-place order and our work-from-home policies may negatively impact productivity, disrupt our business and delay our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. These and similar, and perhaps more severe, disruptions in our operations could negatively impact our business, operating results and financial condition.

Additionally, some of our suppliers of certain materials used in the production of our drug products are located in China, Japan, Canada, Italy and the United States. While many of these materials may be obtained by more than one supplier, including suppliers outside of China, Japan, Canada, Italy and the United States, port closures and other restrictions resulting from the coronavirus outbreak in the region may disrupt our supply chain or limit our ability to obtain sufficient materials for our drug products.

In addition, our clinical trials have been and may continue to be affected by the COVID-19 pandemic. Site initiation and patient enrollment has been delayed, due to prioritization of hospital resources toward the COVID-19 Pandemic, travel restrictions imposed by governments, and the inability to access sites for initiation and monitoring. In our D-LIVR trial, the COVID-19 pandemic has delayed enrollment in our global clinical trial, some patients may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services, we may be unable to obtain blood samples for testing, and we may not be able to provide study drug to patients.

Further, as a result of the COVID-19 pandemic, the extent and length of which is uncertain, we may be required to develop and implement additional clinical study policies and procedures designed to help protect study participants from the COVID-19 virus, which may include using telemedicine visits, remote monitoring of patients and clinical sites, and measures to ensure that data from clinical studies that may be disrupted as result of the pandemic are collected pursuant to the study protocol and consistent with good clinical practices (GCPs), with any material protocol deviation reviewed and approved by the site Institutional Review Board (IRB). Patients who may miss scheduled appointments, any interruption in study drug supply, or other consequences that may result in incomplete data being generated during a study as a result of the pandemic must be adequately documented and justified. For example, on March 18, 2020, the FDA issued guidance on conducting clinical trials during the pandemic, which describes a number of considerations for sponsors of clinical trials impacted by the pandemic, including the requirement to include in the clinical study report (or as a separate document) contingency measures implemented to manage the study, and any disruption of the study as a result of the COVID-19 pandemic; a list of all study participants affected by the COVID-19-pandemic related study disruption by unique subject identifier and by investigational site, and a description of how the individual's participation was altered; and analyses and corresponding discussions that address the impact of implemented contingency measures (e.g., participant discontinuation from investigational product and/or study, alternative procedures used to collect critical safety and/or efficacy data) on the safety and efficacy results reported for the study.

Further, the FDA is suspending or delaying certain foreign inspections, and the EMA may also, and if there continues to be a suspension or delay in inspections, our product application reviews and potential approvals could be impacted or delayed.

While we expect the COVID-19 pandemic to continue to adversely affect our business operations, the extent of the impact on our clinical development and regulatory efforts and the value of and market for our common stock will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time, such as the ultimate duration of the pandemic, travel restrictions, quarantines, social distancing and business closure requirements in the U.S. and in other countries, and the effectiveness of actions taken globally to contain and treat COVID-19. In addition, to the extent the evolving effects of the ongoing COVID-19 pandemic adversely affects our business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties described elsewhere in this ''Risk Factors'' section.

Risks Related to Ownership of our Common Stock

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

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

- results or delays in preclinical studies or clinical trials;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- unanticipated serious safety concerns related to the use of any of our product candidates;
- reports of adverse events in other gene therapy products or clinical trials of such products;
- inability to obtain additional funding;
- any delay in filing an IND, NDA, or MAA for any of our product candidates and any adverse development or perceived adverse development with respect to the FDA's review of that IND or NDA;
- our ability to obtain regulatory approvals for our product candidates, and delays or failures to obtain such approvals;
- failure of any of our product candidates, if approved, to achieve commercial success;
- failure to obtain Orphan Drug designation;
- failure to maintain our existing third-party license and supply agreements;
- failure by our licensors to prosecute, maintain, or enforce our intellectual property rights;
- changes in laws or regulations applicable to our product candidates;
- any inability to obtain adequate supply of our product candidates or the inability to do so at acceptable prices;
- adverse regulatory authority decisions;
- introduction of new products, services, or technologies by our competitors;
- failure to meet or exceed financial and development projections we may provide to the public;
- failure to meet or exceed the financial and development projections of the investment community;
- the perception of the pharmaceutical industry by the public, legislatures, regulators, and the investment community;
- announcements of significant acquisitions, strategic partnerships, joint ventures, or capital commitments by us or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- additions or departures of key personnel;
- significant lawsuits, including patent or stockholder litigation;
- if securities or industry analysts do not publish research or reports about our business, or if they issue adverse or misleading opinions regarding our business and stock;
- changes in the market valuations of similar companies;
- general market or macroeconomic conditions;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- announcements by commercial partners or competitors of new commercial products, clinical progress or the lack thereof, significant contracts, commercial relationships or capital commitments;
- adverse publicity relating to the hepatitis market generally, including with respect to other products and potential products in such markets;
- the introduction of technological innovations or new therapies that compete with potential products of ours;

- changes in the structure of health care payment systems; and
- period-to-period fluctuations in our financial results.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies, including very recently in connection with the ongoing COVID-19 pandemic, which has resulted in decreased stock prices for many companies notwithstanding the lack of a fundamental change in their underlying business models or prospects. These broad market and industry factors, including potentially worsening economic conditions and other adverse effects or developments relating to the ongoing COVID-19 pandemic, 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.

Effective December 31, 2019, we ceased to be an "emerging growth company," and the reduced reporting requirements applicable to "emerging growth companies" no longer apply, which has increased our costs as a result of being a public company and places additional demands on management.

Effective December 31, 2019, we ceased to be classified as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act (the JOBS Act). We are now considered an Accelerated Filer and a Smaller Reporting Company, which will require accelerated deadlines of periodic reports. In March 2020, the definition of an Accelerated Filer was amended to exclude Smaller Reporting Companies from the requirements of the Sarbanes-Oxley Act Section 404(b).

We have previously taken advantage of the JOBS Act's reduced disclosure requirements applicable to "emerging growth companies" regarding executive compensation and exemptions from the requirements of holding advisory say-on-pay votes on executive compensation. Since we are no longer classified as an "emerging growth company," we are no longer eligible for such reduced disclosure requirements and exemptions and as such, we are required to hold a say-on-pay vote and a say-on-frequency vote at our 2019 annual meeting of stockholders. As a result, we expect that because we are no longer classified as an "emerging growth company," we will require additional attention from management with respect to our disclosures and will incur increased costs, which could include higher legal fees, accounting fees, consultant fees and fees associated with investor relations activities, among others.

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 RA Capital, Vivo Ventures Fund VI, L.P. and Adage Capital Partners, 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.

Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flows, financial condition or results of operations.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business and financial condition. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act (Tax Act), enacted many significant changes to the U.S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to the Tax Act may affect us, and certain aspects of the Tax Act repealed or modified in future legislation. For example, the CARES Act modified certain provisions of the Tax Act. In addition, it is uncertain if and to what extent various states will conform to the Tax Act or any newly enacted federal tax legislation. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses under the Tax Act or future reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future U.S. tax expense.

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

Our federal and state net operating loss (NOL) carry-forwards will begin to expire, if not utilized, beginning in 2030 for federal income tax purposes and 2028 for California state income tax purposes. These NOL carry-forwards could expire unused and be unavailable to offset future income tax liabilities. While the Tax Act allows for federal net operating losses incurred in 2019 and in future years to be carried forward indefinitely, the deductibility of such federal net operating losses incurred in 2019 and in future years will be limited. Moreover, if a corporation undergoes an ownership change within the meaning of Section 382 of the Code (Section 382) the corporation's NOL carryforwards and certain other tax attributes arising from before the ownership change are subject to limitations on use after the "ownership change." In general, an ownership change occurs if there is a cumulative change in the corporation's equity ownership by certain stockholders that exceeds fifty percentage points over a rolling three-year period. Similar rules may apply under state tax laws. Our merger with Celladon resulted in such an ownership change and, accordingly, Celladon's NOL carryforwards and certain other tax attributes will be subject to further limitations on their use. In addition, we assessed whether Eiger had an ownership change, as defined by Section 382 of the Code, as a result of the Merger and other stock issuances that occurred from our formation through August 5, 2019. Based upon this assessment, we have experienced ownership changes on April 20, 2016 and October 18, 2018. Due to these ownership changes, reductions were made to our NOL and tax credit carryforwards under these rules. Additional ownership changes in the future could result in additional limitations on our net operating loss and tax credit carryforwards. Consequently, even if we achieve profitability, we may not be able to utilize a material portion of our NOL carryforwards and other tax attributes, which could have a material adverse effect on cash flow and results of operations. A full valuation allowance has been provided for the entire amount of our remaining net operating losses.

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

None

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

On August 6, 2020, we entered into an Open Market Sale Agreement℠ (Sales Agreement) with Jefferies LLC (Jefferies), as our sales agent, pursuant to which we may sell, from time to time, through Jefferies, shares of our common stock having an aggregate offering price of up to $50.0 million. We are not obligated to make any sales of common stock under the Sales Agreement, and all sales will be made pursuant to a shelf registration statement on Form S-3, which was declared effective by the SEC on December 31, 2019, and as supplemented by a prospectus supplement to be filed with the SEC on or about the date of this Quarterly Report on Form 10-Q. Under the Sales Agreement, common stock may be sold by any method deemed to be an "at-the-market offering" as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, and, as a result, prices may vary. We have agreed to pay Jefferies a commission of up to 3.0% of the aggregate gross proceeds we receive from all sales of common stock under the Sales Agreement, and we have also provided Jefferies with customary indemnification rights. The Sales Agreement will terminate upon the earlier of (i) the sale of all common stock subject to the Sales Agreement and (ii) the termination of the Sales Agreement as permitted therein. Additionally, we and Jefferies may each terminate the Sales Agreement at any time upon three trading days' prior notice.

The foregoing description of the Sales Agreement is qualified in its entirety by reference to the Sales Agreement, a copy of which is attached hereto as Exhibit 1.1 and incorporated herein by reference.

The opinion of our counsel regarding the validity of the common stock that will be issued pursuant to the Sales Agreement is filed with this Quarterly Report on Form 10-Q as Exhibit 5.1.

ITEM 6. EXHIBITS

Exhibit Number	Description of Document
1.1**	Open Market Sale Agreement℠, dated August 6, 2020, between Eiger BioPharmaceuticals, Inc. and Jefferies LLC.
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).
5.1**	Opinion of Cooley LLP.
10.1† **	Amendment No. 1, dated June 15, 2020, to the Collaboration and Supply Agreement, dated May 15, 2018, by and between Eiger BioPharmaceuticals, Inc. and the Progeria Research Foundation.
23.1**	Consent of Cooley LLP (included in Exhibit 5.1).
31.1**	Certification of Principal Executive Officer required by Rule 13a-14(a) or Rule 15d-14(a).
31.2**	Certification of Principal Financial Officer required by Rule 13a-14(a) or Rule 15d-14(a).
32.1+	Certifications of Principal Executive Officer and Principal Financial Officer required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350).
101.INS**	Inline XBRL Instance Document- the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH**	Inline XBRL Taxonomy Extension Schema Document
101.CAL**	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF**	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB**	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE**	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	The cover page from the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2020, has been formatted in Inline XBRL.

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

† Portions of this exhibit have been omitted as being both (i) not material and (ii) would likely cause competitive harm if publicly disclosed.

** Filed herewith.

SIGNATURES

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

Eiger BioPharmaceuticals, Inc.

Date: August 6, 2020

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

Eiger BioPharmaceuticals, Inc.

Date: August 6, 2020

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

Exhibit 1.1

OPEN MARKET SALE AGREEMENT[SM]

August 6, 2020

JEFFERIES LLC
520 Madison Avenue
New York, New York 10022

Ladies and Gentlemen:

Eiger BioPharmaceuticals, Inc., a Delaware corporation (the "**Company**"), proposes, subject to the terms and conditions stated herein, to issue and sell from time to time through Jefferies LLC, as sales agent and/or principal (the "**Agent**"), shares of the Company's common stock, par value $0.001 per share (the "**Common Shares**"), having an aggregate offering price of up to $50,000,000 on the terms set forth in this agreement (this "**Agreement**").

Section 1. DEFINITIONS

(a) Certain Definitions. For purposes of this Agreement, capitalized terms used herein and not otherwise defined shall have the following respective meanings:

"**Affiliate**" of a Person means another Person that directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with, such first-mentioned Person. The term "control" (including the terms "controlling," "controlled by" and "under common control with") means the possession, direct or indirect, of the power to direct or cause the direction of the management and policies of a Person, whether through the ownership of voting securities, by contract or otherwise.

"**Agency Period**" means the period commencing on the date of this Agreement and expiring on the earliest to occur of (x) the date on which the Agent shall have placed the Maximum Program Amount pursuant to this Agreement and (y) the date this Agreement is terminated pursuant to Section 7.

"**Commission**" means the U.S. Securities and Exchange Commission.

"**Exchange Act**" means the Securities Exchange Act of 1934, as amended, and the rules and regulations of the Commission thereunder.

"**Floor Price**" means the minimum price set by the Company in the Issuance Notice below which the Agent shall not sell Shares during the applicable period set forth in the Issuance Notice, which may be adjusted by the Company at any time during the period set forth in the Issuance Notice by delivering written notice of such change to the Agent and which in no event shall be less

[SM] "Open Market Sale Agreement" is a service mark of Jefferies LLC

than $1.00 without the prior written consent of the Agent, which may be withheld in the Agent's sole discretion.

"**Issuance Amount**" means the aggregate Sales Price of the Shares to be sold by the Agent pursuant to any Issuance Notice.

"**Issuance Notice**" means a written notice delivered to the Agent by the Company in accordance with this Agreement in the form attached hereto as Exhibit A that is executed by its Chief Executive Officer, President or Chief Financial Officer.

"**Issuance Notice Date**" means any Trading Day during the Agency Period that an Issuance Notice is delivered pursuant to Section 3(b)(i).

"**Issuance Price**" means the Sales Price less the Selling Commission.

"**Maximum Program Amount**" means Common Shares with an aggregate Sales Price of the lesser of (a) the number or dollar amount of Common Shares registered under the effective Registration Statement (as defined below) pursuant to which the offering is being made, (b) the number of authorized but unissued Common Shares (less Common Shares issuable upon exercise, conversion or exchange of any outstanding securities of the Company or otherwise reserved from the Company's authorized capital stock), (c) the number or dollar amount of Common Shares permitted to be sold under Form S-3 (including General Instruction I.B.6 thereof, if applicable), or (d) the number or dollar amount of Common Shares for which the Company has filed a Prospectus (as defined below).

"**Person**" means an individual or a corporation, partnership, limited liability company, trust, incorporated or unincorporated association, joint venture, joint stock company, governmental authority or other entity of any kind.

"**Principal Market**" means the Nasdaq Global Market or such other national securities exchange on which the Common Shares, including any Shares, are then listed.

"**Sales Price**" means the actual sale execution price of each Share placed by the Agent pursuant to this Agreement.

"**Securities Act**" means the Securities Act of 1933, as amended, and the rules and regulations of the Commission thereunder.

"**Selling Commission**" means three percent (3%) of the gross proceeds of Shares sold pursuant to this Agreement, or as otherwise agreed between the Company and the Agent with respect to any Shares sold pursuant to this Agreement.

"**Settlement Date**" means the second business day following each Trading Day during the period set forth in the Issuance Notice on which Shares are sold pursuant to this Agreement, when the Company shall deliver to the Agent the amount of Shares sold on such Trading Day and the Agent shall deliver to the Company the Issuance Price received on such sales.

"**Shares**" means the Company's Common Shares issued or issuable pursuant to this Agreement.

"**Trading Day**" means any day on which the Principal Market is open for trading.

Section 2. REPRESENTATIONS AND WARRANTIES OF THE COMPANY

The Company represents and warrants to, and agrees with, the Agent that as of (1) the date of this Agreement, (2) each Issuance Notice Date, (3) each Settlement Date, (4) each Triggering Event Date (as defined below) and (5) as of each Time of Sale (as defined below) (each of the times referenced above is referred to herein as a "**Representation Date**"), except as may be disclosed in the Prospectus (including any documents incorporated by reference therein and any supplements thereto) on or before a Representation Date:

(a) Registration Statement. The Company has prepared and filed or will file with the Commission a shelf registration statement on Form S-3 that contains a base prospectus. Such registration statement registers the issuance and sale by the Company of the Shares under the Securities Act. The Company may file one or more additional registration statements from time to time that will contain a base prospectus and related prospectus or prospectus supplement, if applicable, with respect to the Shares. Except where the context otherwise requires, such registration statement(s), including any information deemed to be a part thereof pursuant to Rule 430B under the Securities Act, including all financial statements, exhibits and schedules thereto and all documents incorporated or deemed to be incorporated therein by reference pursuant to Item 12 of Form S-3 under the Securities Act as from time to time amended or supplemented, is herein referred to as the "**Registration Statement**," and the prospectus constituting a part of such registration statement(s), together with any prospectus supplement filed with the Commission pursuant to Rule 424(b) under the Securities Act relating to a particular issuance of the Shares, including all documents incorporated or deemed to be incorporated therein by reference pursuant to Item 12 of Form S-3 under the Securities Act, in each case, as from time to time amended or supplemented, is referred to herein as the "**Prospectus**," except that if any revised prospectus is provided to the Agent by the Company for use in connection with the offering of the Shares that is not required to be filed by the Company pursuant to Rule 424(b) under the Securities Act, the term "**Prospectus**" shall refer to such revised prospectus from and after the time it is first provided to the Agent for such use. The Registration Statement at the time it originally became effective is herein called the "**Original Registration Statement**." As used in this Agreement, the terms "amendment" or "supplement" when applied to the Registration Statement or the Prospectus shall be deemed to include the filing by the Company with the Commission of any document under the Exchange Act after the date hereof that is or is deemed to be incorporated therein by reference.

All references in this Agreement to financial statements and schedules and other information which is "contained," "included" or "stated" in the Registration Statement or the Prospectus (and all other references of like import) shall be deemed to mean and include all such financial statements and schedules and other information which is or is deemed to be incorporated by reference in or otherwise deemed under the Securities Act to be a part of or included in the Registration Statement or the Prospectus, as the case may be, as of any specified date; and all references in this Agreement to amendments or supplements to the Registration Statement or the Prospectus shall be deemed to mean and include, without limitation, the filing of any document under the Exchange Act which is

or is deemed to be incorporated by reference in or otherwise deemed under the Securities Act to be a part of or included in the Registration Statement or the Prospectus, as the case may be, as of any specified date.

At the time the Registration Statement was or will be originally declared effective and at the time the Company's most recent annual report on Form 10-K was filed with the Commission, if later, the Company met the then-applicable requirements for use of Form S-3 under the Securities Act. During the Agency Period, each time the Company files an annual report on Form 10-K the Company will meet the then-applicable requirements for use of Form S-3 under the Securities Act.

(b) Compliance with Registration Requirements. The Original Registration Statement and any Rule 462(b) Registration Statement have been or will be declared effective by the Commission under the Securities Act. The Company has complied or will comply to the Commission's satisfaction with all requests of the Commission for additional or supplemental information. No stop order suspending the effectiveness of the Registration Statement or any Rule 462(b) Registration Statement is in effect and no proceedings for such purpose have been instituted or are pending or, to the best knowledge of the Company, are contemplated or threatened by the Commission.

The Prospectus, when filed, complied or will comply in all material respects with the Securities Act and, if filed with the Commission through its Electronic Data Gathering, Analysis and Retrieval system (except as may be permitted by Regulation S-T under the Securities Act), was identical to the copy thereof delivered to the Agent for use in connection with the issuance and sale of the Shares. Each of the Registration Statement, any Rule 462(b) Registration Statement and any post-effective amendment thereto, at the time it became or becomes effective and at all subsequent times, complied and will comply in all material respects with the Securities Act and did not and will not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading. As of the date of this Agreement, the Prospectus and any Free Writing Prospectus (as defined below) considered together (collectively, the "**Time of Sale Information**") did not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading. The Prospectus, as amended or supplemented, as of its date and at all subsequent times, did not and will not contain any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. The representations and warranties set forth in the three immediately preceding sentences do not apply to statements in or omissions from the Registration Statement, any Rule 462(b) Registration Statement, or any post-effective amendment thereto, or the Prospectus, or any amendments or supplements thereto, made in reliance upon and in conformity with information relating to the Agent furnished to the Company in writing by the Agent expressly for use therein, it being understood and agreed that the only such information furnished by the Agent to the Company consists of the information described in Section 6 below. There are no contracts or other documents required to be described in the Prospectus or to be filed as exhibits to the Registration Statement which have not been described or filed as required. The Registration Statement and the offer and sale of the Shares as contemplated hereby meet the requirements of Rule 415 under the Securities Act and comply in all material respects with said rule.

(c) Ineligible Issuer Status. The Company is not an "ineligible issuer" in connection with the offering of the Shares pursuant to Rules 164, 405 and 433 under the Securities Act. Any Free Writing Prospectus that the Company is required to file pursuant to Rule 433(d) under the Securities Act has been, or will be, filed with the Commission in accordance with the requirements of the Securities Act. Each Free Writing Prospectus that the Company has filed, or is required to file, pursuant to Rule 433(d) under the Securities Act or that was prepared by or on behalf of or used or referred to by the Company complies or will comply in all material respects with the requirements of Rule 433 under the Securities Act including timely filing with the Commission or retention where required and legending, and each such Free Writing Prospectus, as of its issue date and at all subsequent times through the completion of the issuance and sale of the Shares did not, does not and will not include any information that conflicted, conflicts with or will conflict with the information contained in the Registration Statement or the Prospectus, including any document incorporated by reference therein. Except for the Free Writing Prospectuses, if any, and electronic road shows, if any, furnished to you before first use, the Company has not prepared, used or referred to, and will not, without your prior consent, prepare, use or refer to, any Free Writing Prospectus.

(d) This Agreement. This Agreement has been duly authorized, executed and delivered by the Company.

(e) Authorization of the Shares. The Shares have been duly authorized for issuance and sale pursuant to this Agreement and, when issued and delivered by the Company against payment therefor pursuant to this Agreement, will be validly issued, fully paid and nonassessable, and the issuance and sale of the Shares is not subject to any preemptive rights, rights of first refusal or other similar rights to subscribe for or purchase the Shares.

(f) No Applicable Registration or Other Similar Rights. There are no persons with registration or other similar rights to have any equity or debt securities registered for sale under the Registration Statement or included in the offering contemplated by this Agreement, except for such rights as have been duly waived.

(g) No Material Adverse Change. Except as otherwise disclosed in the Registration Statement and the Prospectus, subsequent to the respective dates as of which information is given in the Registration Statement and the Prospectus: (i) there has been no material adverse change, or any development that would reasonably be expected to result in a material adverse change, in the condition, financial or otherwise, or in the earnings, business, properties, operations, assets, liabilities or prospects, whether or not arising from transactions in the ordinary course of business, of the Company and its subsidiaries, considered as one entity (any such change being referred to herein as a "**Material Adverse Change**"); (ii) the Company and its subsidiaries, considered as one entity, have not incurred any material liability or obligation, indirect, direct or contingent, including without limitation any losses or interference with its business from fire, explosion, flood, earthquakes, accident or other calamity, whether or not covered by insurance, or from any strike, labor dispute or court or governmental action, order or decree, that are material, individually or in the aggregate, to the Company and its subsidiaries, considered as one entity, and have not entered into any transactions not in the ordinary course of business; and (iii) there has not been any material decrease in the capital stock or any material increase in any short-term or long-term indebtedness of the Company or its subsidiaries and there has been no dividend or distribution of any kind

declared, paid or made by the Company or, except for dividends paid to the Company or other subsidiaries, by any of the Company's subsidiaries on any class of capital stock, or any repurchase or redemption by the Company or any of its subsidiaries of any class of capital stock.

(h) Independent Accountants. KPMG LLP, which has expressed its opinion with respect to the financial statements (which term as used in this Agreement includes the related notes thereto) and supporting schedules incorporated by reference in the Registration Statement and the Prospectus, is (i) an independent registered public accounting firm as required by the Exchange Act, and the rules of the Public Company Accounting Oversight Board ("**PCAOB**"), (ii) in compliance with the applicable requirements relating to the qualification of accountants under Rule 2-01 of Regulation S-X under the Securities Act and (iii) a registered public accounting firm as defined by the PCAOB whose registration has not been suspended or revoked and who has not requested such registration to be withdrawn.

(i) Financial Statements. The financial statements incorporated by reference in the Registration Statement and the Prospectus present fairly the consolidated financial position of the Company and its subsidiaries as of the dates indicated and the results of their operations, changes in stockholders' equity and cash flows for the periods specified. Such financial statements have been prepared in conformity with generally accepted accounting principles applied on a consistent basis throughout the periods involved, except as may be expressly stated in the related notes thereto. The interactive data in eXtensible Business Reporting Language included or incorporated by reference in the Registration Statement fairly presents the information called for in all material respects and has been prepared in accordance with the Commission's rules and guidelines applicable thereto. No other financial statements or supporting schedules are required to be included in the Registration Statement or the Prospectus. To the Company's knowledge, no person who has been suspended or barred from being associated with a registered public accounting firm, or who has failed to comply with any sanction pursuant to Rule 5300 promulgated by the PCAOB, has participated in or otherwise aided the preparation of, or audited, the financial statements, supporting schedules or other financial data filed with the Commission as a part of the Registration Statement and the Prospectus.

(j) Company's Accounting System. The Company and each of its subsidiaries make and keep accurate books and records and maintain a system of internal accounting controls sufficient to provide reasonable assurance that: (i) transactions are executed in accordance with management's general or specific authorization; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with generally accepted accounting principles and to maintain accountability for assets; (iii) access to assets is permitted only in accordance with management's general or specific authorization; (iv) the recorded accountability for assets is compared with existing assets at reasonable intervals and appropriate action is taken with respect to any differences; and (v) the interactive data in eXtensible Business Reporting Language included or incorporated by reference in the Registration Statement and the Prospectus fairly presents the information called for in all material respects and is prepared in accordance with the Commission's rules and guidelines applicable thereto.

(k) Disclosure Controls and Procedures; Deficiencies in or Changes to Internal Control Over Financial Reporting. The Company has established and maintains disclosure controls and procedures (as defined in Rules 13a-15 and 15d-15 under the Exchange Act), which (i) are designed to ensure that material information relating to the Company, including its consolidated

subsidiaries, is made known to the Company's principal executive officer and its principal financial officer by others within those entities, particularly during the periods in which the periodic reports required under the Exchange Act are being prepared; (ii) have been evaluated by management of the Company for effectiveness as of the end of the Company's most recent fiscal quarter; and (iii) except as otherwise disclosed in the Registration Statement and the Prospectus, are effective in all material respects to perform the functions for which they were established. Since the end of the Company's most recent audited fiscal year, other than those described in the Registration Statement and the Prospectus, there have been no significant deficiencies or material weakness in the Company's internal control over financial reporting (whether or not remediated) and no change in the Company's internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting. The Company is not aware of any change in its internal control over financial reporting that has occurred during its most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

(l) Incorporation and Good Standing of the Company. The Company has been duly incorporated and is validly existing as a corporation in good standing under the laws of the jurisdiction of its incorporation and has the corporate power and authority to own, lease and operate its properties and to conduct its business as described in the Registration Statement and the Prospectus and to enter into and perform its obligations under this Agreement. The Company is duly qualified as a foreign corporation to transact business and is in good standing in the States of Delaware and California and each other jurisdiction in which such qualification is required, whether by reason of the ownership or leasing of property or the conduct of business, except where the failure to so qualify or be in good standing in each such jurisdiction would not reasonably be expected to have a Material Adverse Effect (as defined below).

(m) Subsidiaries. Each of the Company's "subsidiaries" (for purposes of this Agreement, as defined in Rule 405 under the Securities Act) has been duly incorporated or organized, as the case may be, and is validly existing as a corporation, partnership or limited liability company, as applicable, in good standing under the laws of the jurisdiction of its incorporation or organization and has the power and authority (corporate or other) to own, lease and operate its properties and to conduct its business as described in the Registration Statement and the Prospectus. Each of the Company's subsidiaries is duly qualified as a foreign corporation, partnership or limited liability company, as applicable, to transact business and is in good standing in each jurisdiction in which such qualification is required, whether by reason of the ownership or leasing of property or the conduct of business. All of the issued and outstanding capital stock or other equity or ownership interests of each of the Company's subsidiaries have been duly authorized and validly issued, are fully paid and nonassessable and are owned by the Company, directly or through subsidiaries, free and clear of any security interest, mortgage, pledge, lien, encumbrance or adverse claim. The Company does not own or control, directly or indirectly, any corporation, association or other entity other than the subsidiaries listed in Exhibit 21.1 to the Company's most recent Annual Report on Form 10-K.

(n) Capitalization and Other Capital Stock Matters. The authorized capital stock of the Company is as set forth in the Registration Statement and the Prospectus under the caption "Description of Capital Stock." The Common Shares (including the Shares) conform in all material respects to the description thereof contained in the Prospectus. All of the issued and

outstanding Common Shares have been duly authorized and validly issued, are fully paid and nonassessable and have been issued in compliance with all federal and state securities laws. None of the outstanding Common Shares was issued in violation of any preemptive rights, rights of first refusal or other similar rights to subscribe for or purchase securities of the Company. There are no authorized or outstanding options, warrants, preemptive rights, rights of first refusal or other rights to purchase, or equity or debt securities convertible into or exchangeable or exercisable for, any capital stock of the Company or any of its subsidiaries other than those described in the Registration Statement and the Prospectus. The descriptions of the Company's stock option, stock bonus and other stock plans or arrangements, and the options or other rights granted thereunder, set forth in the Registration Statement and the Prospectus accurately and fairly presents in all material respects the information required to be shown with respect to such plans, arrangements, options and rights.

(o) Stock Exchange Listing. The Common Shares are registered pursuant to Section 12(b) or 12(g) of the Exchange Act and are listed on the Principal Market, and the Company has taken no action designed to, or likely to have the effect of, terminating the registration of the Common Shares under the Exchange Act or delisting the Common Shares from the Principal Market, nor has the Company received any notification that the Commission or the Principal Market is contemplating terminating such registration or listing. To the Company's knowledge, it is in compliance with all applicable listing requirements of the Principal Market.

(p) Non-Contravention of Existing Instruments; No Further Authorizations or Approvals Required. Neither the Company nor any of its subsidiaries is in violation of its charter or by-laws, partnership agreement or operating agreement or similar organizational documents, as applicable, or is in default (or, with the giving of notice or lapse of time, would be in default) ("**Default**") under any indenture, loan, credit agreement, note, lease, license agreement, contract, franchise or other instrument (including, without limitation, any pledge agreement, security agreement, mortgage or other instrument or agreement evidencing, guaranteeing, securing or relating to indebtedness) to which the Company or any of its subsidiaries is a party or by which it or any of them may be bound, or to which any of their respective properties or assets are subject (each, an "**Existing Instrument**"), except for such Defaults as would not be expected, individually or in the aggregate, to have a material adverse effect on the condition (financial or other), earnings, business, properties, operations, assets, liabilities or prospects of the Company and its subsidiaries, considered as one entity (a "**Material Adverse Effect**"). The Company's execution, delivery and performance of this Agreement, consummation of the transactions contemplated hereby and by the Registration Statement and the Prospectus and the issuance and sale of the Shares (including the use of proceeds from the sale of the Shares as described in the Registration Statement and the Prospectus under the caption "Use of Proceeds") (i) have been duly authorized by all necessary corporate action and will not result in any violation of the provisions of the charter or by-laws, partnership agreement or operating agreement or similar organizational documents, as applicable, of the Company or any subsidiary (ii) will not conflict with or constitute a breach of, or Default or a Debt Repayment Triggering Event (as defined below) under, or result in the creation or imposition of any lien, charge or encumbrance upon any property or assets of the Company or any of its subsidiaries pursuant to, or require the consent of any other party to, any Existing Instrument and (iii) will not result in any violation of any law, administrative regulation or administrative or court decree applicable to the Company or any of its subsidiaries, except for such conflicts, breaches, Defaults, violations, Debt Repayment Triggering Event, lien, charge or encumbrance specified in clauses (ii) and (iii) above that would not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Effect. No consent, approval, authorization or other order of, or registration or filing with, any court or other governmental or regulatory authority or agency, is required for the Company's execution, delivery and performance of this Agreement

and consummation of the transactions contemplated hereby and by the Registration Statement and the Prospectus, except such as have been obtained or made by the Company and are in full force and effect under the Securities Act and such as may be required under applicable state securities or blue sky laws or the Financial Industry Regulation Authority, Inc. ("**FINRA**"). As used herein, a "**Debt Repayment Triggering Event**" means any event or condition which gives, or with the giving of notice or lapse of time would give, the holder of any note, debenture or other evidence of indebtedness (or any person acting on such holder's behalf) the right to require the repurchase, redemption or repayment of all or a portion of such indebtedness by the Company or any of its subsidiaries.

(q) Compliance with Laws. The Company and its subsidiaries have been and are in compliance with all applicable laws, rules and regulations, except where failure to be so in compliance would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect.

(r) No Material Actions or Proceedings. Except as otherwise disclosed in the Registration Statement or the Prospectus, there is no action, suit, proceeding, inquiry or investigation brought by or before any governmental entity now pending or, to the knowledge of the Company, threatened, against or affecting the Company or any of its subsidiaries, which would reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect or materially and adversely affect the consummation of the transactions contemplated by this Agreement or the performance by the Company of its obligations hereunder; and the aggregate of all pending legal or governmental proceedings to which the Company or any such subsidiary is a party or of which any of their respective properties or assets is the subject, including ordinary routine litigation incidental to the business, if determined adversely to the Company, would not reasonably be expected to have a Material Adverse Effect. No material labor dispute with the employees of the Company or any of its subsidiaries, or with the employees of any principal supplier, manufacturer, customer or contractor of the Company, exists or, to the knowledge of the Company, is threatened or imminent.

(s) Intellectual Property Rights. Except as otherwise disclosed in the Registration Statement or the Prospectus, the Company and its subsidiaries own, or possess sufficient rights to use, all trademarks, service marks, trade names (including all goodwill associated with the foregoing), patent rights, copyrights, domain names, licenses, approvals, trade secrets, inventions, technology, know-how and other intellectual property and similar rights, including registrations and applications for registration thereof (collectively, "**Intellectual Property Rights**") used in, or necessary for the conduct of the business now conducted or proposed in the Registration Statement and the Prospectus to be conducted by the Company or its subsidiaries. Except as disclosed in the Registration Statement and the Prospectus, (i) there are no rights of third parties to any of the Intellectual Property Rights owned or purported to be owned by the Company or its subsidiaries, (ii) there is no infringement, misappropriation, breach, default or other violation, or the occurrence of any event that with notice or the passage of time would constitute any of the foregoing, by any third party of any of the Intellectual Property Rights of the Company or any of its subsidiaries, (iii) none of the Intellectual Property Rights used or held for use by the Company or any of its subsidiaries in their businesses has been obtained or is being used or held for use by the Company or any of its subsidiaries in violation of any contractual obligation binding on the Company or any of its subsidiaries or in violation of any rights of any third party, (iv) the Company and its subsidiaries have taken reasonable steps in accordance with normal industry practice to maintain the confidentiality of all Intellectual Property Rights the value of which to the Company or any

subsidiary is contingent upon maintaining the confidentiality thereof, (v) the Company is not obligated to pay a material royalty, grant a license to, or provide other material consideration to any third party in connection with the Company Intellectual Property, and (vi) to the Company's knowledge, all Intellectual Property Rights owned by, or exclusively licensed to, the Company or any of its subsidiaries are valid and enforceable. Neither the Company nor any of its subsidiaries has materially infringed, misappropriated or otherwise violated the Intellectual Property Rights of any third party, and neither the manufacture of, nor the use or sale of, any of the product candidates described in the Registration Statement and the Prospectus, would materially infringe or otherwise violate the Intellectual Property Rights of any third party. Except as disclosed in the Registration Statement and the Prospectus, there is no pending or threatened action, suit, proceeding or claim by any third party (A) challenging the Company's or any of its subsidiaries' rights in or to, or alleging the violation of any of the terms of, any of their Intellectual Property Rights, (B) challenging the validity, enforceability or scope of any Intellectual Property Rights owned by, or exclusively licensed to, the Company or any of its subsidiaries, or (C) alleging that the Company or any of its subsidiaries has infringed, misappropriated or otherwise violated or conflicted with any Intellectual Property Rights of any third party, and in the case of each of (A), (B) and (C) above, the Company is unaware of any fact which would form a reasonable basis for any such action, suit, proceeding or claim.

(t) Patents and Patent Applications. All patents and patent applications owned by, or exclusively licensed to, the Company or its subsidiaries or under which the Company or its subsidiaries has rights have, to the knowledge of the Company, been duly and properly filed and each issued patent is being diligently maintained; to the knowledge of the Company, the parties prosecuting such applications have complied with their duty of candor and disclosure to the U.S. Patent and Trademark Office (the "**USPTO**") in connection with such applications; to the Company's knowledge, there is no patent that contains claims that dominate or may dominate (as such term is described in 35 U.S.C. §135 and 37 C.F.R. 41.100 to 41.208) with the issued or pending claims of any of the Company Intellectual Property; to the Company's knowledge, there is no prior art material to any patent or patent application of the Company Intellectual Property that may render any U.S. patent held by the Company or its subsidiaries invalid or any U.S. patent application held by the Company or its subsidiaries unpatentable; and the Company is not aware of any facts required to be disclosed to the USPTO that were not disclosed to the USPTO and which would preclude the grant of a patent in connection with any such application or would reasonably be expected to form the basis of a finding of invalidity with respect to any patents that have been issued with respect to such applications.

(u) Regulatory Matters; Products and Product Candidates. Except as described in the Registration Statement and the Prospectus, the Company and its subsidiaries: (i) have operated and currently operate their respective businesses in compliance in all material respects with applicable provisions of the Health Care Laws (as defined below) of the Food and Drug Administration ("**FDA**"), the Department of Health and Human Services and any comparable foreign or other regulatory authority to which they are subject (collectively, the "**Applicable Regulatory Authorities**") applicable to the ownership, testing, development, manufacture, packaging, processing, use, distribution, storage, import, export or disposal of any of the Company's or its subsidiaries' product candidates or any product manufactured or distributed by the Company and its subsidiaries; (ii) have not received any FDA Form 483, written notice of adverse finding, warning letter, untitled letter or other correspondence or written notice from any

court or arbitrator or governmental or regulatory authority alleging or asserting non-compliance with (A) any Health Care Laws or (B) or any licenses, certificates, approvals, clearances, exemptions, authorizations, permits and supplements or amendments thereto required by any such Health Care Laws ("**Regulatory Authorizations**"); (iii) possess all Regulatory Authorizations required to conduct their respective businesses as currently conducted and such Regulatory Authorizations are valid and in full force and effect and the Company is not in violation, in any material respect, of any term of any such Regulatory Authorizations; (iv) have not received notice of any claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from the Applicable Regulatory Authorities or any other third party alleging that any product operation or activity is in material violation of any Health Care Laws or Regulatory Authorizations and has no knowledge that the Applicable Regulatory Authorities or any other third party is considering any such claim, litigation, arbitration, action, suit, investigation or proceeding; (v) have not received notice that any of the Applicable Regulatory Authorities has taken, is taking or intends to take action to limit, suspend, modify or revoke any material Regulatory Authorizations and has no knowledge that any of the Applicable Regulatory Authorities is considering such action; (vi) have filed, obtained, maintained or submitted all material reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments as required by any Health Care Laws or Regulatory Authorizations and that all such reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments were materially complete and correct on the date filed (or were materially corrected or supplemented by a subsequent submission); (vii) are not a party to or have any ongoing reporting obligations pursuant to any corporate integrity agreements, deferred prosecution agreements, monitoring agreements, consent decrees, settlement orders, plans of correction or similar agreements with or imposed by any Applicable Regulatory Authority; and (viii) along with their respective employees, officers and directors, have not been excluded, suspended or debarred from participation in any government health care program or human clinical research or, to the knowledge of the Company, is subject to a governmental inquiry, investigation, proceeding, or other similar action that could reasonably be expected to result in debarment, suspension, or exclusion.

The term "**Health Care Laws**" means Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395hhh (the Medicare statute); Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396v (the Medicaid statute); the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b); the civil False Claims Act, 31 U.S.C. §§ 3729 et seq.; the criminal False Claims Act 42 U.S.C. 1320a-7b(a); any criminal laws relating to health care fraud and abuse, including but not limited to 18 U.S.C. Sections 286 and 287 and the health care fraud criminal provisions under the Health Insurance Portability and Accountability Act of 1996, 42 U.S.C. §§ 1320d et seq., ("**HIPAA**"); the Civil Monetary Penalties Law, 42 U.S.C. §§ 1320a-7a and 1320a-7b; the Physician Payments Sunshine Act, 42 U.S.C. § 1320a-7h; the Exclusion Laws, 42 U.S.C. § 1320a-7; HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, 42 U.S.C. §§ 17921 et seq.; the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et seq.; the Public Health Service Act, 42 U.S.C. §§ 201 et seq.; the regulations promulgated pursuant to such laws; and any similar federal, state and local laws and regulations.

(v) Regulatory Matters: Manufacturing. To the Company's knowledge, the manufacturing facilities and operations of its suppliers are operated in compliance in all material

respects with all applicable statutes, rules, regulations and policies of the Applicable Regulatory Authorities.

(w) Regulatory Matters: Clinical Trials. None of the Company's or its subsidiaries' product candidates have received marketing approval from any Applicable Regulatory Authority. All clinical and pre-clinical studies and trials conducted by or on behalf of or sponsored by the Company or its subsidiaries, or in which the Company or its subsidiaries have participated, with respect to the Company's or its subsidiaries' product candidates, including any such studies and trials that are described in the Registration Statement and the Prospectus, or the results of which are referred to in the Registration Statement and the Prospectus, as applicable (collectively, "**Company Trials**"), were, and if still pending are, being conducted in all material respects in accordance with all applicable Health Care Laws of the Applicable Regulatory Authorities and current Good Clinical Practices and Good Laboratory Practices, standard medical and scientific research procedures and any applicable rules, regulations and policies of the jurisdiction in which such trials and studies are being conducted; the descriptions in the Registration Statement and the Prospectus of the results of any Company Trials are accurate and complete descriptions in all material respects and fairly present the data derived therefrom; the Company has no knowledge of any other studies or trials not described in the Registration Statement and the Prospectus, the results of which are inconsistent with or call into question the results described or referred to in the Registration Statement and the Prospectus; the Company and each of its subsidiaries have operated at all times and are currently in compliance in all material respects with all applicable Health Care Laws of the Applicable Regulatory Authorities; neither the Company nor any of its subsidiaries have received, nor does the Company have knowledge after due inquiry that any of its or its subsidiaries' collaboration partners have received any written notices, correspondence or other communications from the Applicable Regulatory Authorities or any other governmental entity requiring or threatening the termination, material modification or suspension of Company Trials, other than ordinary course communications with respect to modifications in connection with the design and implementation of such studies or trials, and, to the Company's knowledge, there are no reasonable grounds for the same. No investigational new drug application or comparable submission filed by or on behalf of the Company or its subsidiaries with the FDA has been terminated or suspended by the FDA or any other Applicable Regulatory Authority. The Company and the subsidiaries, as applicable, have obtained (or caused to be obtained) informed consent by or on behalf of each human subject who participated in a Company Trial. In using or disclosing patient information received by the Company or a subsidiary in connection with a Company Trial, the Company or such subsidiary has complied in all material respects with all applicable laws and regulatory rules or requirements, including, without limitation, HIPAA and the rules and regulations thereunder. To the Company's knowledge, none of the Company Trials involved any investigator who has been disqualified as a clinical investigator or has been found by the FDA to have engaged in scientific misconduct.

(x) All Necessary Permits, etc. Except as otherwise disclosed in the Prospectus, the Company and its subsidiaries possess such valid and current certificates, authorizations or permits required by state, federal or foreign regulatory agencies or bodies to conduct their respective businesses as currently conducted and as described in the Registration Statement or the Prospectus ("**Permits**"). Neither the Company nor any of its subsidiaries is in violation of, or in default under, any of the Permits or has received any notice of proceedings relating to the revocation or modification of, or non-compliance with, any such certificate, authorization or permit.

(y) Title to Properties. Except as otherwise disclosed in the Prospectus, the Company and its subsidiaries have good and marketable title to all of the real and personal property and other assets reflected as owned in the financial statements referred to in Section 2(i) above (or elsewhere in the Registration Statement or the Prospectus), in each case free and clear of any security interests, mortgages, liens, encumbrances, equities, adverse claims and other defects, except such defects as are described in the Registration Statement or the Prospectus or such as would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect. The real property, improvements, equipment and personal property held under lease by the Company or any of its subsidiaries are held under valid and enforceable leases, with such exceptions as are not material and do not materially interfere with the use made or proposed to be made of such real property, improvements, equipment or personal property by the Company or such subsidiary.

(z) Tax Law Compliance. The Company and its subsidiaries have filed all necessary federal, state and foreign income and franchise tax returns, or have properly requested extensions thereof and have paid all taxes required to be paid by any of them and, if due and payable, any related or similar assessment, fine or penalty levied against any of them except as may be being contested in good faith and by appropriate proceedings. The Company has made adequate charges, accruals and reserves, in conformity with generally accepted accounting principles, in the applicable financial statements referred to in Section 2(i) above in respect of all federal, state and foreign income and franchise taxes for all periods as to which the tax liability of the Company or any of its subsidiaries has not been finally determined.

(aa) Insurance. Except as otherwise disclosed in the Prospectus, each of the Company and its subsidiaries are insured by recognized, financially sound and reputable institutions with policies in such amounts and with such deductibles and covering such risks as are generally deemed adequate and customary for their businesses including, but not limited to, policies covering real and personal property owned or leased by the Company and its subsidiaries against theft, damage, destruction, acts of vandalism and earthquakes and policies covering the Company and its subsidiaries for product liability claims and clinical trial liability claims. The Company has no reason to believe that it or any of its subsidiaries will not be able (i) to renew its existing insurance coverage as and when such policies expire or (ii) to obtain comparable coverage from similar institutions as may be necessary or appropriate to conduct its business as now conducted and at a cost that would not reasonably be expected to have a Material Adverse Effect. Neither the Company nor any of its subsidiaries has been denied any insurance coverage which it has sought or for which it has applied.

(bb) Compliance with Environmental Laws. Except as described in the Prospectus and except as would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect: (i) neither the Company nor any of its subsidiaries is in violation of any federal, state, local or foreign statute, law, rule, regulation, ordinance, code, policy or rule of common law or any judicial or administrative interpretation thereof, including any judicial or administrative order, consent, decree or judgment, relating to pollution or protection of human health, the environment (including, without limitation, ambient air, surface water, groundwater, land surface or subsurface strata) or wildlife, including, without limitation, laws and regulations relating to the release or threatened release of chemicals, pollutants, contaminants, wastes, toxic substances, hazardous substances, petroleum or petroleum products (collectively, "**Hazardous Materials**") or to the manufacture, processing, distribution, use, treatment, storage, disposal, transport or handling

of Hazardous Materials (collectively, "**Environmental Laws**"); (ii) the Company and its subsidiaries have all permits, authorizations and approvals required under any applicable Environmental Laws and are each in compliance with their requirements; (iii) there are no pending or, to the Company's knowledge, threatened administrative, regulatory or judicial actions, suits, demands, demand letters, claims, liens, notices of noncompliance or violation, investigation or proceedings relating to any Environmental Law against the Company or any of its subsidiaries; and (iv) to the Company's knowledge, there are no events or circumstances that would reasonably be expected to form the basis of an order for clean-up or remediation, or an action, suit or proceeding by any private party or governmental body or agency, against or affecting the Company or any of its subsidiaries relating to Hazardous Materials or any Environmental Laws.

(cc) Company Not an "Investment Company." The Company is not, and will not be, either after receipt of payment for the Shares or after the application of the proceeds therefrom as described under "Use of Proceeds" in the Registration Statement or the Prospectus, required to register as an "investment company" under the Investment Company Act of 1940, as amended (the "**Investment Company Act**").

(dd) No Price Stabilization or Manipulation; Compliance with Regulation M. Neither the Company nor any of its subsidiaries has taken, directly or indirectly, any action designed to or that would reasonably be expected to cause or result in stabilization or manipulation of the price of the Common Shares or of any "reference security" (as defined in Rule 100 of Regulation M under the Exchange Act ("**Regulation M**")) with respect to the Common Shares, whether to facilitate the sale or resale of the Shares or otherwise, and has taken no action which would directly or indirectly violate Regulation M.

(ee) Related-Party Transactions. There are no business relationships or related-party transactions involving the Company or any of its subsidiaries or any other person required to be described in the Registration Statement or the Prospectus that have not been described as required.

(ff) FINRA Matters. All of the information provided to the Agent or to counsel for the Agent by the Company, its counsel, its officers and directors and the holders of any securities (debt or equity) or options to acquire any securities of the Company in connection with the offering of the Shares is true, complete, correct and compliant with FINRA's rules and any letters, filings or other supplemental information provided to FINRA pursuant to FINRA Rules or NASD Conduct Rules is true, complete and correct.

(gg) Statistical and Market-Related Data. All statistical, demographic and market-related data included in the Registration Statement or the Prospectus are based on or derived from sources that the Company believes, after reasonable inquiry, to be reliable and accurate. To the extent required, the Company has obtained the written consent to the use of such data from such sources.

(hh) Sarbanes-Oxley Act. The Company is in compliance with all applicable provisions of the Sarbanes-Oxley Act and the rules and regulations of the Commission thereunder.

(ii) Anti-Bribery and Anti-Money Laundering Laws. Each of the Company, its subsidiaries, its Affiliates and any of their respective officers, directors, supervisors, managers,

agents, or employees, has not violated, its participation in the offering will not violate, and the Company and each of its subsidiaries has instituted and maintains policies and procedures designed to ensure continued compliance with, each of the following laws: (A) anti-bribery laws, including but not limited to, any applicable law, rule, or regulation of any locality, including but not limited to any law, rule, or regulation promulgated to implement the OECD Convention on Combating Bribery of Foreign Public Officials in International Business Transactions, signed December 17, 1997, including the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.K. Bribery Act 2010, or any other law, rule or regulation of similar purposes and scope or (B) anti-money laundering laws, including but not limited to, applicable federal, state, international, foreign or other laws, regulations or government guidance regarding anti-money laundering, including, without limitation, Title 18 U.S. Code section 1956 and 1957, the Patriot Act, the Bank Secrecy Act, and international anti-money laundering principles or procedures by an intergovernmental group or organization, such as the Financial Action Task Force on Money Laundering, of which the United States is a member and with which designation the United States representative to the group or organization continues to concur, all as amended, and any Executive order, directive, or regulation pursuant to the authority of any of the foregoing, or any orders or licenses issued thereunder.

(jj) OFAC.

(A) Neither the Company nor any of its subsidiaries, nor any or their directors, officers or employees, nor, to the Company's knowledge, any agent, Affiliate or representative of the Company or its subsidiaries, is an individual or entity that is, or is owned or controlled by an individual or entity that is:

(1) the subject of any sanctions administered or enforced by the U.S. Department of Treasury's Office of Foreign Assets Control, the United Nations Security Council, the European Union, Her Majesty's Treasury, or other relevant sanctions authority (collectively, "**Sanctions**"), nor

(2) located, organized or resident in a country or territory that is the subject of Sanctions (including, without limitation, Crimea, Cuba, Iran, Libya, North Korea and Syria).

(B) Neither the Company nor any of its subsidiaries will, directly or indirectly, use the proceeds of the offering, or lend, contribute or otherwise make available such proceeds to any subsidiary, joint venture partner or other individual or entity:

(1) to fund or facilitate any activities or business of or with any individual or entity or in any country or territory that, at the time of such funding or facilitation, is the subject of Sanctions; or

(2) in any other manner that will result in a violation of Sanctions by any individual or entity (including any individual or entity participating in the offering, whether as underwriter, advisor, investor or otherwise).

(C) For the past five years, neither the Company nor any of its subsidiaries has knowingly engaged in, and is not now knowingly engaged in, any dealings or transactions with any individual or entity, or in any country or territory, that at the time of the dealing or transaction is or was the subject of Sanctions.

(kk) Compliance with Occupational Laws. The Company and each of its subsidiaries (A) is in compliance, in all material respects, with any and all applicable foreign, federal, state and local laws, rules, regulations, treaties, statutes and codes promulgated by any and all Governmental Authorities (including pursuant to the Occupational Health and Safety Act) relating to the protection of human health and safety in the workplace ("**Occupational Laws**"); (B) has received all material permits, licenses or other approvals required of it under applicable Occupational Laws to conduct its business as currently conducted; and (C) is in compliance, in all material respects, with all terms and conditions of such permit, license or approval. No action, proceeding, revocation proceeding, writ, injunction or claim is pending or, to the Company's knowledge, threatened against the Company or any of its subsidiaries relating to Occupational Laws, and the Company does not have knowledge of any facts, circumstances or developments relating to its operations or cost accounting practices that could reasonably be expected to form the basis for or give rise to such actions, suits, investigations or proceedings.

(ll) ERISA and Employee Benefits Matters. (A) To the knowledge of the Company, no "prohibited transaction" as defined under Section 406 of ERISA or Section 4975 of the Code and not exempt under ERISA Section 408 and the regulations and published interpretations thereunder has occurred or is reasonably expected to occur with respect to any Employee Benefit Plan. At no time has the Company, any subsidiary of the Company or any of their respective ERISA Affiliates maintained, sponsored, participated in, contributed to or has incurred, or reasonably expects to incur, any liability or obligation in respect of any Employee Benefit Plan subject to Part 3 of Subtitle B of Title I of ERISA, Title IV of ERISA, or Section 412 of the Code or any "multiemployer plan" as defined in Section 3(37) of ERISA or any multiple employer plan for which the Company, any subsidiary of the Company or any of their respective ERISA Affiliates has incurred or could incur liability under Section 4063 or 4064 of ERISA. No Employee Benefit Plan provides or promises, or at any time provided or promised, retiree health, life insurance, or other retiree welfare benefits except as may be required by the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended, or similar state law. Each Employee Benefit Plan is and has been operated in material compliance with its terms and all applicable laws, including but not limited to ERISA and the Code and, no event has occurred or is reasonably expected to occur (including a "reportable event" as such term is defined in Section 4043(c) of ERISA) and no condition exists that would subject the Company, any subsidiary of the Company or any of their respective ERISA Affiliates to any material tax, fine, lien, penalty or liability imposed by ERISA, the Code or other applicable law. Each Employee Benefit Plan intended to be qualified under Code Section 401(a) is so qualified and has a favorable determination or opinion letter from the Internal Revenue Service upon which it can rely, and any such determination or opinion letter remains in effect and has not been revoked; to the knowledge of the Company, nothing has occurred since the date of any such determination or opinion letter that is reasonably likely to adversely affect such qualification; (B) with respect to each Foreign Benefit Plan, such Foreign Benefit Plan (1) if intended to qualify for special tax treatment, meets, in all material respects, the requirements for such treatment, and (2) if required to be funded, is funded to the extent required

by applicable law, and with respect to all other Foreign Benefit Plans, adequate reserves therefor have been established on the accounting statements of the applicable Company or subsidiary; and (C) neither the Company nor any subsidiary of the Company does has any obligations under any collective bargaining agreement with any union and no organization efforts are underway with respect to its employees. As used in this Agreement, **"Code"** means the Internal Revenue Code of 1986, as amended; **"Employee Benefit Plan"** means any "employee benefit plan" within the meaning of Section 3(3) of ERISA, including, without limitation, all stock purchase, stock option, stock-based severance, employment, change-in-control, medical, disability, fringe benefit, bonus, incentive, deferred compensation, employee loan and all other employee benefit plans, agreements, programs, policies or other arrangements, whether or not subject to ERISA, under which (x) any current or former employee, director or independent contractor of the Company or its subsidiaries has any present or future right to benefits or payments and which are contributed to, sponsored by or maintained by the Company or any of its respective subsidiaries or (y) the Company or any of its subsidiaries has had or has any present or future obligation or liability; **"ERISA"** means the Employee Retirement Income Security Act of 1974, as amended; **"ERISA Affiliate"** means any member of a company's controlled group as defined in Code Section 414(b), (c), (m) or (o); and **"Foreign Benefit Plan"** means any Employee Benefit Plan established, maintained or contributed to outside of the United States of America or which covers any employee working or residing outside of the United States of America.

(mm) Restrictions on Subsidiary Payments to the Company. No subsidiary of the Company is currently prohibited, directly or indirectly, from paying any dividends to the Company, from making any other distribution on such subsidiary's capital stock, from repaying to the Company any loans or advances to such subsidiary from the Company or from transferring any of such subsidiary's property or assets to the Company or any other subsidiary of the Company, except as described in or contemplated by the Prospectus.

(nn) Disclosure of Legal Matters. There are no statutes, regulations, legal or governmental proceedings or contracts or other documents required to be described in the Prospectus or included as exhibits to the Registration Statement that are not described or included as required.

(oo) Statistical Information. Any third-party statistical and market-related data included in the Registration Statement and the Prospectus are based on or derived from sources that the Company believes to be reliable and accurate in all material respects.

(pp) Brokers. Except pursuant to this Agreement, there is no broker, finder or other party that is entitled to receive from the Company any brokerage or finder's fee or other fee or commission as a result of any transactions contemplated by this Agreement.

(qq) Forward-Looking Statements. Each financial or operational projection or other "forward-looking statement" (as defined by Section 27A of the Securities Act or Section 21E of the Exchange Act) contained in the Registration Statement or the Prospectus (i) was so included by the Company in good faith and with reasonable basis after due consideration by the Company of the underlying assumptions, estimates and other applicable facts and circumstances and (ii) is accompanied by meaningful cautionary statements identifying those factors that could cause actual results to differ materially from those in such forward-looking statement. No such statement was

made with the knowledge of an executive officer or director of the Company that is was false or misleading.

(rr) Emerging Growth Company Status. From the time of the initial filing of the Company's first registration statement with the Commission through the date hereof, the Company has been and is an "emerging growth company," as defined in Section 2(a) of the Securities Act.

(ss) No Contract Terminations. Neither the Company nor any of its subsidiaries has sent or received any communication regarding termination of, or intent not to renew, any of the contracts or agreements referred to or described in the Prospectus or any Free Writing Prospectus, or referred to or described in, or filed as an exhibit to, the Registration Statement, or any document incorporated by reference therein, and no such termination or non-renewal has been threatened by the Company or any of its subsidiaries or, to the Company's knowledge, any other party to any such contract or agreement, which threat of termination or non-renewal has not been rescinded as of the date hereof.

(tt) Cybersecurity. (i) Except as may be included or incorporated by reference in the Registration Statement and the Prospectus, (x) to the Company's knowledge, there has been no material security breach or other material compromise of or relating to any of the Company's information technology and computer systems, networks, hardware, software, data (including the data of their respective customers, employees, suppliers, vendors and any third party data maintained by or on behalf of them), equipment or technology (collectively, "**IT Systems and Data**") and (y) the Company has not been notified of, and have no knowledge of any event or condition that would reasonably be expected to result in, any material security breach or other material compromise to their IT Systems and Data; (ii) the Company is presently in compliance with all applicable laws or statutes and all judgments, orders, rules and regulations of any court or arbitrator or governmental or regulatory authority, internal policies and contractual obligations relating to the privacy and security of IT Systems and Data and to the protection of such IT Systems and Data from unauthorized use, access, misappropriation or modification, except as would not, in the case of this clause (ii), individually or in the aggregate, result in a Material Adverse Change; and (iii) the Company has implemented backup and disaster recovery technology consistent with industry standards and practices.

(uu) Incorporated Documents. The documents incorporated or deemed to be incorporated by reference in the Registration Statement and the Prospectus, at the time they were filed with the Commission, complied in all material respects with the requirements of the Exchange Act, as applicable, and, when read together with the other information in the Prospectus, do not contain an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading.

(vv) Exchange Act Compliance. The documents incorporated or deemed to be incorporated by reference in the Prospectus, at the time they were or hereafter are filed with the Commission, and any Free Writing Prospectus or amendment or supplement thereto complied and will comply in all material respects with the requirements of the Exchange Act, and, when read together with the other information in the Prospectus, at the time the Registration Statement and any amendments thereto become effective and at each Time of Sale (as defined below), as the case

may be, will not contain an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading.

(ww) Compliance with Data Privacy Laws. The Company and its subsidiaries are, and at all prior times were, in material compliance with all applicable state and federal data privacy and security laws and regulations, including without limitation HIPAA, and the Company and its subsidiaries have taken commercially reasonable actions to prepare to comply with, and since May 25, 2018, have been and currently are in compliance with, the European Union General Data Protection Regulation (EU 2016/679) (collectively, the "**Privacy Laws**"). To ensure compliance with the Privacy Laws, the Company and its subsidiaries have in place, comply with, and take appropriate steps reasonably designed to ensure compliance in all material respects with their policies and procedures relating to data privacy and security and the collection, storage, use, disclosure, handling, and analysis of personal data (the "**Policies**"). The Company and its subsidiaries have at all times made all disclosures to users or customers required by applicable laws and regulatory rules or requirements, and none of such disclosures made or contained in any Policy have, to the knowledge of the Company, been inaccurate or in violation of any applicable laws and regulatory rules or requirements in any material respect. The Company further certifies that neither it nor any subsidiary: (i) has received notice of any actual or potential liability under or relating to, or actual or potential violation of, any of the Privacy Laws, and has no knowledge of any event or condition that would reasonably be expected to result in any such notice; (ii) is currently conducting or paying for, in whole or in part, any investigation, remediation, or other corrective action pursuant to any Privacy Law; or (iii) is a party to any order, decree, or agreement that imposes any obligation or liability under any Privacy Law.

(xx) Other Underwriting Agreements. The Company is not a party to any agreement with an agent or underwriter for any other "at the market" or continuous equity transaction.

Any certificate signed by any officer or representative of the Company or any of its subsidiaries and delivered to the Agent or counsel for the Agent in connection with an issuance of Shares shall be deemed a representation and warranty by the Company to the Agent as to the matters covered thereby on the date of such certificate.

The Company acknowledges that the Agent and, for purposes of the opinions to be delivered pursuant to Section 4(o) hereof, counsel to the Company and counsel to the Agent, will rely upon the accuracy and truthfulness of the foregoing representations and hereby consents to such reliance.

Section 3. ISSUANCE AND SALE OF COMMON SHARES

(a) Sale of Securities. On the basis of the representations, warranties and agreements herein contained, but subject to the terms and conditions herein set forth, the Company and the Agent agree that the Company may from time to time seek to sell Shares through the Agent, acting as sales agent, or directly to the Agent, acting as principal, as follows, with an aggregate Sales Price of up to the Maximum Program Amount, based on and in accordance with Issuance Notices as the Company may deliver, during the Agency Period.

(b) Mechanics of Issuances.

(i) Issuance Notice. Upon the terms and subject to the conditions set forth herein, on any Trading Day during the Agency Period on which the conditions set forth in Section 5(a) and Section 5(b) shall have been satisfied, the Company may exercise its right to request an issuance of Shares by delivering to the Agent an Issuance Notice; *provided*, *however*, that (A) in no event may the Company deliver an Issuance Notice to the extent that (I) the sum of (x) the aggregate Sales Price of the requested Issuance Amount, plus (y) the aggregate Sales Price of all Shares issued under all previous Issuance Notices effected pursuant to this Agreement, would exceed the Maximum Program Amount; and (B) prior to delivery of any Issuance Notice, the period set forth for any previous Issuance Notice shall have expired or been terminated. An Issuance Notice shall be considered delivered on the Trading Day that it is received by e-mail to the persons set forth in Schedule A hereto and confirmed by the Company by telephone (including a voicemail message to the persons so identified), with the understanding that, with adequate prior written notice, the Agent may modify the list of such persons from time to time.

(ii) Agent Efforts. Upon the terms and subject to the conditions set forth in this Agreement, upon the receipt of an Issuance Notice, the Agent will use its commercially reasonable efforts consistent with its normal sales and trading practices to place the Shares with respect to which the Agent has agreed to act as sales agent, subject to, and in accordance with the information specified in, the Issuance Notice, unless the sale of the Shares described therein has been suspended, cancelled or otherwise terminated in accordance with the terms of this Agreement. For the avoidance of doubt, the parties to this Agreement may modify an Issuance Notice at any time provided they both agree in writing to any such modification.

(iii) Method of Offer and Sale. The Shares may be offered and sold (A) in privately negotiated transactions with the consent of the Company; (B) as block transactions; or (C) by any other method permitted by law deemed to be an "at the market offering" as defined in Rule 415(a)(4) under the Securities Act, including sales made directly on the Principal Market or sales made into any other existing trading market of the Common Shares. Nothing in this Agreement shall be deemed to require either party to agree to the method of offer and sale specified in the preceding sentence, and (except as specified in clauses (A) and (B) above) the method of placement of any Shares by the Agent shall be at the Agent's discretion.

(iv) Confirmation to the Company. If acting as sales agent hereunder, the Agent will provide written confirmation to the Company no later than the opening of the Trading Day next following the Trading Day on which it has placed Shares hereunder setting forth the number of shares sold on such Trading Day, the corresponding Sales Price and the Issuance Price payable to the Company in respect thereof.

(v) Settlement. Each issuance of Shares will be settled on the applicable Settlement Date for such issuance of Shares and, subject to the provisions of Section 5, on or before each Settlement Date, the Company will, or will cause its transfer agent to, electronically transfer the Shares being sold by crediting the Agent or its designee's account at The Depository Trust Company through its Deposit/Withdrawal At Custodian (DWAC) System, or by such other means of delivery as may be mutually agreed upon by the parties hereto and, upon receipt of such Shares, which in all cases shall be freely tradable, transferable, registered shares in good deliverable form,

the Agent will deliver, by wire transfer of immediately available funds, the related Issuance Price in same day funds delivered to an account designated by the Company prior to the Settlement Date. The Company may sell Shares to the Agent as principal at a price agreed upon at each relevant time Shares are sold pursuant to this Agreement (each, a "**Time of Sale**").

(vi) Suspension or Termination of Sales. Consistent with standard market settlement practices, the Company or the Agent may, upon notice to the other party hereto in writing or by telephone (confirmed immediately by verifiable email), suspend any sale of Shares, and the period set forth in an Issuance Notice shall immediately terminate; *provided*, *however*, that (A) such suspension and termination shall not affect or impair either party's obligations with respect to any Shares placed or sold hereunder prior to the receipt of such notice; (B) if the Company suspends or terminates any sale of Shares after the Agent confirms such sale to the Company, the Company shall still be obligated to comply with Section 3(b)(v) with respect to such Shares; and (C) if the Company defaults in its obligation to deliver Shares on a Settlement Date, the Company agrees that it will hold the Agent harmless against any loss, claim, damage or expense (including, without limitation, penalties, interest and reasonable legal fees and expenses), as incurred, arising out of or in connection with such default by the Company. The parties hereto acknowledge and agree that, in performing its obligations under this Agreement, the Agent may borrow Common Shares from stock lenders in the event that the Company has not delivered Shares to settle sales as required by subsection (v) above, and may use the Shares to settle or close out such borrowings. The Company agrees that no such notice shall be effective against the Agent unless it is made to the persons identified in writing by the Agent pursuant to Section 3(b)(i).

(vii) No Guarantee of Placement, Etc. The Company acknowledges and agrees that (A) there can be no assurance that the Agent will be successful in placing Shares; (B) the Agent will incur no liability or obligation to the Company or any other Person if it does not sell Shares; and (C) the Agent shall be under no obligation to purchase Shares on a principal basis pursuant to this Agreement, except as otherwise specifically agreed by the Agent and the Company.

(viii) Material Non-Public Information. Notwithstanding any other provision of this Agreement, the Company and the Agent agree that the Company shall not deliver any Issuance Notice to the Agent, and the Agent shall not be obligated to place any Shares, during any period in which the Company is in possession of material non-public information.

(c) Fees. As compensation for services rendered, the Company shall pay to the Agent, on the applicable Settlement Date, the Selling Commission for the applicable Issuance Amount (including with respect to any suspended or terminated sale pursuant to Section 3(b)(vi)) by the Agent deducting the Selling Commission from the applicable Issuance Amount.

(d) Expenses. The Company agrees to pay all costs, fees and expenses incurred in connection with the performance of its obligations hereunder and in connection with the transactions contemplated hereby, including without limitation (i) all expenses incident to the issuance and delivery of the Shares (including all printing and engraving costs); (ii) all fees and expenses of the registrar and transfer agent of the Shares; (iii) all necessary issue, transfer and other stamp taxes in connection with the issuance and sale of the Shares; (iv) all fees and expenses of the Company's counsel, independent public or certified public accountants and other advisors; (v) all costs and expenses incurred in connection with the preparation, printing, filing, shipping

and distribution of the Registration Statement (including financial statements, exhibits, schedules, consents and certificates of experts), the Prospectus, any Free Writing Prospectus prepared by or on behalf of, used by, or referred to by the Company, and all amendments and supplements thereto, and this Agreement; (vi) all filing fees, attorneys' fees and expenses incurred by the Company or the Agent in connection with qualifying or registering (or obtaining exemptions from the qualification or registration of) all or any part of the Shares for offer and sale under the state securities or blue sky laws or the provincial securities laws of Canada, and, if requested by the Agent, preparing and printing a "Blue Sky Survey" or memorandum and a "Canadian wrapper," and any supplements thereto, advising the Agent of such qualifications, registrations, determinations and exemptions; (vii) the reasonable fees and disbursements of the Agent's counsel, including the reasonable fees and expenses of counsel for the Agent in connection with, FINRA review, if any, and approval of the Agent's participation in the offering and distribution of the Shares; (viii) the filing fees incident to FINRA review, if any; and (ix) all fees, expenses and disbursements relating to background checks of the Company's directors, director nominees and executive officers; and (x) the fees and expenses associated with listing the Shares on the Principal Market. The fees and disbursements of the Agent's counsel pursuant to subsections (vi) and (vii) above shall not exceed $50,000.

Section 4. ADDITIONAL COVENANTS

The Company covenants and agrees with the Agent as follows, in addition to any other covenants and agreements made elsewhere in this Agreement:

(a) Exchange Act Compliance. During the Agency Period, the Company shall (i) file, on a timely basis, with the Commission all reports and documents required to be filed under Section 13, 14 or 15 of the Exchange Act in the manner and within the time periods required by the Exchange Act; and (ii) either (A) include in its quarterly reports on Form 10-Q and its annual reports on Form 10-K, a summary detailing, for the relevant reporting period, (1) the number of Shares sold through the Agent pursuant to this Agreement and (2) the net proceeds received by the Company from such sales or (B) prepare a prospectus supplement containing, or include in such other filing permitted by the Securities Act or Exchange Act (each an "**Interim Prospectus Supplement**"), such summary information and, at least once a quarter and subject to this Section 4, file such Interim Prospectus Supplement pursuant to Rule 424(b) under the Securities Act (and within the time periods required by Rule 424(b) and Rule 430B under the Securities Act).

(b) Securities Act Compliance. After the date of this Agreement, the Company shall promptly advise the Agent in writing (i) of the receipt of any comments of, or requests for additional or supplemental information from, the Commission; (ii) of the time and date of any filing of any post-effective amendment to the Registration Statement, any Rule 462(b) Registration Statement or any amendment or supplement to the Prospectus, or any Free Writing Prospectus; (iii) of the time and date that any post-effective amendment to the Registration Statement or any Rule 462(b) Registration Statement becomes effective; and (iv) of the issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement or any post-effective amendment thereto, any Rule 462(b) Registration Statement or any amendment or supplement to the Prospectus or of any order preventing or suspending the use of any Free Writing Prospectus or the Prospectus, or of any proceedings to remove, suspend or terminate from listing or quotation the Common Shares from any securities exchange upon which they are listed for trading or

included or designated for quotation, or of the threatening or initiation of any proceedings for any of such purposes. If the Commission shall enter any such stop order at any time, the Company will use its best efforts to obtain the lifting of such order at the earliest possible moment. Additionally, the Company agrees that it shall comply with the provisions of Rule 424(b) and Rule 433, as applicable, under the Securities Act and will use its reasonable efforts to confirm that any filings made by the Company under such Rule 424(b) or Rule 433 were received in a timely manner by the Commission.

(c) Amendments and Supplements to the Prospectus and Other Securities Act Matters. If any event shall occur or condition exist as a result of which it is necessary to amend or supplement the Prospectus so that the Prospectus does not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances when the Prospectus is delivered to a purchaser, not misleading, or if in the opinion of the Agent or counsel for the Agent it is otherwise necessary to amend or supplement the Prospectus to comply with applicable law, including the Securities Act, the Company agrees (subject to Section 4(d) and 4(f)) to promptly prepare, file with the Commission and furnish at its own expense to the Agent, amendments or supplements to the Prospectus so that the statements in the Prospectus as so amended or supplemented will not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances when the Prospectus is delivered to a purchaser, not be misleading or so that the Prospectus, as amended or supplemented, will comply with applicable law including the Securities Act. Neither the Agent's consent to, or delivery of, any such amendment or supplement shall constitute a waiver of any of the Company's obligations under Sections 4(d) and 4(f).

(d) Agent's Review of Proposed Amendments and Supplements. Prior to amending or supplementing the Registration Statement (including any registration statement filed under Rule 462(b) under the Securities Act) or the Prospectus (excluding any amendment or supplement through incorporation of any report filed under the Exchange Act), the Company shall furnish to the Agent for review, a reasonable amount of time prior to the proposed time of filing or use thereof, a copy of each such proposed amendment or supplement, and the Company shall not file or use any such proposed amendment or supplement without the Agent's prior consent, and to file with the Commission within the applicable period specified in Rule 424(b) under the Securities Act any prospectus required to be filed pursuant to such Rule.

(e) Use of Free Writing Prospectus. Neither the Company nor the Agent has prepared, used, referred to or distributed, or will prepare, use, refer to or distribute, without the other party's prior written consent, any "written communication" that constitutes a "free writing prospectus" as such terms are defined in Rule 405 under the Securities Act with respect to the offering contemplated by this Agreement (any such free writing prospectus being referred to herein as a "**Free Writing Prospectus**").

(f) Free Writing Prospectuses. The Company shall furnish to the Agent for review, a reasonable amount of time prior to the proposed time of filing or use thereof, a copy of each proposed free writing prospectus or any amendment or supplement thereto to be prepared by or on behalf of, used by, or referred to by the Company and the Company shall not file, use or refer to any proposed free writing prospectus or any amendment or supplement thereto without the Agent's consent. The Company shall furnish to the Agent, without charge, as many copies of any free

writing prospectus prepared by or on behalf of, or used by the Company, as the Agent may reasonably request. If at any time when a prospectus is required by the Securities Act (including, without limitation, pursuant to Rule 173(d)) to be delivered in connection with sales of the Shares (but in any event if at any time through and including the date of this Agreement) there occurred or occurs an event or development as a result of which any free writing prospectus prepared by or on behalf of, used by, or referred to by the Company conflicted or would conflict with the information contained in the Registration Statement or included or would include an untrue statement of a material fact or omitted or would omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances prevailing at that subsequent time, not misleading, the Company shall promptly amend or supplement such free writing prospectus to eliminate or correct such conflict or so that the statements in such free writing prospectus as so amended or supplemented will not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances prevailing at such subsequent time, not misleading, as the case may be; *provided*, *however*, that prior to amending or supplementing any such free writing prospectus, the Company shall furnish to the Agent for review, a reasonable amount of time prior to the proposed time of filing or use thereof, a copy of such proposed amended or supplemented free writing prospectus and the Company shall not file, use or refer to any such amended or supplemented free writing prospectus without the Agent's consent.

(g) Filing of Agent Free Writing Prospectuses. The Company shall not take any action that would result in the Agent or the Company being required to file with the Commission pursuant to Rule 433(d) under the Securities Act a free writing prospectus prepared by or on behalf of the Agent that the Agent otherwise would not have been required to file thereunder.

(h) Copies of Registration Statement and Prospectus. After the date of this Agreement through the last time that a prospectus is required by the Securities Act (including, without limitation, pursuant to Rule 173(d)) to be delivered in connection with sales of the Shares, the Company agrees to furnish the Agent with copies (which may be electronic copies) of the Registration Statement and each amendment thereto, and with copies of the Prospectus and each amendment or supplement thereto in the form in which it is filed with the Commission pursuant to the Securities Act or Rule 424(b) under the Securities Act, both in such quantities as the Agent may reasonably request from time to time; and, if the delivery of a prospectus is required under the Securities Act or under the blue sky or securities laws of any jurisdiction at any time on or prior to the applicable Settlement Date for any period set forth in an Issuance Notice in connection with the offering or sale of the Shares and if at such time any event has occurred as a result of which the Prospectus as then amended or supplemented would include an untrue statement of a material fact or omit to state any material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made when such Prospectus is delivered, not misleading, or, if for any other reason it is necessary during such same period to amend or supplement the Prospectus or to file under the Exchange Act any document incorporated by reference in the Prospectus in order to comply with the Securities Act or the Exchange Act, to notify the Agent and to request that the Agent suspend offers to sell Shares (and, if so notified, the Agent shall cease such offers as soon as practicable); and if the Company decides to amend or supplement the Registration Statement or the Prospectus as then amended or supplemented, to advise the Agent promptly by telephone (with confirmation in writing) and to prepare and cause to be filed promptly with the Commission an amendment or supplement to the Registration

Statement or the Prospectus as then amended or supplemented that will correct such statement or omission or effect such compliance; provided, however, that if during such same period the Agent is required to deliver a prospectus in respect of transactions in the Shares, the Company shall promptly prepare and file with the Commission such an amendment or supplement.

(i) Blue Sky Compliance. The Company shall cooperate with the Agent and counsel for the Agent to qualify or register the Shares for sale under (or obtain exemptions from the application of) the state securities or blue sky laws or Canadian provincial securities laws of those jurisdictions designated by the Agent, shall comply with such laws and shall continue such qualifications, registrations and exemptions in effect so long as required for the distribution of the Shares. The Company shall not be required to qualify as a foreign corporation or to take any action that would subject it to general service of process in any such jurisdiction where it is not presently qualified or where it would be subject to taxation as a foreign corporation. The Company will advise the Agent promptly of the suspension of the qualification or registration of (or any such exemption relating to) the Shares for offering, sale or trading in any jurisdiction or any initiation or threat of any proceeding for any such purpose, and in the event of the issuance of any order suspending such qualification, registration or exemption, the Company shall use its best efforts to obtain the withdrawal thereof at the earliest possible moment.

(j) Earnings Statement. As soon as practicable, the Company will make generally available to its security holders and to the Agent an earnings statement (which need not be audited) covering a period of at least twelve months beginning with the first fiscal quarter of the Company occurring after the date of this Agreement which shall satisfy the provisions of Section 11(a) of the Securities Act and Rule 158 under the Securities Act.

(k) Listing; Reservation of Shares. (a) The Company will maintain the listing of the Shares on the Principal Market; and (b) the Company will reserve and keep available at all times, free of preemptive rights, Shares for the purpose of enabling the Company to satisfy its obligations under this Agreement.

(l) Transfer Agent. The Company shall engage and maintain, at its expense, a registrar and transfer agent for the Shares.

(m) Due Diligence. During the term of this Agreement, the Company will reasonably cooperate with any reasonable due diligence review conducted by the Agent in connection with the transactions contemplated hereby, including, without limitation, providing information and making available documents and senior corporate officers, during normal business hours and at the Company's principal offices, as the Agent may reasonably request from time to time.

(n) Representations and Warranties. The Company acknowledges that each delivery of an Issuance Notice and each delivery of Shares on a Settlement Date shall be deemed to be (i) an affirmation to the Agent that the representations and warranties of the Company contained in or made pursuant to this Agreement are true and correct as of the date of such Issuance Notice or of such Settlement Date, as the case may be, as though made at and as of each such date, except as may be disclosed in the Prospectus (including any documents incorporated by reference therein and any supplements thereto); and (ii) an undertaking that the Company will advise the Agent if any of such representations and warranties will not be true and correct as of the Settlement Date

for the Shares relating to such Issuance Notice, as though made at and as of each such date (except that such representations and warranties shall be deemed to relate to the Registration Statement and the Prospectus as amended and supplemented relating to such Shares).

(o) Deliverables at Triggering Event Dates; Certificates. The Company agrees that on or prior to the date of the first Issuance Notice and, during the term of this Agreement after the date of the first Issuance Notice, upon:

(A) the filing of the Prospectus or the amendment or supplement of any Registration Statement or Prospectus (other than a prospectus supplement relating solely to an offering of securities other than the Shares or a prospectus filed pursuant to Section 4(a)(ii)(B)), by means of a post-effective amendment, sticker or supplement, but not by means of incorporation of documents by reference into the Registration Statement or Prospectus;

(B) the filing with the Commission of an annual report on Form 10-K or a quarterly report on Form 10-Q (including any Form 10-K/A or Form 10-Q/A containing amended financial information or a material amendment to the previously filed annual report on Form 10-K or quarterly report on Form 10-Q), in each case, of the Company; or

(C) the filing with the Commission of a current report on Form 8-K of the Company containing amended financial information (other than information "furnished" pursuant to Item 2.02 or 7.01 of Form 8-K or to provide disclosure pursuant to Item 8.01 of Form 8-K relating to reclassification of certain properties as discontinued operations in accordance with Statement of Financial Accounting Standards No. 144) that is material to the offering of securities of the Company in the Agent's reasonable discretion;

(any such event, a "**Triggering Event Date**"), the Company shall furnish the Agent (but in the case of clause (C) above only if the Agent reasonably determines that the information contained in such current report on Form 8-K of the Company is material) with a certificate as of the Triggering Event Date, in the form and substance satisfactory to the Agent and its counsel, substantially similar to the form previously provided to the Agent and its counsel, modified, as necessary, to relate to the Registration Statement and the Prospectus as amended or supplemented, (A) confirming that the representations and warranties of the Company contained in this Agreement are true and correct, (B) that the Company has performed all of its obligations hereunder to be performed on or prior to the date of such certificate and as to the matters set forth in Section 5(a)(iii) hereof, and (C) containing any other certification that the Agent shall reasonably request. The requirement to provide a certificate under this Section 4(o) shall be waived for any Triggering Event Date occurring at a time when no Issuance Notice is pending or a suspension is in effect, which waiver shall continue until the earlier to occur of the date the Company delivers instructions for the sale of Shares hereunder (which for such calendar quarter shall be considered a Triggering Event Date) and the next occurring Triggering Event Date. Notwithstanding the foregoing, if the Company subsequently decides to sell Shares following a Triggering Event Date when a suspension was in effect and did not provide the Agent with a certificate under this Section 4(o), then before the Company delivers the instructions for the sale of Shares or the Agent sells any Shares pursuant to such instructions, the Company shall provide the Agent with a certificate in conformity with this Section 4(o) dated as of the date that the instructions for the sale of Shares are issued.

(p) Legal Opinions. On or prior to the date of the first Issuance Notice and on or prior to each Triggering Event Date with respect to which the Company is obligated to deliver a certificate pursuant to Section 4(o) for which no waiver is applicable and excluding the date of this Agreement, a negative assurances letter and the written legal opinion of Cooley LLP, counsel to the Company, Latham & Watkins LLP, counsel to the Agent, and Kilpatrick Townsend & Stockton LLP, intellectual property counsel to the Company, each dated the date of delivery, each in form and substance reasonably satisfactory to the Agent and its counsel, substantially similar to the form previously provided to the Agent and its counsel, modified, as necessary, to relate to the Registration Statement and the Prospectus as then amended or supplemented. In lieu of such opinions for subsequent periodic filings, in the discretion of the Agent, the Company may furnish a reliance letter from such counsel to the Agent, permitting the Agent to rely on a previously delivered opinion letter, modified as appropriate for any passage of time or Triggering Event Date (except that statements in such prior opinion shall be deemed to relate to the Registration Statement and the Prospectus as amended or supplemented as of such Triggering Event Date).

(q) Comfort Letter. On or prior to the date of the first Issuance Notice and on or prior to each Triggering Event Date with respect to which the Company is obligated to deliver a certificate pursuant to Section 4(o) for which no waiver is applicable and excluding the date of this Agreement, the Company shall cause KPMG LLP, the independent registered public accounting firm who has audited the financial statements included or incorporated by reference in the Registration Statement, to furnish the Agent a comfort letter, dated the date of delivery, in form and substance reasonably satisfactory to the Agent and its counsel, substantially similar to the form previously provided to the Agent and its counsel; provided, however, that any such comfort letter will only be required on the Triggering Event Date specified to the extent that it contains financial statements filed with the Commission under the Exchange Act and incorporated or deemed to be incorporated by reference into a Prospectus. If requested by the Agent, the Company shall also cause a comfort letter to be furnished to the Agent within ten (10) Trading Days of the date of occurrence of any material transaction or event requiring the filing of a current report on Form 8-K containing material amended financial information of the Company, including the restatement of the Company's financial statements. The Company shall be required to furnish no more than one comfort letter hereunder per calendar quarter.

(r) Secretary's Certificate. On or prior to the date of the first Issuance Notice and on or prior to each Triggering Event Date, the Company shall furnish the Agent a certificate executed by the Secretary of the Company, signing in such capacity, dated the date of delivery (i) certifying that attached thereto are true and complete copies of the resolutions duly adopted by the Board of Directors of the Company authorizing the execution and delivery of this Agreement and the consummation of the transactions contemplated hereby (including, without limitation, the issuance of the Shares pursuant to this Agreement), which authorization shall be in full force and effect on and as of the date of such certificate, (ii) certifying and attesting to the office, incumbency, due authority and specimen signatures of each Person who executed this Agreement for or on behalf of the Company, and (iii) containing any other certification that the Agent shall reasonably request.

(s) Agent's Own Account; Clients' Account. The Company consents to the Agent trading, in compliance with applicable law, in the Common Shares for the Agent's own account and for the account of its clients at the same time as sales of the Shares occur pursuant to this Agreement.

(t) Investment Limitation. The Company shall not invest, or otherwise use the proceeds received by the Company from its sale of the Shares in such a manner as would require the Company or any of its subsidiaries to register as an investment company under the Investment Company Act.

(u) Market Activities. The Company will not take, directly or indirectly, any action designed to or that might be reasonably expected to cause or result in stabilization or manipulation of the price of the Shares or any other reference security, whether to facilitate the sale or resale of the Shares or otherwise, and the Company will, and shall cause each of its Affiliates to, comply with all applicable provisions of Regulation M. If the limitations of Rule 102 of Regulation M ("**Rule 102**") do not apply with respect to the Shares or any other reference security pursuant to any exception set forth in Section (d) of Rule 102, then promptly upon notice from the Agent (or, if later, at the time stated in the notice), the Company will, and shall cause each of its Affiliates to, comply with Rule 102 as though such exception were not available but the other provisions of Rule 102 (as interpreted by the Commission) did apply. The Company shall promptly notify the Agent if it no longer meets the requirements set forth in Section (d) of Rule 102.

(v) Notice of Other Sale. Without the written consent of the Agent, the Company will not, directly or indirectly, (i) offer to sell, sell, contract to sell, grant any option to sell or otherwise dispose of any Common Shares or securities convertible into or exchangeable for Common Shares (other than Shares hereunder), warrants or any rights to purchase or acquire Common Shares, during the period beginning on the third Trading Day immediately prior to the date on which any Issuance Notice is delivered to the Agent hereunder and ending on the third Trading Day immediately following the Settlement Date with respect to Shares sold pursuant to such Issuance Notice; (ii) effect a reverse stock split, recapitalization, share consolidation, reclassification or similar transaction affecting the outstanding Common Shares; or (iii) enter into any other "at the market" or continuous equity transaction offer to sell, sell, contract to sell, grant any option to sell or otherwise dispose of any Common Shares (other than the Shares offered pursuant to this Agreement) or securities convertible into or exchangeable for Common Shares, warrants or any rights to purchase or acquire, Common Shares prior to the termination of this Agreement; provided, however, that such restrictions will not be required in connection with the Company's (i) issuance or sale of Common Shares, options to purchase Common Shares or Common Shares issuable upon the exercise of options or other equity awards pursuant to any employee or director share option, incentive or benefit plan, share purchase or ownership plan, long-term incentive plan, dividend reinvestment plan, inducement award under Nasdaq rules or other compensation plan of the Company or its subsidiaries, as in effect on the date of this Agreement, (ii) issuance or sale of Common Shares issuable upon exchange, conversion or redemption of securities or the exercise or vesting of warrants, options or other equity awards outstanding at the date of this Agreement, and (iii) modification of any outstanding options, warrants of any rights to purchase or acquire Common Shares.

Section 5. CONDITIONS TO DELIVERY OF ISSUANCE NOTICES AND TO SETTLEMENT

(a) Conditions Precedent to the Right of the Company to Deliver an Issuance Notice and the Obligation of the Agent to Sell Shares. The right of the Company to deliver an Issuance Notice hereunder is subject to the satisfaction, on the date of delivery of such Issuance Notice, and

the obligation of the Agent to use its commercially reasonable efforts to place Shares during the applicable period set forth in the Issuance Notice is subject to the satisfaction, on each Trading Day during the applicable period set forth in the Issuance Notice, of each of the following conditions:

(i) Accuracy of the Company's Representations and Warranties; Performance by the Company. The Company shall have delivered the certificate required to be delivered pursuant to Section 4(o) on or before the date on which delivery of such certificate is required pursuant to Section 4(o). The Company shall have performed, satisfied and complied with all covenants, agreements and conditions required by this Agreement to be performed, satisfied or complied with by the Company at or prior to such date, including, but not limited to, the covenants contained in Section 4(p), Section 4(q) and Section 4(r).

(ii) No Injunction. No statute, rule, regulation, executive order, decree, ruling or injunction shall have been enacted, entered, promulgated or endorsed by any court or governmental authority of competent jurisdiction or any self-regulatory organization having authority over the matters contemplated hereby that prohibits or directly and materially adversely affects any of the transactions contemplated by this Agreement, and no proceeding shall have been commenced that may have the effect of prohibiting or materially adversely affecting any of the transactions contemplated by this Agreement.

(iii) Material Adverse Changes. Except as disclosed in the Prospectus and the Time of Sale Information, (a) in the judgment of the Agent there shall not have occurred any Material Adverse Change; and (b) there shall not have occurred any downgrading, nor shall any notice have been given of any intended or potential downgrading or of any review for a possible change that does not indicate the direction of the possible change, in the rating accorded any securities of the Company or any of its subsidiaries by any "nationally recognized statistical rating organization" as such term is defined for purposes of Section 3(a)(62) of the Exchange Act.

(iv) No Suspension of Trading in or Delisting of Common Shares; Other Events. The trading of the Common Shares (including without limitation the Shares) shall not have been suspended by the Commission, the Principal Market or FINRA and the Common Shares (including without limitation the Shares) shall have been approved for listing or quotation on and shall not have been delisted from the Nasdaq Stock Market, the New York Stock Exchange or any of their constituent markets. There shall not have occurred (and be continuing in the case of occurrences under clauses (i) and (ii) below) any of the following: (i) trading or quotation in any of the Company's securities shall have been suspended or limited by the Commission or by the Principal Market or trading in securities generally on either the Principal Market shall have been suspended or limited, or minimum or maximum prices shall have been generally established on any of such stock exchanges by the Commission or FINRA; (ii) a general banking moratorium shall have been declared by any of federal or New York, authorities; or (iii) there shall have occurred any outbreak or

escalation of national or international hostilities or any crisis or calamity, or any change in the United States or international financial markets, or any substantial change or development involving a prospective substantial change in United States' or international political, financial or economic conditions, as in the judgment of the Agent is material and adverse and makes it impracticable to market the Shares in the manner and on the terms described in the Prospectus or to enforce contracts for the sale of securities.

(b) Documents Required to be Delivered on each Issuance Notice Date. The Agent's obligation to use its commercially reasonable efforts to place Shares hereunder shall additionally be conditioned upon the delivery to the Agent on or before the Issuance Notice Date of a certificate in form and substance reasonably satisfactory to the Agent, executed by the Chief Executive Officer, President or Chief Financial Officer of the Company, to the effect that all conditions to the delivery of such Issuance Notice shall have been satisfied as at the date of such certificate (which certificate shall not be required if the foregoing representations shall be set forth in the Issuance Notice).

(c) No Misstatement or Material Omission. The Agent shall not have advised the Company that the Registration Statement, the Prospectus or the Time of Sales Information, or any amendment or supplement thereto, contains an untrue statement of fact that in the Agent's reasonable opinion is material, or omits to state a fact that in the Agent's reasonable opinion is material and is required to be stated therein or is necessary to make the statements therein not misleading.

Section 6. INDEMNIFICATION AND CONTRIBUTION

(a) Indemnification of the Agent. The Company agrees to indemnify and hold harmless the Agent, its officers and employees, and each person, if any, who controls the Agent within the meaning of the Securities Act or the Exchange Act against any loss, claim, damage, liability or expense, as incurred, to which the Agent or such officer, employee or controlling person may become subject, under the Securities Act, the Exchange Act, other federal or state statutory law or regulation, or the laws or regulations of foreign jurisdictions where Shares have been offered or sold or at common law or otherwise (including in settlement of any litigation), insofar as such loss, claim, damage, liability or expense (or actions in respect thereof as contemplated below) arises out of or is based upon: (i) any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement, or any amendment thereto, including any information deemed to be a part thereof pursuant to Rule 430B under the Securities Act, or the omission or alleged omission therefrom of a material fact required to be stated therein or necessary to make the statements therein not misleading; (ii) any untrue statement or alleged untrue statement of a material fact contained in any Free Writing Prospectus that the Company has used, referred to or filed, or is required to file, pursuant to Rule 433(d) of the Securities Act or the Prospectus (or any amendment or supplement thereto), or the omission or alleged omission therefrom of a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; or (iii) any act or failure to act or any alleged act or failure to act by the Agent in connection with, or relating in any manner to, the Common Shares or the offering contemplated hereby, and which is included as part of or referred to in any loss, claim, damage, liability or action arising out of or based upon any matter covered by clause (i) or (ii)

above, provided that the Company shall not be liable under this clause (iii) to the extent that a court of competent jurisdiction shall have determined by a final judgment that such loss, claim, damage, liability or action resulted directly from any such acts or failures to act undertaken or omitted to be taken by the Agent through its bad faith or willful misconduct, and to reimburse the Agent and each such officer, employee and controlling person for any and all expenses (including the fees and disbursements of counsel chosen by the Agent) as such expenses are reasonably incurred by the Agent or such officer, employee or controlling person in connection with investigating, defending, settling, compromising or paying any such loss, claim, damage, liability, expense or action; provided, however, that the foregoing indemnity agreement shall not apply to any loss, claim, damage, liability or expense to the extent, but only to the extent, arising out of or based upon any untrue statement or alleged untrue statement or omission or alleged omission made in reliance upon and in conformity with written information furnished to the Company by the Agent expressly for use in the Registration Statement, any such Free Writing Prospectus or the Prospectus (or any amendment or supplement thereto), it being understood and agreed that the only such information furnished by the Agent to the Company consists of the information set forth in the first sentence of the ninth paragraph under the caption "Plan of Distribution" in the Prospectus. The indemnity agreement set forth in this Section 6(a) shall be in addition to any liabilities that the Company may otherwise have.

(b) Notifications and Other Indemnification Procedures. Promptly after receipt by an indemnified party under this Section 6 of notice of the commencement of any action, such indemnified party will, if a claim in respect thereof is to be made against an indemnifying party under this Section 6, notify the indemnifying party in writing of the commencement thereof, but the omission to so notify the indemnifying party will not relieve it from any liability which it may have to any indemnified party for contribution or otherwise than under the indemnity agreement contained in this Section 6 or to the extent it is not prejudiced as a proximate result of such failure. In case any such action is brought against any indemnified party and such indemnified party seeks or intends to seek indemnity from an indemnifying party, the indemnifying party will be entitled to participate in, and, to the extent that it shall elect, jointly with all other indemnifying parties similarly notified, by written notice delivered to the indemnified party promptly after receiving the aforesaid notice from such indemnified party, to assume the defense thereof with counsel reasonably satisfactory to such indemnified party; provided, however, if the defendants in any such action include both the indemnified party and the indemnifying party and the indemnified party shall have reasonably concluded that a conflict may arise between the positions of the indemnifying party and the indemnified party in conducting the defense of any such action or that there may be legal defenses available to it and/or other indemnified parties which are different from or additional to those available to the indemnifying party, the indemnified party or parties shall have the right to select separate counsel to assume such legal defenses and to otherwise participate in the defense of such action on behalf of such indemnified party or parties. Upon receipt of notice from the indemnifying party to such indemnified party of such indemnifying party's election to so assume the defense of such action and approval by the indemnified party of counsel, the indemnifying party will not be liable to such indemnified party under this Section 6 for any legal or other expenses subsequently incurred by such indemnified party in connection with the defense thereof unless (i) the indemnified party shall have employed separate counsel in accordance with the proviso to the preceding sentence (it being understood, however, that the indemnifying party shall not be liable for the fees and expenses of more than one separate counsel (together with local counsel), representing the indemnified parties who are parties to such action),

which counsel (together with any local counsel) for the indemnified parties shall be selected by the Agent (in the case of counsel for the indemnified parties referred to in Section 6(a) above), (ii) the indemnifying party shall not have employed counsel satisfactory to the indemnified party to represent the indemnified party within a reasonable time after notice of commencement of the action or (iii) the indemnifying party has authorized in writing the employment of counsel for the indemnified party at the expense of the indemnifying party, in each of which cases the fees and expenses of counsel shall be at the expense of the indemnifying party and shall be paid as they are incurred.

(c) Settlements. The indemnifying party under this Section 6 shall not be liable for any settlement of any proceeding effected without its written consent, but if settled with such consent or if there be a final judgment for the plaintiff, the indemnifying party agrees to indemnify the indemnified party against any loss, claim, damage, liability or expense by reason of such settlement or judgment. Notwithstanding the foregoing sentence, if at any time an indemnified party shall have requested an indemnifying party to reimburse the indemnified party for fees and expenses of counsel as contemplated by Section 6(b) hereof, the indemnifying party agrees that it shall be liable for any settlement of any proceeding effected without its written consent if (i) such settlement is entered into more than 30 days after receipt by such indemnifying party of the aforesaid request; and (ii) such indemnifying party shall not have reimbursed the indemnified party in accordance with such request prior to the date of such settlement. No indemnifying party shall, without the prior written consent of the indemnified party, effect any settlement, compromise or consent to the entry of judgment in any pending or threatened action, suit or proceeding in respect of which any indemnified party is or could have been a party and indemnity was or could have been sought hereunder by such indemnified party, unless such settlement, compromise or consent includes an unconditional release of such indemnified party from all liability on claims that are the subject matter of such action, suit or proceeding.

(d) Contribution. If the indemnification provided for in this Section 6 is for any reason held to be unavailable to or otherwise insufficient to hold harmless an indemnified party in respect of any losses, claims, damages, liabilities or expenses referred to therein, then each indemnifying party shall contribute to the aggregate amount paid or payable by such indemnified party, as incurred, as a result of any losses, claims, damages, liabilities or expenses referred to therein (i) in such proportion as is appropriate to reflect the relative benefits received by the Company, on the one hand, and the Agent, on the other hand, from the offering of the Shares pursuant to this Agreement; or (ii) if the allocation provided by clause (i) above is not permitted by applicable law, in such proportion as is appropriate to reflect not only the relative benefits referred to in clause (i) above but also the relative fault of the Company, on the one hand, and the Agent, on the other hand, in connection with the statements or omissions which resulted in such losses, claims, damages, liabilities or expenses, as well as any other relevant equitable considerations. The relative benefits received by the Company, on the one hand, and the Agent, on the other hand, in connection with the offering of the Shares pursuant to this Agreement shall be deemed to be in the same respective proportions as the total gross proceeds from the offering of the Shares (before deducting expenses) received by the Company bear to the total commissions received by the Agent. The relative fault of the Company, on the one hand, and the Agent, on the other hand, shall be determined by reference to, among other things, whether any such untrue or alleged untrue statement of a material fact or omission or alleged omission to state a material fact relates to information supplied by the Company, on the one hand, or the Agent, on the other hand, and the

parties' relative intent, knowledge, access to information and opportunity to correct or prevent such statement or omission.

The amount paid or payable by a party as a result of the losses, claims, damages, liabilities and expenses referred to above shall be deemed to include, subject to the limitations set forth in Section 6(b), any legal or other fees or expenses reasonably incurred by such party in connection with investigating or defending any action or claim. The provisions set forth in Section 6(b) with respect to notice of commencement of any action shall apply if a claim for contribution is to be made under this Section 6(d); *provided, however,* that no additional notice shall be required with respect to any action for which notice has been given under Section 6(b) for purposes of indemnification.

The Company and the Agent agree that it would not be just and equitable if contribution pursuant to this Section 6(d) were determined by pro rata allocation or by any other method of allocation which does not take account of the equitable considerations referred to in this Section 6(d).

Notwithstanding the provisions of this Section 6(d), the Agent shall not be required to contribute any amount in excess of the agent fees received by the Agent in connection with the offering contemplated hereby. No person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. For purposes of this Section 6(d), each officer and employee of the Agent and each person, if any, who controls the Agent within the meaning of the Securities Act or the Exchange Act shall have the same rights to contribution as the Agent, and each director of the Company, each officer of the Company who signed the Registration Statement, and each person, if any, who controls the Company with the meaning of the Securities Act and the Exchange Act shall have the same rights to contribution as the Company.

Section 7. TERMINATION & SURVIVAL

(a) Term. Subject to the provisions of this Section 7, the term of this Agreement shall continue from the date of this Agreement until the end of the Agency Period, unless earlier terminated by the parties to this Agreement pursuant to this Section 7.

(b) Termination; Survival Following Termination.

(i) Either party may terminate this Agreement prior to the end of the Agency Period, by giving written notice as required by this Agreement, upon ten (10) Trading Days' notice to the other party; provided that, (A) if the Company terminates this Agreement after the Agent confirms to the Company any sale of Shares, the Company shall remain obligated to comply with Section 3(b)(v) with respect to such Shares and (B) Section 2, Section 6, Section 7 and Section 8 shall survive termination of this Agreement. If termination shall occur prior to the Settlement Date for any sale of Shares, such sale shall nevertheless settle in accordance with the terms of this Agreement.

(ii) In addition to the survival provision of Section 7(b)(i), the respective indemnities, agreements, representations, warranties and other statements of the Company, of

its officers and of the Agent set forth in or made pursuant to this Agreement will remain in full force and effect, regardless of any investigation made by or on behalf of the Agent or the Company or any of its or their partners, officers or directors or any controlling person, as the case may be, and, anything herein to the contrary notwithstanding, will survive delivery of and payment for the Shares sold hereunder and any termination of this Agreement.

Section 8. MISCELLANEOUS

(a) Press Releases and Disclosure. The Company may issue a press release describing the material terms of the transactions contemplated hereby as soon as practicable following the date of this Agreement, and may file with the Commission a Current Report on Form 8-K, with this Agreement attached as an exhibit thereto, describing the material terms of the transactions contemplated hereby, and the Company shall consult with the Agent prior to making such disclosures, and the parties hereto shall use all commercially reasonable efforts, acting in good faith, to agree upon a text for such disclosures that is reasonably satisfactory to all parties hereto. No party hereto shall issue thereafter any press release or like public statement (including, without limitation, any disclosure required in reports filed with the Commission pursuant to the Exchange Act) related to this Agreement or any of the transactions contemplated hereby without the prior written approval of the other party hereto, except as may be necessary or appropriate in the reasonable opinion of the party seeking to make disclosure to comply with the requirements of applicable law or stock exchange rules. If any such press release or like public statement is so required, the party making such disclosure shall consult with the other party prior to making such disclosure, and the parties shall use all commercially reasonable efforts, acting in good faith, to agree upon a text for such disclosure that is reasonably satisfactory to all parties hereto.

(b) No Advisory or Fiduciary Relationship. The Company acknowledges and agrees that (i) the transactions contemplated by this Agreement, including the determination of any fees, are arm's-length commercial transactions between the Company and the Agent, (ii) when acting as a principal under this Agreement, the Agent is and has been acting solely as a principal and is not the agent or fiduciary of the Company, or its stockholders, creditors, employees or any other party, (iii) the Agent has not assumed nor will assume an advisory or fiduciary responsibility in favor of the Company with respect to the transactions contemplated hereby or the process leading thereto (irrespective of whether the Agent has advised or is currently advising the Company on other matters) and the Agent does not have any obligation to the Company with respect to the transactions contemplated hereby except the obligations expressly set forth in this Agreement, (iv) the Agent and its respective Affiliates may be engaged in a broad range of transactions that involve interests that differ from those of the Company, and (v) the Agent has not provided any legal, accounting, regulatory or tax advice with respect to the transactions contemplated hereby and the Company has consulted its own legal, accounting, regulatory and tax advisors to the extent it deemed appropriate.

(c) Research Analyst Independence. The Company acknowledges that the Agent's research analysts and research departments are required to and should be independent from their respective investment banking divisions and are subject to certain regulations and internal policies, and as such the Agent's research analysts may hold views and make statements or investment recommendations and/or publish research reports with respect to the Company or the offering that

differ from the views of their respective investment banking divisions. The Company understands that the Agent is a full service securities firm and as such from time to time, subject to applicable securities laws, may effect transactions for its own account or the account of its customers and hold long or short positions in debt or equity securities of the companies that may be the subject of the transactions contemplated by this Agreement.

(d) Notices. All communications hereunder shall be in writing and shall be mailed, hand delivered or telecopied and confirmed to the parties hereto as follows:

If to the Agent:

Jefferies LLC
520 Madison Avenue
New York, NY 10022
Facsimile:
Attention: General Counsel

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

Latham & Watkins LLP
12670 High Bluff Drive
San Diego, CA 92130
Facsimile: (858) 523-5450
Attention: Michael E. Sullivan, Esq.

If to the Company:

Eiger BioPharmaceuticals, Inc.
2155 Park Boulevard
Palo Alto, CA 94306
Attention: Chief Executive Officer

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

Cooley LLP
3175 Hanover Street
Palo Alto, CA 94304
Facsimile: (650) 849-7400
Attention: Carlton Fleming

Any party hereto may change the address for receipt of communications by giving written notice to the others in accordance with this Section 8(d).

(e) Successors. This Agreement will inure to the benefit of and be binding upon the parties hereto, and to the benefit of the employees, officers and directors and controlling persons referred to in Section 6, and in each case their respective successors, and no other person will have

any right or obligation hereunder. The term "successors" shall not include any purchaser of the Shares as such from the Agent merely by reason of such purchase.

(f) Partial Unenforceability. The invalidity or unenforceability of any Article, Section, paragraph or provision of this Agreement shall not affect the validity or enforceability of any other Article, Section, paragraph or provision hereof. If any Article, Section, paragraph or provision of this Agreement is for any reason determined to be invalid or unenforceable, there shall be deemed to be made such minor changes (and only such minor changes) as are necessary to make it valid and enforceable.

(g) Governing Law Provisions. This Agreement shall be governed by and construed in accordance with the internal laws of the State of New York applicable to agreements made and to be performed in such state. Any legal suit, action or proceeding arising out of or based upon this Agreement or the transactions contemplated hereby may be instituted in the federal courts of the United States of America located in the Borough of Manhattan in the City of New York or the courts of the State of New York in each case located in the Borough of Manhattan in the City of New York (collectively, the "**Specified Courts**"), and each party irrevocably submits to the exclusive jurisdiction (except for proceedings instituted in regard to the enforcement of a judgment of any such court, as to which such jurisdiction is non-exclusive) of such courts in any such suit, action or proceeding. Service of any process, summons, notice or document by mail to such party's address set forth above shall be effective service of process for any suit, action or other proceeding brought in any such court. The parties irrevocably and unconditionally waive any objection to the laying of venue of any suit, action or other proceeding in the Specified Courts and irrevocably and unconditionally waive and agree not to plead or claim in any such court that any such suit, action or other proceeding brought in any such court has been brought in an inconvenient forum.

(h) General Provisions. This Agreement constitutes the entire agreement of the parties to this Agreement and supersedes all prior written or oral and all contemporaneous oral agreements, understandings and negotiations with respect to the subject matter hereof. This Agreement may be executed in two or more counterparts, each one of which shall be an original, with the same effect as if the signatures thereto and hereto were upon the same instrument, and may be delivered by facsimile transmission or by electronic delivery of a portable document format (PDF) file. This Agreement may not be amended or modified unless in writing by all of the parties hereto, and no condition herein (express or implied) may be waived unless waived in writing by each party whom the condition is meant to benefit. The Article and Section headings herein are for the convenience of the parties only and shall not affect the construction or interpretation of this Agreement.

[Signature Page Immediately Follows]

If the foregoing is in accordance with your understanding of our agreement, kindly sign and return to the Company the enclosed copies hereof, whereupon this instrument, along with all counterparts hereof, shall become a binding agreement in accordance with its terms

Very truly yours,

EIGER BIOPHARMACEUTICALS, INC.

By: /s/ Sriram Ryali
Name: Sriram Ryali
Title: Chief Financial Officer

The foregoing Agreement is hereby confirmed and accepted by the Agent in New York, New York as of the date first above written.

JEFFERIES LLC

By: /s/ Michael Brinkman
Name: Michael Brinkman
Title: Managing Director

EXHIBIT A

ISSUANCE NOTICE

[Date]

Jefferies LLC
520 Madison Avenue
New York, New York 10022

Attn: [_____]

Reference is made to the Open Market Sale Agreement between Eiger BioPharmaceuticals, Inc. (the "**Company**") and Jefferies LLC (the "**Agent**") dated as of August 6, 2020. The Company confirms that all conditions to the delivery of this Issuance Notice are satisfied as of the date hereof.

Date of Delivery of Issuance Notice (determined pursuant to Section 3(b)(i)): _____

Issuance Amount (equal to the total Sales Price for such Shares):

$

Number of days in selling period:

First date of selling period:

Last date of selling period:

Settlement Date(s) if other than standard T+2 settlement:

Floor Price Limitation (in no event less than $1.00 without the prior written consent of the Agent, which consent may be withheld in the Agent's sole discretion): $ ____ per share

Comments:

_____

By:
Name:
Title:

Schedule A

Notice Parties

The Company

David Cory (dcory@eigerbio.com)

Sri Ryali (sryali@eigerbio.com)

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August 6, 2020

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

Ladies and Gentlemen:

We have acted as counsel to Eiger BioPharmaceuticals, Inc., a Delaware corporation (the "***Company***"), in connection with the sale of shares of its common stock, par value $0.001 per share, having an aggregate offering price of up to $50,000,000 (the "***Shares***") pursuant to the Registration Statement on Form S-3 (File No. 333-235655) (the "***Registration Statement***") filed with the Securities and Exchange Commission (the "***Commission***") under the Securities Act of 1933, as amended (the "***Act***"), the prospectus included within the Registration Statement (the "***Base Prospectus***") and the prospectus supplement dated August 6, 2020 to be filed with the Commission pursuant to Rule 424(b) promulgated under the Act (together with the Base Prospectus, the "***Prospectus***"). The Shares are to be sold by the Company in accordance with that certain Open Market Sale Agreement℠, dated August 6, 2020, by and between the Company and Jefferies LLC (the "***Agreement***"), as described in the Prospectus.

In connection with this opinion, we have examined and relied upon the Registration Statement and the Prospectus, the Agreement, the Company's Amended and Restated Certificate of Incorporation, as amended, the Company's Amended and Restated Bylaws, each as currently in effect, and originals or copies certified to our satisfaction of such records, documents, certificates, memoranda and other instruments as in our judgment are necessary or appropriate to enable us to render the opinion expressed below. We have assumed the genuineness of all signatures; the authenticity of all documents submitted to us as originals; the conformity to originals of all documents submitted to us as copies; the accuracy, completeness and authenticity of certificates of public officials and the due authorization, execution and delivery by all persons other than the Company of all documents where authorization, execution and delivery are prerequisites to the effectiveness of such documents. As to certain factual matters, we have relied upon a certificate of an officer of the Company and have not independently verified such matters.

We have assumed (i) that each sale of Shares will be duly authorized by the Board of Directors of the Company, a duly authorized committee thereof or a person or body pursuant to an authorization granted in accordance with Section 152 of the General Corporation Law of the State of Delaware (the "***DGCL***"), (ii) that no more than 10,000,000 Shares will be sold under the Agreement pursuant to the Prospectus and (iii) that the price at which the Shares are sold will equal or exceed the par value of the Shares. We express no opinion to the extent that future issuances of securities of the Company and/or anti-dilution adjustments to outstanding securities of the Company cause the number of shares of the Company's common stock outstanding or issuable upon conversion or exercise of outstanding securities of the Company to exceed the number of Shares then issuable under the Agreement.

Our opinion herein is expressed solely with respect to the DGCL. Our opinion is based on these laws as in effect on the date hereof. We express no opinion to the extent that any other laws are applicable to the subject matter hereof and express no opinion and provide no assurance as to compliance with any federal or state securities law, rule or regulation.

On the basis of the foregoing, and in reliance thereon, we are of the opinion that the Shares, when sold and issued against payment therefor in accordance with the Agreement, the Registration Statement and the Prospectus, will be validly issued, fully paid and nonassessable.

We consent to the reference to our firm under the caption “Legal Matters” in the Prospectus and to the filing of this opinion as an exhibit to the Company’s Quarterly Report on Form 10-Q to be filed with the Commission for incorporation by reference into the Registration Statement.

Very truly yours,

Cooley LLP

By: /s/ Carlton Fleming
Carlton Fleming

[*] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM IF PUBLICLY DISCLOSED.

Exhibit 10.1

AMENDMENT NO. 1 TO THE COLLABORATION AND SUPPLY AGREEMENT
by and between
Eiger BioPharmaceuticals, Inc. and The Progeria Research Foundation, Inc.

This **AMENDMENT NO. 1** ("**Amendment**") is effective as of June 15, 2020 (the "**Amendment Effective Date**") by and between Eiger BioPharmaceuticals, Inc., a Delaware corporation currently located at 2155 Park Boulevard, Palo Alto, CA 94306 ("**Eiger**"), and The Progeria Research Foundation, Inc., a 501(c)(3) not-for-profit organization currently located at 200 Lake St., Peabody MA 01960 ("**PRF**") and amends the Collaboration and Supply Agreement, dated May 15, 2018, by and between Eiger and PRF ("**Agreement**"). Certain capitalized terms used herein but not expressly defined in this Amendment will have the meanings given in the Agreement.

BACKGROUND

A. Pursuant to the Agreement, if a Progeria PRV is awarded to Eiger, Eiger and PRF shall share the proceeds of any PRV Sale equally, as the term "proceeds" is defined in the Agreement; and

B. Eiger and PRF mutually desire to amend such definition of "proceeds" in the Agreement as set forth in this Amendment.

For good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, and intending to be legally bound, Eiger and PRF hereby agree as follows:

AGREEMENT

1. AMENDMENT TO DEFINITION OF "PROCEEDS". Eiger and PRF agree that the last sentence of Section 6(b) of the Agreement is hereby deleted in its entirety and replaced with the following:

For clarity, as used in this Section 6(b), "proceeds" means the gross amounts received by Eiger with respect to any PRV Sale, less [*].

2. EFFECT OF AMENDMENT. Except as specifically set forth in this Amendment, all terms and conditions of the Agreement remain in full force and effect and are not amended or modified by this Amendment. This Amendment is hereby incorporated into and deemed part of the Agreement as of the Amendment Effective Date. On and after the Amendment Effective Date, any reference to the Agreement includes the terms and conditions of this Amendment. In the event of any conflict, ambiguity or inconsistency between any of the terms or conditions of this Amendment and the Agreement, the terms and conditions of this Amendment will control.

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

[*Remainder of page left blank; signature page follows*]

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

Eiger BioPharmaceuticals, Inc.		**The Progeria Research Foundation, Inc.**	
By:	/s/ Sri Ryali	By:	/s/ Audrey Gordon
Name:	Sri Ryali	Name:	Audrey Gordon
Title:	CFO	Title:	President, Executive Director

Exhibit 31.1

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

I, David A. Cory, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: August 6, 2020

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

Exhibit 31.2

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

I, Sriram Ryali, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: August 6, 2020

/s/ Sriram Ryali
Sriram Ryali
Chief Financial Officer

Exhibit 32.1

CERTIFICATION

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

1. The Company's Quarterly Report on Form 10-Q for the period ended June 30, 2020, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

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

Dated: August 6, 2020

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

/s/ Sriram Ryali
Sriram Ryali
Chief Financial Officer

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