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

Form 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2016

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
(State or Other Jurisdiction of
Incorporation or Organization)

350 Cambridge Ave, Suite 350
Palo Alto, CA
(Address of Principal Executive Offices)

33-0971591
(I.R.S. Employer
Identification No.)

94306
(Zip Code)

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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

Large accelerated filer Accelerated filer
Non-accelerated filer (Do not check if a smaller reporting company) Smaller reporting company

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 March 31, 2016, the number of outstanding shares of the registrant's common stock, par value \$0.001 per share, was 6,945,401.

Table of Contents

EIGER BIOPHARMACEUTICALS, INC. TABLE OF CONTENTS

	<u>Page No.</u>
<u>PART I. FINANCIAL INFORMATION</u>	
<u>Item 1. Financial Statements:</u>	
<u>Condensed Consolidated Balance Sheets as of March 31, 2016 (unaudited) and December 31, 2015</u>	3
<u>Condensed Consolidated Statements of Operations and Comprehensive Loss for the three months ended March 31, 2016 and 2015 (unaudited).</u>	4
<u>Condensed Consolidated Statements of Stockholders' (Deficit) Equity for the three months ended March 31, 2016 (unaudited).</u>	5
<u>Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2016 and 2015 (unaudited).</u>	6
<u>Notes to the Condensed Consolidated Financial Statements (unaudited).</u>	7
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	19
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	26
<u>Item 4. Controls and Procedures</u>	27
<u>PART II. OTHER INFORMATION</u>	
<u>Item 1. Legal Proceedings</u>	27
<u>Item 1A. Risk Factors</u>	27
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	59
<u>Item 3. Defaults Upon Senior Securities</u>	59
<u>Item 4. Mine Safety Disclosures</u>	59
<u>Item 5. Other Information</u>	59
<u>Item 6. Exhibits</u>	59
<u>Signatures</u>	60
<u>Exhibit Index</u>	61

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

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Eiger BioPharmaceuticals, Inc.
Condensed Consolidated Balance Sheets
(In thousands, except shares and per share amounts)

	March 31, 2016 <u>(unaudited)</u>	December 31, 2015 <u></u>
Assets		
Current assets:		
Cash	\$ 61,197	\$ 4,778
Prepaid expenses and other current assets	475	717
Total current assets	61,672	5,495
Property and equipment, net	46	41
Other assets	155	46
Total assets	\$ 61,873	\$ 5,582
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	\$ 6,062	\$ 1,940
Accrued liabilities	2,049	1,006
Convertible promissory note	—	5,444
Total current liabilities	8,111	8,390
Warrant liability	—	885
Obligation to issue common stock	—	1,457
Other long term liabilities	15	2
Total liabilities	8,126	10,734
Stockholders' equity (deficit):		
Convertible preferred stock, \$0.001 par value; 0 and 2,694,579 shares authorized as of March 31, 2016 and December 31, 2015, respectively; 0 and 2,609,102 shares issued and outstanding as of March 31, 2016 and December 31, 2015, respectively	—	22,567
Common stock, \$0.001 and \$0.0001 par value as of March 31, 2016 and December 31, 2015, respectively; 200,000,000 and 5,951,487 shares authorized as of March 31, 2016 and December 31, 2015, respectively; 6,945,401 and 273,993 shares issued and outstanding at March 31, 2016 and December 31, 2015, respectively	7	—
Additional paid-in capital	92,759	1,552
Accumulated deficit	(39,019)	(29,271)
Total stockholders' equity (deficit)	53,747	(5,152)
Total liabilities and stockholders' equity (deficit)	\$ 61,873	\$ 5,582

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

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

	Three Months Ended	
	March 31,	
	2016	2015
Operating expenses:		
Research and development	\$ 4,845	\$ 375
General and administrative	3,833	429
Total operating expenses	<u>8,678</u>	<u>804</u>
Loss from operations	(8,678)	(804)
Interest expense	(685)	—
Other expense, net	(385)	—
Net loss and comprehensive loss	<u>\$ (9,748)</u>	<u>\$ (804)</u>
Net loss per common share:		
Basic and diluted	<u>\$ (10.42)</u>	<u>\$ (4.15)</u>
Shares used to compute net loss per common share:		
Basic and diluted	<u>935,650</u>	<u>193,850</u>

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

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

	<u>Convertible Preferred Stock</u>		<u>Common Stock</u>		<u>Additional Paid-In Capital</u>	<u>Accumulated Deficit</u>	<u>Total Stockholders' (Deficit) Equity</u>
	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>			
Balance at December 31, 2015	2,609,102	\$ 22,567	273,993	\$ —	\$ 1,552	\$ (29,271)	\$ (5,152)
Issuance of common stock upon private placement, net of issuance costs	—	—	1,954,390	2	32,106	—	32,108
Issuance of common stock upon conversion of convertible promissory note	—	—	350,040	—	6,129	—	6,129
Issuance of common stock upon exercise of warrants	—	—	61,254	—	1,057	—	1,057
Issuance of common stock to Eicose upon private placement	—	—	96,300	—	1,661	—	1,661
Issuance of common stock upon options exercised	—	—	3,363	—	7	—	7
Conversion of preferred stock into common stock	(2,609,102)	(22,567)	2,609,102	3	22,564	—	—
Issuance of common stock upon reverse merger	—	—	1,596,959	2	27,345	—	27,347
Stock-based compensation expense	—	—	—	—	338	—	338
Net loss	—	—	—	—	—	(9,748)	(9,748)
Balance at March 31, 2016	<u>—</u>	<u>\$ —</u>	<u>6,945,401</u>	<u>\$ 7</u>	<u>\$ 92,759</u>	<u>\$ (39,019)</u>	<u>\$ 53,747</u>

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

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

	Three Months Ended	
	March 31,	
	2016	2015
Cash flows from operating activities		
Net loss	\$ (9,748)	\$ (804)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	4	2
Noncash interest expense	685	—
Stock-based compensation expense	338	3
Change in fair value of obligation to issue common stock to Eicose	204	—
Change in fair value of warrant liability	165	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	433	(43)
Other assets	(101)	(21)
Accounts payable	4,122	68
Accrued liabilities	184	25
Other long term liabilities	1	—
Net cash used in operating activities	<u>(3,713)</u>	<u>(770)</u>
Cash flows from investing activities		
Cash acquired in reverse merger	28,018	—
Purchase of property and equipment	(8)	(2)
Net cash flows provided by (used in) investing activities	<u>28,010</u>	<u>(2)</u>
Cash flows from financing activities		
Proceeds from issuance of common stock upon private placement, net of issuance costs	32,108	—
Proceeds from issuance of common stock upon option exercises	7	—
Proceeds from issuance of common stock upon warrants exercises	7	—
Proceeds from the issuance of preferred stock, net of issuance costs	—	7,201
Net cash provided by financing activities	<u>32,122</u>	<u>7,201</u>
Net increase in cash	56,419	6,429
Cash at beginning of period	4,778	777
Cash at end of period	<u>\$ 61,197</u>	<u>\$ 7,206</u>
Supplemental Disclosure of cash flow information		
Conversion of warrant liability to common stock upon private placement	<u>\$ 1,050</u>	<u>\$ —</u>
Issuance of common stock to Eicose upon private placement	<u>\$ 1,661</u>	<u>\$ —</u>
Non-cash net liabilities assumed in reverse merger	<u>\$ 671</u>	<u>\$ —</u>
Conversion of convertible promissory note to common stock upon private placement	<u>\$ 6,129</u>	<u>\$ —</u>
Conversion of preferred stock to common stock upon reverse merger	<u>\$ 22,567</u>	<u>\$ —</u>

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

Eiger BioPharmaceuticals, Inc.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

1. Description of Business

Eiger BioPharmaceuticals, Inc. (the “Company”) was incorporated in the State of Delaware on November 6, 2008. The Company is a clinical-stage biopharmaceutical company committed to bringing to market novel products for the treatment of orphan diseases. The Company has built a diverse portfolio of well-characterized product candidates with the potential to address diseases for which the unmet medical need is high, the biology for treatment is clear, and for which an effective therapy is urgently needed. The Company’s principal operations are based in Palo Alto, California and it operates in one segment.

Reverse Merger

On March 22, 2016, Eiger BioPharmaceuticals, Inc. (“Eiger”) completed its merger with Celladon Corporation (“Celladon”) in accordance with the terms of the Agreement and Plan of Merger and Reorganization, dated November 18, 2015 (the “Merger Agreement”), by and among Celladon, Celladon Merger Sub, Inc. (“Merger Sub”) and Eiger (the “Merger”). Pursuant to the Merger Agreement, Merger Sub merged with and into Eiger, with Eiger becoming a wholly-owned subsidiary of Celladon and the surviving corporation of the Merger. Pursuant to the terms and subject to the conditions set forth in the Merger Agreement, Eiger stockholders became the majority stockholders of the surviving company. In connection with, and immediately prior to, the closing of the Merger, on March 22, 2016, Celladon filed an amendment to its amended and restated certificate of incorporation with the Secretary of State of the State of Delaware to effect a fifteen-for-one reverse stock split of its common stock (the “Reverse Stock Split”). In connection with and immediately following the consummation of the Merger, on March 22, 2016, Celladon filed an amendment to its amended and restated certificate of incorporation with the Secretary of State of the State of Delaware to change its name to Eiger BioPharmaceuticals, Inc. The Company’s shares of common stock listed on the NASDAQ Global Market, previously trading through the close of business on Tuesday, March 22, 2016 under the ticker symbol “CLDN,” commenced trading on the NASDAQ Global Market, on a post-reverse stock split adjusted basis, under the ticker symbol “EIGR” on March 23, 2016. On March 22, 2016, a Certificate of Merger was filed with the Secretary of State of the State of Delaware to effect the Merger of Merger Sub with and into Eiger. See Note 4 for further details.

The Company, or Eiger, as used in the accompanying notes to the condensed consolidated financial statements, refers to Private Eiger prior to the completion of the Merger and Public Eiger subsequent to the completion of the Merger.

Reverse Stock Split and Exchange Ratio

On March 22, 2016, and prior to the closing of the Merger, Celladon completed a fifteen-for-one reverse stock split. As a result of the reverse stock split, every fifteen shares of Celladon common stock outstanding immediately prior to the Merger were combined and reclassified into one share of Celladon common stock. No fractional shares were issued in connection with the reverse stock split.

The holders of shares of Eiger common stock outstanding immediately prior to the Merger received approximately 0.09 shares of Celladon common stock in exchange for each share of Eiger common stock in the Merger. Following the reverse stock split and the Merger on March 22, 2016, the combined company had 6,945,401 shares of common stock outstanding.

The accompanying unaudited condensed consolidated financial statements and notes to the unaudited condensed consolidated financial statements give retroactive effect to the Reverse Stock Split for all periods presented.

Liquidity

The Company has an accumulated deficit of \$39.0 million as of March 31, 2016 and negative cash flows from operating activities and expects to continue to incur losses for the next several years. On March 22, 2016, the Company completed the Merger which provided \$28.0 million in net cash (see Note 4). In addition, prior to the closing of the Merger, the Company received \$33.5 million in cash from the issuance of common stock issued to third parties and existing stockholders (see Note 8). Management believes that the currently available resources, including the funds obtained will provide sufficient funds to

enable the Company to meet its operating plan through at least December 31, 2016. However, if the Company's anticipated operating results are not achieved in future periods, management believes that planned expenditures may need to be reduced in order to extend the time period over which the then-available resources would be able to fund the Company's operations.

2. Summary of Significant Accounting Policies

Basis of Presentation

The unaudited condensed consolidated financial statements include the accounts of Eiger BioPharmaceuticals, Inc. and its wholly owned subsidiaries, EBPI Merger Inc., EB Pharma LLC and Eiger BioPharmaceuticals Europe Limited, and have been prepared in accordance with accounting principles generally accepted in the United States of America, ("U.S. GAAP") and following the requirements of the Securities and Exchange Commission (the "SEC") for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by U.S. GAAP can be condensed or omitted. These financial statements have been prepared on the same basis as the Company's annual financial statements and, in the opinion of management, reflect all adjustments, consisting only of normal recurring adjustments, which are necessary for a fair statement of the Company's financial information. These interim results are not necessarily indicative of the results to be expected for the year ending December 31, 2016 or for any other interim period or for any other future year. The balance sheet as of December 31, 2015 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 Form 8-K/A for the year ended December 31, 2015, filed with the Securities and Exchange Commission on May 13, 2016.

Use of Estimates

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. GAAP. The preparation of 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, valuation of derivatives, common stock, stock-based compensation and income taxes. The Company bases its estimates on historical experience and on various other market-specific and relevant assumptions that the Company believes to be reasonable under the circumstances. Actual results could differ from those estimates.

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 consolidated balance sheets and within research and development expense in the consolidated statements of operations and comprehensive loss. These costs are a significant component of the Company's research and development expenses. 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 significant judgments and estimates in determining the accrued liabilities balance in each reporting period. As actual costs become known, the Company adjusts its accrued liabilities.

Research and Development Expenses

Research and development costs are expensed as incurred and consist of payroll expenses, stock-based compensation expense, lab supplies and allocated facility costs, as well as fees paid to third parties that conduct certain research and development activities on the Company's behalf. Amounts incurred in connection with license and asset purchase agreements are also included in research and development expense.

Stock-Based Compensation

Stock-based awards to employees and directors, including stock options, are recorded at fair value as of the grant date using the Black-Scholes option pricing model and recognized as expense on a straight line-basis over the employee's or director's requisite service period (generally the vesting period). Non-cash stock compensation expense is based on awards ultimately expected to vest and is reduced by an estimate for future forfeitures. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from estimates.

Stock-based awards and stock options issued to non-employee consultants are recorded at fair value and remeasured at the end of each period as they vest using the Black-Scholes option pricing model. Expense is recognized over the vesting period which is generally the same as the service period.

Net Loss per Share

Basic net loss per share is calculated by dividing the net loss by the weighted average number of shares of common stock outstanding during the period, without consideration for common stock equivalents. 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.

Recent Accounting Pronouncements

In August 2014, the Financial Accounting Standards Board, ("FASB"), issued Accounting Standards Update, ("ASU"), ASU 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*. ASU 2014-15 requires management to evaluate relevant conditions, events and certain management plans that are known or reasonably knowable that when, considered in the aggregate, raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued, for both annual and interim periods. ASU 2014-15 also requires certain disclosures around management's plans and evaluation, as well as the plans, if any, that are intended to mitigate those conditions or events that will alleviate the substantial doubt. ASU 2014-15 is effective for fiscal years ending after December 15, 2016. The Company does not anticipate the adoption of ASU 2014-15 to have a material impact on its consolidated financial statements and related disclosures.

In April, 2015, the FASB issued ASU 2015-03, *Interest - Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs*. ASU 2015-03 simplifies the presentation of debt issuance costs and requires debt issuance costs related to a recognized debt liability to be presented in the balance sheet as a direct deduction from the debt liability instead of as an asset. ASU 2015-03 is effective for annual and interim periods beginning on or after December 15, 2015 and early adoption is permitted. The Company adopted ASU 2015-03 in the fourth quarter of 2015 and the adoption of this standard did not have an impact on the Company's consolidated financial statements.

On February 25, 2016 the FASB issued ASU 2016-02, *Leases*, which requires lessees to recognize most leases on their balance sheet. The new standard will be effective for fiscal years beginning after December 15, 2018. Early adoption is permitted. The standard requires use of the modified retrospective transition method, with elective relief, which requires application of the guidance for all periods presented. The Company is evaluating the effect ASU 2016-02 will have on its consolidated financial statements and related disclosures. The Company has not yet selected a transition method nor has it determined the effect of the standard on its ongoing financial reporting.

In March 2016, the FASB issued ASU 2016-09, *Compensation-Stock Compensation (Topic 718) Improvements to Employee Share-Based Payment Accounting*, which is intended to simplify several aspects of the accounting for employee share-based payment transactions, including the accounting and reporting of income taxes, the determination of forfeiture rates, classification of awards as either equity or liabilities, and classification on the statement of cash flows. This ASU is effective for fiscal years and interim periods within those years beginning after December 15, 2016 and early adoption is permitted. The Company is currently evaluating the impact that the adoption of ASU 2016-09 will have on its consolidated financial statements and related disclosures.

3. Fair Value Measurements

Fair value accounting is applied for all financial assets and liabilities that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually). At March 31, 2016 and December 31, 2015 the carrying amount of cash, prepaid expenses, accounts payable and accrued liabilities approximated their estimate fair value due to their relatively short maturities. Management believes the terms of the convertible promissory notes 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 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 did not have any financial instruments that were measured on a recurring basis as of March 31, 2016. The Company's financial instruments as of December 31, 2015 included a warrant liability and an obligation to issue common stock in connection with the Eiccose asset purchase agreement, which were classified as Level 3. See Notes 6 and 7 for further discussion on the obligation to issue common stock and the warrant liability.

As of December 31, 2015, in order to determine the fair value of the Company's warrant liability and the obligation to issue common stock in connection with the Eiccose asset purchase agreement, the Company engaged an independent third-party valuation expert to determine the fair value of these instruments based on the common stock value which is based on probability weighted scenarios, each based on an income approach. The income approach estimates enterprise value based on the expectation of future cash flows that the Company will generate over the forecast horizon and a terminal value at the end of the forecast horizon. These future cash flows and terminal value are discounted to their present values using a discount rate based upon the required rate of return based on the risks associated with the investment. Upon settlement in March 2016, the Company remeasured the fair value of the Company's warrant liability and the obligation to issue common stock in connection with the Eiccose asset purchase agreement based on the fair value of the common stock that was issued upon settlement of these instruments.

There were no transfers between Level 1, Level 2 or Level 3 of the fair value hierarchy during the periods presented.

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

	As of December 31, 2015			
	Level 1	Level 2	Level 3	Total
Financial liabilities:				
Warrant liability	\$ —	\$ —	\$ 885	\$ 885
Obligation to issue common stock	\$ —	\$ —	\$1,457	\$1,457
Total financial liabilities	\$ —	\$ —	\$2,342	\$2,342

[Table of Contents](#)

The following table provides a reconciliation of liabilities measured at fair value using Level 3 significant unobservable inputs (in thousands) for the three months ended March 31, 2016:

	Three Months Ended March 31, 2016
Balance, beginning of period	\$ 2,342
Change in fair value of common stock warrants and obligation to issue common stock to Eiccose (1)	369
Settlement of warrant liability upon exercise of common stock warrants	(1,050)
Settlement of Eiccose obligation upon issuance of common stock	(1,661)
Balance, end of period	<u>\$ —</u>

- (1) Changes in fair value of the obligation to issue common stock are recorded in other income (expense), net on the accompanying condensed consolidated statements of operations and comprehensive loss.

4. Reverse Merger

On March 22, 2016, Eiger completed the Merger with Celladon as discussed in Note 1. For accounting purposes, Eiger is considered to be acquiring Celladon in the Merger. Eiger was determined to be the accounting acquirer based upon the terms of the Merger and other factors including; (i) Eiger security holders own approximately 78% of the combined company immediately following the closing of the Merger, (ii) Eiger directors hold all of the board seats in the combined company, and (iii) Eiger management holds a majority of key positions in the management of the combined company. The Merger will be accounted for as an asset acquisition rather than business combination because the assets acquired and liabilities assumed by Eiger do not meet the definition of a business as defined by U.S. GAAP. The net assets acquired in connection with this transaction were recorded at their estimated acquisition date fair values as of March 22, 2015, the date the Merger with Celladon was completed.

Immediately prior to the effective date of the Merger and in connection with the private placement, the principal outstanding convertible promissory notes ("Promissory Notes" or "Notes") of Eiger converted into shares of common stock of Eiger. Further, all outstanding warrants issued in connection with the Promissory Notes were exercised for common stock (see Note 7) and all shares of preferred stock of Eiger converted into shares of common stock of Eiger.

At the effective date of the Merger, Celladon issued shares of its common stock to Eiger stockholders, at an exchange rate of approximately 0.09 shares of common stock, after taking into account the Reverse Stock Split, in exchange for each share of Eiger common stock outstanding immediately prior to the Merger. The exchange rate was calculated by a formula that was determined through arms-length negotiations between Celladon and Eiger. The combined Company assumed all of the outstanding options, whether or not vested, under the Eiger 2009 Equity Incentive Plan (the "Eiger Plan") with such options henceforth representing the right to purchase a number of shares of Celladon common stock equal to 0.09 multiplied by the number of shares of Eiger common stock previously represented by such options.

Immediately after the Reverse Stock Split and the Merger on March 22, 2016, there were 6,945,401 shares of the combined Company's common stock outstanding. In addition, immediately after the Merger, pre-Merger Eiger stockholders, warrant holders and option holders owned approximately 78% of the aggregate number of shares of the combined Company's common stock, and the stockholders of Celladon immediately prior to the Merger owned approximately 22% of the aggregate number of shares of the combined Company's common stock (on a fully diluted basis).

On the Merger closing date of March 22, 2016, Celladon had 1.6 million shares of common stock outstanding and a market capitalization of \$27.5 million. The estimated fair value of the net assets of Celladon on March 22, 2016 was \$27.3 million. The fair value of Celladon's common stock on the Merger closing date was above the fair value of Celladon's net assets. As Celladon's net assets are predominantly comprised of cash offset by current liabilities, the fair value of Celladon's net assets as of March 22, 2016 is considered to be the best indicator of the fair value and, therefore, the estimated preliminary purchase consideration.

[Table of Contents](#)

The following table summarizes the net assets acquired based on their estimated fair values as of March 22, 2016 (in thousands):

Cash	\$28,018
Prepaid and other assets	198
Current liabilities	(857)
Non-current liabilities	(12)
Net acquired tangible assets	<u>27,347</u>
Estimated total purchase consideration	<u>\$27,347</u>

5. License Agreements

Merck License Agreement

In September 2010, the Company entered into an exclusive license agreement with Schering Corporation, subsequently acquired by Merck & Co., Inc., or Merck, which provides the Company with the exclusive right to develop and commercialize Sarasar/Lonafarnib. As consideration for such exclusive right, the Company issued 27,350 shares of Series A convertible preferred stock with a fair value of \$500,000 when the agreement was executed in September 2010. In addition, the Company is obligated to pay Merck up to an aggregate of \$27.0 million in development milestones and will be required to pay tiered royalties based on aggregate annual net sales of all licensed products ranging from mid-single to low double-digit royalties on net sales. The Company's obligation to pay royalties to Merck expires on a country-by-country and product-by-product basis on the later of either the expiration of the last to expire patent assigned to the Company under the agreement, which is estimated to be in December 2016 or the earliest of the tenth anniversary of the first commercial sale of the product. In May 2015, the first regulatory milestone was achieved and the Company paid the related milestone payment of \$1.0 million to Merck. The amount has been recorded as a charge to research and development expense for the year ended December 31, 2015.

Janssen License Agreement

In December 2014, the Company entered into a license agreement with Janssen Pharmaceutica NV, ("Janssen"). In connection with this license agreement, the Company is obligated to make development milestone payments in aggregate of up to \$38.0 million, sales milestone payments in aggregate up to \$65.8 million and will be required to pay tiered royalties based on aggregate annual net sales of all licensed products ranging from mid-single to low double-digit royalties of net sales. As of March 31, 2016, the product has not reached any development milestones nor achieved regulatory approval.

6. Asset Purchase Agreements and Related License Agreements

EGI Asset Purchase Agreement

In December 2010, the Company entered into an asset purchase agreement with Eiger Group International, Inc. ("EGI"). Dr. Jeffrey Glenn, a director of the Company, is the sole owner of EGI. Pursuant to the agreement, the Company purchased all of the assets related to the use of farnesyl transferase inhibitors as anti-viral agents and methods to treat viral infections with those inhibitors and inhibitors of prenylation, prenyl cysteine methyltransferase and a protease that removes the XXX tripeptide from the CXXX polypeptide following prenylation including any related intellectual property to EGI. The Company paid EGI an upfront payment of \$350,000 when the agreement was executed in December 2010. Additionally, the Company will not pay royalties until it has recouped the development costs of any drug product that incorporates clemizole. Once the costs have been recouped, the Company will pay a low single digit royalty of future aggregate annual net sales if there is no generic competition for the product and a lower single digit royalty of future aggregate annual net sales if there is generic competition for the product. Within the first ten years after commercialization, the Company may make a one-time payment of \$500,000 for each contract for the three types of product related to such intellectual property that would reduce the payment term for the three products to the tenth anniversary of the first commercial sale. The obligation to pay royalties expires on a country-by-country and product-by-product basis on the later of either when the product is no longer sold in any country or the earliest of the tenth anniversary of the first commercial sale of the product. As of March 31, 2016, the product has not achieved regulatory approval.

In November 2012, the Company entered into an agreement with EGI whereby the Company sold all of the assets related to the compound clemizole, including any related intellectual property. EGI will pay to the Company a high single digit royalty on future aggregate annual net sales, subject to certain reductions and exceptions. EGI's obligation to pay royalties expires on a country-by-country and product-by-product basis on the later of either expiration of the last to expire patent sold to EGI under the agreement or the earliest of the tenth anniversary of the first commercial sale of the product. As of March 31, 2016, the product has not achieved regulatory approval.

Exendin Purchase Agreement and Related Stanford License Agreement

In September 2015, the Company entered into an asset purchase agreement with two individuals, Drs. Tracey McLaughlin and Colleen Craig, (the "Sellers"), whereby the Company purchased all of the assets related to the compound exendin including any related intellectual property from the Sellers (the "Exendin APA"). The Company also entered into a consulting agreement with the Sellers as part of the agreement. The Company issued 15,378 shares of common stock that were valued at \$211,000 and options to purchase 46,134 shares of common stock with an exercise price of \$2.06 per share when the agreement was executed in September 2015.

Of the 46,134 options to purchase common stock, 15,378 shares vest monthly over four years as services are provided by the Sellers and 30,756 vest upon the earlier of the first commercial sale of the product or the approval of new drug application by the U.S. Food and Drug Administration (the milestone-vested options).

On March 22, 2016, immediately following the closing of the Merger, the Company issued additional "top-up" options to Drs. Tracey McLaughlin and Colleen Craig to purchase an aggregate of 48,544 shares of common stock, pursuant to the terms of the Exendin APA, with an exercise price of \$17.25 per option. The top-up options consist of both time-vested and milestone-vested options.

The fair value of the time-vested options is recognized as non-employee share-based compensation expense as the awards vest over time, with the unvested portion revalued each period. The fair value of the milestone-vested options will be recognized as research and development expense when it is probable that the earliest milestone will be achieved at their then fair value. For the three months ended March 31, 2016, \$197,000 and \$0 of non-employee compensation expense related to the time-vested and milestone-vested options, respectively, were recognized.

The Company is also obligated to pay milestone payments in aggregate up to \$1.0 million to each Seller. Additionally, the Company is obligated to pay each Seller royalties of low single digits based on aggregate annual net sales, subject to certain reductions and exceptions. The Company's obligation to pay royalties expires on the expiration of the last to expire patent assigned to the Company under the agreement. Additionally, the Company has assumed the license agreement the Sellers had previously entered into with the Board of Trustees of the Leland Stanford Junior University ("Stanford"). After the Merger, Stanford became a holder of common stock shares of the Company. The Company is obligated to pay a royalty to Stanford in the low single digits on annual net sales after the first commercial sale. As of March 31, 2016, the Company had not reached any of the milestone events.

Eiccose Purchase Agreement and Related Stanford and Nippon License Agreements

In October 2015, the Company entered into an asset purchase agreement with Eiccose, LLC., or Eiccose, whereby Eiccose sold all of the assets related to the treatment of pulmonary arterial hypertension, or PAH, treatment of lymphedema and products containing ubenimex for the treatment of PAH including any related intellectual property to the Company (the "Eiccose APA"). David Cory, the President, Chief Executive Officer and a director of the Company, is a managing member and significant equity interest holder of Eiccose. The Company made a payment to Eiccose of \$120,000 representing reimbursement of certain previously incurred expenses, including payments and accrued amounts owed to Stanford in connection with the license agreement for the treatment of Lymphedema (the "Lymphedema License Agreement") and the license agreement for the treatment of PAH (the "PAH License Agreement"). The Eiccose APA also provided that, upon a next round of financing pursuant to which the Company sells shares of capital stock resulting in gross proceeds to the Company of at least \$25.0 million, the Company would issue to Eiccose fully vested shares of the Company's common stock equal to 1.75% of the total number of the Company's outstanding capital stock. In October 2015, the Company recorded \$1.5 million in research and development expenses and a corresponding liability representing the fair value of the Company's obligation to issue common stock to Eiccose.

On March 22, 2016, the Company issued to Eiccose 96,300 fully vested shares of the Company's common stock pursuant to the terms of the Eiccose APA. In connection with this transaction the Company remeasured the fair value of the obligation to

issue common stock at the settlement date and the change in fair value of \$204,000 was recognized within other income (expense), net in the condensed consolidated statement of operations and comprehensive loss during the three months ended March 31, 2016. Upon the settlement of the obligation with the issuance of shares on March 22, 2016, the liability was reclassified to common stock and additional paid-in capital within stockholders' equity.

The Company is also obligated to pay to Eiccosse an aggregate of \$10.0 million of commercial milestones in connection with future sales of the product and royalties in the low single digits based on aggregate annual net sales following the first commercial sale of any product. As of March 31, 2016, the product has not reached any development milestones nor achieved regulatory approval.

In addition, as a result of this agreement, the Company has assumed the license agreements Eiccosse had previously entered into. These include the PAH License Agreement, the Lymphedema License Agreement for the treatment of lymphedema and the license agreement with Nippon Kayaku Co., Ltd, ("Nippon"). As part of the agreement, Nippon is obligated to make a payment for royalties in the low single digits of sales to the Company. After the Merger, Stanford became a holder of common stock shares of the Company. In connection with the PAH License Agreement and the Lymphedema License Agreement, the Company is obligated to make milestone payments in aggregate of \$500,000 for each contract, increasing annual license maintenance fees ranging from \$10,000 to \$75,000 over the term of each license agreement and royalty payments in low single digits on annual net sales after the first commercial sale of a product under each license. For the three months ended March 31, 2016, no amounts have been recorded to research and development expense in connection with the Eiccosse APA.

7. Convertible Promissory Note and Warrant Purchase Agreement

On November 12, 2015, the Company entered into a convertible note and warrant purchase agreement with three lenders under which the Company issued convertible promissory notes (the "Notes") for an aggregate principal amount of \$6.0 million and warrants exercisable for shares of the Company's equity securities at a purchase price of \$0.01 per share. The terms of the Notes included a provision whereby the Notes would be automatically converted into equity securities from a qualified financing with proceeds of at least \$25.0 million. The terms of the warrants included a provision whereby the warrants would be automatically exercised if the Company consummated a public offering ("PO") including a reverse merger. If the PO or reverse merger did not occur by February 28, 2016, the warrant coverage amount was equal to 17.5% of the outstanding principal balance of the Notes. The number of warrant shares into which the warrants could be exercised was equal to the warrant coverage amount divided by the per share price of the equity securities sold in a qualified financing for an exercise price of \$0.12 per share. The warrants also include a provision whereby in the event of a PO or reverse merger which would result in the automatic exercise of the warrants and the automatic conversion of the Notes, the exercise price of the warrants would be paid by cancelling any unpaid interest on the Notes.

On November 18, 2015, the Company entered into a Subscription Agreement (the "Private Placement") with the holders of the Notes and new investors for the sale of 2,304,430 shares of its common stock at purchase price of \$17.14 per share for total gross proceeds of \$39.5 million. The proceeds were comprised of \$6.0 million from the conversion of the Notes and \$33.5 million of cash.

The Company allocated the aggregate proceeds from the issuance of the Notes first to the warrants based on the warrants' fair value and then the residual proceeds were allocated to the debt obligation. As of December 31, 2015 the fair value of warrants of \$885,000 was recorded as a debt discount to be amortized as interest expense over the term of the Note using the effective interest rate method. The fair value of the warrants was also recorded as a corresponding warrant liability.

In addition, the Company incurred debt issuance costs of \$21,000 in connection with the Note and Warrant Purchase Agreement. The debt issuance costs was being amortized to interest expense over the term of the Note using the effective interest rate method.

Upon the closing of the private placement on March 22, 2016, immediately prior to the closing of the Merger, the outstanding balance of the Notes totaling \$6.0 million was converted into 350,040 shares of the Company's common stock and the accrued interest of \$122,000 was paid in cash. The warrants were exercised for 61,254 shares of the Company's common stock. During the three months ended March 31, 2016, the Company recognized a loss

related to the change in fair value of the warrants of \$165,000. The warrant liability was reclassified to common stock and additional paid-in capital within stockholders' equity, upon the exercise of the warrants and issuance of shares on March 22, 2016.

For the three months ended March 31, 2016, the Company recognized \$85,000 and \$600,000 related to the accrued interest and amortization of the debt discount within interest expense on the Company's condensed consolidated statements of operations and comprehensive loss. The discount was fully amortized upon the conversion of the Notes.

8. Stockholder's Equity

Common Stock

Immediately prior to the effective date of the Merger, the principal and outstanding balance of the Notes was converted into shares of the Company's common stock. In addition, common stock warrants were also exercised and all outstanding preferred stock of the Company converted into common stock.

Private Placement

On November 18, 2015, Eiger entered into a Subscription Agreement, which provided for the sale and issuance, prior to the consummation of the Merger, of 2,304,430 shares of Eiger common stock to certain current stockholders and new investors of Eiger at a purchase price of \$17.14 per share for aggregate gross proceeds of \$39.5 million, including the conversion of the Notes. Prior to the Merger, the Company closed their private placement and issued additional common stock for cash proceeds of \$33.5 million. Immediately prior to the effective date of the Merger and in connection with the private placement, the Notes were converted into shares of the Company's common stock. Further, all outstanding warrants issued in connection with the Promissory Notes were exercised for shares of common stock (see Note 7) and all shares of preferred stock of Eiger converted into shares of common stock of Eiger.

At the effective date of the Merger, each outstanding share of the Company's common stock was converted into the right to receive approximately 0.09 shares of Celladon common stock.

Warrant Liability

The Company issued warrants to purchase equity securities of the Company in connection with the issuance of convertible promissory notes (see Note 7). As of December 31, 2015 the Company accounted for these warrants as a liability at fair value as the number of shares were not fixed and determinable at the issuance date. The Company adjusted the liability for changes in fair value until the exercise of the warrant in March, 2016, when the number of shares to be exercised became fixed, and the warrants were automatically exercised into common stock. The warrant liability was immediately reclassified to common stock and additional paid in capital within stockholders' deficit. The change in fair value of the warrant liability was recognized as a component of other income (expense), net in the condensed consolidated statements of operations and comprehensive loss.

The Company assumed from Celladon fully exercisable warrants outstanding for the purchase of 10,182 shares of common stock. The warrants have an exercise price of \$84.15 and expire in October 2018.

9. Stock Based Compensation

As discussed in Note 4, the Company assumed all of the outstanding options, whether or not vested, under the Eiger Plan, with such options henceforth representing the right to purchase a number of shares of the Company's common stock equal to approximately 0.09 multiplied by the number of shares of Eiger common stock previously represented by such options. For accounting purposes, however, the Company is deemed to have assumed the Celladon 2013 Equity Incentive Plan.

Because the Company is considered to be the acquirer for accounting purposes, the pre-Merger vested stock options granted by Celladon are deemed to have been exchanged for equity awards of the Company and, as such, the portion of the acquisition date fair value of these equity awards attributable to pre-Merger service to Celladon were accounted for as a component of the consideration transferred, which was not material to the condensed consolidated financial statements.

[Table of Contents](#)

The exchange of options to purchase shares of Eiger common stock for options to purchase shares of the Combined Company, was accounted for as a modification of the awards because the legal exchange of the awards is considered a modification of Eiger stock options. The modification of the stock options did not result in any incremental compensation expense as the modification did not increase the fair value of the stock options.

The Company records stock-based compensation of stock options granted to employees and non-employees by estimating the fair value of stock-based awards using the Black-Scholes option pricing model and amortizing the fair value of the stock-based awards granted over the applicable vesting period of the awards on a straight-line basis.

The following table summarizes stock option activity under the Company's stock based compensation plan during the three months ended March 31, 2016 (in thousands, except share data):

	<u>Number of Outstanding Options</u>	<u>Weighted Average Exercise Price Per Option</u>	<u>Weighted Average Remaining Contractual Term (in years)</u>	<u>Aggregate Intrinsic Value</u>
Balance as of December 31, 2015	254,058	\$ 1.94		<u>\$ 3,369</u>
Options assumed in the Merger	37,276	177.57		
Stock options granted	48,544	17.25		
Stock options exercised	(3,363)	2.06		
Balance as of March 31, 2016	<u>336,515</u>	<u>23.12</u>		<u>\$ 3,881</u>
Vested and expected to vest, March 31, 2016	<u>336,515</u>	<u>23.12</u>	<u>8.65</u>	<u>\$ 3,881</u>
Stock options exercisable as of March 31, 2016	<u>77,435</u>	<u>\$ 89.54</u>	<u>8.25</u>	<u>\$ 430</u>

Stock Options Granted to Employees

There were no stock options granted to employees during the three months ended March 31, 2016 and 2015.

Stock Options Granted to Non-Employees

The Company grants stock options to non-employees in exchange for services rendered. During the three months ended March 31, 2016, the Company granted to non-employees stock options for 48,544. There were no stock options granted to non-employees during the three months ended March 31, 2015. Stock-based compensation expense related to stock options granted to non-employees is recognized as the stock options are earned and will fluctuate as the estimated fair value of the common stock fluctuates until the awards vest. The Company believes that the estimated fair value of the stock options is more readily measurable than the fair value of the services rendered.

The fair value of stock option awards to non-employees was estimated at the date of grant using a Black-Scholes option-pricing model using similar assumptions as for employees except that the expected term is based on the options' remaining contractual term instead of the simplified method:

[Table of Contents](#)

	<u>Three Months Ended March 31,</u> <u>2016</u>
Contractual term (in years)	7.5 - 10.0
Volatility	90.6% - 95.2%
Risk-free interest rate	1.6% - 2.0%
Dividend yield	—

Stock-Based Compensation Expense

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

	<u>Three Months Ended March 31,</u>	
	<u>2016</u>	<u>2015</u>
Research and development	\$ 234	\$ 1
General and administrative	104	2
Total stock-based compensation expense	<u>\$ 338</u>	<u>\$ 3</u>

As of March 31, 2016, the total unrecognized compensation expense related to unvested employee options, net of estimated forfeitures, was \$1.8 million, which the Company expects to recognize over an estimated weighted average period of 3.4 years.

10. Net Loss per Share

The following table sets forth the computation of the basic and diluted net loss per share during the three months ended March 31, 2016 and 2015 (in thousands, except share and per share data):

	<u>Three Months Ended</u> <u>March 31,</u>	
	<u>2016</u>	<u>2015</u>
Net loss, basic and diluted	\$ (9,748)	\$ (804)
Weighted-average number of shares used in computing net loss per share, basic and diluted	935,650	193,850
Net loss per share, basic and diluted	<u>\$ (10.42)</u>	<u>\$ (4.15)</u>

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. Potentially dilutive securities on an as-if converted basis that were not included in the diluted per share calculations because they would be anti-dilutive were as follows:

	<u>Three Months Ended</u> <u>March 31,</u>	
	<u>2016</u>	<u>2015</u>
Options to purchase common stock	336,515	105,900
Warrants to purchase common stock	10,180	—
Convertible preferred stock	—	2,609,102
Total	<u>346,695</u>	<u>2,715,002</u>

11. Related Party Transactions

As of December 31, 2015 the Company owed \$55,000 to Stanford for reimbursement of patent and license fees in connection with the Exendin APA and the Lymphedema License Agreement, which was recorded in accounts payable.

For the three months ended March 31, 2015, the Company reimbursed Dr. Jeffrey Glenn travel-related expenses of \$16,000, which was included in research and development expenses.

Stanford was a related party prior to the Merger due to its ownership of more than 5% of the Company's voting common stock. Upon the closing of the Merger, Stanford owns less than 5% of the combined Company's voting common stock and is, therefore, no longer considered a related party as of March 31, 2016.

12. Legal Matters

In July 2015, three putative securities class action complaints (captioned Fialkov v. Celladon Corporation, Case No. 15-cv-1458-AJB-DHB, Lorusso v. Celladon Corporation, Case No. 15-cv-1501-L-JLB and Jacobs v. Celladon Corporation, Case No. 15-cv-1529-AJB-MDD) were filed in the U.S. District Court for the Southern District of California against Celladon and certain of Celladon's current and former officers. The complaints generally allege that the defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, by making materially false and misleading statements regarding the clinical trial program for MYDICAR, thereby artificially inflating the price of Celladon's common stock. The complaints seek unspecified monetary damages and other relief, including attorneys' fees. On September 1, 2015, six stockholders (or groups of stockholders) filed motions to consolidate the three putative securities class actions and to appoint lead plaintiffs (the "Motions to Consolidate"). A hearing on the Motions to Consolidate was held on December 3, 2015. On December 9, 2015, the Court consolidated the three putative securities class actions and appointed a lead plaintiff to represent the putative class. The lead plaintiff filed a consolidated amended complaint on February 29, 2016. On April 29, 2016, the defendants, including Eiger, filed a motion to dismiss the consolidated amendment complaint. The Company believes that it has meritorious defenses and intends to defend these lawsuits vigorously. Due to the early stage of these proceedings, the Company is not able to predict or reasonably estimate the ultimate outcome or possible losses relating to these claims.

13. Subsequent events

On April 20, 2016, the Company and Bristol-Myers Squibb Company ("BMS") entered into a License Agreement (the "BMS License Agreement") and a Common Stock Purchase Agreement (the "BMS Purchase Agreement").

Under the License Agreement, BMS granted the Company an exclusive, worldwide, license to research, develop, manufacture, and sell products containing the proprietary BMS molecule known as PEG-interferon Lambda-1a (the "Licensed Product") for all therapeutic and diagnostic uses in humans and animals. The Company is responsible for the development and commercialization of the Licensed Product at its sole cost and expense. The License Agreement requires the Company to make an upfront payment of \$2.0 million in cash and issue \$3.0 million in Company common stock and includes development and regulatory milestone payments totaling \$61.0 million and commercial sales milestones of up to \$128.0 million. The Company is obligated to pay BMS annual net sales royalties in the range of mid-single to mid-double digits, depending on net sales levels. In addition, if the Company grants a sublicense, the Company is obligated to pay BMS a portion of the sublicensing income received.

The Purchase Agreement provides for the sale and issuance of 157,587 shares of common stock of the Company to BMS in consideration of the license granted to the Company under the BMS License Agreement and grants BMS certain registration rights with respect to the shares of common stock delivered, and BMS has agreed to certain trading and other restrictions with respect to the shares purchased.

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 condensed consolidated financial statements and related notes thereto included in Part I, Item 1 this Quarterly Report on Form 10-Q, Celladon’s consolidated financial statements and related notes thereto for the year ended December 31, 2015, included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission (“SEC”) and Eiger’s consolidated financial statement and pro forma financial statements included in our Form 8-K/A filed with the SEC on May 13, 2016. 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 discussion contains certain 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, or the Exchange Act. 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 our future plans, objectives, expectations, intentions and financial performance and the assumptions that underlie these statements. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements. Factors that might cause such a difference include, but are not limited to, those discussed in this Quarterly Report on Form 10-Q in Part II, Item 1A — “Risk Factors,” and elsewhere in this Quarterly Report on Form 10-Q. Forward-looking statements are based on our management’s beliefs and assumptions and on information currently available to our management. These statements, like all statements in this Quarterly Report on Form 10-Q, speak only as of their date, and we undertake no obligation to update or revise these statements in light of future developments. We caution investors that our business and financial performance are subject to substantial risks and uncertainties.

Overview

We are a clinical stage biopharmaceutical company focused on bringing to market novel product candidates for the treatment of orphan diseases. Since our founding in 2008, we have worked with investigators at Stanford University and evaluated a number of potential development candidates from pharmaceutical companies to comprise a pipeline of novel product candidates. Our resulting pipeline includes four Phase 2 candidates addressing four distinct orphan diseases. The programs have several aspects in common: the disease targets represent conditions of high medical need which are inadequately treated by current standard of care; the therapeutic approaches are supported by an understanding of disease biology and mechanism as elucidated by our academic research relationships; prior clinical experience with the product candidates guides an understanding of safety; and the development paths leverage the experience and capabilities of our experienced, commercially focused management team. The pipeline includes Sarasar[®] (lonafarnib) for HDV, PEG-interferon Lambda-1a (Lambda) for HCV, exendin (9-39) for severe hypoglycemia and Bestatin[™] (ubenimex) for PAH and lymphedema. We plan to deliver Phase 2 data on all five programs over the course of the next one to three years beginning in 2016.

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. Our net losses were \$9.7 million and \$0.8 million for the three months ended March 31, 2016 and 2015, respectively. As of March 31, 2016, we had an accumulated deficit of \$39.0 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, our product candidates and add personnel

[Table of Contents](#)

necessary to operate as a public company with an advanced clinical candidate pipeline of products. In addition, we are now operating as a publicly traded company following the reverse Merger with Celladon Corporation (“Celladon”), and we will be hiring additional financial and other personnel, upgrading our financial information systems and incurring costs associated with operating as a public company. We expect that our operating losses will fluctuate significantly from quarter to quarter and year to year due to timing of clinical development programs and efforts to achieve regulatory approval.

Recent Events

On March 22, 2016, we completed the reverse merger (“Merger”) between pre-merger Eiger (“Private Eiger”) and Celladon in accordance with the terms of the Agreement and Plan of Merger, dated as of November 18, 2015, by and among Private Eiger, Celladon and Celladon Merger Sub, Inc. Also on March 22, 2016, in connection with, and prior to the completion of, the Merger, we effected a fifteen for one reverse stock split of our common stock (the “Reverse Stock Split”) and changed our name to “Eiger BioPharmaceuticals, Inc.”

Immediately prior to and in connection with the Merger, each share of Private Eiger’s preferred stock outstanding was converted into shares of Private Eiger’s common stock at an exchange ratio of one share of common stock for each share of preferred stock.

Under the terms of the Merger Agreement, at the effective time of the Merger, Celladon issued shares of common stock to Private Eiger stockholders, at an exchange ratio of 0.09 shares of common stock, after taking into account the Reverse Stock Split, in exchange for each share of Private Eiger’s common stock outstanding immediately prior to the Merger. The exchange ratio was calculated by a formula that was determined through arms-length negotiations between Celladon and Private Eiger. Immediately after the Merger, the former Private Eiger equity holders beneficially owned approximately 78% of post-merger Eiger’s common stock. The Merger was accounted for as a reverse asset acquisition.

Financial Operations Overview

Research and Development Expenses

Research and development expenses represent costs we 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 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 supplies; 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 research and development activities. However, we do not allocate internal research and development costs, such as salaries, benefits, stock-based compensation expense and indirect costs to product candidates on a program-specific basis. The following table shows our research and development expenses for the three months ended March 31, 2016 and 2015:

[Table of Contents](#)

	Three Months Ended March 31,	
	2016	2015
	(in thousands)	
Product candidates		
Ubenimex	\$ 3,129	\$ 156
Lonafarnib	733	—
Other clinical programs and research related costs	140	—
Internal research and development costs	843	219
Total research and development expenses	<u>\$ 4,845</u>	<u>\$ 375</u>

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

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

General and Administrative Expenses

General and administrative expenses consist of personnel costs, allocated expenses and expenses for outside professional services, including legal, audit and accounting services. 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. During the three months ended March 31, 2016, we incurred incremental expenses as a result of the Merger and incremental expenses as a result of becoming a public company following completion of the Merger, including expenses related to compliance with the rules and regulations of the SEC and NASDAQ, additional insurance, investor relations and other administrative expenses and professional services.

Interest Expense

Interest expense consists of interest and amortization of the debt discount related to the convertible promissory notes outstanding and then converted into common stock in March 2016.

[Table of Contents](#)

Other expense, net

Other expense, net consists of the change in fair value of the obligation to issue common stock to Eiccosse and the change in fair value of warrant liability.

The change in fair value of the obligation to issue common stock to Eiccosse was related to our obligation to issue shares to Eiccosse upon the closing of the next round of financing that resulted in at least \$25.0 million in gross proceeds to us. Upon the closing of the private placement on March 22, 2016, we issued to Eiccosse 96,300 fully vested shares of our common stock in settlement of this obligation. In connection with this transaction we remeasured the fair value of the obligation to issue common stock at the settlement date and the change in fair value of \$204,000 was recognized within other income (expense), net during the three months ended March 31, 2016. Upon the settlement of the obligation with the issuance of shares on March 22, 2016, the liability was reclassified to common stock and additional paid-in capital within stockholders' equity.

In connection with our issuance of convertible promissory notes in November 2015, we issued warrants to the noteholders to purchase shares of our common stock at an exercise price of \$0.01 per share. The number of shares into which the warrants could be exercised was equal to the warrant coverage amount divided by the per share price of the equity securities sold in a qualified financing and thus was accounted for as a liability. Upon the closing of the private placement on March 22, 2016, the number of shares of common stock under the warrants was fixed and the fair value remeasured at that date, then the warrants were automatically exercised for cash into common stock. During the three months ended March 31, 2016, we recognized a loss related to the change in fair value of the warrant liability of \$165,000. The warrant liability was reclassified to common stock and additional paid-in capital within stockholders' equity, upon the exercise of the warrants and issuance of shares on March 22, 2016.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of these 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 Expenses

We record accrued expenses for estimated costs of research and development activities conducted by external service providers, which include the conduct of clinical 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 consolidated balance sheet and within development expense in the consolidated statement of operations and comprehensive loss. These costs are a significant component our research and development expenses. 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 significant judgments and estimates in determining the accrued balance in each reporting period. As actual costs become known, we adjust our accrued estimates.

Results of Operations**Comparison of the three months ended March 31, 2016 and 2015**

	Three Months Ended March 31,	
	2016	2015
	(in thousands)	
Operating expenses		
Research and development	\$ 4,845	\$ 375
General and administrative	3,833	429
Total operating expenses	8,678	804
Loss from operations	(8,678)	(804)
Interest expense	(685)	—
Other expense, net	(385)	—
Net loss	<u>\$ (9,748)</u>	<u>\$ (804)</u>

Research and development

Research and development expenses increased by \$4.4 million to \$4.8 million for the three months ended March 31, 2016 from \$0.4 million for the three months ended March 31, 2015. The increase was primarily due to \$3.5 million in expenses incurred mainly related to clinical trial activities for our product candidates, including material purchases, production and manufacturing of our product candidates. Additionally, personnel-related costs increased by \$0.5 million due to additional headcount and costs related to consultant services increased \$0.4 million in support of our research and development activities.

General and administrative

General and administrative expenses increased by \$3.4 million to \$3.8 million for the three months ended March 31, 2016 from \$0.4 million for the three months ended March 31, 2015. The increase was primarily due to \$2.8 million in consulting and advisory, legal and accounting services incurred in connection with the Merger with Celladon and in preparing Private Eiger to be a public company, and \$0.3 million in personnel-related costs due to an increase in headcount.

Interest expenses

Interest expense of \$0.7 million for the three months ended March 31, 2016 consists of interest and amortization of the debt discount related to the convertible promissory notes outstanding prior to their conversion into common stock in March 2016. We did not have any debt obligations during the three months ended March 31, 2015.

Other expenses, net

Other expense, net of \$0.4 million for the three months ended March 31, 2016 consists of the change in fair value of the obligation to issue common stock to Eiccose and the change in fair value of warrant liability. We did not have any such items outstanding during the three months ended March 31, 2015.

[Table of Contents](#)

Liquidity and Capital Resources

Sources of Liquidity

On March 22, 2016, we completed the Merger with Celladon, which provided \$28.0 million in cash, and issued common stock in a private placement, which provided \$32.1 million in cash, net of issuance costs. Prior to that time, our operations had been financed primarily by net proceeds from the sale of convertible preferred stock and the issuance of convertible promissory notes. As of March 31, 2016, we had \$61.2 million of cash and cash equivalents and an accumulated deficit of \$39.0 million.

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

Future Funding Requirements

We have not generated any revenue from product sales. We do not know when, or if, we will generate any revenue from product sales. We do not expect to generate any revenue from product sales unless and until we obtain regulatory approval for and commercializes 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 seeks regulatory approval for, our product candidates.

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

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

Cash Flows

The following table summarizes our cash flows for the periods indicated:

	Three Months Ended	
	March 31,	
	2016	2015
	(in thousands)	
Cash used in operating activities	\$ (3,713)	\$ (770)
Cash provided by (used in) investing activities	28,010	(2)
Cash provided by financing activities	32,122	7,201
Net increase in cash	<u>\$56,419</u>	<u>\$6,429</u>

[Table of Contents](#)

Cash flows from operating activities

Cash used in operating activities for the three months ended March 31, 2016 was \$3.7 million, consisting of a net loss of \$9.7 million, which was partially offset by accounts payable of \$4.1 million related to expenses incurred in connection with the private placement, the Merger and to prepare to be a public company, noncash charges of \$0.7 million related to non-cash interest expense, \$0.4 million related to changes in fair value of the obligation to issue common stock to Eiccose and our warrant liability and \$0.3 million for stock-based compensation expense.

Cash used in operating activities for the three months ended March 31, 2015 was \$0.8 million, which primarily consisted of the net loss of \$0.8 million.

Cash flows from investing activities

Cash provided by investing activities for the three months ended March 31, 2016 primarily resulted from the \$28.0 million of proceeds received upon the consummation of the Merger.

Cash flows from financing activities

Cash provided by financing activities for the three months ended March 31, 2016 primarily consisted of \$32.1 million of proceeds from the issuance of common stock in the private placement, net of issuance costs.

Cash provided by financing activities for the three months ended March 31, 2015 consisted of \$7.2 million of proceeds from the issuance of convertible preferred stock, net of issuance costs.

Contractual Obligations and Other Commitments

The following table summarizes our contractual obligations at March 31, 2016 (in thousands):

	Payments due by period			
	Total	Less than 1 year	1-2 years	2-3 years
Operating lease obligations	\$420	\$ 229	\$162	\$ 29

At March 31, 2016, operating lease obligations consisted of future rent payments under two Palo Alto facility lease contracts.

Off-Balance Sheet Arrangements

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

ITEM 3. Quantitative and Qualitative Disclosures About Market Risk

As of March 31, 2016, we had market risk exposure related to our cash and cash equivalents. We had cash of \$61.0 million, which consisted of bank deposits. Such interest-earning instruments carry a degree of interest rate risk; however, historical fluctuations of interest income have not been significant. We have not been exposed nor do we anticipate being exposed to material risks due to changes in interest rates. A hypothetical 10% change in interest rates during any of the periods presented would not have had a material impact on our consolidated financial statements.

We also have an ongoing agreement for the manufacturing of one of our product candidates denominated in yen. We do not participate in any foreign currency hedging activities and we do not have any other derivative financial instruments. We did not recognize any significant exchange rate losses during the three month period ended March 31, 2016. A hypothetical 10% change in the yen-to-dollar exchange rate on March 31, 2016 would not have had a material effect on our results of operations or financial condition.

Additionally, inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation has had a material effect on our results of operations during the periods presented.

ITEM 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended), as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that as of March 31, 2016, our disclosure controls and procedures were not effective at the reasonable assurance level as a result of the material weakness described below.

Material Weakness

In connection with the audit of our financial statements for the years ended December 31, 2015 and December 31, 2014, we identified control deficiencies in the design and operation of our internal control over financial reporting that aggregated to a material weakness. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis. The material weakness identified in our internal control over financial reporting related to a lack of sufficient number of qualified personnel within our accounting function to adequately segregate duties, perform sufficient review and approval of manual journal entries posted to the general ledger, establish defined accounting policies and procedures or perform timely reviews of account reconciliations or accounting estimates. We have taken certain actions to remediate this material weakness, including adding additional accounting personnel for review of account reconciliations and manual journal entries. We intend to implement further segregation of duties and to establish formal written policies for our accounting function by the end of 2016.

Changes in Internal Control

Other than the aforementioned remediation efforts, there have been no changes in our internal control over financial reporting that occurred during our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on Effectiveness of Controls and Procedures

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

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

See Note 12 of the Notes to the Condensed Consolidated Financial Statements contained within this Quarterly Report on Form 10-Q for a further discussion of our legal proceedings.

ITEM 1A. RISK FACTORS

You should carefully consider the following risk factors, as well as the other information in this Quarterly Report on Form 10-Q, and in our other public filings. The occurrence of any of the following risks could harm our business, financial condition, results of operations and/or growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this Quarterly Report on Form 10-Q and those we may make from time to time. You should consider all of the risk factors described when evaluating our business.

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 the incorporation of our predecessor, Celladon in 2000. For the three months ended March 31, 2016 and 2015, we reported a net loss of \$9.7 million and \$0.8 million respectively. As of March 31, 2016, we had an accumulated deficit of approximately \$39.0 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 will continue to require substantial additional capital to continue our clinical development and potential commercialization activities. Accordingly, we will need to raise substantial additional capital to continue to fund our operations. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our clinical development efforts. Failure to raise capital as and when needed, on favorable terms or at all, would have a negative impact on our financial condition and our ability to develop our product candidates.

We have devoted substantially all of our financial resources to identify, acquire, and develop our product candidates, including 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. The amount of our future net losses will depend, in part, on the rate of our future expenditures and our ability to obtain funding through equity or debt financings, strategic collaborations, or grants. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We expect losses to increase as we advance four clinical candidates into Phase 2 development for potentially four indications. While we have not yet commenced pivotal clinical studies for any product candidate and it may be several years, if ever, before we complete pivotal clinical studies and have a product candidate approved for commercialization, we expect to invest significant funds into these clinical candidates to determine the potential to advance these compounds to regulatory approval.

If we obtain regulatory approval to market a product candidate, our future revenue will depend upon the size of any markets in which our product candidates may receive approval, and our ability to achieve sufficient market acceptance, pricing, reimbursement from third-party payors, and adequate market share for our product candidates in those markets. Even if we obtain adequate market share for our product candidates, because the potential markets in which our product candidates may ultimately receive regulatory approval could be very small, we may never become profitable despite obtaining such market share and acceptance of our products.

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

- continue the clinical development of our product candidates;
- in-license or acquire additional product candidates;
- undertake the manufacturing or have manufactured our product candidates;
- advance our programs into larger, more expensive clinical studies;

Table of Contents

- initiate additional nonclinical, clinical, or other studies for our product candidates;
- identify, educate and develop potential commercial opportunities, such as hepatitis D virus biology for our lonafarnib product candidate;
- 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 for ourself;
- seek to identify, assess, acquire, and/or develop other product candidates;
- make milestone, royalty or other payments under third party license agreements;
- seek to maintain, protect, and expand our intellectual property portfolio;
- seek to attract and retain skilled personnel;
- create additional infrastructure to support our operations as a public company and our product development and planned future commercialization efforts; and
- experience any delays or encounter issues with the development and potential for regulatory approval of our clinical candidates such as safety issues, clinical trial accrual delays, longer follow-up for planned studies, additional major studies, or supportive studies necessary to support marketing approval.

Further, the net losses we incur may fluctuate significantly from quarter to quarter and year to year, such that a period-to-period comparison of our results of operations may not be a representative indication of our future performance. In particular, our historical financial statements, including for the year ended December 31, 2015, include the financial performance of Celladon and to the extent that they reflect Celladon's historical business operations, would not be comparable to our financial statements as Eiger. Celladon's historical financial results will not be indicative of our financial results following the Merger.

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

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

- completing research and development of our product candidates;

Table of Contents

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

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

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

To the extent that we raise additional capital through the sale of equity, debt or other securities convertible into equity, your ownership interest will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing, if available at all, would likely involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, making additional product acquisitions, or declaring dividends. If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates or future revenue streams or grant licenses on terms that are not favorable to us. We cannot assure you that we will 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.

We recently completed the Merger with Celladon and the failure to successfully integrate could adversely affect our future results.

Our success will depend, in significant part, on our ability to integrate successfully and to manage successfully the challenges presented by the integration process in the Merger with Celladon that was completed in March 2016. Potential difficulties that may be encountered in the integration process include the following:

- using our cash and assets efficiently to develop our business;
- appropriately managing our liabilities;
- potential unknown or currently unquantifiable liabilities associated with the Merger and our operations;
- difficulties in operating with a new management team as a public company; and
- performance shortfalls as a result of the diversion of the management's attention caused by integrating the companies' operations, in particular operating as a public company immediately post-merger with Celladon.

Risks Related to the Development of our Product Candidates

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

To date, we have invested substantially all of our efforts and financial resources to identify, acquire, and develop our portfolio of product candidates. Our future success is dependent on our ability to successfully further develop, obtain regulatory approval for, and commercialize one or more of these product candidates. We currently generate no revenue from sales of any drugs, and we may never be able to develop or commercialize a product candidate.

We currently have four product candidates in or ready for four Phase 1/2 or Phase 2 clinical studies. One of our product candidates, exendin (9-39), has only generated data in an academic setting and we may not be able to replicate or develop additional data to satisfy regulatory requirements for approval. For ubenimex, data to date has been developed for use in indications other than those that we have rights to or in which we plan to develop the product candidate. For our recently acquired pegylated interferon lambda, we are in the process of completing the technology transfer from Bristol-Myers Squibb Company, or BMS, in order to undertake development of this product candidate. There can be no assurance that the data that we develop for our product candidates in our planned indications will be sufficient to obtain regulatory approval.

In addition, none of our product candidates have advanced into a pivotal study for our proposed indications and it may be years before such study is initiated and completed, if at all. 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.

[Table of Contents](#)

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

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

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 to support the submission of a new drug application, or NDA, or other submission or to obtain regulatory approval in the United States or foreign jurisdictions;
- the FDA or comparable foreign regulatory authorities may find failures in our manufacturing processes, validation procedures and specifications, or facilities of our third-party manufacturers with which we contract for clinical and commercial supplies that may delay or limit our ability to obtain regulatory approval for our product candidates; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our NDA or other submission insufficient for approval.

[Table of Contents](#)

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, which would significantly harm our business, results of operations, and prospects. In addition, although we have obtained orphan drug designation for two of our product candidates in our planned indications to date, there can be no assurance that the FDA will grant our similar status for our other proposed development indications or other product candidates in the future.

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

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

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

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

The eligibility criteria of our planned clinical studies may further limit the available eligible study participants as we expect to require that patients have specific characteristics that we can measure or meet the criteria to assure their conditions are appropriate for inclusion in our clinical studies. We may not be able to identify, recruit, and enroll a sufficient number of patients to complete our clinical studies in a timely manner because of the perceived risks and benefits of the product candidate under study, the availability and efficacy of competing therapies and clinical studies, and the willingness of physicians to participate in our planned clinical studies. If patients are unwilling to participate in our clinical studies for any reason, the timeline for conducting studies and obtaining regulatory approval of our product candidates may be delayed.

If we experience delays in the completion of, or termination of, any clinical study of our product candidates, the commercial prospects of our product candidates could be harmed, and our ability to generate product revenue from any of these product candidates could be delayed or prevented. In addition, any delays in completing our clinical studies would likely increase our overall costs, impair product candidate development and jeopardize our ability to obtain regulatory approval relative to our current plans. Any of these occurrences may harm our business, financial condition, and prospects significantly.

Clinical studies are costly, time consuming and inherently risky, and we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities.

Clinical development is expensive, time consuming and involves significant risk. We cannot guarantee that any clinical studies will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical studies can occur at any stage of development. Events that may prevent successful or timely completion of clinical development include but are not limited to:

Table of Contents

- 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 CROs and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical study sites;
- delays in obtaining required Institutional Review Board, or IRB, approval at each clinical study site;
- failure to permit the conduct of a study by regulatory authorities, after review of an investigational new drug, or IND, or equivalent foreign application or amendment;
- delays in recruiting qualified patients in our clinical studies;
- failure by clinical sites or our CROs or other third parties to adhere to clinical study requirements;
- failure to perform the clinical studies in accordance with the FDA's good clinical practices requirements, or applicable foreign regulatory guidelines;
- patients dropping out of our clinical studies;
- occurrence of adverse events associated with our product candidates;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- the cost of clinical studies of our product candidates;
- negative or inconclusive results from our clinical trials which may result in our deciding, or regulators requiring us, to conduct additional clinical studies or abandon development programs in other ongoing or planned indications for a product candidate; and
- delays in reaching agreement on acceptable terms with third party manufacturers and the time for manufacture of sufficient quantities of our product candidates for use in clinical studies.

Any inability to successfully complete clinical development and obtain regulatory approval could result in additional costs to us or impair our ability to generate revenue. In addition, if we make manufacturing or formulation changes to our product candidates, such as our plan to manufacture a new subcutaneous formulation of exendin (9-39), we may need to conduct additional studies or the results obtained from such new formulation may not be consistent with previous results obtained. 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.

[Table of Contents](#)

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.

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay, or terminate clinical studies or even if approved, result in a restrictive label or delay regulatory approval by the FDA or comparable foreign authorities.

In addition, while 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), fatigue and rash, treatment discontinuation across the lonafarnib clinical studies conducted in oncology has been in the range of approximately 20-25% and we may experience comparable or higher rates of discontinuation in testing in our anti-viral, hepatitis D virus studies. There is no guarantee that additional or more severe side effects will not be identified through ongoing clinical studies by other licensees of lonafarnib for other indications or our own clinical trials. Merck, our licensor, has granted rights to develop lonafarnib in progeria, a rare, fatal rapid aging disease, to The Progeria Research Foundation, which studies may result in side effects in indications other than our use of lonafarnib for hepatitis D. Additionally, while we have a license to another farnesyltransferase inhibitor compound, tipifarnib, from Janssen Pharmaceutica, N.V., or Janssen, Janssen has granted rights to tipifarnib to Kura Oncology, Inc., or Kura, in oncology (as tipifarnib) and negative results or undesirable side effects from Kura's clinical trials for a compound with a similar mechanism of action may negatively impact the perception of lonafarnib for anti-viral indications. Merck may also grant rights to other anti-viral or potentially other indications to other third parties. Undesirable side effects and negative results for other indications may negatively impact the development and potential for approval of our product candidates for our proposed indications.

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

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

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

[Table of Contents](#)

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

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

Manufacturers and manufacturers' facilities are required to continuously comply with FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to current Good Manufacturing Practices, or cGMP, regulations and corresponding foreign regulatory manufacturing requirements. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any NDA or marketing authorization application, or MAA.

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product candidate may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase IV clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. We will be required to report certain adverse reactions and production problems, if any, to the FDA and comparable foreign regulatory authorities. Any new legislation addressing drug safety issues could result in delays in product development or commercialization, or increased costs to assure compliance. If our original marketing approval for a product candidate was obtained through an accelerated approval pathway, we could be required to conduct a successful post-marketing clinical study in order to confirm the clinical benefit for our products. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of marketing approval.

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

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

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

[Table of Contents](#)

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 plans to continue to rely upon 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 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 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, which would be costly and delay the regulatory approval process.

If any of our relationships with these 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 CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, our clinical studies may be delayed or terminated and we may not be able to meet our current plans with respect to our product candidates. CROs may also involve higher costs than anticipated, which could negatively affect our financial condition and operations.

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

With respect to our lonafarnib, lambda and ubenimex product candidates, we rely on Merck, BMS and Nippon Kayaku, respectively to supply our clinical study materials and we do not have long-term supply agreements or commitments from those parties to supply all of our materials. With respect to pegylated interferon lambda, we will receive existing supplies of the product candidate from BMS but will be required to undertake further manufacturing of this product for ourselves. Moreover, even if we have a longer term supply arrangement from these licensors, we may be precluded from entering into a back-up or alternative supplier arrangement which may increase the risk for further development, regulatory approval, or commercialization of our product candidates. For example, our current agreement with Nippon Kayaku provides for such party to be our exclusive supplier for our ubenimex product candidate, which may increase our cost of goods and may not support FDA or other regulatory authority approval for manufacturing.

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.

[Table of Contents](#)

We do not currently have nor do we plan to acquire the infrastructure or capability internally to manufacture our clinical supplies for use in the conduct of our clinical trials, and we lack the resources and the capability to manufacture any of our product candidates on a clinical or commercial scale. We currently rely on outside vendors to source raw materials and manufacture our clinical supplies of our product candidates and plan to continue relying on third parties to manufacture our product candidates on a commercial scale, if approved.

The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit our marketing applications to the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements, known as cGMPs, for manufacture of our product candidates. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

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

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

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

[Table of Contents](#)

- Our third-party manufacturers could breach or terminate their agreement with us.

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

The manufacture 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 orphan 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 related to hepatitis B virus, and there is limited scientific literature in support of a causal link between these two viruses. Although we believe that the data are supportive of the increased severity of hepatitis in the presence of hepatitis D with hepatitis B virus, there can be no assurance that our clinical trials will successfully address this recently observed condition. Likewise, the potentially addressable patient population for each of our product candidates may be limited or may not be amenable to treatment with our product candidates, and new patients may become increasingly difficult to identify or gain access to, which would adversely affect our results of operations and our business.

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

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. We are currently aware of various existing therapies that may compete with our product candidates. For example, we have competitors both in the United States and internationally, including multinational pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies. Some of the pharmaceutical and biotechnology companies we

[Table of Contents](#)

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

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

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

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

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

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

- the efficacy of the product as demonstrated in clinical studies and potential advantages over competing treatments;
- the prevalence and severity of the disease and any side effects;
- the clinical indications for which approval is granted, including any limitations or warnings contained in a product's approved labeling;

[Table of Contents](#)

- the convenience and ease of administration;
- the cost of treatment;
- the willingness of the patients and physicians to accept these therapies;
- the marketing, sales and distribution support for the product;
- the publicity concerning our products or competing products and treatments; and
- the pricing and availability of third-party insurance coverage and reimbursement.

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

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

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

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

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

[Table of Contents](#)

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

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

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

Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is intended to treat a rare disease or condition, defined as a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the European Union, the EMA's Committee for Orphan Medicinal Products, or COMP, grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention, or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the European Union. 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 European Union 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 European Union, orphan drug designation entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity following drug or biological product approval. This period may be reduced to six years if the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity.

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

Even though we have orphan drug designation for lonafarnib in the United States and Europe, we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing pharmaceutical products. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not

[Table of Contents](#)

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

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

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

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

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

Patents have a limited term. In the United States, the statutory expiration of a patent is generally 20 years after it is filed. Although various extensions may be available, the life of a patent, and the protection it affords, is limited. Even if patents

[Table of Contents](#)

covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from generic medications. In addition, upon issuance in the United States any patent term can be adjusted based on certain delays caused by the applicant(s) or the United States Patent and Trademark Office, or USPTO. For example, a patent term can be reduced based on certain delays caused by the patent applicant during patent prosecution.

Patent term extensions under the Hatch-Waxman Act in the United States and under supplementary protection certificates in Europe may be available to extend the patent or data exclusivity terms of products. With respect to ubenimex, lonafarnib, lambda and exendin (9-39), a substantial portion of the potential commercial opportunity will likely rely on patent term extensions, and we cannot provide any assurances that any such patent term extensions will be obtained and, if so, for how long. As a result, we may not be able to maintain exclusivity for our products for an extended period after regulatory approval, which would negatively impact our business and results of operations. If we do not have sufficient patent terms or regulatory exclusivity to protect our products, our business and results of operations will be adversely affected.

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

Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. We therefore cannot be certain that it or our licensors were the first to make the invention claimed in our owned and licensed patents or pending applications, or that we or our licensor were the first to file for patent protection of such inventions. Assuming the other requirements for patentability are met, in the United States prior to March 15, 2013, the first to make the claimed invention is entitled to the patent, while outside the United States, the first to file a patent application is entitled to the patent. After March 15, 2013, under the Leahy-Smith America Invents Act, or the Leahy-Smith Act, enacted on September 16, 2011, the United States has moved to a first to file system. The Leahy-Smith Act also includes a number of significant changes that affect the way patent applications will be prosecuted and may also affect patent litigation. The effects of these changes are currently unclear as the USPTO must still implement various regulations, the courts have yet to address any of these provisions and the applicability of the act and new regulations on specific patents discussed herein have not been determined and would need to be reviewed. In general, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

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

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

Although we expect all of our employees and consultants to assign their inventions to us, and all of our employees, consultants, advisors, and any third parties who have access to our proprietary know-how, information, or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed or that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise

[Table of Contents](#)

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 employing 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. We have conducted freedom to operate analyses with respect to only certain of our product candidates, and therefore we do not know whether there are any third-party patents that would impair our ability to commercialize these product candidates. We also cannot guarantee that any of our analyses are complete and thorough, nor can we be sure that we have identified each and every patent and pending application in the United States and abroad that is relevant or necessary to the 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.

In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. 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.

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

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

We currently have rights to the intellectual property, through licenses from third parties and under patents that we do not own, to develop and commercialize our product candidates. Because our programs may require the use of proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to maintain in effect these proprietary rights. For example, we have certain specified diligence obligations under our Stanford license agreements for our ubenimex and lonafarnib product candidates. We may not be able to achieve the required diligence milestones in a timely manner, which may result in a right of termination by Stanford, 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.

[Table of Contents](#)

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

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

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

Our product candidates may be subject to generic competition.

Under the Hatch-Waxman Act, a pharmaceutical manufacturer may file an abbreviated new drug application, or ANDA, seeking approval of a generic copy of an approved innovator product. Under the Hatch-Waxman Act, a manufacturer may also submit an NDA under section 505(b)(2) that references the FDA's finding of safety and effectiveness of a previously approved drug. A 505(b)(2) NDA product may be for a new or improved version of the original innovator product. Innovative small molecule drugs may be eligible for certain periods of regulatory exclusivity (e.g., five years for new chemical entities, three years for changes to an approved drug requiring a new clinical study, seven years for orphan drugs), which preclude FDA approval (or in some circumstances, FDA filing and review of) an ANDA or 505(b)(2) NDA relying on the FDA's finding of safety and effectiveness for the innovative drug. In addition to the benefits of regulatory exclusivity, an innovator NDA holder may have patents claiming the active ingredient, product formulation or an approved use of the drug, which would be listed with the product in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," known as the "Orange Book." If there are patents listed in the Orange Book, a generic applicant that seeks to market its product before expiration of the patents must include in the ANDA or 505(b)(2) what is known as a "Paragraph IV certification," challenging the validity or enforceability of, or claiming non-infringement of, the listed patent or patents. Notice of the certification must be given to the innovator, too, and if within 45 days of receiving notice the innovator sues to protect its patents, approval of the ANDA is stayed for 30 months, or as lengthened or shortened by the court.

If there are patents listed for our product candidates in the Orange Book, ANDAs and 505(b)(2) NDAs with respect to those product candidates would be required to include a certification as to each listed patent indicating whether the ANDA applicant does or does not intend to challenge the patent. We cannot predict whether any patents issuing from our pending patent applications will be eligible for listing in the Orange Book, how any generic competitor would address such patents, whether we would sue on any such patents, or the outcome of any such suit.

We may not be successful in securing or maintaining proprietary patent protection 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.

[Table of Contents](#)

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

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

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

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

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

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

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

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There

[Table of Contents](#)

could also be public announcements of the results of hearings, motions, or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

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

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

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

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

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

Risks Related to our Business Operations

We have identified a material weakness in our internal control over financial reporting and our current management team may fail to maintain an effective system of internal control, which may result in material misstatements of our financial statements or cause us to fail to meet our periodic reporting obligations as a public company.

Prior to the Merger, the financial reporting for Private Eiger's operations was based on capabilities as a private company and we had limited accounting and financial reporting personnel and other resources with which to address our internal controls and procedures. In connection with the audit of our consolidated financial statements for the years ended December 31, 2015 and 2014 as a private company, we and our independent auditors identified a material weakness in our internal control over

[Table of Contents](#)

financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the subject company's annual or interim financial statements will not be prevented or detected on a timely basis. Our lack of sufficient accounting personnel resulted in the identification of a material weakness in our internal control over financial reporting. Specifically, the material weakness that was identified related to a lack of sufficient accounting resources and personnel that had limited our ability to adequately segregate duties, perform sufficient review and approval of manual journal entries posted to the general ledger, establish defined accounting policies and procedures or perform timely reviews of account reconciliations or accounting estimates. Following the Merger, no former employees of Celladon remain employed by us and Celladon did not have similar issues or report a material weakness or significant deficiency. Consequently, following the Merger we will need to build out and maintain our own public company financial reporting functions and other resources.

To address the deficiency in our team's accounting processes, we have begun hiring additional accounting personnel, and establishing and documenting accounting policies and procedures and implementing management review controls. In particular, we intend to implement further segregation of duties and to establish formal written policies for our accounting function by the end of 2016. While we intend to implement a plan to remediate this deficiency, we cannot predict the success of such plan or the outcome of our assessment of these plans at this time. We can give no assurance that this implementation will remediate this deficiency in internal control or that material weaknesses or significant deficiencies in our internal control over financial reporting will not be identified in the future. Our failure to implement and maintain effective internal control over financial reporting could result in errors in our financial statements that could result in a restatement of our financial statements or cause us to fail to meet our reporting obligations. In addition, although we are not currently required to formally test our internal controls for attestation, we are required as an "emerging growth company" to report on our internal controls. After we are no longer an emerging growth company, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our consolidated financial statements or identify other areas for further attention or improvement. Inadequate internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

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 May 9, 2016, we had 12 full-time employees. As our development and commercialization plans and strategies develop, we expect to need additional managerial, operational, sales, marketing, financial, legal, and other resources. Our management may need to divert a disproportionate amount of their attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, operational mistakes, loss of business opportunities, loss of employees, and reduced productivity among remaining employees. Our expected growth could require significant capital

expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth.

Failure in our information technology and storage systems could significantly disrupt the operation of our business.

Our ability to execute our business plan and maintain operations depends on the continued and uninterrupted performance of our information technology, or IT, systems. IT systems are vulnerable to risks and damages from a variety of sources, including telecommunications or network failures, malicious human acts and natural disasters. Moreover, despite network security and back-up measures, some of our and our vendors' servers are potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptive problems. Despite precautionary measures to prevent unanticipated problems that could affect our IT systems, sustained or repeated system failures that interrupt our ability to generate and maintain data could adversely affect our ability to operate our business.

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

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

- our research or business development methodology or search criteria and process may be unsuccessful in identifying potential product candidates;
- we may not be able or willing to assemble sufficient resources to acquire or discover additional product candidates;
- our product candidates may not succeed in preclinical or clinical testing;
- our potential product candidates may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- product candidates we develop may be covered by third parties' patents or other exclusive rights;
- the market for a product candidate may change during our program so that such a product may become unreasonable to continue to develop;

Table of Contents

- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by patients, the medical community, or third-party payors.

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

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

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or the Health Care Reform Law, was passed, which substantially changes the way health care is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. The Health Care Reform Law, among other things, addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected, increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations, establishes annual fees and taxes on manufacturers of certain branded prescription drugs, and promotes a new Medicare Part D coverage gap discount program.

In addition, other legislative changes have been proposed and adopted in the United States since the Health Care Reform Law was enacted and 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.

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

If we obtain FDA approval for any of our product candidates and begins commercializing those products in the United States, our operations may be subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, the federal False Claims Act, and physician sunshine laws and regulations. These laws may impact, among other things, our proposed sales, marketing, and education programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;

Table of Contents

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology and Clinical Health Act, or HITECH, and our implementing regulations, which imposes certain requirements relating to the privacy, security, and transmission of individually identifiable health information;
- the federal physician sunshine requirements under the Health Care Reform Laws requires manufacturers of drugs, devices, biologics, and medical supplies to report annually to the U.S. Department of Health and Human Services information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers, state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent health care reform legislation has strengthened these laws. For example, the Health Care Reform Law, among other things, amends the intent requirement of the federal anti-kickback and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. Moreover, the Health Care Reform Law provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in government health care programs, such as Medicare and Medicaid, imprisonment, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

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

We are exposed to the risk of fraudulent conduct or other illegal activity by our employees, independent contractors, principal investigators, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to: comply with the regulations of the FDA and non-U.S. regulators, provide accurate information to the FDA and non-U.S. regulators, comply with healthcare fraud and abuse laws in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, promotion,

[Table of Contents](#)

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 harms 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

[Table of Contents](#)

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

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

Risks Related to Celladon’s Historical Business Operations

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

In July 2015, following Celladon’s announcements of the negative CUPID 2 data and the suspension of further research and development activities and the subsequent declines of the price of its common stock, three putative class actions were filed in the U.S. District Court for the Southern District of California against Celladon and certain of its current and former officers. The complaints generally allege that the defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, by making materially false and misleading statements regarding the clinical trial program for MYDICAR, thereby artificially inflating the price of Celladon’s common stock. The complaints seek unspecified monetary damages and other relief, including attorneys’ fees. On September 1, 2015, six stockholders (or groups of stockholders) filed motions to consolidate the three putative securities class actions and to appoint lead plaintiffs (the “Motions to Consolidate”). A hearing on the Motions to Consolidate was held on December 3, 2015. On December 9, 2015, the Court consolidated the three putative securities class actions and appointed a lead plaintiff to represent the putative class. The lead plaintiff filed a consolidated amended complaint on February 29, 2016. On April 29, 2016, the defendants, including Eiger, filed a motion to dismiss the consolidated amendment complaint. It is possible that additional suits will be filed, or allegations made by stockholders, with respect to these same or other matters and also naming us and/or our former officers and directors as defendants. We believe that we have meritorious defenses and intend to defend these lawsuits vigorously. Due to the early stage of these proceedings, we are not able to predict or reasonably estimate the ultimate outcome or possible losses relating to these claims. While we and Celladon’s former directors’ and officers’ have a separate liability insurance policy dedicated to any claims that may arise from pre-merger events, there is no assurance that the coverage will be sufficient. In addition, any such litigation could result in substantial costs and a diversion of our management’s attention and resources, which could harm our business.

Risks Related to Ownership of our Common Stock

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

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

- results or delays in preclinical studies or clinical trials;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- unanticipated serious safety concerns related to the use of any of our product candidates;
- reports of adverse events in other gene therapy products or clinical trials of such products;
- inability to obtain additional funding;
- any delay in filing an IND or NDA for any of our product candidates and any adverse development or perceived adverse development with respect to the FDA’s review of that IND or NDA;

Table of Contents

- our ability to obtain regulatory approvals for lonafarnib or other 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;

Table of Contents

- if securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinions regarding our business and stock;
- changes in the market valuations of similar companies;
- general market or macroeconomic conditions;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock.
- announcements by commercial partners or competitors of new commercial products, clinical progress or the lack thereof, significant contracts, commercial relationships or capital commitments;
- adverse publicity relating to the hepatitis market generally, including with respect to other products and potential products in such markets;
- the introduction of technological innovations or new therapies that compete with potential products of ours;
- changes in the structure of health care payment systems; and
- period-to-period fluctuations in our financial results.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common stock.

In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our profitability and reputation.

We will incur costs and demands upon management as a result of complying with the laws and regulations affecting public companies.

We 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.

[Table of Contents](#)

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 acquirors 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 are at risk of additional securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities, including against Celladon in 2015 which we are continuing to defend. The risk of securities litigation is especially relevant for us because biotechnology companies have experienced significant stock price volatility in recent years. If we face such additional securities litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

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

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

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

If existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after legal restrictions on resale lapse, the trading price of our common stock could decline. Certain of our existing stockholders, including Vivo Ventures Fund VI, L.P. and Interwest Partners X, L.P., 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 approximately 28% 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.

Because the recent Merger resulted in an ownership change under Section 382 of the Internal Revenue Code our net operating loss carryforwards and certain other tax attributes are now subject to limitations.

If a corporation undergoes an "ownership change" within the meaning of Section 382 of the Internal Revenue Code of 1986, as amended, or Section 382, the corporation's net operating loss carryforwards and certain other tax attributes arising from before the ownership change are subject to limitations on use after the ownership change. In general, an ownership change

[Table of Contents](#)

occurs if there is a cumulative change in the corporation's equity ownership by certain stockholders that exceeds fifty percentage points over a rolling three-year period. Similar rules may apply under state tax laws. The recent Merger resulted in an ownership change and, accordingly, both parties' net operating loss carryforwards and certain other tax attributes will be subject to further limitations on their use. Additional ownership changes in the future could result in additional limitations on the combined organization's net operating loss carryforwards. Consequently, even if we achieve profitability, we may not be able to utilize a material portion of our net operating loss carryforwards and other tax attributes, which could have a material adverse effect on cash flow and results of operations.

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

On March 22, 2015, immediately prior to the Merger, pursuant to a Subscription Agreement dated November 18, 2015, Private Eiger issued and sold an aggregate of 2,304,430 shares of common stock for \$17.14 per share (on a post-split basis), for aggregate consideration of approximately \$39.5 million, including conversion of \$6.0 million in outstanding convertible debt, to certain current stockholders of Private Eiger and certain new investors. Jefferies LLC acted as placement agent for the sale.

The offer, sale, and issuance of the securities described above was deemed to be exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act and/or Regulation S or Regulation D promulgated thereunder as a transaction by an issuer not involving a public offering. The recipients of securities in these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in this transaction. The recipients of securities in these transactions were accredited investors and had adequate access, through employment, business or other relationships, to information about us.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

See the Exhibit Index at the end of this Quarterly Report on Form 10-Q, which is incorporated by reference herein. The exhibits listed in the accompanying Exhibit Index are filed as part of this Quarterly Report on Form 10-Q.

SIGNATURES

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

Eiger BioPharmaceuticals, Inc.

Date: May 16, 2016

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

Eiger BioPharmaceuticals, Inc.

Date: May 16, 2016

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

EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description of Document</u>
3.1	Amended and Restated Certificate of Incorporation of Celladon Corporation (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K of Celladon Corporation, filed with the SEC on February 10, 2014).
3.2	Amended and Restated Bylaws of Celladon Corporation (incorporated by reference to Exhibit 3.2 to the Current Report on Form 8-K, filed with the SEC on February 10, 2014).
3.3	Certificate of Amendment of Amended and Restated Certificate of Incorporation of Celladon Corporation (incorporated by reference to Annex D to the Registration Statement on Form S-4, as amended (File No. 333-208521), originally filed with the SEC on December 14, 2015).
3.4	Certificate of Amendment of Amended and Restated Certificate of Incorporation of Celladon Corporation (incorporated by reference to Annex E to the Registration Statement on Form S-4, as amended (File No. 333-208521), originally filed with the SEC on December 14, 2015).
10.1	Sublease Agreement, dated as of January 8, 2016, by and between Baker Hughes Oilfield Operations, Inc. and Eiger BioPharmaceuticals, Inc. (incorporated by reference to Exhibit 10.53 to the Registration Statement on Form S-4/A, as amended (File No. 333-208521), originally filed with the SEC on January 22, 2016).
31.1	Certification of Principal Executive Officer required by Rule 13a-14(a) or Rule 15d-14(a)
31.2	Certification of Principal Financial Officer required by Rule 13a-14(a) or Rule 15d-14(a)
32.1+	Certification Principal Executive Officer and Principal Financial Officer required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350)
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

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

**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)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 16, 2016

/s/ David A. Cory

David A. Cory
Chief Executive Officer

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

I, James Welch, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Eiger BioPharmaceuticals, Inc.
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 16, 2016

/s/ James Welch
James Welch
Chief Financial Officer

CERTIFICATION

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

1. The Company's Quarterly Report on Form 10-Q for the period ended March 31, 2016, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and
2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: May 16, 2016

/s/ David A. Cory

David A. Cory
Chief Executive Officer

/s/ James Welch

James Welch
Chief Financial Officer

This certification accompanies the Quarterly Report on Form 10-Q 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.