
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549**

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2015

OR

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

Commission file number: 001-36183

CELLADON CORPORATION

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

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

**11988 El Camino Real, Suite 650,
San Diego CA**
(Address of principal executive offices)

92130
(Zip Code)

Registrant's telephone number, including area code: (858) 366-4288

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 (§232.405 of this chapter) 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 Act). Yes No

The number of outstanding shares of the registrant's common stock, par value \$0.001 per share, as of October 31, 2015 was 23,916,021.

CELLADON CORPORATION

TABLE OF CONTENTS FOR QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2015

PART I — FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited)	2
Consolidated Balance Sheets	2
Consolidated Statements of Operations and Comprehensive Loss	3
Consolidated Statements of Cash Flows	4
Notes to Consolidated Financial Statements	5
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	14
Item 3. Quantitative and Qualitative Disclosures About Market Risk	22
Item 4. Controls and Procedures	23

PART II — OTHER INFORMATION

Item 1. Legal Proceedings	24
Item 1A. Risk Factors	24
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	43
Item 3. Defaults Upon Senior Securities	43
Item 4. Mine Safety Disclosures	43
Item 5. Other Information	43
Item 6. Exhibits	43
SIGNATURES	44

PART I — FINANCIAL INFORMATION**Item 1. Financial Statements****Celladon Corporation****Consolidated Balance Sheets**
(in thousands, except share and per share data)

	September 30, 2015	December 31, 2014
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 37,092	\$ 14,435
Short-term investments	—	70,513
Prepaid expenses and other assets	1,001	3,135
Total current assets	38,093	88,083
Property and equipment, net	133	763
Other assets	10	264
Total assets	<u>\$ 38,236</u>	<u>\$ 89,110</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 1,025	\$ 5,803
Accrued restructuring charges	609	—
Accrued clinical expenses	163	731
Accrued interest	—	71
Current portion of long-term obligations	—	1
Total current liabilities	1,797	6,606
Long-term obligations, net of discount	—	10,102
Non-current liabilities	29	298
Commitments and contingencies (Note 5)		
Stockholders' equity:		
Preferred stock, \$0.001 par value; authorized shares — 10,000,000 at September 30, 2015 and December 31, 2014, respectively; no shares issued and outstanding	—	—
Common stock, \$0.001 par value; authorized shares — 200,000,000 at September 30, 2015 and December 31, 2014, respectively; issued and outstanding — 23,916,021 and 23,490,737 at September 30, 2015 and December 31, 2014, respectively	24	23
Additional paid-in capital	222,492	218,528
Accumulated other comprehensive loss	—	(8)
Accumulated deficit	(186,106)	(146,439)
Total stockholders' equity	36,410	72,104
Total liabilities and stockholders' equity	<u>\$ 38,236</u>	<u>\$ 89,110</u>

See accompanying notes.

Celladon Corporation

Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Operating expenses:				
Research and development	\$ 738	\$ 5,316	\$ 21,757	\$ 15,515
General and administrative	2,533	2,815	10,805	6,545
Restructuring charges	1,781	—	4,862	—
Total operating expenses	<u>5,052</u>	<u>8,131</u>	<u>37,424</u>	<u>22,060</u>
Loss from operations	(5,052)	(8,131)	(37,424)	(22,060)
Other income (expense):				
Interest income	6	36	60	65
Interest expense	(1,347)	(271)	(2,302)	(330)
Other income (expense)	(3)	8	(1)	(4)
Change in fair value of warrant liability	—	—	—	(183)
Consolidated net loss	<u>\$ (6,396)</u>	<u>\$ (8,358)</u>	<u>\$ (39,667)</u>	<u>\$ (22,512)</u>
Other comprehensive loss:				
Unrealized gain on investments	—	(26)	8	(10)
Comprehensive loss	<u>\$ (6,396)</u>	<u>\$ (8,384)</u>	<u>\$ (39,659)</u>	<u>\$ (22,522)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.27)</u>	<u>\$ (0.40)</u>	<u>\$ (1.66)</u>	<u>\$ (1.32)</u>
Weighted-average shares outstanding, basic and diluted	<u>23,915,361</u>	<u>20,752,895</u>	<u>23,830,668</u>	<u>16,999,766</u>

See accompanying notes.

Celladon Corporation
Consolidated Statements of Cash Flows
(in thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2015	2014
Cash flows from operating activities		
Consolidated net loss	\$(39,667)	\$(22,512)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation	371	110
Asset impairments	192	—
Stock-based compensation	3,183	2,178
Noncash interest expense	1,807	190
Amortization of investment premium	194	163
Change in fair value of warrant liability	—	183
Loss on disposal of property and equipment	2	1
Deferred rent	(117)	84
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	2,239	(689)
Accounts payable and accrued expenses	(4,937)	910
Other liabilities	—	8
Net cash used in operating activities	<u>(36,733)</u>	<u>(19,374)</u>
Cash flows from investing activities		
Purchases of investment securities	—	(88,661)
Proceeds from maturities of investment securities	70,327	18,200
Purchases of property and equipment	(235)	(549)
Proceeds from sale of property and equipment	277	—
Net cash provided by (used in) investing activities	<u>70,369</u>	<u>(71,010)</u>
Cash flows from financing activities		
Proceeds from issuance of common stock	783	94,578
Costs paid in connection with common stock offering	—	(7,396)
Proceeds from borrowing under term loan	—	10,000
Repayment of term loan	(10,000)	—
Costs paid in connection with term loan	(1,750)	(334)
Other	(12)	—
Net cash provided by (used in) financing activities	<u>(10,979)</u>	<u>96,848</u>
Net increase in cash and cash equivalents	22,657	6,464
Cash and cash equivalents, beginning of period	14,435	7,903
Cash and cash equivalents, end of period	<u>\$ 37,092</u>	<u>\$ 14,367</u>

See accompanying notes.

Celladon Corporation

Notes to Consolidated Financial Statements

(Unaudited)

1. Basis of Presentation, Organization and Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited consolidated financial statements of Celladon Corporation (Celladon or the Company) should be read in conjunction with the audited financial statements and notes thereto as of and for the year ended December 31, 2014 included in the Company's Annual Report on Form 10-K (Annual Report) filed with the Securities and Exchange Commission (SEC). The accompanying financial statements have been prepared in accordance with U.S. generally accepted accounting principles (GAAP) for interim financial information and in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, since they are interim statements, the accompanying financial statements do not include all of the information and notes required by GAAP for complete financial statements. In the opinion of management, the accompanying financial statements reflect all adjustments (consisting of normal recurring adjustments) that are necessary for a fair statement of the financial position, results of operations and cash flows for the interim periods presented. Interim results are not necessarily indicative of results for a full year. The preparation of the Company's consolidated financial statements requires it to make estimates and assumptions that impact the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in the Company's consolidated financial statements and accompanying notes. The most significant estimates in the Company's consolidated financial statements relate to the fair value of equity awards and clinical trial expense accruals. Although these estimates are based on the Company's knowledge of current events and actions it may undertake in the future, actual results may ultimately materially differ from these estimates and assumptions.

Organization

Celladon was incorporated in California on December 21, 2000 (inception) and reincorporated in Delaware in April 2012. The Company is a biotechnology company that has been focused on the development of cardiovascular gene therapy. As a consequence of the negative results from the Phase 2b clinical trial of its lead product candidate, MYDICAR (AAV1/SERCA2a), the Company is evaluating its strategic opportunities to maximize shareholder value, including the possibility of seeking a merger, sale of the Company or all or some of its assets, and/or a liquidation. At this time, the Company's current development activities are limited to the oversight of the long-term follow up period in the CUPID 2 trial, which is expected to continue through February 2016.

As of September 30, 2015, the Company has devoted substantially all of its efforts to product development, raising capital and building infrastructure and has not generated revenues from product sales or other sources.

Principles of Consolidation

The financial statements of the Company's former subsidiary Celladon Europe B.V. (Celladon Europe) were consolidated with those of the Company through Celladon Europe's dissolution on December 30, 2014. All intercompany transactions and balances were eliminated in consolidation.

Investment Securities

Investment securities primarily consist of investment grade corporate debt securities. The Company classifies all investment securities as available-for-sale. Investments with maturity dates greater than 12 months from the end of each reporting period are classified as long-term. Investment securities are carried at fair value, with the unrealized gains and losses reported as a component of other comprehensive income (loss) in stockholders' equity (deficit) until realized. Realized gains and losses from the sale of investment securities, if any, are determined on a specific identification basis. A decline in the market value of any investment security below cost that is determined to be other than temporary will result in an impairment charge to earnings and a new cost basis for the security is established. No such impairment charges were recorded for any period presented. As of December 31, 2014, none of the investment securities had been in an unrealized loss position for more than 12 months. Premiums and discounts are amortized or accreted over the life of the related security as an adjustment to yield using the straight-line method and are included in interest income. Interest income is recognized when earned. During the third quarter of 2015 the Company's investment securities matured and the Company held the proceeds as cash equivalents. As of September 30, 2015, the Company had no investment securities.

[Table of Contents](#)

The following table sets forth the composition of the Company's investment securities (in thousands) as of December 31, 2014:

As of December 31, 2014	Maturity in Years	Amortized Cost	Unrealized		Fair Value
			Gains	Losses	
Corporate debt securities	Less than 1 year	\$ 70,521	\$—	\$ (8)	\$70,513

Net Loss Per Share Attributable to Common Stockholders

Basic and diluted net loss per common share is calculated by dividing net loss applicable to common stockholders by the weighted-average number of common shares outstanding during the period, without consideration for common stock equivalents. Potentially dilutive shares, which include convertible preferred stock and rights to acquire convertible preferred stock (non-controlling interest), warrants for the purchase of common stock and options outstanding under the Company's equity incentive plans, are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive.

Potentially dilutive securities not included in the calculation of diluted net loss per share attributable to common stockholders because to do so would be anti-dilutive are as follows (in common stock equivalent shares):

	Nine Months Ended September 30,	
	2015	2014
Warrants for common stock	152,735	206,340
Common stock options and restricted stock units	1,527,098	2,527,067
	<u>1,679,833</u>	<u>2,733,407</u>

Recent Accounting Pronouncements

In April 2015, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("ASU") No. 2015-03, Interest - Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs. The amendments in this ASU require that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The amendments in this ASU are effective for financial statements issued for fiscal years beginning after December 15, 2015, and interim periods within those fiscal years. Early adoption of the amendments is permitted. The new guidance shall be applied on a retrospective basis, wherein the balance sheet of each individual period presented should be adjusted to reflect the period-specific effects of applying the new guidance. The Company is currently evaluating the impact of the adoption of this standard on its consolidated financial statements.

In August 2014, the FASB issued ASU 2014-15, which defined management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related disclosure. ASU 2014-15 defined the term substantial doubt and requires an assessment for a period of one year after the date of the issuance of the financial statements. It requires certain disclosures when substantial doubt is alleviated as a result of consideration of management's plans and requires an express statement and other disclosures when substantial doubt is not alleviated. The guidance becomes effective for reporting periods beginning after December 15, 2016, with early adoption permitted. The Company does not believe that the adoption of this guidance will have a material impact on its consolidated financial statements.

2. Balance Sheet Details

Prepaid expenses and other assets consist of the following (in thousands):

	September 30, 2015	December 31, 2014
Prepaid clinical expenses (1)	\$ 388	\$ —
Prepaid other expenses	546	756
Commercial manufacturing costs (2)	—	1,751
Other receivables	67	628
	<u>\$ 1,001</u>	<u>\$ 3,135</u>

- (1) During the second half of 2015, following the reduction in workforce initiatives (see Note 7), the Company prepaid certain contract research organizations, or CROs, to manage most aspects of the ongoing CUPID2 trial, including the future payments to clinical sites for patient costs. Additionally, the Company prepaid \$0.4 million to CROs in October 2015.
- (2) The commercial manufacturing costs consisted mainly of design and engineering services for commercial drug manufacturing capabilities. The Company determined that it was probable that it would not complete the commercial manufacturing project in light of the CUPID 2 clinical data announced in April 2015 (see Note 7). The Company therefore recorded the costs accumulated as of December 31, 2014 and activity in 2015 as a period expense in the consolidated financial statements in the nine month period ended September 30, 2015.

[Table of Contents](#)

Property and equipment consist of the following (in thousands):

	September 30, 2015	December 31, 2014
Office furniture and other equipment (1)	\$ 174	\$ 881
Leasehold improvements (2)	246	246
Accumulated depreciation (1) (2)	(287)	(364)
	<u>\$ 133</u>	<u>\$ 763</u>

- (1) Following the CUPID 2 trial results and the decision to not pursue additional previously planned development activities with MYDICAR, the Company sold certain MYDICAR manufacturing assets in the third quarter of 2015. The assets had a historical cost of \$0.8 million and accumulated depreciation of \$0.3 million. The Company had recognized an impairment charge of \$0.2 million in the second quarter of 2015 related to the assets which had reduced the net asset value to \$0.3 million, the amount of cash proceeds received (see Note 7).
- (2) In September 2015, in light of the scale-down of certain operations, the Company terminated a sublease agreement effective November 13, 2015, as amended, in order to reduce the Company's office space and corresponding rent obligations. The sublease was originally scheduled to expire in September 2021. The Company revised the estimated depreciable life of the leasehold improvements associated with the facility to end on November 13, 2015. The change in estimated life resulted in an acceleration of depreciation expense in the amount of \$0.1 million in the third quarter of 2015. The net book value of the leasehold improvements was \$0.1 million at September 30, 2015.

Accounts payable and accrued expenses consist of the following (in thousands):

	September 30, 2015	December 31, 2014
Accounts payable	\$ 228	\$ 3,293
Accrued compensation	93	1,909
Accrued other	547	596
Current portion of deferred rent	157	5
	<u>\$ 1,025</u>	<u>\$ 5,803</u>

3. Fair Value Measurements

The Company's financial instruments primarily consist of cash and cash equivalents, accounts payable and accrued liabilities and historically have included investment securities. The carrying value of these financial instruments generally approximates fair value due to their short-term nature. Investment securities are recorded at fair value.

[Table of Contents](#)

The accounting guidance defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the accounting guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1: Observable inputs such as quoted prices in active markets;

Level 2: Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly; and

Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions

As of September 30, 2015 and December 31, 2014, cash and cash equivalents consist primarily of bank deposits with third-party financial institutions and highly liquid money market securities with original maturities at date of purchase of 90 days or less and are stated at cost which approximate fair value and are classified within the Level 1 designation discussed above. Marketable securities are recorded at fair value, defined as the exit price in the principal market in which the Company would transact, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. Level 2 securities are valued using quoted market prices for similar instruments, non-binding market prices that are corroborated by observable market data, or discounted cash flow techniques and include the Company's investments in corporate debt securities and commercial paper. Financial liabilities that were measured or disclosed at fair value on a recurring basis, and were classified within the Level 3 designation, included the warrant liability and convertible notes prior to their conversion to equity upon the Company's initial public offering in February 2014. None of the Company's non-financial assets and liabilities are recorded at fair value on a non-recurring basis. No transfers between levels have occurred during the periods presented.

Cash equivalents measured at fair value as of September 30, 2015 and December 31, 2014 are all classified within Level 1. As of September 30, 2015, the Company had no investment securities. Below is a summary of other assets and liabilities measured at fair value (in thousands):

	As of December 31, 2014	Fair Value Measurements at Reporting Date Using		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Corporate debt securities	\$ 70,513	\$ —	\$ 70,513	\$ —

4. Commitments and Contingencies

Sublicense Agreement and Amended and Restated License Agreement with AmpliPhi

Sublicense Agreement

In June 2012, the Company entered into a sublicense agreement (the AmpliPhi Sublicense) with AmpliPhi Biosciences Corporation (AmpliPhi), pursuant to which AmpliPhi sublicensed to the Company certain rights under a separate agreement which AmpliPhi entered into in 2009 with the Trustees of University of Pennsylvania (UPenn). Under the terms of the AmpliPhi Sublicense, the Company obtained an exclusive, worldwide sublicense from AmpliPhi under certain UPenn patents related to AAV1 vectors for the development, manufacture, use and sale of companion diagnostics to MYDICAR. In addition, the Company is required to use commercially reasonable efforts to meet certain developmental, regulatory and commercial milestones with respect to companion diagnostics under the agreement. Following the decision to not pursue additional previously planned development activities with MYDICAR and its companion diagnostic, the Company may not currently be in compliance with these milestone requirements and may in the future choose to terminate the agreement. In consideration for the sublicense granted to the Company under the agreement, the Company paid to AmpliPhi a sublicense initiation fee of \$310,000, and the Company is obligated to pay to AmpliPhi an annual sublicense maintenance fee of \$310,000. The Company is also required to pay to AmpliPhi a low single-digit percentage royalty based on net sales of any companion diagnostic covered by a licensed patent sold by the Company, its affiliates or its sublicensees. The Company's royalty obligations continue on a companion diagnostic-by-companion diagnostic and country-by-country basis until the expiration of the last-to-expire valid claim in a licensed patent covering the applicable companion diagnostic in such country. Finally, the Company is obligated to pay to AmpliPhi all royalty and milestone payments that become due and payable by AmpliPhi to UPenn under AmpliPhi's agreement with UPenn as a result of the Company's exercise of the sublicense granted under the Company's agreement with AmpliPhi, including a low single-digit tiered percentage royalty on net sales of any companion diagnostic sold by the Company, its affiliates or its sublicensees, which royalty is separate from and in addition to the royalty payable to AmpliPhi described above, and up to an aggregate of \$850,000 in potential milestone payments per product covered by the licensed patents.

[Table of Contents](#)

The Company may unilaterally terminate the agreement upon 30 days' written notice to AmpliPhi. Absent early termination, the agreement will automatically terminate upon the expiration of the last-to-expire licensed patent, which is expected to be in 2019.

The Company recorded \$0.3 million in research and development expense in each of the nine month periods ended September 30, 2015 and September 30, 2014. Through September 30, 2015, no milestone obligations were incurred under the agreement.

Amended and Restated License Agreement

The Company entered into an amended and restated license agreement with AmpliPhi concurrently with the AmpliPhi Sublicense that both amended the terms of the license agreement which the Company entered into with AmpliPhi in 2009 and terminated its manufacturing agreement with AmpliPhi which the Company entered into in 2009. Under the agreement, the Company obtained an exclusive, worldwide license under certain patents and know-how related to AmpliPhi's AAV vector and manufacturing technology for the development, manufacture, use and sale of MYDICAR. In addition, the Company has agreed to use commercially reasonable efforts to meet certain diligence milestones with respect to the development and commercialization of at least one product covered by the UPenn patent rights licensed to AmpliPhi by UPenn under the Company's agreement with UPenn. Following the decision to not pursue additional previously planned development activities with MYDICAR and its companion diagnostic, the Company may not currently be in compliance with these milestone requirements.

During the term of the agreement, the Company is not obligated to make annual license or maintenance payments, but is obligated to pay to AmpliPhi all royalty and milestone payments that become due and payable by AmpliPhi to UPenn under AmpliPhi's agreement with UPenn as a result of the Company's exercise of the sublicense granted under the Company's agreement with AmpliPhi. This includes a low single-digit tiered percentage royalty on net sales of MYDICAR and any other product covered by the licensed patents sold by the Company, its affiliates or its sublicensees, and up to \$850,000 in milestone payments upon the achievement of certain developmental and regulatory milestones related to MYDICAR and any other product covered by the licensed patents. Through September 30, 2015, no milestone obligations were incurred under the agreement. The agreement does not provide either party with termination rights and does not have a provision for expiration or automatic termination.

Exclusive Patent License with the Regents of the University of Minnesota

In May 2009, the Company entered into an exclusive patent license agreement with the Regents of the University of Minnesota (UMinn) under which it obtained an exclusive license to UMinn's joint ownership interest in a patent application related to screening technology for isolation of small molecule modulators of SERCA enzymes. The agreement did not encompass a manufacturing agreement. The Company suspended further development of the small molecule program in the first half of 2015 and, after review of its strategic alternatives, cancelled the patent license agreement in September 2015. The Company recorded \$0.1 million in research and development expense in each of the nine month periods ended September 30, 2015 and September 30, 2014. No milestone obligations were incurred under the agreement.

Material Transfer and Exclusivity Agreement

In February 2014, the Company and Les Laboratoires Servier (Servier) entered into a material transfer and exclusivity agreement, pursuant to which the Company agreed to transfer to Servier samples of certain proprietary compounds from the Company's small molecule SERCA2b modulator program and granted to Servier a non-exclusive, non-sublicensable, royalty-free license to conduct certain studies of the samples for the purpose of evaluating Servier's interest in negotiating a potential license and research collaboration agreement with the Company relating to small molecule SERCA2b modulators (Compounds), for the treatment of type 2 diabetes and other metabolic diseases. In 2015 the Company concluded certain pre-clinical studies in coordination with Servier and the evaluation period has expired.

License Agreement with Enterprise

On July 18, 2014, the Company and Enterprise Partners Management, LLC (Enterprise), an affiliate of Enterprise Partners Venture Capital, entered into an Assignment and License Agreement (the Enterprise License Agreement), pursuant to which Enterprise granted to the Company an exclusive, worldwide license and the assignment of patents held by Enterprise relating to certain gene therapy applications of the membrane-bound form of the Stem Cell Factor gene (mSCF) for treatment of cardiac ischemia. The Company has the right to grant sublicenses to third parties under the Enterprise License Agreement. Entities affiliated with Enterprise beneficially owned more than 10% of the Company's stock as of the date the Enterprise License Agreement was executed.

[Table of Contents](#)

In consideration for the rights granted to the Company under the Enterprise License Agreement, the Company paid an upfront fee to Enterprise of \$160,000. The Company is also obligated to pay to Enterprise a milestone payment in the amount of \$1,000,000 upon the grant to the Company, a Company affiliate or a Company sublicensee of the first regulatory approval in the United States of a product that is covered by the licensed patents. In addition, the Company is required to pay to Enterprise a 2% royalty on net sales of products sold by the Company, Company affiliates and Company sublicensees that are covered by the licensed patents. The Company's royalty obligations continue on a product-by-product and country-by-country basis until the expiration of the last-to-expire valid claim in the licensed patents covering a licensed product in such country.

The Company may unilaterally terminate the Enterprise License Agreement upon written notice to Enterprise. Enterprise may terminate the agreement in the event of the Company's material breach of the Enterprise License Agreement if such breach remains uncured for 90 days following receipt of written notice of such breach. Absent early termination, the Enterprise License Agreement will automatically terminate upon the expiration of the last-to-expire of the licensed patents containing a valid claim.

Other License Agreements

The Company has entered into various license agreements pursuant to which the Company acquired certain intellectual property. Pursuant to each agreement the Company paid a license fee and reimbursed historical patent costs. Additionally, under each agreement, the Company may be required to pay annual maintenance fees, royalties, milestone payments and sublicensing fees. Each of the license agreements is generally cancelable by the Company, given appropriate prior written notice. The Company cancelled certain license agreements following the CUPID 2 clinical trial results in April 2015 (see Note 7). Minimum annual payments to maintain these cancelable licenses total an aggregate of approximately \$0.1 million and potential future milestone payments total an aggregate of approximately \$0.9 million. The Company has recorded research and development expense related to license and annual maintenance fees under the agreements of \$0.2 million and \$0.2 million for the nine month periods ended September 30, 2015 and September 30, 2014, respectively.

Through September 30, 2015, the Company has recorded research and development expense of \$0.1 million related to milestone obligations incurred under the agreements.

Leases

The Company leases office space in San Diego, California under a long-term operating lease that expires in October 2017 and a short-term operating lease that expires in January 2016. In September 2015, in light of the scale-down of certain operations, the Company terminated a sublease agreement for office space effective November 13, 2015, as amended, and paid an early termination fee of approximately \$1.0 million. The subleased office space was in San Diego, California and the sublease was originally scheduled to expire in September 2021. In the third quarter of 2015 the Company also terminated its Seattle, Washington leases and paid an early termination fee of \$0.2 million. Rent expense for the three months and nine months ended September 30, 2015 was \$31,000 and \$0.3 million, respectively, which expense included \$0.1 million for the acceleration of deferred rent due to the early termination of the sublease agreements. Rent expense for the three months and nine months ended September 30, 2014 was \$94,000 and \$136,000, respectively. Future minimum payments under the long-term operating leases net of contractual sublease payments total \$51,000.

5. Stockholders' Equity

Common Stock Warrants

The following table summarizes the fully exercisable warrants outstanding for the purchase of common stock as of September 30, 2015 and December 31, 2014:

<u>September 30, 2015</u>	<u>December 31, 2014</u>	<u>Exercise Price</u>	<u>Expiration Date</u>
<u>152,735</u>	<u>206,340</u>	\$ 5.61	October 2018

Stock Options

Options granted under the Company's equity incentive plans generally expire no more than ten years from the date of grant and generally vest and become exercisable over a period not to exceed four years, as determined by the Company's board of directors. Recipients of stock options are eligible to purchase shares of the Company's common stock at an exercise price equal to no less than the estimated fair market value of such stock on the date of grant. The Company has also granted inducement stock options outside an equity incentive plan that are subject to the terms and conditions of the Company's 2013 Equity Incentive Plan.

Prior Plans

In December 2001, the Company adopted its 2001 Stock Option Plan (the 2001 Plan) and in January 2012 adopted its 2012 Equity Incentive Plan (the 2012 Plan, and together with the 2001 Plan, the Prior Plans). The Prior Plans have terminated and no further shares may be granted under the Prior Plans.

2013 Equity Incentive Plan

The 2013 Equity Incentive Plan became effective in February 2014. Under the 2013 Equity Incentive Plan, the Company may grant stock options, stock appreciation rights, restricted stock, restricted stock units (RSUs), performance-based stock awards and other awards to individuals who are then employees, officers, non-employee directors or consultants of the Company and its affiliates. Additionally, the 2013 Equity Incentive Plan provides for the grant of performance cash awards. The number of shares of common stock reserved for issuance under the 2013 Equity Incentive Plan will automatically increase on January 1 of each year continuing through and including January 1, 2023 by 5% of the total number of shares of the Company's capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by the Company's board of directors.

A summary of the Company's stock option and RSU activity is as follows:

	<u>Options and RSUs</u>
Outstanding at December 31, 2014	2,408,634
Granted	1,342,750
Exercised	(383,011)
Cancelled	(1,841,275)
Outstanding at September 30, 2015	<u>1,527,098</u>

2013 Employee Stock Purchase Plan

The 2013 Equity Stock Purchase Plan (ESPP) became effective in January 2014. The number of shares of common stock reserved for issuance will automatically increase on January 1 of each calendar year through January 1, 2023 by the least of (1) 1% of the total number of shares of the Company's common stock outstanding on December 31 of the preceding calendar year, (2) 384,307 shares, or (3) a number determined by the Company's board of directors that is less than (1) and (2).

Stock-Based Compensation Expense

The allocation of stock-based compensation for all equity awards is as follows (in thousands):

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2015</u>	<u>2014</u>	<u>2015</u>	<u>2014</u>
Research and development (1)	\$(663)	\$391	\$ 929	\$1,175
General and administrative	645	520	2,254	1,003
	<u>\$ (18)</u>	<u>\$911</u>	<u>\$3,183</u>	<u>\$2,178</u>

- (1) During the three months ended September 30, 2015, following the reduction in workforce initiatives (see Note 7), the Company reversed the previously recorded expense for unvested options of terminated employees aggregating \$0.8 million.

As of September 30, 2015 the unrecognized compensation cost related to outstanding employee options was \$7.3 million and is expected to be recognized as expense over approximately 2.9 years.

6. Long-Term Obligations

Hercules Loan Agreement

On July 31, 2014, the Company entered into a Loan and Security Agreement (the Loan Agreement) with Hercules Technology III, L.P. and Hercules Technology Growth Capital, Inc. (as agent and as a lender, and together with Hercules Technology III, L.P., the Lenders) under which up to \$25.0 million was available for the Company to borrow in two tranches (the Loan).

The Company borrowed the first tranche of \$10.0 million on August 1, 2014. The Loan accrued interest at a rate equal to the greater of either (i) 8.25% plus the prime rate as reported from time to time in The Wall Street Journal minus 5.25%, and (ii) 8.25%. Contractual payments under the Loan Agreement were interest only until August 1, 2015 followed by equal monthly payments of principal and interest, through the scheduled maturity date on February 1, 2018. In addition, a final payment equal to \$1,750,000 was due at such time as the Loan was prepaid or became due and payable in full as specified in the Loan Agreement.

The second tranche of up to \$15.0 million was available to be drawn through June 30, 2015, but only if the Company provided the Lenders with notice that data from the Company's Phase 2b clinical trial for MYDICAR supported the continued development of MYDICAR for its Breakthrough Therapy designation to either a Phase 3 clinical trial or for registration for approval, as reasonably determined by the Company's senior management and board of directors (the Milestone). In April 2015, the Company's senior management and board of directors determined that the Company did not achieve the Milestone (see Note 7). Accordingly, the Company could not draw down the second tranche of \$15.0 million.

In June 2015 the Company announced it would prepay the outstanding amounts due under the Loan Agreement and on August 3, 2015, the Company paid the Lenders (i) the \$10,000,000 outstanding principal balance, (ii) \$75,625 in accrued and unpaid interest, and (iii) an end of term charge of \$1,750,000, for a total payment of \$11,825,625. Upon the prepayment on August 3, 2015, the Company's obligations, covenants, debts and liabilities under the Loan Agreement were satisfied in full and the Lender's commitments to extend further credit to the Company were terminated.

Capital Lease

In 2014 the Company entered into a capital lease arrangement for office equipment in the Company's San Diego, California office. The Company was obligated to make 60 payments of approximately \$600. In September 2015 the Company purchased and obtained title to the office equipment. At September 30, 2015, the Company had no capital lease obligations.

7. Restructuring charges

On April 26, 2015, the Company announced that its Phase 2b CUPID 2 trial did not meet its primary and secondary endpoints. No safety issues were noted. In light of the CUPID 2 results and following analysis of the CUPID 2 data, the Company's board of directors, in two phases prior to September 30, 2015, approved an approximately 70% aggregate reduction of the Company's peak workforce of 34 employees to reduce operating expenses and conserve cash resources. The Company has also committed to retention payments payable to certain key employees if such employees remain with the Company until December 31, 2015 or are terminated by the Company without cause prior to such date.

Restructuring charges for each period were as follows (in thousands):

	Three Months Ended		Nine Months Ended	
	September 30, 2015	2014	September 30, 2015	2014
Employee severance and related costs	\$ 675	\$—	\$3,543	\$—
Facility lease termination costs	1,127	—	1,127	—
Asset impairments	(21)	—	192	—
Total restructuring and asset impairment charges	<u>\$1,781</u>	<u>\$—</u>	<u>\$4,862</u>	<u>\$—</u>

[Table of Contents](#)

The accrued restructuring activity during the nine months ended September 30, 2015 was as follows:

	<u>Employee Severance and Related Costs</u>	<u>Facility Lease Termination Costs</u>	<u>Total</u>
Accrued restructuring balance as of December 31, 2014	\$ —	\$ —	\$ —
Additional accruals	3,543	1,127	4,670
Cash payments	(2,934)	(1,127)	(4,061)
Accrued restructuring balance as of September 30, 2015	<u>\$ 609</u>	<u>\$ —</u>	<u>\$ 609</u>

The Company recorded the additional accruals as restructuring charges in the consolidated statements of operations. The accrued restructuring balance as of September 30, 2015, is presented as a current liability in the consolidated balance sheets and is expected to be paid within the fourth quarter of 2015. The charges incurred during the nine months ended September 30, 2015, included \$2.4 million related to employee severance costs, which impacted 25 employees who were notified of their termination prior to September 30, 2015, \$1.1 million related to retention payment accruals, and \$1.1 million related to facility lease termination costs. The Company expects to record an additional \$0.3 million related to retention payments in the fourth quarter of 2015.

Following the announcement on June 26, 2015, that the Company had suspended further research and development of its MYDICAR programs, the Company determined that certain equipment used in the MYDICAR manufacturing process was impaired and an asset impairment charge of \$0.2 million was recorded to restructuring charges in the consolidated statements of operations for the nine months ended September 30, 2015. The equipment was subsequently sold in September 2015.

The Company may incur additional charges in connection with future restructuring activities.

8. Litigation

In July 2015, following the Company'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 the Company's common stock, 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 the Company and certain of the Company'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 by making materially false and misleading statements regarding the clinical trial program for MYDICAR, thereby artificially inflating the price of the Company's common stock. The complaints seek unspecified monetary damages and other relief, including attorneys' fees. The Company expects the court to consolidate the three putative securities class actions and to appoint a lead plaintiff to represent the putative class. The Company then expects the lead plaintiff to file a consolidated 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 the Company and/or the Company's officers and directors as defendants. The Company believes that it has meritorious defenses and intends to defend these lawsuits vigorously. Due to the early stage of these proceedings, the Company is not able to predict or reasonably estimate the ultimate outcome or possible losses relating to these claims.

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

The following Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with our unaudited consolidated financial statements and related notes thereto included in this Quarterly Report on Form 10-Q and with our consolidated financial statements and the related notes thereto that are contained in our Annual Report on Form 10-K for the year ended December 31, 2014, or Annual Report, which has been filed with the Securities and Exchange Commission, or SEC. In addition to historical information, the following discussion and analysis includes forward-looking information that involves risks, uncertainties, and assumptions. Actual results and the timing of events could differ materially from those anticipated by these forward-looking statements as a result of many factors, including those discussed under "Risk Factors" elsewhere in this Form 10-Q and in our Annual Report.

Forward-Looking Statements

This Quarterly Report on Form 10-Q may contain "forward-looking statements." We may, in some cases, use words such as "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "will," "would" or the negative of those terms, and similar expressions that convey uncertainty of future events or outcomes, to identify these forward-looking statements. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- Whether, and to what extent, we continue our business operations as a drug development company;
- our ability to identify and implement a potential strategic transaction, including the possible merger, sale of our company or some or all of our assets, and/or a liquidation and distribution of the remaining cash to our shareholders;
- the timing of a merger, sale and/or liquidation and distribution, if any;
- the possibility of dissolving our company;
- our ability to obtain funding for our operations in the event we continue drug development activities;
- our ability to maintain our listing on the NASDAQ Stock Market;
- the amount and timing of charges expected to be incurred with our restructuring activities;
- our future operating expenses and other results of operations;
- our ongoing development activities;
- the accuracy of our estimates regarding expenses, capital requirements and future funding needs;
- our ability to obtain funding for our operations;
- our ability to retain key personnel;
- our agreements with third parties;
- regulatory developments in the United States and foreign countries;
- our expectations regarding our ability to obtain and maintain intellectual property protection;
- our expectations regarding the period during which we qualify as an emerging growth company under the Jumpstart Our Business Startups Act of 2012, or the JOBS Act; and
- the outcome and resolution of litigation pending against us.

These forward-looking statements reflect our management's beliefs and views with respect to future events and are based on estimates and assumptions as of the filing date of this Quarterly Report and are subject to risks and uncertainties. We discuss many of these risks in greater detail under "Risk Factors." Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise.

Overview

We are a biotechnology company that has been focused on the development of cardiovascular gene therapy. As a consequence of the negative results from the Phase 2b clinical trial of our lead product candidate, MYDICAR (AAV1/SERCA2a), we are evaluating our strategic opportunities to maximize shareholder value, including the possibility of a merger or sale of our company, or all or some of our assets, and/or a liquidation. Our ability to continue our operations involves numerous significant risks and uncertainties, including the risks and uncertainties set forth in Item 1A under the heading “Risk Factors” of this Quarterly Report on Form 10-Q.

We are currently in the long-term follow-up stage of a 250-patient randomized, double-blind, placebo-controlled multinational Phase 2b trial that was designed to evaluate MYDICAR in patients with heart failure for reduced ejection fraction, or HFrEF (also referred to as systolic heart failure). We refer to this Phase 2b trial as the CUPID 2 trial. CUPID 2 evaluated a single, one-time, intracoronary infusion of the cardiovascular gene therapy agent MYDICAR versus placebo, in each case added to a maximal, optimized heart failure drug and device regimen. We completed enrollment of CUPID 2 in February 2014 and un-blinded the results from the active observation period in late April 2015.

On April 26, 2015, we announced that the CUPID 2 trial did not meet its primary and secondary endpoints and failed to show any treatment effect. Following our un-blinding of the CUPID 2 data, we implemented cost-cutting measures, including a reduction in workforce and termination of certain contracts related to MYDICAR, and subsequently decided to not pursue additional previously planned development activities.

During the second quarter of 2015, our board of directors approved, in two phases, an aggregate reduction of approximately 70% of our peak workforce of 34 employees as of April 30, 2015 in order to reduce operating expenses and conserve cash resources. The majority of employees included in this workforce reduction were separated during the second quarter of 2015, with the remainder separated during the third quarter of 2015. We also committed to retention payments payable to certain key employees if such employees remain employed by us until December 31, 2015 or are terminated by us without cause prior to such date.

On June 23, 2015, our Board of Directors approved the voluntary prepayment of the outstanding amounts due under our Loan and Security Agreement with Hercules Technology III, L.P. and Hercules Technology Growth Capital, Inc. (as agent and as a lender, and together with Hercules Technology III, L.P., the “Lenders”) dated July 31, 2014 (the “Loan Agreement”), with such prepayment to be effected on August 3, 2015 (the “Prepayment Date”). On the Prepayment Date, the Company paid the Lenders: (i) the \$10.0 million outstanding principal balance, (ii) \$0.1 million in accrued and unpaid interest, and (iii) an end of term charge of \$1.8 million for a total payment of \$11.8 million.

On September 10, 2015, we entered into a Sublease Termination and Settlement Agreement (the “Termination Agreement”) with Brandes Investment Partners, L.P. (“Brandes”) providing for the termination of that certain Sublease Agreement by and between us and Brandes dated May 28, 2014 (the “Lease”). Pursuant to the Termination Agreement, the parties agreed to terminate the Lease, effective October 31, 2015, which the parties subsequently extended to November 13, 2015 (the “Effective Date”). We agreed to pay an early termination fee of \$950,000 to Brandes in consideration of Brandes’ entry into the Termination Agreement and release of us from any further base rent or other payment obligations that would otherwise arise pursuant to the Lease after the Effective Date. At this time, our current development activities are limited to the oversight of the long-term follow up period in the CUPID 2 trial, which is expected to continue through February 2016.

Historically, we have devoted substantially all of our resources to research and development efforts relating to our product candidates, including conducting clinical trials and developing manufacturing capabilities, in-licensing related intellectual property, providing general and administrative support for these operations and protecting our intellectual property. We do not have any products approved for sale and have not generated any revenue from product sales or other sources. From our inception through September 30, 2015, we have funded our operations primarily through the sales of equity and debt securities totaling approximately \$208.3 million.

We have incurred net losses in each year since our inception. As of September 30, 2015, we had an accumulated deficit of approximately \$186.1 million. Substantially all of our net losses, including those incurred during the periods presented in this report, have resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations.

We cannot predict whether and to what extent we will resume drug development activities, and what our future cash needs would be for any such activities.

[Table of Contents](#)

If we are unable to seek an appropriate use for our remaining assets, our board of directors may decide to pursue a dissolution and liquidation of our company. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities.

Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the results of our identification and evaluation of potential strategic alternatives;
- the extent to which we elect to pursue drug development activities in the future; and
- the costs associated with litigation, including the costs incurred in defending against claims made in the three putative class action complaints filed in July 2015 following our announcements regarding the negative CUPID 2 data and suspension of further research and development activities and the subsequent decline of the price of our common stock.

Financial Operations Overview

Research and Development Expenses

Prior to the suspension of our further research and clinical development activities, we devoted substantially all of our resources to research and development efforts relating to our product candidates, including conducting clinical trials, developing manufacturing capabilities, in-licensing related intellectual property, providing general and administrative support for these operations and protecting our intellectual property. We recognize research and development expenses as they are incurred. Our research and development expenses have consisted primarily of:

- salaries and related overhead expenses, which include stock-based compensation and benefits for personnel in research and development functions;
- fees paid to contract manufacturers for commercial scale-up activities;
- fees paid to consultants and contract research organizations, or CROs, including in connection with our preclinical studies and clinical trials and other related clinical trial fees, such as for investigator grants, patient screening, laboratory work, clinical trial material management and statistical compilation and analysis;
- costs related to acquiring and manufacturing clinical trial materials, including continued testing such as process validation and stability of drug product;
- costs related to compliance with regulatory requirements; and
- payments related to licensed products and technologies.

From our inception through September 30, 2015, we have incurred approximately \$136.5 million in research and development expenses, of which we estimate \$129.8 million relates to our development of MYDICAR. Our direct research and development expenses have consisted principally of external costs, such as fees paid to investigators, consultants, central laboratories and CROs, in connection with our clinical trials, developing manufacturing capabilities and costs related to acquiring and manufacturing clinical trial materials. Prior to our reductions in force including all our research and development staff, we typically used our employee and infrastructure resources across multiple research and development programs. We expect our research and development expenses to decrease compared to prior periods through the completion of the CUPID 2 trial in the first quarter of 2016 due to a reduction in workforce, the suspension of further research and development activities and reduced facility space and rent.

MYDICAR-HFrEF

Prior to the suspension of our further research and clinical development activities, the majority of our research and development resources were focused on our CUPID 2 trial, commercialization and manufacturing preparations, clinical trials and other work needed to submit MYDICAR for regulatory approval in the United States and Europe.

MYDICAR-PAH

Prior to the suspension of our further research and clinical development activities, our research and development expenses for MYDICAR for PAH related primarily to the preclinical testing in porcine models of PAH.

[Table of Contents](#)

Stem Cell Factor Program

Prior to the suspension of our further research and clinical development activities, our research and development expenses for our stem cell factor program related primarily to the preclinical testing of the membrane-bound form of the Stem Cell Factor gene, or mSCF, in myocardial infarction porcine models.

Small Molecule Program

Prior to the suspension of our further research and clinical development activities, our research and development expenses for our small molecule program related primarily to identification and pre-clinical testing of small molecule SERCA2 enzyme modulators.

General and Administrative Expenses

General and administrative expenses have consisted primarily of salaries and related costs for employees in executive, finance, legal and administration, corporate development and administrative support functions, including stock-based compensation expenses and benefits. Other significant general and administrative expenses have included accounting and legal services, expenses associated with obtaining and maintaining patents, the cost of various consultants, occupancy costs and information systems costs. We expect our general and administrative expenses to decrease compared to prior periods for the foreseeable future due to a reduction in workforce, suspended activities related to pre-commercial planning and reduced facility space and rent.

Restructuring Charges

In light of the CUPID 2 results and following analysis of the CUPID 2 data, we implemented two reductions in workforce starting in the second quarter of 2015 to reduce operating expenses and conserve cash resources while we evaluate our strategic alternatives. We have also committed to retention payments payable to certain key employees if such employees remain with our company until December 31, 2015 or are terminated by us without cause prior to such date. The restructuring charges consisting of severance and retention commitments are expected to be fully settled in 2015. Also included in restructuring charges were asset impairments related to certain equipment used in the MYDICAR manufacturing process and early termination fees incurred upon the termination of certain facility subleases. We may incur additional charges in the future for additional restructuring activities.

Other Income (Expense)

Other income consists primarily of interest income earned on our cash, cash equivalents and investments. We expect our interest income to decrease as we reduce our investment balance to fund current operations. Other expense consists primarily of the accretion of debt discount and interest charges on our prior debt agreements and the change in the fair value of our outstanding warrant liability prior to its reclassification to stockholders' equity in February 2014 in connection with the closing of our initial public offering. In August 2015 we prepaid the outstanding amounts due under our Loan and Security Agreement and recorded the debt discount balance as interest expense in our financial statements.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which we have prepared in accordance with generally accepted accounting principles in the United States, or GAAP. The preparation of our consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of our consolidated financial statements, as well as the reported expenses during the reported periods. We evaluate these estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are further described in Note 1 to our consolidated financial statements appearing elsewhere in this Form 10-Q, we believe that the following accounting policies related to clinical trial expenses and valuation of stock-based compensation are the most critical for fully understanding and evaluating our financial condition and results of operations.

Clinical Trial Accruals

As part of the process of preparing our consolidated financial statements, we are required to estimate our expenses resulting from our obligations under contracts with vendors and consultants and clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided to us under such contracts. Our clinical trial accrual is dependent upon the timely and accurate reporting of CROs and other third-party vendors.

Our objective is to reflect the appropriate clinical trial expenses in our consolidated financial statements by matching those expenses with the period in which services and efforts are expended. We account for these expenses according to the progress of the trial as measured by patient progression and the timing of various aspects of the trial. We determine accrual estimates through discussion with applicable personnel and outside service providers as to the progress or state of completion of clinical trials, or the services completed. During the course of a clinical trial, we adjust the rate of clinical trial expense recognition if actual results differ from the estimates. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known at that time. Although we do not expect that our estimates will be materially different from amounts actually incurred, our understanding of status and timing of services performed relative to the actual status and timing of services performed may vary and may result in our reporting amounts that are too high or too low for any particular period. Through September 30, 2015, there had been no material adjustments to our prior period estimates of accrued expenses for clinical trials. However, due to the nature of estimates, we cannot assure you that we will not make changes to our estimates in the future as we become aware of additional information about the status or conduct of our clinical trials.

Stock-Based Compensation

Stock-based compensation expense represents the grant date fair value of employee equity grants recognized over the requisite service period of the awards (usually the vesting period) on a straight-line basis, net of estimated forfeitures. For awards with performance-based milestones, the expense is recorded over the remaining service period after the point when the achievement of the milestone is probable or the performance condition has been achieved.

We account for awards granted to non-employees using the fair-value approach. These awards are subject to periodic revaluation over their vesting terms.

We estimate the fair value of our stock options granted to employees and non-employees using the Black-Scholes option pricing model, which requires the input of highly subjective assumptions, including (a) the risk-free interest rate, (b) the expected volatility of our stock, (c) the expected term of the award and (d) the expected dividend yield. Until our recently completed initial public offering, there was no public market for the trading of our common stock. Due to this fact and a lack of company specific historical and implied volatility data, we have based our estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. For these analyses, we have selected companies with comparable characteristics to ours, including enterprise value, risk profiles, position within the industry and with historical share price information sufficient to meet the expected life of the stock-based awards. We compute the historical volatility data using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of our stock-based awards. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our own stock price becomes available. We have estimated the expected life of our employee stock options using the "simplified" method, whereby, the expected life equals the average of the vesting term and the original contractual term of the option. The risk-free interest rate is based on U.S. Treasury zero-coupon bonds with maturities similar to those of the expected term of the award being valued.

Recent Accounting Pronouncements

See Item 1 of Part I, "Notes to Consolidated Financial Statements — Note 1 — Basis of Presentation, Organization and Summary of Significant Accounting Policies" of this Quarterly Report on Form 10-Q.

Results of Operations**Comparison of the Three Months Ended September 30, 2015 and 2014**

The following table summarizes our results of operations for the three months ended September 30, 2015 and 2014 (in thousands):

	Three Months Ended September 30,		Increase / (Decrease)
	2015	2014	
Research and development	\$ 738	\$5,316	\$ (4,578)
General and administrative	2,533	2,815	(282)
Restructuring charges	1,781	—	1,781
Total other (expense) income	(1,344)	(227)	(1,117)

Research and Development Expenses. Research and development expenses were \$0.7 million and \$5.3 million for the three months ended September 30, 2015 and 2014, respectively. The decrease of approximately \$4.6 million was primarily due to a decrease of \$1.2 million in expenses incurred during the third quarter of 2015 associated with drug substance manufacturing scale-up as a result of suspension of MYDICAR manufacturing activities, \$1.1 million in stock based compensation and \$0.8 million in compensation costs due to a reduction in workforce including all the research and development staff, \$0.9 million in clinical and preclinical costs, and \$0.6 million in consulting and various other expenses. We anticipate a further reduction in our research and development expenses for the foreseeable future due to the suspension of further development of MYDICAR and other pre-clinical programs and the reduction in workforce as we evaluate our strategic alternatives.

General and Administrative Expenses. General and administrative expenses were \$2.5 million and \$2.8 million for the three months ended September 30, 2015 and 2014, respectively. The decrease of approximately \$0.3 million was due to a decrease of \$0.3 million in compensation costs due to a reduction in workforce as compared to the same period in 2014, \$0.2 million in pre-commercial planning costs due to the suspension of pre-commercial planning activities, \$0.2 million in patent related costs, and \$0.4 million in rent, recruiting and other administrative expenses offset by an increase of \$0.3 million in consulting costs and \$0.2 million in legal and various other public company costs due to additional service fees incurred as a result of strategic planning activities, \$0.2 million in depreciation expense as a result of a change in the estimated useful life of certain assets, and \$0.1 million in stock based compensation. We expect our general and administrative expenses to decrease in the foreseeable future due to a reduction in workforce and the suspended activities related to pre-commercial planning efforts.

Restructuring Charges. Restructuring charges were \$1.8 million and zero for the three months ended September 30, 2015 and 2014, respectively. In light of the CUPID 2 results and following analysis of the CUPID 2 data in the second quarter of 2015, our board of directors, in two phases prior to September 30, 2015, approved an approximately 70% aggregate reduction of our peak workforce of 34 employees to reduce operating expenses and conserve cash resources. We have also committed to retention payments payable to certain key employees if such employees remain with Celladon until December 31, 2015 or are terminated by the Company without cause prior to such date. We suspended further research or development of our MYDICAR (AAV1/SERCA2a) program and our pre-clinical programs. The charges incurred during the three months ended September 30, 2015, included \$1.1 million in facility lease termination costs, \$0.6 million related to retention payment costs and \$0.1 million related to employee severance costs. In connection with the restructuring activities executed to date, we anticipate recording \$0.3 million in charges related to retention payments in the fourth quarter of 2015. We have committed to approximately \$3.8 million in aggregate charges related to employee severance and related costs which are expected to be settled in 2015. We estimate that employee actions implemented to date will result in gross quarterly savings of approximately \$1.5 million, which will be realized within research and development and within general and administrative. We began to realize these savings in the second quarter of 2015 and expect to fully realize these savings by the end of 2015. We may incur additional charges in the future in connection with future restructuring activities.

Other (Expense) Income. Other expense was \$1.3 million and \$0.2 million for the three months ended September 30, 2015 and 2014, respectively. Other expense for the three months ended September 30, 2015 consisted primarily of \$1.3 million of expense related to the accelerated accretion of debt discount and interest charges on our term loan that was prepaid in full in August 2015. Other expense for the three months ended September 30, 2014 consisted primarily of \$0.3 million of expense related to the accretion of debt discount and interest charges on our prior term loan offset by \$44,000 in interest and other income.

[Table of Contents](#)

Comparison of the Nine Months Ended September 30, 2015 and 2014

The following table summarizes our results of operations for the nine months ended September 30, 2015 and 2014 (in thousands):

	Nine Months Ended September 30,		Increase / (Decrease)
	2015	2014	
Research and development	\$21,757	\$15,515	\$ 6,242
General and administrative	10,805	6,545	4,260
Restructuring charges	4,862	—	4,862
Total other (expense) income	(2,243)	(452)	(1,791)

Research and Development Expenses. Research and development expenses were \$21.8 million and \$15.5 million for the nine months ended September 30, 2015 and 2014, respectively. The increase of approximately \$6.2 million was primarily due to an increase of \$7.0 million in expenses incurred during the first nine months of 2015 associated with drug substance manufacturing scale-up prior the negative results of the CUPID 2 trial, \$0.9 million in preclinical costs and \$0.1 million in rent expense, offset by a decrease of \$1.4 million in clinical expenses due to completion of CUPID 2 clinical trial during the first quarter of 2015, a decrease of \$0.2 million in stock-based compensation and \$0.2 million in cash compensation costs due to reduction in force including all the research and development staff compared to the same period in 2014. We anticipate a further reduction in our research and development expenses for the foreseeable future due to the suspension of development of MYDICAR and other pre-clinical programs and the reduction in workforce.

General and Administrative Expenses. General and administrative expenses were \$10.8 million and \$6.5 million for the nine months ended September 30, 2015 and 2014, respectively. The increase of approximately \$4.3 million was primarily due an increase of \$1.3 million in stock-based compensation due to additional grants, \$1.2 million in pre-commercial planning efforts, \$1.0 million in compensation costs related to both an increase in staff through May 2015 compared to the same period in the prior year and separation charges associated with the departure of our chief executive officer, \$1.0 million in consulting and public company related costs, and \$0.2 million in depreciation expense offset by a decrease of \$0.4 million in recruiting, investor relations and various other administrative costs. We expect our general and administrative expenses to decrease in the foreseeable future due to a reduction in workforce and the suspended activities related to pre-commercial planning efforts.

Restructuring Charges. Restructuring charges were \$4.9 million and zero for the nine months ended September 30, 2015 and 2014, respectively. In light of the CUPID 2 results and following analysis of the CUPID 2 data in the second quarter of 2015, our board of directors, in two phases prior to September 30, 2015, approved an approximately 70% aggregate reduction of our peak workforce of 34 employees to reduce operating expenses and conserve cash resources. We have also committed to retention payments payable to certain key employees if such employees remain with Celladon until December 31, 2015 or are terminated by the Company without cause prior to such date. We suspended further research or development of our MYDICAR (AAV1/SERCA2a) program and our pre-clinical programs. The charges incurred during the nine months ended September 30, 2015, included \$2.4 million related to employee severance costs, which impacted 25 employees, \$1.1 million related to retention payment charges, \$1.1 million in facility lease termination costs and \$0.2 million in asset impairment charges. In connection with the restructuring activities executed to date, we anticipate recording \$0.3 million in charges related to retention payments in the fourth quarter of 2015. We have committed to approximately \$3.8 million in aggregate charges related to employee severance and related costs which are expected to be settled in 2015. We estimate that employee actions implemented to date will result in gross quarterly savings of approximately \$1.5 million, which will be realized within research and development and within general and administrative. We began to realize these savings in the second quarter of 2015 and expect to fully realize these savings by the end of 2015. We may incur additional charges in the future in connection with future restructuring activities.

Other Expense. Other expense was \$2.2 million and \$0.5 million for the nine months ended September 30, 2015 and 2014, respectively. Other expense for the nine months ended September 30, 2015 consisted primarily of \$2.3 million of expense related to the accelerated accretion of debt discount and interest charges on our term loan which was prepaid in full in August 2015 offset by \$0.1 million in interest income. Other expense for the nine months ended September 30, 2014 consisted primarily of \$0.3 million of expense related to the accretion of debt discount and interest charges on our prior term loan and \$0.2 million related to an increase in the fair value of the warrant liability prior to conversion to equity upon the closing of our initial public offering.

Liquidity and Capital Resources

We have incurred net losses each year since our inception and as of September 30, 2015, we had an accumulated deficit of approximately \$186.1 million. We anticipate that we will continue to incur net losses for the foreseeable future. We expect that our research and development and general and administrative expenses will decrease for the foreseeable future due to a reduction in workforce, suspended activities related to pre-commercial planning and the suspension of further development of MYDICAR and other pre-clinical programs. Should we choose to continue drug development, we expect that we may need additional capital to fund our operations, which we may obtain through one or more public or private equity offerings, debt financings, government or other third-party funding, strategic alliances and licensing or collaboration arrangements. On August 3, 2015, we prepaid the outstanding amounts due under our loan facility with Hercules, including the \$10 million principal borrowed in 2014. Upon the prepayment in August 2015, our obligations, covenants, debts and liabilities under the loan facility were satisfied in full and Hercules' commitments to extend further credit to us were terminated.

[Table of Contents](#)

Since our inception through September 30, 2015, we have funded our operations primarily through the sale of our equity and debt securities. As of September 30, 2015, we had cash and cash equivalents of approximately \$37.1 million. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation.

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

	Nine Months Ended September 30,	
	2015	2014
Net cash provided by (used in):		
Operating activities	\$(36,733)	\$(19,374)
Investing activities	70,369	(71,010)
Financing activities	(10,979)	96,848
Net increase (decrease) in cash and cash equivalents	<u>\$ 22,657</u>	<u>\$ 6,464</u>

Operating activities. Net cash used in operating activities of \$36.7 million during the nine months ended September 30, 2015 was primarily a result of our net loss of \$39.7 million. The primary difference between our net loss and our cash used in operating activities was \$3.2 million of stock-based compensation, \$1.8 million of non-cash interest related to the accretion of debt discount on our prior term loan with Hercules, \$0.4 million of depreciation expense, \$0.2 million of asset impairment charges, \$0.2 million amortization of premiums paid on investment securities, \$0.1 million of deferred rent charges, and \$2.7 million of changes in our operating assets and liabilities.

Net cash used in operating activities of \$19.4 million during the nine months ended September 30, 2014, was primarily a result of our net loss of \$22.5 million. The primary difference between our net loss and our cash used in operating activities was \$2.2 million of stock-based compensation, \$0.2 million related to the change in fair value of the warrant liability, \$0.2 million of non-cash interest related to the accretion of debt discount on our prior debt arrangements, \$0.2 million amortization of premiums paid on investment securities, \$0.2 million of changes in our operating assets and liabilities and \$0.1 million of depreciation expense. In connection with our initial public offering which was completed in February 2014, the warrant liability was reclassified to additional paid-in capital, the outstanding principal and accrued interest on our convertible debt were converted into shares of our common stock and the unamortized debt discount related to the convertible debt was charged to expense.

Investing Activities. Net cash provided by investing activities of \$70.4 million during the nine months ended September 30, 2015 was primarily a result of \$70.3 million in the net maturities of investments used to fund our operating activities and \$0.3 million in proceeds from the sale of property and equipment. Net cash used by investing activities of \$71.0 million during the nine months ended September 30, 2014 was primarily a result of purchases of investment securities of \$88.7 million offset by \$18.2 million net maturities of investments. In 2015 and 2014, amounts of \$0.2 million and \$0.5 million, respectively, were also used to purchase property and equipment.

Financing Activities. Net cash used in financing activities of \$11.0 million during the nine months ended September 30, 2015 consisted of \$11.8 million prepayment in full of our prior term loan and related costs offset by \$0.8 million in proceeds received upon the exercise of employee and consultant stock options. Net cash provided by financing activities of \$96.8 million during the nine months ended September 30, 2014 consisted primarily of \$94.3 million in proceeds received and \$7.4 million in costs paid in connection with our public offerings, \$9.7 million in net borrowings under our prior term loan, \$0.1 million in proceeds upon the exercise of warrants in exchange for common stock and \$0.1 million in proceeds from the sale of shares under our employee stock purchase plan.

Future Funding Requirements

To date, 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 expect that our expenses will decrease for the foreseeable future due to a reduction in workforce, suspended activities related to pre-commercial planning and the suspension of certain research and development activities. We anticipate that we would need additional capital to fund research and development operations, if resumed in the future.

[Table of Contents](#)

Based upon our current operating plan, we believe that our existing cash and cash equivalents will enable us to fund our operations for at least the next 12 months. We are currently evaluating various strategic alternatives for the use of our existing resources. We have based our planning estimates on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect.

Our future capital requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the results of our identification and evaluation of potential strategic alternatives;
- the extent to which we elect to pursue drug development activities in the future; and
- the costs associated with litigation, including the costs incurred in defending against claims made in the three putative class action complaints filed in July 2015 following our announcements regarding the negative CUPID 2 data and suspension of further research and development activities and the subsequent decline of the price of our common stock.

Depending upon our future business prospects and developments, we expect to finance our operating activities through our existing cash and cash equivalents, public or private equity or debt financings, government or other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements or a combination of these approaches. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our common stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through government or other third-party funding, marketing and distribution arrangements or other collaborations, or strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations at September 30, 2015 (in thousands):

	Payments due by period				
	Total	Less than 1 year	1 – 3 Years	3 – 5 Years	More than 5 years
Operating lease obligations	\$214	\$ 106	\$108	\$—	\$ —

During 2015 we prepaid our term loan in full and terminated several facility lease contracts. At September 30, 2015, our operating lease obligations consisted of future rent payments under two San Diego 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.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

As of September 30, 2015, we had market risk exposure related to our cash and cash equivalents. Historically, we have invested our excess cash in highly liquid short-term investments such as money market funds. Changes in interest rates affect the investment income we earn on our investments and therefore impacts our cash flows and results of operations.

We do not believe that our cash and cash equivalents have significant risk of default or illiquidity. While we believe our cash and cash equivalents do not contain excessive risk, we cannot provide absolute assurance that in the future our investments will not be subject to adverse changes in market value. In addition, we maintain significant amounts of cash and cash equivalents at one or more financial institutions that are in excess of federally insured limits.

As of September 30, 2015, all of our short-term investments had matured and we did not have any investments, nor did we have any outstanding indebtedness for amounts borrowed. Accordingly, a 10% change in interest rates from the interest rates on September 30, 2015 would not have had a material effect on our financial condition.

[Table of Contents](#)

We have ongoing clinical trial agreements denominated in euros. 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 nine month period ended September 30, 2015. A 10% change in the euro-to-dollar exchange rate on September 30, 2015 would not have had a material effect on our results of operations or financial condition.

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.

We are responsible for maintaining disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Disclosure controls and procedures are controls and other procedures designed to ensure that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and our principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Based on our management's evaluation (with the participation of our principal executive officer and our principal financial officer) of our disclosure controls and procedures as required by Rule 13a-15 under the Exchange Act, our principal executive officer and our principal financial officer have concluded that our disclosure controls and procedures were effective to achieve their stated purpose as of September 30, 2015, the end of the period covered by this report.

Changes in Internal Control over Financial Reporting.

There were no changes in our internal control over financial reporting during the quarter ended September 30, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1. Legal Proceedings

In July 2015, following our announcements of the negative CUPID 2 data and the suspension of further research and development activities and the subsequent declines of the price of our common stock, 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 us and certain of our 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 by making materially false and misleading statements regarding the clinical trial program for MYDICAR, thereby artificially inflating the price of our common stock. The complaints seek unspecified monetary damages and other relief, including attorneys' fees. We expect the court to consolidate the three putative securities class actions and to appoint a lead plaintiff to represent the putative class. We then expect the lead plaintiff to file a consolidated 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 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.

In May 2015, we received a subpoena from the United States Department of Justice. The subpoena requests specified documents and other records relating to trading in our common stock. We have responded to the subpoena. To date, we have not received further requests related to this matter from the Department of Justice.

Item 1A. Risk Factors

You should carefully consider the following risk factors, as well as the other information in this report, before deciding whether to purchase, hold or sell shares of our common stock. 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 report and those we may make from time to time. You should consider all of the factors described when evaluating our business. The risk factors set forth below that are marked with an asterisk () did not appear as separate risk factors in Item 1A of our Annual Report or contain changes to the similarly titled risk factors included in Item 1A of our Annual Report. If any of the following risks actually occurs, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock would likely decline.*

Risks Related to our Business

Our business to date has been almost entirely dependent on the success of MYDICAR, which recently failed to show a treatment effect in the Phase 2b clinical trial known as CUPID 2. Following the analysis of the data from CUPID 2, we decided to substantially suspend further research and development while we seek a merger or sale, and there is no guarantee that this strategic path will be successful.*

On April 26, 2015, we announced that the CUPID 2 trial did not meet its primary and secondary endpoints. CUPID 2 is a 250-patient randomized, double-blind, placebo-controlled multinational Phase 2b trial that was designed to evaluate MYDICAR in patients with HFrfEF. We had previously devoted substantially all of our research, development and clinical efforts and financial resources toward the development of MYDICAR. As a result of the negative results from CUPID 2, we have suspended further research and development of MYDICAR and our pre-clinical programs to reduce operating expenses while we seek a merger or sale.

There can be no assurance that our process to identify and evaluate potential strategic alternatives will result in any definitive offer to acquire our company or any of its assets, or if made what the terms thereof will be or that any transaction will be approved or consummated. If any definitive offer to acquire our company or assets is received, there can be no assurance that a definitive agreement will be executed or that, if a definitive agreement is executed, the transaction will be consummated. In addition, there can be no assurance that any transaction, involving our company and/or assets, that is consummated would enhance stockholder value. There also can be no assurance that we will conduct drug development activities in the future.

[Table of Contents](#)

If we do not consummate a strategic transaction, our board of directors may decide to pursue a dissolution and liquidation of our company. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities.

There can be no assurance that the process to identify a merger or sale will result in a successful alternative for our business. If no transaction is completed, our board of directors may decide to pursue a dissolution and liquidation of our company. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such decision, as with the passage of time the amount of cash available for distribution will be reduced as we continue to fund our operations while we seek a merger or sale. In addition, if our board of directors were to approve and recommend, and our stockholders were to approve, a dissolution and liquidation of our company, we would be required under Delaware corporate law to pay our outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions in liquidation to our stockholders. Our commitments and contingent liabilities may include (i) regulatory and clinical obligations remaining under our CUPID 2 trial, which is currently in the long-term follow up stage until February 2016; (ii) obligations under our employment and separation agreements with certain employees that provide for severance and other payments following a termination of employment occurring for various reasons, including a change in control of our company; (iii) the pending litigation against us, and other various claims and legal actions arising in the ordinary course of business; and (iv) non-cancelable lease obligations. As a result of this requirement, a portion of our assets may need to be reserved pending the resolution of such obligations. In addition, we may be subject to litigation or other claims related to a dissolution and liquidation of our company. If a dissolution and liquidation were pursued, our board of directors, in consultation with its advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of our common stock could lose all or a significant portion of their investment in the event of a liquidation, dissolution or winding up of our company.

If we fail to continue to meet all applicable NASDAQ Global Market requirements and NASDAQ determines to delist our common stock, the delisting could adversely affect the market liquidity of our common stock and the market price of our common stock could decrease.*

Our common stock is listed on The NASDAQ Global Market. In order to maintain our listing, we must meet minimum financial and other requirements, including requirements for a minimum amount of capital, a minimum price per share and continued business operations so that we are not characterized as a “public shell company.” If we are unable to comply with NASDAQ’s listing standards, NASDAQ may determine to delist our common stock from The NASDAQ Global Market. If our common stock is delisted for any reason, it could reduce the value of our common stock and its liquidity.

As a result of the CUPID 2 data and the reductions in our workforce that we announced in April 2015 and June 2015, we may not be successful in retaining key employees. If we are unable to retain key employees, our ability to identify and consummate a transaction will be seriously jeopardized.*

On April 30, 2015 and again on June 26, 2015, we announced workforce reductions, which have reduced our headcount by approximately 70% and additional reductions in our workforce are likely. Our cash conservation activities may yield unintended consequences, such as attrition beyond our planned reductions in workforce and reduced employee morale which may cause our remaining employees to seek alternate employment. Competition among biotechnology companies for qualified employees is intense, and the ability to retain our key employees is critical to our ability to effectively manage our resources following the CUPID 2 data and to consummate a transaction or continue operations. Additional attrition could have a material adverse effect on our business. In addition, as a result of the reduction in our workforce, we face an increased risk of employment litigation.

Risks Related to our Financial Condition and Capital Requirements

We have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future.*

We are a biotechnology company and we have not yet generated any revenues. We have incurred net losses in each year since our inception in December 2000, including consolidated net losses of \$33.9 million for the year ended December 31, 2014. As of September 30, 2015, we had an accumulated deficit of approximately \$186.1 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.

[Table of Contents](#)

Prior to the recent suspension of our further research and clinical development activities, we have devoted most of our financial resources to research and development, including developing our manufacturing capabilities and preclinical and clinical development activities. To date, we have financed our operations primarily through the sale of equity securities and convertible debt. 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 or strategic collaborations.

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 good indication of our future performance. In any particular quarter or quarters, our operating results could be below the expectations of securities analysts or investors, which could cause our stock price to decline.

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

Our ability to generate meaningful revenue and achieve profitability depends on our ability, and the ability of any third party with which we may partner, to successfully complete the development of, and obtain the regulatory approvals necessary to, commercialize product candidates. We do not anticipate generating revenues from product sales for the foreseeable future, if ever. If any future product candidates fail in clinical trials or do not gain regulatory approval, or if any product candidates, if approved, fail to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our ability to generate future revenues from product sales will depend heavily on our success in:

- completing research and preclinical and clinical development of product candidates;
- seeking and obtaining regulatory and marketing approvals for product candidates for which we complete clinical trials;
- developing a sustainable, scalable, reproducible, and transferable manufacturing process for and product candidates;
- establishing and maintaining supply and manufacturing relationships with third parties that can provide adequate (in amount and quality) products and services to support clinical development and, if approved, the market demand for our product candidates;
- launching and commercializing product candidates for which we obtain regulatory and marketing approval, either by establishing a sales force, marketing and distribution infrastructure, or by collaborating with a partner;
- obtaining market acceptance of any approved products;
- addressing any competing technological and market developments;
- implementing additional internal systems and infrastructure, as needed;
- identifying and validating new product candidates;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter;
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how; and
- attracting, hiring and retaining qualified personnel.

Even if one or more product candidates is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product. Our expenses could increase beyond expectations if we are required by the FDA, the EMA, or other foreign regulatory authorities to perform clinical trials and other studies in addition to those that we originally anticipated. Even if we are able to generate revenues from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations.

We may need to raise substantial additional funding to the extent we continue our product development efforts, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development efforts or other operations.*

Our operations have consumed substantial amounts of cash since inception. As of September 30, 2015, our cash, cash equivalents and investments were approximately \$37.1 million. Our research and development expenses were \$0.7 million and \$5.3 million for the three months ended September 30, 2015 and 2014, respectively. We believe that our existing cash, cash equivalents and investments will enable us to fund our operations for at least the next 12 months. However, drug development is expensive and time-consuming and if we undertake development efforts, we will need to raise substantial additional capital to fund future activities.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. We could also be required to seek funds through arrangements with collaborative partners or otherwise at an earlier stage than would otherwise be ideal and we may be required to relinquish rights to some of our technologies, product candidates, or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects.

[Table of Contents](#)

If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs or the commercialization of any approved products, or be unable to deploy the capital necessary to refocus or expand our operations or otherwise capitalize on our business opportunities, as desired, any of which could materially adversely affect our business, financial condition and results of operations and could even require us to cease operations entirely.

Raising additional funds through debt or equity financing is likely to be challenging, could be dilutive and may cause the market price of our common stock to decline further.*

To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of those securities could result in substantial dilution for our current stockholders and the terms may include liquidation or other preferences that adversely affect the rights of our current stockholders. Furthermore, the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our common stock to decline further and existing stockholders may not agree with our financing plans or the terms of such financings.

Our product candidates may cause undesirable side effects or have other properties that could result in significant negative consequences.*

As with many pharmaceutical and biological products, treatment with MYDICAR may produce undesirable side effects or adverse reactions or events. Although extensive preclinical safety and biodistribution testing conducted on MYDICAR and other AAV vectors, including the CUPID 1 trial of MYDICAR for HFrEF and data from previous clinical trials of other AAV vectors, suggests that MYDICAR will be well tolerated, known adverse side effects that could present with treatment with AAV vectors include an immunologic reaction to the capsid protein or gene at early time points after administration. In previous clinical trials involving AAV viral vectors for gene therapy, some subjects experienced serious adverse events, including the development of a T-cell mediated immune response against the vector capsid proteins. In addition, theoretical adverse side effects of AAV vectors include replication and spread of the virus to other parts of the body and insertional oncogenesis, which is the process whereby the insertion of a gene near a gene that is important in cell growth or division results in uncontrolled cell division, which could potentially enhance the risk of malignant transformation or cancer. Potential procedure-related events are similar to those associated with standard coronary diagnostic procedures, and may include vascular injury (e.g., damage to the femoral, radial, or brachial arteries at the site of vascular access, or damage to the coronary arteries) or myocardial injury. If any such adverse events occur the product-related side effects could result in potential claims, which may harm our business, financial condition and prospects significantly.

Even if we resume or initiate and complete any necessary preclinical studies and clinical trials for any product candidates we may choose to develop, we cannot predict when, or if, we will obtain regulatory approval to commercialize a product candidate or the approval may be for a more narrow indication than we expect.*

Even if we resume or initiate any necessary preclinical studies and clinical trials for any product candidates we may choose to develop, we cannot commercialize a product until the appropriate regulatory authorities have reviewed and approved the product candidate. Even if our product candidates demonstrate safety and efficacy in clinical trials, the regulatory agencies may not complete their review processes in a timely manner, or we may not be able to obtain regulatory approval. Additional delays may result if an FDA advisory committee or other regulatory authority recommends non-approval or restrictions on approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory agency policy during the period of product development, clinical trials and the review process. Regulatory agencies also may approve a treatment candidate for fewer or more limited indications than requested or may grant approval subject to the performance of post-marketing studies. In addition, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our treatment candidates.

Even if we obtain regulatory approval for a product candidate, our products will remain subject to regulatory scrutiny.

Even if we obtain regulatory approval in a jurisdiction, regulatory authorities may still impose significant restrictions on the indicated uses or marketing of our product candidates, or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. For example, the holder of an approved Biologic Licence Application, or BLA, is obligated to monitor and report adverse events and any failure of a product to meet the specifications in the BLA. The holder of an approved BLA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws.

[Table of Contents](#)

In addition, product manufacturers and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with good manufacturing practices, or GMP, and adherence to commitments made in the BLA. If we or a regulatory agency discover 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, a regulatory agency may impose restrictions relative to that product or the manufacturing facility, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

If we fail to comply with applicable regulatory requirements following approval of any of our product candidates, a regulatory agency may:

- issue a warning letter asserting that we are in violation of the law;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending BLA or supplements to a BLA submitted by us;
- seize product; or
- refuse to allow us to enter into supply contracts, including government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenues.

Risks Related to our Reliance on Third Parties

We rely on third parties to conduct, supervise and monitor our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our any future product candidates and our business could be substantially harmed.*

We have historically relied on CROs and clinical trial sites to ensure our clinical trials are conducted properly and on time. While we will have agreements governing their activities, we will have limited influence over their actual performance. We will control only certain aspects of our CROs' activities. Nevertheless, we will be responsible for ensuring that each of our clinical trials 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 principal investigators and CROs are required to comply with the FDA's and the ICH's (the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use) GCPs for conducting, recording and reporting the results of clinical trials to assure that the data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical trial participants are protected. The FDA, the Competent Authorities of the Member States of the EEA, and comparable foreign regulatory authorities, enforce these GCPs through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we, our principal investigators or our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, the EMA, or other foreign regulatory authorities may require us to perform additional clinical trials before approving any marketing applications. Upon inspection, the FDA may determine that our clinical trials did not comply with GCPs. In addition, our future clinical trials will require a sufficient number of patients to evaluate the safety and effectiveness of our product candidates. Accordingly, if our CROs fail to comply with these regulations or fail to recruit a sufficient number of patients, we may be required to repeat such clinical trials, which would delay the regulatory approval process.

Our CROs are not our employees, and we are therefore unable to directly monitor whether or not they devote sufficient time and resources to our clinical and nonclinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities that could harm our competitive position. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements, or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize, our product candidates. If any such event were to occur, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase, and our ability to generate revenues could be delayed.

[Table of Contents](#)

We may seek to form strategic alliances in the future with respect to product candidates, and we may not realize the benefits of such alliances.*

We may form strategic alliances, create joint ventures or collaborations or enter into licensing arrangements with third parties for the development and commercialization of product candidates. We face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Any delays in entering into new strategic partnership agreements related to product candidates could delay the development and commercialization of our product candidates and reduce their competitiveness even if they reach the market. Moreover, we may not be successful in our efforts to establish a strategic partnership or other collaborative arrangement for any future product candidates because the potential partner may consider that our research and development pipeline is insufficiently developed to justify a collaborative effort, or that our product candidates and programs do not have the requisite potential to demonstrate safety and efficacy in the target population. Even if we are successful in establishing such a strategic partnership or collaboration, we cannot be certain that, following such a strategic transaction or license, we will be able to progress the development and commercialization of the applicable product candidates as envisaged, or that we will achieve the revenues that would justify such transaction.

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

In the United States, the legislative landscape continues to evolve. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or the Affordable Care Act, was passed, which has the potential to substantially change health care financing by both governmental and private insurers, and significantly impact the U.S. pharmaceutical industry. The Affordable Care Act, among other things, subjects biological products to potential competition by lower-cost biosimilars, revised the methodology by which rebates owed by manufacturers for covered outpatient drugs under the Medicaid Drug Rebate Program are calculated, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program, extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, subjected manufacturers to new annual fees and taxes for certain branded prescription drugs, and provided incentives to programs that increase the federal government's comparative effectiveness research.

In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. On August 2, 2011, the Budget Control Act of 2011 among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of up to 2% per fiscal year, which went into effect on April 1, 2013 and will remain in effect through 2024 unless additional Congressional action is taken. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, or the ATRA, which, among other things, further reduced Medicare payments to certain providers, including physicians, hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. 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 for any product candidates we seek to develop or additional pricing pressures.

Risks Related to our Business Operations

We are the subject of securities class action lawsuits, and additional securities litigation may be brought against us in the future.*

In July 2015, following our announcements of the negative CUPID 2 data and the suspension of further research and development activities and the subsequent declines of the price of our common stock, three putative class action were filed in the U.S. District Court for the Southern District of California against us and certain of our 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 by making materially false and misleading statements regarding the clinical trial program for MYDICAR, thereby artificially inflating the price of our common stock. The complaints seek unspecified monetary damages and other relief, including attorneys' fees. We expect the court to consolidate the three putative securities class actions and to appoint a lead plaintiff to represent the putative class. We then expect the lead plaintiff to file a consolidated 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 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 have directors' and officers' liability insurance, there is no assurance that the coverage will be sufficient. In addition, any such litigation could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

[Table of Contents](#)

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

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

We 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 have not fully complied, with such laws, we could face substantial penalties.

If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our operations may be directly, or indirectly through our prescribers, customers and purchasers, subject to various federal and state fraud and abuse laws, including, without limitation, the federal Health Care Program Anti-Kickback Statute and the federal civil and criminal False Claims Acts. These laws may impact, among other things, our proposed promotional, sales, marketing and educational programs. In addition, we may be subject to patient privacy laws by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include, but are not limited to:

- the federal Health Care Program Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind in return for, the purchase, recommendation, leasing or furnishing 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 or approval from Medicare, Medicaid, or other government payers that are false or fraudulent;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit a person from knowingly and willfully executing a scheme or from making false or fraudulent statements to defraud any healthcare benefit program, regardless of the payor (e.g., public or private);
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, and as amended again by the final HIPAA omnibus rule, Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under HITECH and the Genetic Information Nondiscrimination Act; Other Modifications to HIPAA, published in January 2013, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization by entities subject to the rule, such as health plans, health care clearinghouses and health care providers;
- the federal Food, Drug and Cosmetic Act, or FDCA, which prohibits, among other things, the adulteration or misbranding of drugs and devices;
- federal transparency laws, including the federal Physician Payment Sunshine Act that requires certain drug manufacturers to disclose payments and other transfers of value provided to physicians and teaching hospitals, as well as ownership and investment interests held by such physicians and their immediate family members;
- the Affordable Care Act, and its implementing regulations, which may impact, among other things, reimbursement rates by federal health care programs and commercial insurers; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which 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 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; 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 in certain circumstances, such as specific disease states.

[Table of Contents](#)

Further, the Affordable Care Act, among other things, amends the intent requirements of the federal Anti-Kickback Statute and the criminal statute governing healthcare fraud. A person or entity can now be found guilty of violating the Anti-Kickback Statute and the federal criminal healthcare fraud statute without actual knowledge of the statute or specific intent to violate it. In addition, the Affordable Care Act 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 federal False Claims Act.

If our operations are found to be in violation of any of the health regulatory laws described above or any other laws that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in federal health care programs and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results.

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 carry product liability insurance of \$10.0 million per occurrence and a \$10.0 million aggregate limit. We believe our product liability insurance coverage is appropriate in light of our current clinical programs; however, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If and when we obtain marketing approval for product candidates, we intend to expand 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.

[Table of Contents](#)

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.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials, 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 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. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions. We do not currently carry biological or hazardous waste insurance coverage.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities.

We may not be successful in identifying or discovering additional product candidates.*

Our research programs, if resumed, may fail to identify other potential product candidates for clinical development for a number of reasons. For example, our research methodology may be unsuccessful in identifying potential product candidates or 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.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs, which may have a material adverse effect on our business and could potentially cause us to cease operations. 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.

Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. The recent global financial crisis caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn, such as the recent global financial crisis, could result in a variety of risks to our business, including, weakened demand for our product candidates and a decreased ability to raise additional capital when needed on acceptable terms, if at all. This is particularly true in Europe, which is undergoing a continued severe economic crisis. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

Our business and operations would suffer in the event of system failures.*

Despite the implementation of security measures, our internal computer systems and those of our current and any future CROs and other contractors, consultants and potential collaborators are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of product candidates could be delayed.

Interruptions in the supply of product or inventory loss may adversely affect our operating results and financial condition.

Many product candidates are manufactured and distributed using technically complex processes requiring specialized facilities, highly specific raw materials and other production constraints. The complexity of these processes, as well as strict company and government standards for the manufacture and storage of our products, subjects us to production risks. While product batches released for use in clinical trials or for commercialization undergo sample testing, some defects may only be identified following product release. In addition, process deviations or unanticipated effects of approved process changes may result in these intermediate products not complying with stability requirements or specifications. Most of our product candidates must be stored and transported at temperatures within a certain range. If these environmental conditions deviate, our product candidates' remaining shelf-lives could be impaired or their efficacy and safety could become adversely affected, making them no longer suitable for use. The occurrence or suspected occurrence of production and distribution difficulties can lead to lost inventories, and in some cases product recalls, with consequential reputational damage and the risk of product liability. The investigation and remediation of any identified problems can cause production delays, substantial expense, lost sales and delays of new product launches. Any interruption in the supply of finished products or the loss thereof could hinder our ability to timely distribute our products and satisfy customer demand. Any unforeseen failure in the storage of the product or loss in supply could delay our clinical trials and, if our product candidates are approved, result in a loss of our market share and negatively affect our revenues and operations.

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.*

Earthquakes or other natural disasters could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects. A majority of our management operates in our principal executive offices located in San Diego, California. If our San Diego offices were affected by a natural or man-made disaster, particularly those that are characteristic of the region, such as wildfires and earthquakes, or other business interruption, our ability to manage our domestic and foreign operations could be impaired, which could materially and adversely affect our results of operations and financial condition. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business.

Risks Related to our Intellectual Property

If we are unable to obtain or protect intellectual property rights related to our product candidates, we may not be able to compete effectively in our markets.*

Biotechnology companies typically rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to product candidates. The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. 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 of the 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 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. Also, the setback to our MYDICAR development program that resulted from the failure of CUPID 2 could also reduce the benefits of patents covering MYDICAR given the increased timeline to potential commercialization. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

If the patent applications we hold or have in-licensed with respect to our programs and product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for our product candidates, it could dissuade companies from collaborating with us to develop product candidates, and threaten our ability to commercialize future products. Several patent applications covering our product candidates have been filed recently. 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 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. Since patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we were the first to file any patent application related to a product candidate. Furthermore, if third parties have filed such patent applications, an interference proceeding in the United States can be initiated by a third party to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. In addition, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from generic medications.

Table of Contents

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 candidates 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 those who have access to our confidential information, including our employees, consultants, scientific advisors and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors.

Although we expect all of our employees and consultants to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed or that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Misappropriation or unauthorized disclosure of our trade secrets could impair our competitive position and may have a material adverse effect on our business. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. In addition, others may independently discover our trade secrets and proprietary information. For example, the FDA, as part of its Transparency Initiative, is currently considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future, if at all. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent material disclosure of the non-patented intellectual property related to our technologies to third parties, and there is no guarantee that we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

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

We are a party to a number of license agreements under which we are granted rights to intellectual property that historically have been important to our business and we expect that we may need to enter into additional license agreements in the future. Our existing license agreements impose, and we expect that future license agreements will impose on us, various development, regulatory and/or commercial diligence obligations, payment of milestones and/or royalties and other obligations. If we fail to comply with our obligations under these agreements, or we are subject to a bankruptcy, the licensor may have the right to terminate the license, in which event we would not be able to market products covered by the license.

As we have done previously, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates, and we cannot provide any assurances that third-party patents do not exist which might be enforced against our current product candidates or future products in the absence of such a license. We may fail to obtain any of these licenses on commercially reasonable terms, if at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could materially harm our business and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation.

[Table of Contents](#)

Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues. Disputes may arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

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 is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and *inter partes* review proceedings before the U.S. Patent and Trademark Office, or U.S. PTO, 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 pursuing development 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. Because patent applications can take many years to issue, third parties may have currently pending patent applications which may later result in issued patents that our product candidates may infringe, or which such third parties claim are infringed by the use of our technologies. If any third-party patents are held by a court of competent jurisdiction to cover any aspect of the manufacturing process for any of our product candidates, any molecules formed during the manufacturing process, or any final product candidate, including the formulation or method of use of such product candidate, 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. In any such case, such a license may not be available on commercially reasonable terms or at all.

Parties making claims against us for infringement of their intellectual property rights 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 could be required to redesign our infringing products or obtain a license from such third party to continue developing and commercializing our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms, or at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. It may be impossible to redesign our products and technology, or it may require substantial time and monetary expenditure, which could force us to cease commercialization of one or more of our product candidates, or some of our business operations, which could materially harm our business. In addition, in any such proceeding, we may be required to pay substantial damages, including treble damages and attorneys' fees in the event we are found liable for willful infringement.

We may not be successful in obtaining or maintaining necessary rights to product components and processes for our development pipeline through acquisitions and in-licenses.*

Because potential future programs may involve product candidates that 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 acquire, in-license or use these proprietary rights. In addition, our product candidates may require specific formulations to work effectively and efficiently and these rights may be held by others. 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. The licensing and acquisition of third-party intellectual property rights is a competitive area, and companies, which may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

[Table of Contents](#)

For example, we collaborate with U.S. and foreign academic institutions to accelerate our preclinical research or development under written agreements with these institutions. Typically, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such right of first negotiation for intellectual property, we may be unable to negotiate a license within the specified time frame 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 our program.

In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us, either on reasonable terms, or at all. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment, or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights, our ability to commercialize our products, and our business, financial condition and prospects for growth could suffer.

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. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid, is unenforceable and/or is not infringed, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. A third-party defendant may also request post grant review or *inter partes* review by the U.S. PTO of any patent we assert. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

Interference proceedings provoked by third parties or brought by us 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. We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

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

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

While we normally seek to obtain the right to control the prosecution and maintenance of the patents relating to our product candidates, there may be times when the filing and prosecution activities for platform technology patents that relate to our product candidates are controlled by our licensors. If our licensors or any of our future licensors fail to appropriately 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 and selling competing products.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because biotechnology companies frequently rely on third parties to manufacture product candidates, and because collaborations with various organizations and academic institutions on the advancement of product candidates is often necessary, we must, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business.

[Table of Contents](#)

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. For example, any academic institution that we may collaborate with in the future will usually expect to be granted rights to publish data arising out of such collaboration, provided that we are notified in advance and given the opportunity to delay publication for a limited time period in order for us to secure patent protection of intellectual property rights arising from the collaboration, in addition to the opportunity to remove confidential or trade secret information from any such publication. In the future we may also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development partnerships or similar agreements. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

In September 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law, including provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The U.S. PTO is currently developing regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, were enacted in March 2013. It is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. Moreover, 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.

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.

Although we seek to protect our ownership of intellectual property rights by ensuring that our agreements with our employees, collaborators and other third parties with whom we do business include provisions requiring such parties to assign rights in inventions to us, we may also be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. We may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on 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 be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may also be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. We may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on 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.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

[Table of Contents](#)

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the U.S. PTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. We have systems in place to remind us to pay these fees, and we employ an outside firm and rely on our outside counsel to pay these fees due to non-U.S. patent agencies. The U.S. PTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business.

Issued patents covering our product candidates could be found invalid or unenforceable if challenged in court or the U.S. PTO. *

If we or one of our licensing partners initiated 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, as applicable, is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous ground upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our product candidates or related. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection could have a material adverse impact on our business.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biotechnology companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology industry involve both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the U.S. PTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. For example, in the recent case, *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.*, the U.S. Supreme Court held that certain claims to DNA molecules are not patentable. While we do not believe that any of the patents owned or licensed by us will be found invalid based on this decision, we cannot predict how future decisions by the courts, the U.S. Congress or the U.S. PTO may impact the value of our patents.

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

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise 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 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.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. For example:

- others may be able to make gene therapies or small molecule compounds that are similar to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business, results of operations and prospects.

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. Since our initial public offering in January 2014 at a price of \$8.00 per share, the sale price of stock as reported on The NASDAQ Global Market has ranged from \$1.00 to \$28.25, through October 29, 2015. Our stock price could be subject to wide fluctuations in response to a variety of factors, including the following:

- adverse 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;
- announcements of significant changes in our business or operations, including the decision not to pursue one or more drug development programs;
- unanticipated serious safety concerns related to the use of any of our product candidates;
- inability to obtain additional funding;
- sales or potential sales of our common stock by us or our stockholders in the future;
- failure to successfully develop, manufacture and commercialize our product candidates;
- failure to enter into collaborations;
- failure by us or our licensors to prosecute, maintain or enforce our intellectual property rights;
- our dependence on third parties, including, commercial manufactures and CROs;
- changes in laws or regulations applicable to future products;
- inability to obtain adequate clinical and commercial product supply for our product candidates or the inability to do so at acceptable prices;

Table of Contents

- adverse regulatory decisions;
- introduction of new products, services or technologies by our competitors;
- failure to meet or exceed financial projections we may provide to the public;
- failure to meet or exceed the financial 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;
- announcement of a strategic transaction, including the acquisition of our company or its assets;
- 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;
- changes in the market valuations of similar companies;
- overall performance of the equity markets and other factors that may be unrelated to our operating performance or the operating performance of our competitors, including changes in market valuations of similar companies; and
- trading volume of our common stock.

In addition, companies trading in the stock market in general, and the NASDAQ Global Market in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

If securities or industry analysts issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. If any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our clinical trials and operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

Our principal stockholders own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.*

Our principal stockholders and their affiliates currently beneficially own a significant percentage of our outstanding voting stock. Therefore, these stockholders have the ability and may continue to have the ability to influence us through this ownership position. These stockholders may be able to determine some or all matters requiring stockholder approval. For example, these stockholders, acting together, may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may believe are in your best interest as one of our stockholders.

We are an “emerging growth company,” and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an “emerging growth company,” as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not “emerging growth companies,” including exemption from compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002 (Sarbanes-Oxley Act), reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of our initial public offering, (b) in which we have total annual gross revenue of at least \$1.0 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeded \$700.0 million as of the prior June 30th, and (2) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period.

[Table of Contents](#)

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Our quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.*

We expect our operating results to be subject to quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, including:

- variations in the level of expenses related to our product candidates, future development programs or general and administrative expenses (including as the result of a significant decrease or increase in employee headcount);
- if any product candidates receives regulatory approval, the level of underlying demand for these product candidates and wholesalers' buying patterns;
- addition or termination of clinical trials or funding support;
- our execution of any collaborative, licensing or similar arrangements, and the timing of payments we may make or receive under these arrangements.
- any intellectual property infringement lawsuit in which we may become involved; and
- regulatory developments affecting our product candidates or those of our competitors.

If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, 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. Inferior 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.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our common stock.

Certain holders of our securities are entitled to rights with respect to the registration of their shares under the Securities Act of 1933, as amended, or the Securities Act. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by our affiliates as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

[Table of Contents](#)

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We expect that significant additional capital will be needed in the future to continue operations, should we decide to continue our historical business operations. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. These sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

Pursuant to our 2013 equity incentive plan, or the 2013 plan, our management is authorized to grant stock options and other equity-based awards to our employees, directors and consultants. The number of shares available for future grant under the 2013 plan will automatically increase on January 1 of each year by 5% of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year, subject to the ability of our board of directors to take action to reduce the size of the increase in any given year. In addition, we may grant or provide for the grant of rights to purchase shares of our common stock pursuant to our 2013 employee stock purchase plan, or ESPP. The number of shares of our common stock reserved for issuance under the ESPP will automatically increase on January 1 of each calendar year by the lesser of 1% of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year and 384,307 shares, subject to the ability of our board of directors to take action to reduce the size of the increase in any given year. Currently, we plan to register the increased number of shares available for issuance under the 2013 plan and ESPP each year. Increases in the number of shares available for future grant or purchase may result in additional dilution, which could cause our stock price to decline. In addition, we have in the past and may in the future grant inducement grants to prospective employees and consultants, which may result in further dilution and cause our stock price to decline.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

Under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an “ownership change,” generally defined as a greater than 50% change (by value) in its equity ownership over a three year period, the corporation’s ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes (such as research tax credits) to offset its post-change income may be limited. We have determined that several ownership changes have occurred since our inception and have reduced our deferred tax asset accordingly. We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

We have never declared or paid any cash dividends on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition our ability to pay dividends is currently restricted by the terms of our loan agreement with Hercules. Any return to stockholders will therefore be limited to the appreciation of their stock.

Provisions in our amended and restated certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders or remove our current management.

Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management. These provisions include:

- authorizing the issuance of “blank check” preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;
- limiting the removal of directors by the stockholders;
- creating a staggered board of directors;
- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;
- eliminating the ability of stockholders to call a special meeting of stockholders; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

[Table of Contents](#)

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. In addition, we are subject to Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder, unless such transactions are approved by our board of directors. This provision could have the effect of delaying or preventing a change of control, whether or not it is desired by or beneficial to our stockholders. Further, other provisions of Delaware law may also discourage, delay or prevent someone from acquiring us or merging with us.

*Our employment agreements with our executive officers and certain other employees may require us to pay severance benefits to any of those persons who are terminated under specified circumstances, including in connection with a change of control of us, which could harm our financial condition or results.**

Our executive officers and certain other employees are parties to employment agreements that contain change of control and severance provisions providing for severance and other benefits and acceleration of vesting of stock options in the event of a termination of employment under specified circumstances. The payment of these severance benefits could harm our financial condition and results. In addition, these potential severance payments may discourage or prevent third parties from seeking a business combination with us.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Use of Proceeds

On January 29, 2014, the SEC declared effective the registration statement on Form S-1 (File Nos. 333-191688 and 333-193647) for our initial public offering of our common stock. Pursuant to the registration statement, we registered the offer and sale of 6,325,000 shares of our common stock. On February 4, 2014, we sold 5,500,000 shares of our common stock at a public offering price of \$8.00 per share and on February 27, 2014, we sold 825,000 shares of our common stock at a public offering price of \$8.00 per share pursuant to the full exercise of the underwriters' option to purchase additional shares. The offering has terminated. The sole book-running managing underwriter for the offering was Barclays Capital Inc. After deducting underwriting discounts, commissions and offering costs paid by us of \$6.3 million, the net proceeds from the offering were approximately \$44.3 million. No offering expenses were paid or are payable, directly or indirectly, to our directors or officers, to persons owning 10% or more of any class of our equity securities, or to any of our affiliates.

The net proceeds from our initial public offering were invested in highly-liquid money market funds and investment grade corporate debt securities, pending their use. As of September 30, 2015, we have used all of the net proceeds from our initial public offering. We used the net proceeds to fund continued development of MYDICAR for the treatment of systolic heart failure, other ongoing preclinical and research programs, and working capital and other general corporate purposes, including costs and expenses associated with being a public company. We cannot specify with certainty all of the particular uses for the net proceeds from our initial public offering.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Not applicable.

Item 6. Exhibits

A list of the exhibits filed as part of this Quarterly Report on Form 10-Q is set forth on the Exhibit Index, which is incorporated herein by reference.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Celladon Corporation

Dated: November 9, 2015

/s/ Paul B. Cleveland

Paul B. Cleveland
President and Chief Executive Officer
(Principal Executive Officer)

Dated: November 9, 2015

/s/ Andrew C. Jackson

Andrew C. Jackson
Chief Financial Officer
(Principal Financial Officer)

EXHIBIT INDEX

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on February 10, 2014).
3.2	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on February 10, 2014).
4.1	Reference is made to Exhibits 3.1 and 3.2.
4.2	Form of Common Stock Certificate of the Registrant (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-191688), originally filed with the SEC on October 11, 2013).
4.3	Amended and Restated Investor Rights Agreement by and among the Registrant and certain of its stockholders, dated February 4, 2014 (incorporated by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-191688), originally filed with the SEC on October 11, 2013).
4.4	Form of Warrant to Purchase Common Stock issued to participants in the Registrant's Convertible Debt and Warrant financing, dated October 15, 2013 (incorporated by reference to Exhibit 4.3 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-191688), originally filed with the SEC on October 11, 2013).
10.1	Sublease Termination and Settlement Agreement, dated September 10, 2015, by and between the Registrant and Brandes Investment Partners, L.P., as amended on October 23, 2015.
10.2+	Amendment to Employment Agreement, dated October 20, 2015, by and between the Registrant and Paul Cleveland.
10.3+	Amendment to Employment Agreement, dated October 20, 2015, by and between the Registrant and Andrew Jackson.
10.4+	Amendment to Employment Agreement, dated October 20, 2015, by and between the Registrant and Rebecque Laba.
10.5+	Amendment to Employment Agreement, dated October 20, 2015, by and between the Registrant and Elizabeth Reed.
10.6+	Amendment to Employment Agreement, dated October 20, 2015, by and between the Registrant and Fredrik Wiklund.
31.1	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
31.2	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
32.1	Certification of the Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of the Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
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

+ Indicates management contract.

SUBLEASE TERMINATION AND SETTLEMENT AGREEMENT

THIS SUBLEASE TERMINATION AND SETTLEMENT AGREEMENT (this “**Agreement**”) is made and entered into as of September 10, 2015 (the “**Effective Date**”), by and between Brandes Investment Partners, L.P., a Delaware limited partnership (“**Sublandlord**”), and Celladon Corporation, a Delaware corporation (“**Subtenant**”). Except as otherwise provided herein, all capitalized terms used herein shall have the same meanings given such terms in the Sublease (as defined below).

RECITALS

A. Sublandlord and Subtenant entered into that certain Sublease dated May 28, 2014 (the “**Sublease**”), pursuant to which Sublandlord sublets to Subtenant and Subtenant sublets from Sublandlord, approximately 10,908 rentable square feet located in Suite 650 of that certain improved real property known as Del Mar Gateway located at 11988 El Camino Real, San Diego, California 92130 (the “**Premises**”).

B. The term of the Sublease commenced on July 1, 2014 and expires on September 30, 2021.

C. Pursuant to the terms of the Sublease, Subtenant has a right to terminate the Sublease from and after December 1, 2018 upon satisfaction of certain conditions (the “**Early Termination Date**”).

D. Subtenant has notified Sublandlord that it desires to terminate the Sublease as of October 31, 2015, more than two years prior to the Early Termination Date.

E. Subject to the terms and conditions of this Agreement, Sublandlord is willing to terminate the Sublease early.

F. This Agreement is made by the parties solely for the following purposes: (i) settling and compromising any disputed claims, (ii) satisfying any outstanding obligations of Subtenant and Sublandlord under the Sublease, and (iii) providing for the orderly termination of the Sublease.

G. In full settlement of all claims related to the Sublease, Sublandlord and Subtenant desire to terminate the Sublease in accordance with this Agreement.

AGREEMENT

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Sublandlord and Subtenant hereby agree as follows:

1. Consideration. In consideration for Sublandlord's early termination of the Sublease, Subtenant shall pay and deliver to Sublandlord the following:

(a) Termination Payment. Subtenant shall pay to Sublandlord the sum of Nine Hundred Fifty Thousand Dollars (\$950,000) (the "**Termination Payment**"). Such Termination Payment shall be paid as follows:

(i) Cash Payment. Subtenant shall pay to Sublandlord the sum of Eight Hundred Fifty Thousand Dollars (\$850,000) cash (the "**Cash Payment**").

(ii) Application of Security Deposit. Pursuant to the Sublease, Subtenant deposited with Sublandlord the sum of One Hundred Thousand Dollars (\$100,000) as a security deposit (the "**Security Deposit**"). Subtenant and Sublandlord agree that Sublandlord shall retain the Security Deposit and credit such amount to the Termination Payment.

(b) Monthly Rent. Subtenant shall pre-pay the Base Rent and Additional Sublease Rent due to Sublandlord for the month of October 2015 (collectively, the "**Pre-Paid Rent**").

(c) Fixtures, Furnishings, and Equipment. Subtenant shall assign, transfer, and convey to Sublandlord all of Subtenant's right, title, and interest in and to certain fixtures, furnishings, and equipment used by Subtenant (the "**FF&E**") in connection with Subtenant's business located at the Premises. Subtenant shall execute and deliver to Sublandlord a bill of sale substantially in the form of Exhibit A attached hereto (the "**Bill of Sale**") evidencing transfer and conveyance of the FF&E effective as of the Termination Date. A description of the FF&E is contained in Schedule 1 to the Bill of Sale.

(d) Payment Date. The Cash Payment and Pre-Paid Rent shall be paid to Sublandlord on or before September 14, 2015. If Subtenant fails to timely pay to Sublandlord the Cash Payment and Pre-Paid Rent, Sublandlord shall be in breach of this Agreement.

2. Termination of Lease. Sublandlord and Subtenant hereby agree that subject to the terms of this Agreement, the Sublease shall terminate and be of no further force and effect as of 11:59 p.m. on October 31, 2015 (the "**Termination Date**"); provided, however, that such termination shall be conditioned on Sublandlord's timely receipt of the Termination Payment and the executed Bill of Sale.

3. Access to Premises. Beginning on the Effective Date and through the Termination Date, Subtenant shall provide Sublandlord and its brokers, agents, and other representatives access to the Premises for the purpose of showing the Premises to prospective subtenants upon reasonable prior notice to Subtenant.

4. Surrender of the Premises. On or before the Termination Date, Subtenant shall surrender possession of the Premises to Sublandlord in good order and broom-clean condition in accordance with the terms of Paragraph XII of the Sublease. Upon surrender, Subtenant shall have no further rights or obligations with respect to the occupancy of the Premises.

5. Mutual Releases. Except for the rights and obligations contained in this Agreement and the other documents executed pursuant to this Agreement, if any, and effective as of the Termination Date, the parties hereby release and discharge each other and their respective past and present agents, representatives, officers, directors, members, employees, insurers, predecessors-in-interest, advisors, successors, assigns, and affiliated persons from any and all suits, causes of action, demands, claims, charges, complaints, obligations, liabilities, costs, losses, damages, injuries, rights, judgments, attorneys' fees, expenses, bills, penalties, fines and all other legal responsibilities in any form whatsoever in law or in equity, whether known or unknown, whether suspected or unsuspected, including, without limitation, all obligations under the Sublease (all of which shall collectively be referred to as the "**Released Matters**").

6. Representations and Warranties of Subtenant. Subtenant represents and warrants to Sublandlord that:

(a) Subtenant has not heretofore assigned all or any portion of its interest in the Sublease or sublet any portion of the Premises.

(b) No other person, firm or entity has any right, title or interest in the Sublease,

(c) Subtenant has the full right, legal power and actual authority to enter into this Agreement, to deliver the Bill of Sale, and to terminate the Sublease.

(d) Subtenant is the sole owner of the FF&E free and clear of any and all security interests, liens, and encumbrances whatsoever, and that Subtenant has the legal authority and power to transfer and convey to Sublandlord the FF&E.

(e) This Agreement has been duly authorized and executed by Subtenant and, upon delivery to and execution by Sublandlord, shall be a valid and binding agreement of Subtenant.

Notwithstanding the termination of the Sublease and the release of liability, as provided herein, the representations and warranties set forth in this Section 6 shall survive the termination of the Sublease and Subtenant shall be liable to Sublandlord for any inaccuracy or any breach thereof.

7. Representations and Warranties of Sublandlord. Sublandlord represents and warrants to Subtenant that as of the date of this Agreement, that this Agreement has been duly authorized and executed by Sublandlord and, upon delivery to and execution by Subtenant, shall be a valid and binding agreement of Sublandlord.

8. General Provisions.

(a) Entire Agreement. This Agreement contains the entire agreement between the parties relating to the transaction contemplated hereby and all prior or contemporaneous agreements, understandings, representations, and statements, oral or written, are merged into this Agreement.

(b) Successors. All of the terms of this Agreement will be binding upon and inure to the benefit of the parties hereto and their respective administrators or executors, successors and assigns.

(c) Counterparts. This Agreement may be executed in any number of original counterparts. Any such counterpart, when executed, shall constitute an original of this Agreement, and all such counterparts together shall constitute one and the same Agreement.

(d) Attorneys' Fees. Should any dispute arise among the parties hereto or the legal representatives, successors and assigns concerning any provision of this Agreement or the rights and duties of any person in relation thereto, the party prevailing in such dispute shall be entitled, in addition to such other relief that may be granted, to recover reasonable attorneys' fees and legal costs in connection with such dispute.

(e) Governing Law. This Agreement shall be governed by and construed under the laws of the State of California.

(f) Survival of Provisions. The representations, warranties, agreements and acknowledgments set forth in this Agreement shall be deemed material and shall survive the termination of the Sublease.

(g) Severability. In case any one or more of the provisions contained in this Agreement shall for any reason be held invalid, illegal or unenforceable in any respect, the invalidity, illegality or unenforceability of that provision shall not affect any other provisions of this Agreement, and this Agreement shall be construed as if the invalid, illegal or unenforceable provision had never been contained in it.

(h) Construction. This Agreement shall not be construed against the party preparing it, but shall be construed as if all parties jointly prepared this Agreement and any uncertainty and ambiguity shall not be interpreted against one party.

(i) Time of Essence. Time is of the essence with respect to the obligations to be performed under the terms of this Agreement.

(j) Authority. Each individual executing this Agreement on behalf of Sublandlord or Subtenant represents and warrants that he or she is duly authorized to execute and deliver this Agreement on behalf of such party.

(k) Full Force and Effect. Except as set forth in this Agreement, each and every provision of the Sublease shall remain in full force and effect and shall not be modified, waived or otherwise affected by this Agreement. In the event of any conflict between the provisions of the Sublease and this Agreement, the terms of this Agreement shall prevail.

(l) Representation of Counsel. Each of the parties is represented by independent legal counsel or has been advised to seek the advice of independent legal counsel and executes this Agreement acting upon their independent judgment and/or upon the advice of their respective independent legal counsel, without any representation, express or implied, of any kind or nature, from each to the other except as only specifically set forth herein.

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

SUBLANDLORD:

Brandes Investment Partners, L.P.
a Delaware limited partnership

By: /s/ Gary Iwamura
Gary Iwamura, Finance Director

SUBTENANT:

Celladon Corporation
a Delaware corporation

By: /s/ Andrew Jackson
Name: Andrew Jackson
Its: CFO

By: /s/ Paul B. Cleveland
Name: Paul B. Cleveland
Its: President & CEO

EXHIBIT A

FORM OF BILL OF SALE

BILL OF SALE

This Bill of Sale ("**Bill of Sale**") dated as of October 31, 2015, by and between by Celladon Corporation, a Delaware corporation ("**Subtenant**"), and Brandes Investment Partners, L.P., a Delaware limited partnership ("**Sublandlord**").

WHEREAS, Subtenant and Sublandlord are parties to that certain Sublease Termination and Settlement Agreement dated as of September 10, 2015 (the "**Agreement**"), pursuant to which Subtenant is assigning, transferring, and conveying to Sublandlord all of Subtenant's right, title, and interest in and to certain fixtures, furnishings and equipment used by Subtenant in connection with Subtenant's business located at 11988 El Camino Real, Suite 650, San Diego, CA 92130.

NOW, THEREFORE, for valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:

1. **Assignment.** Subtenant hereby assigns, transfers, and conveys, and sets over unto Sublandlord, its successors and assigns forever, all of its respective rights, title, and interest in and to certain personal property (e.g., fixtures, furnishings, and equipment) used by Subtenant in connection with its business located at 11988 El Camino Real, Suite 650, San Diego, CA 92130. A description of the property covered by this Bill of Sale is set forth in Schedule 1 attached hereto (the "**FF&E**").

2. **Part Consideration.** Subtenant hereby transfers, conveys, and sets over to Sublandlord the FF&E as partial consideration for Sublandlord's agreement to terminate that certain Sublease by and between Sublandlord and Subtenant dated as of May 28, 2014 (the "**Sublease**") early and settle Subtenant's breach of its obligations under the Lease.

3. **Bill of Sale Binding.** This Bill of Sale and the provisions herein contained shall be binding upon and inure to the benefit of the parties hereto and to their respective successors and assigns.

4. **Governing Law.** This Bill of Sale shall be governed by and construed in accordance with the laws of the State of California without giving effect to choice of law or conflicts of law rules or provisions.

SIGNATURE PAGE FOLLOWS

A-1

The parties hereto have executed and delivered this Bill of Sale as of September 10, 2015.

Subtenant:

Celladon Corporation
a Delaware corporation

By: /s/ Andrew Jackson
Name: Andrew Jackson
Its: CFO

By: /s/ Paul B. Cleveland
Name: Paul B. Cleveland
Its: President & CEO

Sublandlord:

Brandes Investment Partners, L.P.
a Delaware limited partnership

By: /s/ Gary Iwamura
Gary Iwamura, Finance Director

**FIRST AMENDMENT TO
SUBLEASE TERMINATION AND SETTLEMENT AGREEMENT**

THIS FIRST AMENDMENT TO SUBLEASE TERMINATION AND SETTLEMENT AGREEMENT ("**First Amendment**") is dated as of October 23, 2015, by and between Brandes Investment Partners, L.P., a Delaware limited partnership ("**Sublandlord**"), and Celladon Corporation, a Delaware corporation ("**Subtenant**") with respect to the following:

RECITALS

A. Pursuant to a Sublease Termination and Settlement Agreement made and entered into as of September 10, 2015 (the "**Sublease Termination Agreement**"), Sublandlord and Subtenant agreed to an early termination of the sublease described therein.

B. By the terms of the Sublease Termination Agreement, Subtenant committed to vacate the subleased premises on or before October 31, 2015.

C. Subtenant desires to retain possession of the subleased premises for a few additional weeks.

D. Subject to the terms and conditions of this First Amendment, Sublandlord is willing to allow Subtenant to remain in possession of the subleased premises beyond October 31, 2015.

AGREEMENT

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Sublandlord and Subtenant hereby agree as follows:

1. Except as otherwise provided herein, all capitalized terms used herein shall have the same meanings given such terms in the Sublease Termination Agreement.

2. The Termination Date set forth in the Sublease Termination Agreement shall be extended from October 31, 2015 to November 13, 2015. As consideration for such extension, Subtenant shall pay to Sublandlord, in advance, the sum of \$4,550 for rent for the period November 1, 2015 through November 13, 2015. If Subtenant holds over beyond November 13, 2015, Subtenant shall pay to Sublandlord a daily rent of \$1,068.98 for each day of such holdover beyond November 15, 2015, provided Subtenant shall have no right to holdover beyond December 31, 2015. Subtenant shall pay to Sublandlord any such daily rent in advance, and if Subtenant fails to pay such daily rent in advance, then Subtenant shall pay to Sublandlord such rent immediately upon demand.

3. Except as expressly set forth in this First Amendment, the Sublease Termination Agreement remains in full force and effect.

4. This First Amendment may be executed in any number of identical counterparts. Any such counterpart, when executed, shall constitute an original of this First Amendment, and all such counterparts together shall constitute one and the same agreement.

IN WITNESS WHEREOF, the parties hereto have executed this First Amendment as of the date first set forth above.

SUBLANDLORD:

Brandes Investment Partners, L.P.
a Delaware limited partnership

By: /s/ Gary Iwamura
Gary Iwamura, Finance Director

SUBTENANT:

Celladon Corporation
a Delaware corporation

By: /s/ Rebecque J. Laba
Name: Rebecque J. Laba
Its: VP, Corporate Operations

By: _____
Name: _____
Its: _____

AMENDMENT TO EMPLOYMENT LETTER AGREEMENT

THIS AMENDMENT NO. 2 (the "*Amendment*") to the Employment Letter Agreement between CELLADON CORPORATION, a Delaware corporation (the "*Company*") and PAUL CLEVELAND, an individual (the "*Employee*") dated May 28, 2014, as amended on May 29, 2015 (the "*Agreement*"), is entered into and effective as of the 20th day of October, 2015.

WHEREAS, Company and Employee desire to amend the Agreement as set forth below;

NOW THEREFORE, in consideration of the foregoing premises and the covenants and promises contained in the Agreement as amended hereby, the Parties, intending to be bound, hereby agree that the following sections of the Agreement shall be amended as follows:

1. **Section 6 is hereby amended and restated as follows:**

"6. Severance Benefits.

In the event your employment with the Company is terminated for any reason, you will be entitled to all of your earned compensation and benefits or otherwise as required by law through the date of termination (the "*Accrued Amounts*"). For the avoidance of doubt, you shall not be entitled to any additional compensation or benefits in the event your employment is terminated for Cause, due to your resignation without Good Reason, upon your death or upon your disability. If your employment terminates due to an Involuntary Termination (as defined below), you will be eligible to receive the additional compensation and benefits described in Section 6(a).

(a) Involuntary Termination at Any Time. If at any time (i) the Company terminates your employment without Cause (as defined below and other than as a result of your death or disability), or (ii) you resign for Good Reason (as defined below), and provided in any case such termination constitutes a "separation from service", as defined under Treasury Regulation Section 1.409A-1(h) (a "*Separation from Service*") (such termination described in (i) or (ii), an "*Involuntary Termination*"), you shall be entitled to receive the following severance benefits, subject in all events to your compliance with Section 6(c) below:

(i) You shall receive a lump sum payment equivalent to eighteen (18) months of your base salary in effect (ignoring any decrease that forms the basis for your resignation for Good Reason, if applicable) on the effective date of your Involuntary Termination;

(ii) You shall receive a lump sum payment of your target bonus for the year of termination;

(iii) You shall receive a lump sum payment equivalent to eighteen (18) months of the cost of monthly health insurance coverage. For purposes of calculating the amount of the payment described in the foregoing sentence, the monthly cost of health insurance shall be the full cost of your monthly health insurance under the Company's group health plans effective immediately prior to the expiration of the Company's current group health plans (or the cost of your monthly premiums for health insurance coverage under the Company's group health plans under the Consolidated Omnibus Budget Reconciliation Act of 1985 or the state equivalent, if applicable).

(iv) The vesting of all of your outstanding stock options and other equity awards that are subject to time-based vesting requirements shall accelerate in full such that all such equity awards shall be deemed fully vested as of the date of your Involuntary Termination.

The payments described in Section 6(a)(i), (ii) and (iii) above shall be paid to you in a lump sum cash payment, subject to applicable deductions and withholdings, within seven (7) business days after the effective date of the Release (as defined in Section 6(c) below).

(b) Intentionally Omitted.

(c) Conditions for Severance Benefits. The severance benefits set forth in Section 6(a) above are expressly conditioned upon:

- (i) your continuing to comply with your obligations under your Confidential Information Agreement (as defined in Section 8 below); and
- (ii) you signing and not revoking a general release of legal claims in the form attached hereto as **EXHIBIT A** or a substantially similar form provided that, for the avoidance of doubt, such form will include a commitment from you to comply with your continuing obligations under your Confidential Information Agreement, but will not include a noncompetition provision and will not include a release of any rights or claims for indemnification you may have pursuant to any written indemnification agreement with the Company to which you are a party, the Company's bylaws, or applicable law (the "**Release**") within the applicable deadline set forth therein and permitting the Release to become effective in accordance with its terms, which must occur no later than the Release Deadline (as defined in Section 7 below)."

All other terms and conditions of the Agreement shall remain unchanged and in full force and effect. All initially capitalized terms not defined herein shall have the same meaning given to such terms in the Agreement.

IN WITNESS WHEREOF, the parties hereto have caused this Amendment to be duly executed by their authorized representatives effective as of the date set forth above.

ACCEPTED AND AGREED TO FOR:

CELLADON CORPORATION
"Company"

By: /s/ Michael Narachi
Name: Michael Narachi
Title: Chairman of the Board

PAUL CLEVELAND
"Employee"

By: /s/ Paul Cleveland
Name: Paul Cleveland



Celladon Corporation
 11988 El Camino Real Suite 650
 San Diego California 92130-3579
 U.S.A.

Tel. 1.858.366.4081
 Fax 1.858.964.0974
www.celladon.com

AMENDMENT TO EMPLOYMENT LETTER AGREEMENT

THIS AMENDMENT NO. 3 (the “*Amendment*”) to the Employment Letter Agreement between **CELLADON CORPORATION**, a Delaware corporation (the “*Company*”) and **ANDREW JACKSON**, an individual (the “*Employee*”) dated February 28, 2014, as amended on May 27, 2015 and May 29, 2015 (the “*Agreement*”), is entered into and effective as of the 20th day of October, 2015.

WHEREAS, Company and Employee desire to amend the Agreement as set forth below;

NOW THEREFORE, in consideration of the foregoing premises and the covenants and promises contained in the Agreement as amended hereby, the Parties, intending to be bound, hereby agree that the following sections of the Agreement shall be amended as follows:

1. **Section 6 is hereby amended and restated as follows:**

“6. Severance Benefits.

In the event your employment with the Company is terminated for any reason, you will be entitled to all of your earned compensation and benefits or otherwise as required by law through the date of termination (the “*Accrued Amounts*”). For the avoidance of doubt, you shall not be entitled to any additional compensation or benefits in the event your employment is terminated for Cause, due to your resignation without Good Reason, upon your death or upon your disability. If your employment terminates due to an Involuntary Termination (as defined below), you will be eligible to receive the additional compensation and benefits described in Section 6(a).

(a) Involuntary Termination at Any Time. If at any time (i) the Company terminates your employment without Cause (as defined below and other than as a result of your death or disability), or (ii) you resign for Good Reason (as defined below), and provided in any case such termination constitutes a “separation from service”, as defined under Treasury Regulation Section 1.409A-1(h) (a “*Separation from Service*”) (such termination described in (i) or (ii), an “*Involuntary Termination*”), you shall be entitled to receive the following severance benefits, subject in all events to your compliance with Section 6(c) below:

(i) You shall receive a lump sum payment equivalent to twelve (12) months of your base salary in effect (ignoring any decrease that forms the basis for your resignation for Good Reason, if applicable) on the effective date of your Involuntary Termination;

(ii) You shall receive a lump sum payment of your target bonus for the year of termination;

(iii) You shall receive a lump sum payment equivalent to twelve (12) months of the cost of monthly health insurance coverage. For purposes of calculating the amount of the payment described in the foregoing sentence, the monthly cost of health insurance shall be the full cost of your monthly health insurance under the Company’s group health plans effective immediately prior to the expiration of the Company’s current group health

plans (or the cost of your monthly premiums for health insurance coverage under the Company's group health plans under the Consolidated Omnibus Budget Reconciliation Act of 1985 or the state equivalent, if applicable).

(iv) The vesting of all of your outstanding stock options and other equity awards that are subject to time-based vesting requirements shall accelerate in full such that all such equity awards shall be deemed fully vested as of the date of your Involuntary Termination.

The payments described in Section 6(a)(i), (ii) and (iii) above shall be paid to you in a lump sum cash payment, subject to applicable deductions and withholdings, within seven (7) business days after the effective date of the Release (as defined in Section 6(c) below).

(b) Intentionally Omitted.

(c) Conditions for Severance Benefits. The severance benefits set forth in Section 6(a) above are expressly conditioned upon:

- (i) your continuing to comply with your obligations under your Confidential Information Agreement (as defined in Section 8 below); and
- (ii) you signing and not revoking a general release of legal claims in the form attached hereto as **EXHIBIT A** or a substantially similar form provided that, for the avoidance of doubt, such form will include a commitment from you to comply with your continuing obligations under your Confidential Information Agreement, but will not include a noncompetition provision and will not include a release of any rights or claims for indemnification you may have pursuant to any written indemnification agreement with the Company to which you are a party, the Company's bylaws, or applicable law (the "**Release**") within the applicable deadline set forth therein and permitting the Release to become effective in accordance with its terms, which must occur no later than the Release Deadline (as defined in Section 7 below)."

All other terms and conditions of the Agreement shall remain unchanged and in full force and effect. All initially capitalized terms not defined herein shall have the same meaning given to such terms in the Agreement.

IN WITNESS WHEREOF, the parties hereto have caused this Amendment to be duly executed by their authorized representatives effective as of the date set forth above.

ACCEPTED AND AGREED TO FOR:

CELLADON CORPORATION
"Company"

By: /s/ Paul B. Cleveland
Name: Paul B. Cleveland
Title: Chief Executive Officer

ANDREW JACKSON
"Employee"

By: /s/ Andrew Jackson
Name: Andrew Jackson



Celladon Corporation
 11988 El Camino Real Suite 650
 San Diego California 92130-3579
 U.S.A.

Tel. 1.858.366.4081
 Fax 1.858.964.0974
www.celladon.com

AMENDMENT TO EMPLOYMENT LETTER AGREEMENT

THIS AMENDMENT NO. 3 (the "**Amendment**") to the Employment Letter Agreement between **CELLADON CORPORATION**, a Delaware corporation (the "**Company**") and Rebecque J. Laba, an individual (the "**Employee**") dated August 31, 2013, as amended on January 23, 2014 and May 27, 2015 (the "**Agreement**"), is entered into and effective as of the 20th day of October, 2015.

WHEREAS, Company and Employee desire to amend the Agreement as set forth below;

NOW THEREFORE, in consideration of the foregoing premises and the covenants and promises contained in the Agreement as amended hereby, the Parties, intending to be bound, hereby agree that the following sections of the Agreement shall be amended as follows:

1. **Section 6 is hereby amended and restated as follows:**

"6. Severance Benefits.

In the event your employment with the Company is terminated for any reason, you will be entitled to all of your earned compensation and benefits or otherwise as required by law through the date of termination (the "**Accrued Amounts**"). For the avoidance of doubt, you shall not be entitled to any additional compensation or benefits in the event your employment is terminated for Cause, due to your resignation without Good Reason, upon your death or upon your disability. If your employment terminates due to an Involuntary Termination (as defined below), you will be eligible to receive the additional compensation and benefits described in Section 6(a).

(a) Involuntary Termination at Any Time. If at any time (i) the Company terminates your employment without Cause (as defined below and other than as a result of your death or disability), or (ii) you resign for Good Reason (as defined below), and provided in any case such termination constitutes a "separation from service", as defined under Treasury Regulation Section 1.409A-1(h) (a "**Separation from Service**") (such termination described in (i) or (ii), an "**Involuntary Termination**"), you shall be entitled to receive the following severance benefits, subject in all events to your compliance with Section 6(c) below:

(i) You shall receive a lump sum payment equivalent to twelve (12) months of your base salary in effect (ignoring any decrease that forms the basis for your resignation for Good Reason, if applicable) on the effective date of your Involuntary Termination;

(ii) You shall receive a lump sum payment of your target bonus for the year of termination;

(iii) You shall receive a lump sum payment equivalent to twelve (12) months of the cost of monthly health insurance coverage. For purposes of calculating the amount of the payment described in the foregoing sentence, the monthly cost of health insurance shall be the full cost of your monthly health insurance under the Company's group health plans effective immediately prior to the expiration of the Company's current group health

plans (or the cost of your monthly premiums for health insurance coverage under the Company's group health plans under the Consolidated Omnibus Budget Reconciliation Act of 1985 or the state equivalent, if applicable).

(iv) The vesting of all of your outstanding stock options and other equity awards that are subject to time-based vesting requirements shall accelerate in full such that all such equity awards shall be deemed fully vested as of the date of your Involuntary Termination.

The payments described in Section 6(a)(i), (ii) and (iii) above shall be paid to you in a lump sum cash payment, subject to applicable deductions and withholdings, within seven (7) business days after the effective date of the Release (as defined in Section 6(c) below).

(b) Intentionally Omitted.

(c) Conditions for Severance Benefits. The severance benefits set forth in Section 6(a) above are expressly conditioned upon: (i) your continuing to comply with your obligations under your Confidential Information Agreement (as defined in Section 8 below); and (ii) you signing and not revoking a general release of legal claims in the form attached hereto as **EXHIBIT A** or a substantially similar form provided that, for the avoidance of doubt, such form will include a commitment from you to comply with your continuing obligations under your Confidential Information Agreement, but will not include a noncompetition provision and will not include a release of any rights or claims for indemnification you may have pursuant to any written indemnification agreement with the Company to which you are a party, the Company's bylaws, or applicable law (the "**Release**") within the applicable deadline set forth therein and permitting the Release to become effective in accordance with its terms, which must occur no later than the Release Deadline (as defined in Section 7 below)."

All other terms and conditions of the Agreement (other than your current salary and target bonus amount which are as set forth in the January 6, 2015 compensation letter) shall remain unchanged and in full force and effect. All initially capitalized terms not defined herein shall have the same meaning given to such terms in the Agreement.

IN WITNESS WHEREOF, the parties hereto have caused this Amendment to be duly executed by their authorized representatives effective as of the date set forth above.

ACCEPTED AND AGREED TO FOR:

CELLADON CORPORATION
"Company"

By: /s/ Paul B. Cleveland
Name: Paul B. Cleveland
Title: Chief Executive Officer

REBECQUE J. LABA
"Employee"

By: /s/ Rebecque J. Laba
Name: Rebecque J. Laba



Celladon Corporation
 11988 El Camino Real Suite 650
 San Diego California 92130-3579
 U.S.A.

Tel. 1.858.366.4081
 Fax 1.858.964.0974
www.celladon.com

AMENDMENT TO EMPLOYMENT LETTER AGREEMENT

THIS AMENDMENT NO. 2 (the "**Amendment**") to the Employment Letter Agreement between **CELLADON CORPORATION**, a Delaware corporation (the "**Company**") and **ELIZABETH E. REED**, an individual (the "**Employee**") dated May 30, 2014, as amended on May 27, 2015 (the "**Agreement**"), is entered into and effective as of the 20th day of October, 2015.

WHEREAS, Company and Employee desire to amend the Agreement as set forth below;

NOW THEREFORE, in consideration of the foregoing premises and the covenants and promises contained in the Agreement as amended hereby, the Parties, intending to be bound, hereby agree that the following sections of the Agreement shall be amended as follows:

1. **Section 6 is hereby amended and restated as follows:**

"6. Severance Benefits.

In the event your employment with the Company is terminated for any reason, you will be entitled to all of your earned compensation and benefits or otherwise as required by law through the date of termination (the "**Accrued Amounts**"). For the avoidance of doubt, you shall not be entitled to any additional compensation or benefits in the event your employment is terminated for Cause, due to your resignation without Good Reason, upon your death or upon your disability. If your employment terminates due to an Involuntary Termination (as defined below), you will be eligible to receive the additional compensation and benefits described in Section 6(a).

(a) Involuntary Termination at Any Time. If at any time (i) the Company terminates your employment without Cause (as defined below and other than as a result of your death or disability), or (ii) you resign for Good Reason (as defined below), and provided in any case such termination constitutes a "separation from service", as defined under Treasury Regulation Section 1.409A-1(h) (a "**Separation from Service**") (such termination described in (i) or (ii), an "**Involuntary Termination**"), you shall be entitled to receive the following severance benefits, subject in all events to your compliance with Section 6(c) below:

(i) You shall receive a lump sum payment equivalent to twelve (12) months of your base salary in effect (ignoring any decrease that forms the basis for your resignation for Good Reason, if applicable) on the effective date of your Involuntary Termination;

(ii) You shall receive a lump sum payment of your target bonus for the year of termination;

(iii) You shall receive a lump sum payment equivalent to twelve (12) months of the cost of monthly health insurance coverage. For purposes of calculating the amount of the payment described in the foregoing sentence, the monthly cost of health insurance shall be the full cost of your monthly health insurance under the Company's group health plans effective immediately prior to the expiration of the Company's current group health

plans (or the cost of your monthly premiums for health insurance coverage under the Company's group health plans under the Consolidated Omnibus Budget Reconciliation Act of 1985 or the state equivalent, if applicable).

(iv) The vesting of all of your outstanding stock options and other equity awards that are subject to time-based vesting requirements shall accelerate in full such that all such equity awards shall be deemed fully vested as of the date of your Involuntary Termination.

The payments described in Section 6(a)(i), (ii) and (iii) above shall be paid to you in a lump sum cash payment, subject to applicable deductions and withholdings, within seven (7) business days after the effective date of the Release (as defined in Section 6(c) below).

(b) Intentionally Omitted.

(c) Conditions for Severance Benefits. The severance benefits set forth in Section 6(a) above are expressly conditioned upon:

- (i) your continuing to comply with your obligations under your Confidential Information Agreement (as defined in Section 8 below); and
- (ii) you signing and not revoking a general release of legal claims in the form attached hereto as **EXHIBIT A** or a substantially similar form provided that, for the avoidance of doubt, such form will include a commitment from you to comply with your continuing obligations under your Confidential Information Agreement, but will not include a noncompetition provision and will not include a release of any rights or claims for indemnification you may have pursuant to any written indemnification agreement with the Company to which you are a party, the Company's bylaws, or applicable law (the "**Release**") within the applicable deadline set forth therein and permitting the Release to become effective in accordance with its terms, which must occur no later than the Release Deadline (as defined in Section 7 below)."

All other terms and conditions of the Agreement (other than your salary which has been updated for calendar year 2015 as set forth in the January 6, 2015 compensation letter) shall remain unchanged and in full force and effect. All initially capitalized terms not defined herein shall have the same meaning given to such terms in the Agreement.

IN WITNESS WHEREOF, the parties hereto have caused this Amendment to be duly executed by their authorized representatives effective as of the date set forth above.

ACCEPTED AND AGREED TO FOR:

CELLADON CORPORATION
"Company"

ELIZABETH E. REED
"Employee"

By: /s/ Paul B. Cleveland
Name: Paul B. Cleveland
Title: Chief Executive Officer

By: /s/ Elizabeth E. Reed
Name: Elizabeth E. Reed



Celladon Corporation
 11988 El Camino Real Suite 650
 San Diego California 92130-3579
 U.S.A.

Tel. 1.858.366.4081
 Fax 1.858.964.0974
www.celladon.com

AMENDMENT TO EMPLOYMENT LETTER AGREEMENT

THIS AMENDMENT NO. 3 (the "**Amendment**") to the Employment Letter Agreement between **CELLADON CORPORATION**, a Delaware corporation (the "**Company**") and **FREDRIK WIKLUND**, an individual (the "**Employee**") dated August 31, 2013, as amended on January 23, 2014 and May 27, 2015 (the "**Agreement**"), is entered into and effective as of the 20th day of October, 2015.

WHEREAS, Company and Employee desire to amend the Agreement as set forth below;

NOW THEREFORE, in consideration of the foregoing premises and the covenants and promises contained in the Agreement as amended hereby, the Parties, intending to be bound, hereby agree that the following sections of the Agreement shall be amended as follows:

1. **Section 6 is hereby amended and restated as follows:**

"6. Severance Benefits.

In the event your employment with the Company is terminated for any reason, you will be entitled to all of your earned compensation and benefits or otherwise as required by law through the date of termination (the "**Accrued Amounts**"). For the avoidance of doubt, you shall not be entitled to any additional compensation or benefits in the event your employment is terminated for Cause, due to your resignation without Good Reason, upon your death or upon your disability. If your employment terminates due to an Involuntary Termination (as defined below), you will be eligible to receive the additional compensation and benefits described in Section 6(a).

(a) Involuntary Termination at Any Time. If at any time (i) the Company terminates your employment without Cause (as defined below and other than as a result of your death or disability), or (ii) you resign for Good Reason (as defined below), and provided in any case such termination constitutes a "separation from service", as defined under Treasury Regulation Section 1.409A-1(h) (a "**Separation from Service**") (such termination described in (i) or (ii), an "**Involuntary Termination**"), you shall be entitled to receive the following severance benefits, subject in all events to your compliance with Section 6(c) below:

(i) You shall receive a lump sum payment equivalent to twelve (12) months of your base salary in effect (ignoring any decrease that forms the basis for your resignation for Good Reason, if applicable) on the effective date of your Involuntary Termination;

(ii) You shall receive a lump sum payment of your target bonus for the year of termination;

(iii) You shall receive a lump sum payment equivalent to twelve (12) months of the cost of monthly health insurance coverage. For purposes of calculating the amount of the payment described in the foregoing sentence, the monthly cost of health insurance shall be the full cost of your monthly health insurance under the Company's group health plans effective immediately prior to the expiration of the Company's current group health

plans (or the cost of your monthly premiums for health insurance coverage under the Company's group health plans under the Consolidated Omnibus Budget Reconciliation Act of 1985 or the state equivalent, if applicable).

(iv) The vesting of all of your outstanding stock options and other equity awards that are subject to time-based vesting requirements shall accelerate in full such that all such equity awards shall be deemed fully vested as of the date of your Involuntary Termination.

The payments described in Section 6(a)(i), (ii) and (iii) above shall be paid to you in a lump sum cash payment, subject to applicable deductions and withholdings, within seven (7) business days after the effective date of the Release (as defined in Section 6(c) below).

(b) Intentionally Omitted.

(c) Conditions for Severance Benefits. The severance benefits set forth in Section 6(a) above are expressly conditioned upon:

- (i) your continuing to comply with your obligations under your Confidential Information Agreement (as defined in Section 8 below); and
- (ii) you signing and not revoking a general release of legal claims in the form attached hereto as **EXHIBIT A** or a substantially similar form provided that, for the avoidance of doubt, such form will include a commitment from you to comply with your continuing obligations under your Confidential Information Agreement, but will not include a noncompetition provision and will not include a release of any rights or claims for indemnification you may have pursuant to any written indemnification agreement with the Company to which you are a party, the Company's bylaws, or applicable law (the "**Release**") within the applicable deadline set forth therein and permitting the Release to become effective in accordance with its terms, which must occur no later than the Release Deadline (as defined in Section 7 below)."

All other terms and conditions of the Agreement (other than your current salary and target bonus amount which are as set forth in the January 6, 2015 compensation letter) shall remain unchanged and in full force and effect. All initially capitalized terms not defined herein shall have the same meaning given to such terms in the Agreement.

IN WITNESS WHEREOF, the parties hereto have caused this Amendment to be duly executed by their authorized representatives effective as of the date set forth above.

ACCEPTED AND AGREED TO FOR:

CELLADON CORPORATION
"Company"

By: /s/ Paul B. Cleveland
Name: Paul B. Cleveland
Title: Chief Executive Officer

FREDRIK WIKLUND
"Employee"

By: /s/ Fredrik Wiklund
Name: Fredrik Wiklund

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO RULE 13a-14(a) AND 15d-14(a) OF THE SECURITIES EXCHANGE ACT, AS ADOPTED PURSUANT TO SECTION 302 OF THE
SARBANES-OXLEY ACT OF 2002

I, Paul B. Cleveland, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Celladon Corporation;

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

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

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

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

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

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

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

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

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

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

Date: November 9, 2015

/s/ Paul B. Cleveland

Paul B. Cleveland
President and Chief Executive Officer
(Principal Executive Officer)

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO RULE 13a-14(a) AND 15d-14(a) OF THE SECURITIES EXCHANGE ACT, AS ADOPTED PURSUANT TO SECTION 302 OF THE
SARBANES-OXLEY ACT OF 2002

I, Andrew C. Jackson, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Celladon Corporation;

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

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

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

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

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

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

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

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

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

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

Date: November 9, 2015

/s/ Andrew C. Jackson

Andrew C. Jackson
Chief Financial Officer
(Principal Financial Officer)

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Paul B. Cleveland, President and Chief Executive Officer of Celladon Corporation (the "Registrant"), do hereby certify in accordance with 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, based upon my knowledge:

- (1) this Quarterly Report on Form 10-Q of the Registrant, to which this certification is attached as an exhibit (the "Report"), fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m); and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

Date: November 9, 2015

/s/ Paul B. Cleveland

Paul B. Cleveland
President and Chief Executive Officer
(Principal Executive Officer)

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350 and is not being filed as part of the Report or as a separate disclosure document.

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Andrew C. Jackson, Chief Financial Officer of Celladon Corporation (the "Registrant"), do hereby certify in accordance with 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, based upon my knowledge:

- (1) this Quarterly Report on Form 10-Q of the Registrant, to which this certification is attached as an exhibit (the "Report"), fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m); and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

Date: November 9, 2015

/s/ Andrew C. Jackson

Andrew C. Jackson
Chief Financial Officer
(Principal Financial Officer)

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350 and is not being filed as part of the Report or as a separate disclosure document.