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

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**FORM 10-Q**

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

For the quarterly period ended September 30, 2014

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 001-36644

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**CALITHERA BIOSCIENCES, INC.**

(Exact name of registrant as specified in its charter)

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**Delaware**  
(State or other jurisdiction  
of incorporation or organization)

**27-2366329**  
(I.R.S. Employer  
Identification No.)

**343 Oyster Point Blvd., Suite 200**  
**South San Francisco, CA 94080**  
(Address of principal executive offices including zip code)

**Registrant's telephone number, including area code: (650) 870-1000**

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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.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/> (do not check if a smaller reporting company)	Smaller reporting company	<input type="checkbox"/>

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

As of October 31, 2014, the registrant had 17,930,394 shares of common stock, \$0.0001 par value per share, outstanding.

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**Calithera Biosciences, Inc.**  
**Quarterly Report on Form 10-Q**  
**For the Quarter Ended September 30, 2014**  
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PART I. – FINANCIAL INFORMATION

Item 1. Financial Statements

**Calithera Biosciences, Inc.**  
**Condensed Balance Sheets**  
(In thousands, except per share amounts)

	September 30, 2014	December 31, 2013
	(Unaudited)	
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 34,852	\$ 33,820
Prepaid expenses and other current assets	1,398	349
Total current assets	36,250	34,169
Restricted cash	46	116
Property and equipment, net	785	559
Other assets	2,561	-
Total assets	\$ 39,642	\$ 34,844
<b>Liabilities, Convertible Preferred Stock and Stockholders' Deficit</b>		
Current liabilities:		
Accounts payable	\$ 879	\$ 150
Accrued liabilities	3,243	1,194
Total current liabilities	4,122	1,344
Non-current liabilities	292	31
Total liabilities	4,414	1,375
Commitments and contingencies		
Convertible preferred stock, \$0.0001 par value, 11,340 and 7,757 shares authorized as of September 30, 2014 (unaudited) and December 31, 2013; 9,592 and 7,689 shares issued and outstanding as of September 30, 2014 (unaudited) and December 31, 2013	70,241	54,282
Stockholders' deficit:		
Common stock, \$0.0001 par value, 25,000 and 9,896 shares authorized as of September 30, 2014 (unaudited) and December 31, 2013; 338 and 161 shares issued and outstanding as of September 30, 2014 (unaudited) and December 31, 2013	-	-
Additional paid-in capital	10,008	9,329
Accumulated deficit	(45,021)	(30,142)
Total stockholders' deficit	(35,013)	(20,813)
Total liabilities and stockholders' deficit	\$ 39,642	\$ 34,844

See accompanying notes.

**Calithera Biosciences, Inc.**  
**Condensed Statements of Operations and Comprehensive Loss**  
**(Unaudited)**  
(In thousands, except per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Operating expenses:				
Research and development	\$ 3,894	\$ 2,735	\$ 11,395	\$ 6,804
General and administrative	1,347	583	3,488	1,486
Total operating expenses	5,241	3,318	14,883	8,290
Loss from operations	(5,241)	(3,318)	(14,883)	(8,290)
Other income	2	—	4	—
Net loss and comprehensive loss	\$ (5,239)	\$ (3,318)	\$ (14,879)	\$ (8,290)
Net loss per share attributable to common stockholders, basic and diluted	\$ (16.85)	\$ (34.22)	\$ (61.90)	\$ (115.74)
Weighted average common shares used to compute net loss per share attributable to common stockholders, basic and diluted	311	97	240	72

See accompanying notes.

**Calithera Biosciences, Inc.**  
**Statement of Convertible Preferred Stock and Stockholders' Deficit**  
**(Unaudited)**  
(In thousands, except per share amounts)

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
Balance at December 31, 2013	7,689	\$ 54,282	161	\$ -	\$ 9,329	\$ (30,142)	\$ (20,813)
Issuance of Series D convertible preferred stock for cash at \$8.41 per share in July 2014, net of \$41 in issuance costs	1,903	15,959	-	-	-	-	\$ -
Issuance of common stock to nonemployees	-	-	21	-	54	-	\$ 54
Vesting of common stock issued to founders	-	-	1	-	1	-	\$ 1
Exercise of stock options	-	-	155	-	249	-	\$ 249
Stock-based compensation expense	-	-	-	-	375	-	\$ 375
Net loss	-	-	-	-	-	(14,879)	\$ (14,879)
Balance at September 30, 2014	<u>9,592</u>	<u>\$ 70,241</u>	<u>338</u>	<u>\$ -</u>	<u>\$ 10,008</u>	<u>\$ (45,021)</u>	<u>\$ (35,013)</u>

See accompanying notes.

**Calithera Biosciences, Inc.**  
**Condensed Statements of Cash Flows**  
**(Unaudited)**  
**(In thousands)**

	Nine Month Ended September 30,	
	2014	2013
<b>Cash Flows From Operating Activities</b>		
Net loss	\$ (14,879)	\$ (8,290)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	257	210
Stock-based compensation	375	41
Loss on disposal of property and equipment	2	3
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(1,048)	(158)
Other assets	(1,430)	-
Accounts payable	637	131
Accrued liabilities	965	314
Deferred rent	361	5
<b>Net cash used in operating activities</b>	<u>(14,760)</u>	<u>(7,744)</u>
<b>Cash Flows From Investing Activities</b>		
Purchase of property and equipment	(486)	(153)
Change in restricted cash	70	(9)
<b>Net cash used in investing activities</b>	<u>(416)</u>	<u>(162)</u>
<b>Cash Flows From Financing Activities</b>		
Net proceeds from issuance of convertible preferred stock	15,959	8,676
Proceeds from stock option exercises	249	59
<b>Net cash provided by financing activities</b>	<u>16,208</u>	<u>8,735</u>
Net increase in cash and cash equivalents	1,032	829
Cash and cash equivalents at beginning of period	33,820	2,205
Cash and cash equivalents at end of period	<u>\$ 34,852</u>	<u>\$ 3,034</u>
<b>Supplemental Disclosure of Non-Cash Investing and Financing Information:</b>		
Services settled through the issuance of common stock	<u>\$ 55</u>	<u>\$ —</u>

See accompanying notes.

**Calithera Biosciences, Inc.**

**Notes to Condensed Financial Statements**

**1. Organization and Basis of Presentation**

Calithera Biosciences, Inc. (the “Company”) was incorporated in the State of Delaware on March 9, 2010. The Company is a clinical-stage biopharmaceutical company focused on discovering and developing novel small molecule drugs directed against tumor metabolism and tumor immunology targets for the treatment of cancer. The Company’s principal operations are based in South San Francisco, California, and it operates in one segment.

***Reverse Stock Split***

On September 18, 2014, the Company’s board of directors, and on September 19, 2014 the Company’s stockholders, approved the amendment and restatement of the Company’s certificate of incorporation to effect a reverse split of the Company’s common stock and convertible preferred stock at a 1-for-48 ratio (the “Reverse Stock Split”). The Reverse Stock Split became effective on September 19, 2014, upon the filing of the Company’s amended and restated certificate of incorporation. The par value of the common and convertible preferred stock was not adjusted as a result of the Reverse Stock Split. All issued and outstanding common stock, convertible preferred stock, options for common stock and per share amounts contained in the financial statements have been retroactively adjusted to reflect this Reverse Stock Split for all periods presented.

***Initial Public Offering***

In October 2014, the Company completed an initial public offering (“IPO”) of its common stock. In connection with its IPO, the Company issued and sold 8,000,000 shares of its common stock, at a price to the public of \$10.00 per share. As a result of the IPO, the Company received approximately \$71.7 million in net proceeds, after deducting underwriting discounts and commissions of \$5.6 million and offering expenses of approximately \$2.7 million payable by the Company. At the closing of the IPO, 9,592,042 shares of outstanding convertible preferred stock were automatically converted into 9,592,042 shares of common stock. Following the IPO, there were no shares of preferred stock outstanding. In connection with the IPO, the Company amended and restated its Amended and Restated Certificate of Incorporation to change the authorized capital stock to 200,000,000 shares designated as common stock and 10,000,000 shares designated as preferred stock, all with a par value of \$0.0001 per share. As of September 30, 2014, the Company had incurred \$2.6 million of deferred offering costs, which will be offset against the net proceeds received from the sale of common stock. The condensed financial statements, including share and per share amounts, do not give effect to the IPO.

**2. Summary of Significant Accounting Policies**

***Unaudited Interim Financial Information***

The interim condensed balance sheet as of September 30, 2014, and the statements of operations and comprehensive loss, and cash flows for the nine months ended September 30, 2014 and 2013 are unaudited. The unaudited interim financial statements have been prepared on the same basis as the annual financial statements and reflect, in the opinion of management, all adjustments of a normal and recurring nature that are necessary for the fair presentation of the Company’s condensed financial statements included in this report. The financial data and the other information disclosed in these notes to the financial statements related to the nine-month periods are also unaudited. The results of operations for the nine months ended September 30, 2014 are not necessarily indicative of the results to be expected for the year ending December 31, 2014 or for any other future annual or interim period. The balance sheet as of December 31, 2013 included herein was derived from the audited financial statements as of that date. These financial statements should be read in conjunction with the Company’s audited financial statements included in the prospectus dated October 1, 2014 that forms a part of the Company’s Registration Statement on Form S-1, filed with the SEC pursuant to Rule 424 promulgated under the Securities Act of 1933, as amended.

***Use of Estimates***

The accompanying financial statements have been prepared in accordance with U.S. generally accepted accounting principles (“GAAP”). The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. On an ongoing basis, management evaluates its estimates, including those related to clinical trial accrued liabilities, fair value of common stock, income taxes, and stock-based compensation. Management bases its estimates on historical experience and on various other market-specific and relevant assumptions that management believes to be reasonable under the circumstances. Actual results could differ from those estimates.

### ***Cash and Cash Equivalents***

The Company considers all highly liquid investments with original maturities of three months or less at the time from the date of purchase to be cash equivalents. Cash equivalents consist primarily of amounts invested in money market accounts.

### ***Accrued Research and Development Costs***

The Company records accrued liabilities for estimated costs of research and development activities conducted by third-party service providers, which include the conduct of preclinical and clinical studies, and contract manufacturing activities. The Company records the estimated costs of research and development activities based upon the estimated amount of services provided but not yet invoiced, and include these costs in accrued liabilities in the balance sheets and within research and development expense in the statements of operations and comprehensive loss. These costs are a significant component of the Company's research and development expenses. The Company accrues for these costs based on factors such as estimates of the work completed and in accordance with agreements established with its third-party service providers under the service agreements. The Company makes significant judgments and estimates in determining the accrued liabilities balance in each reporting period. As actual costs become known, the Company adjusts its accrued liabilities. The Company has not experienced any material differences between accrued costs and actual costs incurred. However, the status and timing of actual services performed, number of patients enrolled, and the rate of patient enrollments may vary from the Company's estimates, resulting in adjustments to expense in future periods. Changes in these estimates that result in material changes to the Company's accruals could materially affect the Company's results of operations.

### ***Deferred Offering Costs***

Deferred offering costs, consisting primarily of legal, accounting, printer and filing fees related to the initial public offering are capitalized. The deferred offering costs will be offset against proceeds from the initial public offering upon completion of the offering in October 2014. As of September 30, 2014, \$2.6 million of deferred offering costs were capitalized, which are included in other assets in the accompanying condensed balance sheets. No amounts were deferred as of December 31, 2013.

### ***Net Loss per Share Attributable to Common Stockholders***

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

### ***Reclassification***

Certain reclassifications have been made to prior period amounts to conform to current period presentation. These reclassifications did not have an impact on the Company's results of operations or financial condition as of September 30, 2014 and December 31, 2013.

### ***Recent Accounting Pronouncements***

In June 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2014-10, *Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation*. ASU 2014-10 simplifies the accounting guidance by removing all incremental financial reporting requirements for development stage entities. The amendments related to the elimination of the inception-to-date information and other disclosure requirement of Topic 915 should be applied retrospectively, and are effective for annual reporting periods beginning after December 15, 2014, and interim periods therein. The Company early adopted this guidance and accordingly, there is no inception to date information presented in these financial statements.

In August 2014, the FASB issued ASU No. 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*. ASU 2014-15 requires management to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosures. In doing so, companies will have reduced diversity in the timing and content of footnote disclosures than under today's guidance. ASU 2014-15 is effective for the Company in the first quarter of 2016 with early adoption permitted. Management is currently assessing the impact the adoption of ASU 2014-15 will have on the financial statements.



### 3. Fair Value Measurements

Fair value accounting is applied for all financial assets and liabilities that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually). Financial instruments include cash and cash equivalents, accounts payable and accrued liabilities that approximate fair value due to their relatively short maturities. Assets and liabilities recorded at fair value on a recurring basis in the balance sheets are categorized based upon the level of judgment associated with the inputs used to measure their fair values. Fair value is defined as the exchange price that would be received for an asset or an exit price that would be paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The authoritative guidance on fair value measurements establishes a three-tier fair value hierarchy for disclosure of fair value measurements as follows:

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

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

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

The Company's financial instruments consist only of Level 1 assets, which are highly liquid money market funds. At September 30, 2014 and December 31, 2013, the Company had \$46,000 and \$116,000 in money market funds that are included in restricted cash on the balance sheets.

### 4. Balance Sheet Components

#### *Accrued Liabilities*

Accrued liabilities consist of the following (in thousands):

	September 30, 2014	December 31, 2013
Accrued bonus and payroll expenses	\$ 1,081	\$ 934
Accrued professional and consulting services	1,149	127
Accrued clinical expenses	677	-
Other	336	133
Total accrued liabilities	<u>\$ 3,243</u>	<u>\$ 1,194</u>

### 5. Convertible Preferred Stock

In July 2014, the Company issued 1,902,583 shares of Series D convertible preferred stock at a price of \$8.41 per share, with the same provisions of previously issued Series D convertible preferred stock. Aggregate net proceeds were approximately \$16.0 million.

### 6. Stock Based Compensation

#### *Equity Compensation Plans*

On September 18, 2014, the Company's board of directors, and on September 19, 2014, the Company's stockholders, approved the 2014 Equity Incentive Plan (the "2014 Plan") which became effective in October 2014, at which time the 2010 Equity Incentive Plan was terminated. The 2014 Plan provides for the grant of stock options, other forms of equity compensation, and performance cash awards. The maximum number of shares of common stock that may be issued under the 2014 Plan is 971,340. In addition, the number of shares of common stock reserved for issuance under the 2014 Plan will automatically increase on January 1 of each year, beginning on January 1, 2015 and ending on and including January 1, 2024, by 4% 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.

On September 18, 2014, the Company's board of directors, and on September 19, 2014, the Company's stockholders, approved the 2014 Employee Stock Purchase Plan (the "ESPP") which became effective in October 2014. The initial number of shares of common stock that may be issued under the ESPP is 189,883 shares and the number of shares reserved for the ESPP will increase automatically each year, beginning on January 1, 2015 and continuing through and including January 1, 2024, by the lesser of (1) 1% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year; (2) 250,000 shares of common stock; or (3) such lesser number as determined by the Company's board of directors.

A summary of stock option activity under the 2010 Equity Incentive Plan is as follows (in thousands, except share data and contractual term amounts):

	<b>Options Outstanding</b>			
	Number of Shares Underlying Outstanding Options	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term (Years)	Aggregate Value Intrinsic
Outstanding — December 31, 2013	864,829	\$ 1.80		\$ 769
Options granted	547,160	\$ 5.05		
Options exercised	(155,436)	\$ 1.60		
Options canceled	(47,950)	\$ 1.54		
Outstanding — September 30, 2014	<u>1,208,603</u>	\$ 3.31	9.19	\$ 8,567
Exercisable — September 30, 2014	<u>108,178</u>	\$ 2.05	8.43	\$ 913
Vested and expected to vest — September 30, 2014	<u>1,157,584</u>	\$ 3.31	9.19	\$ 8,202

The aggregate intrinsic values of options outstanding, vested and exercisable and vested and expected to vest were calculated as the difference between the exercise price of the options and the fair value of the Company's common stock of \$10.00 per share as of September 30, 2014.

The weighted-average grant-date fair value of options granted during the three and nine months ended September 30, 2014 was \$5.42 and \$4.78 per share, respectively, and during the three and nine months ended September 30, 2013 was \$0.71 and \$0.70 per share, respectively.

#### **Stock-Based Compensation**

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Research and development	\$ 68	\$ 13	\$ 171	\$ 28
General and administrative	96	7	204	13
Total stock-based compensation	<u>\$ 164</u>	<u>\$ 20</u>	<u>\$ 375</u>	<u>\$ 41</u>

As of September 30, 2014, the total unrecognized compensation expense related to unvested options, net of estimated forfeitures, was \$3.2 million, which the Company expects to recognize over an estimated weighted-average period of 3.6 years.

The fair value of stock option awards to employees was estimated at the date of grant using a Black-Scholes option-pricing model with the following assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Expected term	5.96 - 6.02 years	6.25 years	5.96 - 6.25 years	6.25 years
Volatility	97.35 - 97.73%	87.05%	95.40 - 97.73%	87.05 - 87.11%
Risk-free interest rate	1.88 - 1.97%	1.83%	1.88 - 2.00%	1.09 - 1.83%
Expected dividend rate	—%	—%	—%	—%

## 7. Net Loss per Share Attributable to Common Stockholders

Since the Company was in a loss position for all periods presented, basic net loss per share attributable to common stockholders is the same as diluted net loss per share attributable to common stockholders for all periods as the inclusion of all potential common shares outstanding would have been anti-dilutive.

Potentially dilutive securities that were not included in the diluted per share attributable to common stockholders calculations because they would be anti-dilutive were as follows (in thousands):

	September 30,	
	2014	2013
Convertible preferred stock	9,592	3,528
Options to purchase common stock	1,209	426
Common stock subject to repurchase	-	2
Total	<u>10,801</u>	<u>3,956</u>

## 8. Related Party Transactions

The spouse of the Company's Chief Executive Officer was the founder of a management consulting firm that provided services to the Company until he was hired as an employee in April 2013. For the nine months ended September 30, 2014 and 2013, the Company recognized expense of nil and \$62,000, respectively for consulting services which were primarily included in the research and development expenses in the statement of operations and comprehensive loss. As of September 30, 2014 and December 31, 2013, the Company had no outstanding liability to the management consulting firm.

The spouse of one of the Company's executive officers was a consultant who provided accounting services for the Company. For the nine months ended September 30, 2014 and 2013, the Company recognized expense of \$61,000 and \$25,000, respectively, for consulting services within the general and administrative expense in the statements of operations and comprehensive loss. As of September 30, 2014 and December 31, 2013, the Company had an outstanding liability to the spouse, of nil and \$12,000, respectively.

## 9. Subsequent Events

### *Initial Public Offering*

On October 7, 2014, the Company consummated its IPO of 8,000,000 shares of its common stock, as described in Note 1.

### *Contingencies*

In October 2014, the Company received an invoice of approximately \$1.3 million relating to a contingent amount associated with a terminated license agreement, incurred as a result of the closing of its IPO in October 2014. The Company believes that the invoice amount is substantially in excess of the amount actually owed pursuant to the agreement and has initiated discussions with the third party to resolve the matter. The Company does not believe that the ultimate resolution of this matter will be material to the Company's results of operations, financial condition or cash flows.

**Item 2.**

**MANAGEMENT'S DISCUSSION AND ANALYSIS OF  
FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

*You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our unaudited condensed financial statements and related notes included in Part I, Item 1 of this report. This discussion and other parts of this report contain forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations and intentions. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section of this report entitled "Risk factors."*

**Forward-Looking Statements**

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

**Overview**

We are a clinical-stage pharmaceutical company focused on discovering and developing novel small molecule drugs directed against tumor metabolism and tumor immunology targets for the treatment of cancer. Tumor metabolism and tumor immunology have emerged as promising new fields for cancer drug discovery, and recent clinical successes with therapeutic agents in each field have demonstrated the potential to create fundamentally new therapies for cancer patients. Our lead product candidate, CB-839, is an internally discovered, first-in-class inhibitor of glutaminase, a critical enzyme in tumor metabolism. We are currently evaluating CB-839 in three Phase 1 clinical trials in solid and hematological tumors. Our lead preclinical program in tumor immunology is directed at developing inhibitors of the enzyme arginase and may provide a first-in-class therapeutic agent for this novel target. Our ongoing research efforts are focused on discovering additional product candidates against novel tumor metabolism and immunology targets.

The field of tumor metabolism seeks to exploit the unique ways in which cancer cells take up and utilize nutrients in order to grow and survive. Our lead product candidate in tumor metabolism, CB-839, takes advantage of the pronounced dependency many cancers have on the nutrient glutamine for growth and survival. CB-839 inhibits glutaminase, an enzyme required by cancer cells to utilize glutamine effectively. We are currently conducting three Phase 1 clinical trials of CB-839 in the United States in patients with solid tumors, leukemias, lymphomas and multiple myeloma. The purpose of these trials is to evaluate the safety of CB-839 both as a single agent and in combination with approved therapies and to seek preliminary evidence of efficacy. Pending input from the FDA on the results of our Phase 1 trials and Phase 2 trial protocols, we plan to initiate one or more Phase 2 clinical trials of CB-839 in late 2015 or early 2016. We currently hold all commercial rights to CB-839.

The field of tumor immunology seeks to activate the body's own immune system to attack and kill cancer cells. Our preclinical program in tumor immunology is focused on developing selective inhibitors of the enzyme arginase. Arginase depletes arginine, a nutrient that is critical for the activation, growth and survival of the body's cancer-fighting immune cells. We believe that inhibitors of arginase can promote an anti-tumor immune response by restoring arginine levels, thereby allowing activation of the body's cancer-fighting immune cells. We are currently optimizing arginase inhibitors with the aim of submitting an IND application to the FDA near the end of 2015.

Since our inception in 2010, we have devoted substantially all of our resources to identifying and developing CB-839, advancing our preclinical programs, conducting clinical trials and providing general and administrative support for these operations. We have not recorded revenue from product sales, collaboration activities or any other source. We have funded our operations through September 30, 2014 primarily from the issuance and sale of convertible preferred stock.

As of September 30, 2014, we had cash and cash equivalents of \$34.9 million. In October 2014, we completed an initial public offering and sold 8,000,000 shares of common stock for proceeds of approximately \$71.7 million net of underwriting discounts and commissions and offering expenses.

We have never been profitable and have incurred net losses in each year since inception. Our net losses were \$12.4 million for 2013 and \$14.9 million for the nine months ended September 30, 2014. As of September 30, 2014 we had an accumulated deficit of \$45.0 million. Substantially all of our net losses have resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations.

We expect to continue to incur significant expenses and increasing operating losses over at least the next several years. We expect our expenses will increase substantially in connection with our ongoing activities, as we:

- advance product candidates through clinical trials;
- pursue regulatory approval of product candidates;
- operate as a public company;
- continue our preclinical programs and clinical development efforts;
- continue research activities for the discovery of new product candidates; and
- manufacture supplies for our preclinical studies and clinical trials.

### ***Recent Developments***

In October 2014, we completed an initial public offering and sold 8,000,000 shares of common stock for net proceeds of approximately \$71.7 million net of underwriting discounts and commissions and offering expenses.

### **Critical Accounting Policies and Estimates**

There have been no material changes in our critical accounting policies during the nine months ended September 30, 2014, as compared to those disclosed in the *Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Estimates* in our prospectus dated October 1, 2014, filed with the SEC pursuant to Rule 424(b) under the Securities Act of 1933, as amended.

### **Financial Overview**

#### ***Research and Development Expenses***

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

- employee-related expenses, which include salaries, benefits and stock-based compensation;
- expenses incurred under agreements with clinical trial sites that conduct research and development activities on our behalf;
- laboratory and vendor expenses related to the execution of preclinical studies and clinical trials;
- contract manufacturing expenses, primarily for the production of clinical supplies; and
- facilities and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities, depreciation and amortization expense and other supplies.

The largest component of our total operating expenses has historically been our investment in research and development activities including the clinical development of our product candidates. We allocate to research and development expenses the salaries, benefits, stock-based compensation expense, and indirect costs of our clinical and preclinical programs on a program-specific basis, and we include these costs in the program-specific expenses. The following table shows our research and development expenses for the three and nine months ended September 30, 2014 and 2013:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
	(in thousands)			
Development candidate:				
CB-839	\$ 2,920	\$ 2,521	\$ 8,986	\$ 2,521
Preclinical and research:				
CB-839	—	—	—	3,849
Arginase Inhibitors	942	—	1,896	—
Other preclinical and research	32	214	513	434
Total preclinical and research	974	214	2,409	4,283
Total Research and Development	<u>\$ 3,894</u>	<u>\$ 2,735</u>	<u>\$ 11,395</u>	<u>\$ 6,804</u>

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

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

#### *General and Administrative Expenses*

General and administrative expenses consist of personnel costs, allocated expenses and other expenses for outside professional services, including legal, audit and accounting services. Personnel costs consist of salaries, benefits and stock-based compensation. Allocated expenses consist of facilities and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities, depreciation and amortization expense and other supplies. We expect to incur additional expenses as a public company, including expenses related to compliance with the rules and regulations of the SEC, and those of the NASDAQ Global Market on which our securities are traded, additional insurance expenses, investor relations activities and other administration and professional services.

#### **Results of Operations**

##### *Comparison of the Three Months Ended September 30, 2014 and 2013*

	Three Months Ended September 30,		Change	
	2014	2013	\$	%
	(in thousands, except percentages)			
Operating expenses:				
Research and development	\$ 3,894	\$ 2,735	\$ 1,159	42%
General and administrative	1,347	583	764	131%
Total operating expenses	5,241	3,318	1,923	58%
Loss from operations	(5,241)	(3,318)	(1,923)	58%
Other income	2	-	2	*
Net loss	<u>\$ (5,239)</u>	<u>\$ (3,318)</u>	<u>\$ (1,921)</u>	58%

\* Percentage not meaningful

*Research and Development.* Research and development expenses increased \$1.2 million, or 42%, from \$2.7 million for the three months ended September 30, 2013 to \$3.9 million for the three months ended September 30, 2014. The increase was due to an increase of \$1.1 million in clinical trial related expenses in connection with our CB-839 Phase 1 clinical trials which began enrolling patients in February 2014, and an increase of \$0.3 million in personnel-related costs primarily as a result of higher headcount, partially offset by a decrease of \$0.3 million in costs related to the timing of CB-839 manufacturing to support our Phase 1 clinical trials.

*General and Administrative.* General and administrative expenses increased \$0.8 million, or 131%, from \$0.6 million for the three months ended September 30, 2013 to \$1.3 million for the three months ended September 30, 2014. The increase was due to an increase of \$0.7 million in personnel-related costs as a result of higher headcount, salary increases and stock-based compensation expense and an increase of \$0.1 million in professional services costs.

**Comparison of the Nine Months Ended September 30, 2014 and 2013**

	Nine Months Ended September 30,		Change	
	2014	2013	\$	%
(in thousands, except percentages)				
Operating expenses:				
Research and development	\$ 11,395	\$ 6,804	\$ 4,591	67%
General and administrative	3,488	1,486	2,002	135%
Total operating expenses	14,883	8,290	6,593	80%
Loss from operations	(14,883)	(8,290)	(6,593)	80%
Other income	4	-	4	*
Net loss	\$ (14,879)	\$ (8,290)	\$ (6,589)	79%

\* Percentage not meaningful.

*Research and Development.* Research and development expenses increased \$4.6 million, or 67%, from \$6.8 million for the nine months ended September 30, 2013 to \$11.4 million for the nine months ended September 30, 2014. The increase was due to an increase of \$2.8 million in clinical trial related expenses in connection with our CB-839 Phase 1 clinical trials which began enrolling patients in February 2014, an increase of \$1.3 million in personnel-related costs primarily as a result of higher headcount, and an increase of \$0.5 million in costs related to CB-839 development and manufacturing to support our Phase 1 clinical trials and investments in our arginase inhibitors program.

*General and Administrative.* General and administrative expenses increased \$2.0 million, or 135%, from \$1.5 million for the nine months ended September 30, 2013 to \$3.5 million for the nine months ended September 30, 2014. The increase was due to an increase of \$1.3 million in personnel-related costs as a result of higher headcount, salary increases and stock-based compensation expense and an increase, an increase of \$0.5 million in professional services costs and an increase of \$0.2 million in facility costs due to our office expansion in the second half of 2013.

**Liquidity and Capital Resources**

Since inception, our operations have been financed primarily by net proceeds of approximately \$79.4 million from the sale of shares of our preferred stock. As of September 30, 2014, we had cash and cash equivalents of \$34.9 million. In October 2014, we completed an initial public offering and sold 8,000,000 shares of common stock for proceeds of approximately \$71.7 million net of underwriting discounts and commissions and offering expenses. Since we completed our initial public offering in October 2014, such proceeds are not reflected in our cash and cash equivalents at September 30, 2014.

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

We plan to continue to fund our operations and capital funding needs through equity and/or debt financing. We may also consider collaborations or selectively partnering for clinical development and commercialization. The sale of additional equity would result in additional dilution to our stockholders. The incurrence of debt financing would result in debt service obligations and the instruments governing such debt could provide for operating and financing covenants that would restrict our operations. If we are not able to secure adequate additional funding we may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible, and/or suspend or curtail planned programs. Any of these actions could harm our business, results of operations and future prospects.

## Cash Flows

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

	Nine Months Ended September 30,	
	2014	2013
	(in thousands)	
Cash used in operating activities	\$ (14,760)	\$ (7,744)
Cash used in investing activities	\$ (416)	\$ (162)
Cash provided by financing activities	\$ 16,208	\$ 8,735

### Cash Flows from Operating Activities

Cash used in operating activities for the nine months ended September 30, 2014 was \$14.8 million. Our net loss of \$14.9 million was offset in part by non-cash charges of \$0.3 million for depreciation and amortization and \$0.4 million of stock-based compensation. The change in operating assets and liabilities was primarily due to a \$1.0 million increase in prepaid expenses and other current assets primarily related to our prepayment of clinical trial activities, a \$1.4 million increase in other assets related to our deferred offering costs, a \$0.4 million increase in deferred rent and a \$1.6 million increase in accounts payable and accrued liabilities related to an increase in our research and development activities.

Cash used in operating activities for the nine months ended September 30, 2013 was \$7.7 million. Our net loss of \$8.3 million was offset in part by a non-cash charge of \$0.2 million for depreciation and amortization. The change in operating assets and liabilities was primarily due to a \$0.2 million increase in prepaid expenses and other current assets related to an advance payment for manufacturing activities and our Series D deferred offering costs and a \$0.4 million increase in accounts payable and accrued liabilities related to an increase in our research and development activities.

### Cash Flows from Investing Activities

Cash used in investing activities was \$0.4 million for the nine months ended September 30, 2014 and was related to the purchase of property and equipment of \$0.5 million and the reduction in restricted cash of \$0.1 million. Purchases of property and equipment were primarily related to leasehold improvements in connection with our office expansion.

Cash used in investing activities was \$0.2 million for the nine months ended September 30, 2013 and was primarily related to the purchase of property and equipment of \$0.2 million.

### Cash Flows from Financing Activities

Cash provided by financing activities for the nine months ended September 30, 2014 of \$16.2 million was related to \$16.0 million from the sale and issuance of preferred stock and \$0.2 million from the issuance of common stock upon the exercise of stock options.

Cash provided by financing activities for the nine months ended September 30, 2013 was primarily related to net proceeds from the sale and issuance of preferred stock of \$8.7 million.

We expect that our existing cash and cash equivalents, including the net proceeds from our IPO, will be sufficient to enable us to meet our operating plan for at least the next 12 months. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially.

We have based our projections of operating capital requirements on assumptions that may prove to be incorrect and we may use all of our available capital resources sooner than we expect. Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products, we are unable to estimate the exact amount of our operating capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the timing and costs of our planned clinical trials for our product candidates;
- the timing and costs of our planned preclinical studies of our product candidates;
- our success in establishing and scaling commercial manufacturing capabilities;



- the number and characteristics of product candidates that we pursue;
- the outcome, timing and costs of seeking regulatory approvals;
- subject to receipt of regulatory approval, revenue received from commercial sales of our product candidates;
- the terms and timing of any future collaborations, licensing, consulting or other arrangements that we may establish;
- the amount and timing of any payments we may be required to make in connection with the licensing, filing, prosecution, maintenance, defense and enforcement of any patents or patent applications or other intellectual property rights; and
- the extent to which we in-license or acquire other products and technologies.

#### **Contractual Obligations and Other Commitments**

There have been no material changes outside the ordinary course of our business to the contractual obligations during the nine months ended September 30, 2014, as compared to those disclosed in our prospectus dated October 1, 2014, filed with the SEC pursuant to Rule 424(b) under the Securities Act of 1933, as amended.

#### **Off-Balance Sheet Arrangements**

During 2013 and the nine months ended September 30, 2014, we did not have any off balance sheet arrangements.

#### **Recent Accounting Pronouncements**

In June 2014, the Financial Accounting Standards Board issued ASU 2014-10, *Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation*. ASU 2014-10 simplifies the accounting guidance by removing all incremental financial reporting requirements for development stage entities. The amendments related to the elimination of the inception-to-date information and other disclosure requirements of Topic 915 should be applied retrospectively, and are effective for annual reporting periods beginning after December 15, 2014, and interim periods therein. We early adopted this guidance and, accordingly, there is no inception to date information presented in the financial statements.

In August 2014, the FASB issued ASU No. 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*. ASU 2014-15 requires management to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosures. In doing so, companies will have reduced diversity in the timing and content of footnote disclosures than under today's guidance. ASU 2014-15 is effective for the Company in the first quarter of 2016 with early adoption permitted. Management is currently assessing the impact the adoption of ASU 2014-15 will have on the financial statements.

#### **Item 3. Quantitative and Qualitative Disclosures about Market Risk**

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities. We had cash and cash equivalents of \$34.9 million and \$33.8 million as of September 30, 2014 and December 31, 2013, respectively, which consist of bank deposits and money market funds. Such interest-earning instruments carry a degree of interest rate risk; however, historical fluctuations in interest income have not been significant. We had no outstanding debt as of September 30, 2014 and December 31, 2013.

#### **Item 4. Controls and Procedures**

##### **Evaluation of Disclosure Controls and Procedures.**

Our management, with the participation of our President and Chief Executive Officer and our Chief Financial Officer, have evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) prior to the filing of this quarterly report. Based on that evaluation, our President and Chief Executive Officer and our Chief Financial Officer have concluded that, as of the end of the period covered by this quarterly report, our disclosure controls and procedures were, in design and operation, effective.

### **Remediation Efforts on Previously Identified Material Weakness**

In connection with the audit of our financial statements from inception through the year ended December 31, 2013, we and our independent public accounting firm identified a material weakness in our internal control over financial reporting. A “material weakness” is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. The material weakness related to a deficiency in the operation of our internal controls over the accounting for a non-routine, complex equity transaction, which resulted in material post-closing adjustments to the convertible preferred stock and additional paid-in capital balances in the financial statements for the years ended December 31, 2011 and 2012. Specifically, we did not properly account for a reduction in the liquidation preference amount the holders of our Series A preferred stock would be entitled to receive in the event we consummate a change in control.

We have implemented changes to our disclosure controls and procedures and internal control over financial reporting to remediate the material weakness identified above. We have strengthened the operation of our internal controls over the accounting for non-routine, complex equity transactions, including increasing the depth and experience within our accounting and finance organization, as well as designing and implementing improved processes and internal controls to identify such matters. We have hired additional personnel to build our financial management and reporting infrastructure, including the hiring of our Chief Financial Officer and Vice President, Finance, in the second quarter of 2014. Neither we nor our independent registered public accounting firm has performed an evaluation of our internal control over financial reporting during any period in accordance with the provisions of the Sarbanes-Oxley Act. In light of the material weakness that was identified as a result of the limited procedures performed, we believe that it is possible that, had we and our independent registered public accounting firm performed an evaluation of our internal control over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act, additional material weaknesses or significant control deficiencies may have been identified.

### **Changes in Internal Control Over Financial Reporting.**

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the quarter ended September 30, 2014 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting, other than as described above.

### **Limitations on Effectiveness of Controls and Procedures**

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

## PART II. – OTHER INFORMATION

### Item 1. Legal Proceedings

From time to time, we may become involved in legal proceedings relating to claims arising from the ordinary course of business. Our management believes that there are currently no claims or actions pending against us, the ultimate disposition of which could have a material adverse effect on our results of operations, financial condition or cash flows.

### Item 1A. Risk Factors

*You should carefully consider the following risk factors, in addition to the other information contained in this report on Form 10-Q, including the section of this report titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our financial statements and related notes. If any of the events described in the following risk factors and the risks described elsewhere in this report occurs, our business, operating results and financial condition could be seriously harmed. This report on Form 10-Q also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of factors that are described below and elsewhere in this report. The risks relating to our business set forth in our prospectus dated October 1, 2014 that forms a part of the Company’s Registration Statement on Form S-1, filed with the SEC, are set forth below and are unchanged substantively as of September 30, 2014, except for those risks designated by an asterisk (\*).*

#### Risks Related to Our Financial Position and Need For Additional Capital

*We have incurred significant operating losses since our inception and anticipate that we will continue to incur substantial operating losses for the foreseeable future. We may never achieve or maintain profitability.\**

Since our inception, we have incurred significant operating losses. Our net loss was \$12.4 million and \$14.9 million for 2013 and the nine months ended September 30, 2014, respectively. As of September 30, 2014, we had an accumulated deficit of \$45.0 million. To date, we have financed our operations primarily through private placements of our preferred stock. We have devoted substantially all of our financial resources and efforts to research and development. We began Phase 1 clinical trials on our lead product candidate, CB-839, in early 2014 and expect that it will be many years, if ever, before we receive regulatory approval and have a product candidate ready for commercialization. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. Our net losses may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially if and as we:

- advance further into clinical trials our existing clinical product candidate, CB-839, a glutaminase inhibitor for the treatment of solid and hematological tumors;
- continue the preclinical development of our arginase inhibitor program and advance a candidate into clinical trials;
- identify additional product candidates and advance them into preclinical development;
- seek marketing approvals for our product candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure to commercialize any product candidates for which we obtain marketing approval;
- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, regulatory and scientific personnel;
- add operational, financial and management information systems and personnel, including personnel to support product development; and
- acquire or in-license other product candidates and technologies.

To become and remain profitable, we must develop and eventually commercialize one or more products with significant market potential. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials of our product candidates, obtaining marketing approval for these product candidates, manufacturing, marketing and selling those product candidates for which we may obtain marketing approval, and satisfying any post-marketing requirements. We may never succeed in these activities and, even if we do, may never generate revenue that is significant or large enough to achieve profitability. We are currently only in Phase 1 clinical trials for CB-839 and in preclinical studies for our arginase inhibitor program. Our failure to become and remain profitable would decrease the value of the company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

***We will need substantial additional funding. If we are unable to raise capital when needed, we would be forced to delay, reduce or eliminate our product development programs or commercialization efforts.\****

We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development of, continue and initiate clinical trials of and seek marketing approval for our product candidates, specifically CB-839. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution of the approved product. Furthermore, we expect to incur additional costs associated with operating as a public company.

We expect that our existing cash, cash equivalents and marketable securities and anticipated interest income will enable us to fund our operating expenses and capital expenditure requirements for at least the next twelve months. Our future capital requirements will depend on many factors, including:

- the scope, progress, results and costs of drug discovery, preclinical development, laboratory testing and clinical trials for our product candidates, in particular CB-839;
- the costs, timing and outcome of any regulatory review of our product candidate, CB-839;
- the cost of our arginase inhibitor program and any other product programs we pursue;
- the costs and timing of commercialization activities, including manufacturing, marketing, sales and distribution, for any product candidates that receive marketing approval;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our ability to establish and maintain collaborations on favorable terms, if at all; and
- the extent to which we acquire or in-license other product candidates and technologies.

Identifying potential product candidates and conducting preclinical studies and clinical trials are time-consuming, expensive and uncertain processes that take years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales for any of our current or future product candidates. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenue, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if at all.

Accordingly, we will need substantial additional funding in connection with our continuing operations and to achieve our goals. Since inception, our operations have been financed primarily by net proceeds of approximately \$79.4 million from the sale of shares of our preferred stock. As of September 30, 2014, we had cash and cash equivalents of \$34.9 million. We expect that our existing cash and cash equivalents, including the proceeds from our initial public offering of common stock, will be sufficient to meet our current operating plans for at least the next twelve months. However, our existing cash and cash equivalents may prove to be insufficient for these activities. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts. Adequate additional financing may not be available to us on acceptable terms, or at all. In addition, we may seek additional financing due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our operating plans.

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

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity and debt financings, as well as entering into collaborations, strategic alliances and licensing arrangements. We do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. 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, and may be secured by all or a portion of our assets.

If we raise funds by entering into collaborations, 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. If we are unable to raise additional funds through equity or debt financings or through collaborations, strategic alliances or licensing arrangements when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

***Our short operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.***

We were founded in March 2010 and our operations to date have been limited to organizing and staffing our company, business planning, raising capital, developing our technology, identifying potential product candidates, undertaking preclinical studies and commencing Phase 1 clinical trials of our product candidate. We have one product candidate in Phase 1 clinical trials, and all of our other programs are in research and preclinical development. We have not yet demonstrated our ability to successfully complete any clinical trials, including large-scale, pivotal clinical trials required for regulatory approval of our product candidates, obtain marketing approvals, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization. Typically, it takes many years to develop one new product from the time it is discovered to when it is commercially available. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a longer operating history or if we had product candidates in advanced clinical trials.

In addition, as a new business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors that may alter or delay our plans. We will need to transition from a company with a research focus to a company capable of supporting development activities and, if a product candidate is approved, a company with commercial activities. We may not be successful in any step in such a transition.

#### **Risks Related to Drug Discovery, Development and Commercialization**

***Our approach to the discovery and development of product candidates that target tumor metabolism and tumor immunology is unproven and may never lead to marketable products.***

Our scientific approach focuses on using our understanding of cellular metabolic pathways and the role of glutaminase in these pathways, as well as the role of arginase in the anti-tumor immune response, to identify molecules that are potentially promising as therapies for cancer indications. Any product candidates we develop may not effectively modulate metabolic or immunology pathways. The scientific evidence to support the feasibility of developing product candidates based on inhibiting tumor metabolism or impacting the anti-tumor immune response are both preliminary and limited. Although preclinical studies suggest that inhibiting glutaminase can suppress the growth of certain cancer cells, to date no company has translated this mechanism into a drug that has received marketing approval. Even if we are able to develop a product candidate in preclinical studies, we may not succeed in demonstrating the safety and efficacy of the product candidate in human clinical trials. Our expertise in cellular metabolic pathways, the role of glutaminase in these pathways, and the role of arginase in the anti-tumor immune response may not result in the discovery and development of commercially viable products to treat cancer.

***We are very early in our development efforts, which may not be successful.***

We have invested a significant portion of our efforts and financial resources in the identification of our most advanced product candidate, CB-839, which is being evaluated in three Phase 1 clinical trials. Our arginase inhibitor program is in preclinical development. Because of the early stage of our development efforts and our unproven and novel approach to discovery and development of product candidates, we do not have a clearly defined clinical development path. It is also too early in our development efforts to determine whether our product candidates will demonstrate single-agent activity or will be developed for use in combination with other approved therapies, or both. As a result, the timing and costs of the regulatory paths we will follow and marketing approvals remain uncertain. Our ability to generate product revenue, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of CB-839. The success of CB-839, our arginase inhibitor program and any other product candidates we may develop will depend on many factors, including the following:

- successful enrollment in, and completion of, clinical trials;
- demonstrating safety and efficacy;
- receipt of marketing approvals from applicable regulatory authorities;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and non-patent exclusivity for our product candidates;

- launching commercial sales of the product candidates, if and when approved, whether alone or selectively in collaboration with others;
- acceptance of the product candidates, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies;
- a continued acceptable safety profile of the products following approval; and
- enforcing and defending intellectual property rights and claims.

If we do not accomplish one or more of these goals in a timely manner, or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would harm our business.

***We may not be successful in our efforts to identify or discover potential product candidates.***

Our drug discovery efforts may not be successful in identifying compounds that are useful in treating cancer. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for a number of reasons. In particular, our research methodology used may not be successful in identifying compounds with sufficient potency or bioavailability to be potential product candidates. In addition, our potential product candidates may, on further study, be shown to have harmful side effects or other negative characteristics.

Research programs to identify new product candidates require substantial technical, financial and human resources. We may choose to focus our efforts and resources on potential product candidates that ultimately prove to be unsuccessful. If we are unable to identify suitable compounds for preclinical and clinical development, we will not be able to generate product revenue, which would harm our financial position and adversely impact our stock price.

***If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.***

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials could occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a particular clinical trial do not necessarily predict final results of that trial.

Moreover, preclinical and clinical data are often susceptible to multiple interpretations and analyses. Many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including that:

- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may have delays in reaching or fail to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate; enrollment in these clinical trials may be slower than we anticipate, or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;

- regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate; and
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings;
- be subject to additional post-marketing testing requirements; or
- have the product removed from the market after obtaining marketing approval.

Product development costs will also increase if we experience delays in testing or in receiving marketing approvals. We do not know whether any clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates, could allow our competitors to bring products to market before we do, and could impair our ability to successfully commercialize our product candidates, any of which may harm our business and results of operations.

***If we experience delays or difficulties in enrolling patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.***

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to identify and enroll a sufficient number of eligible patients to participate in these trials as required by the U.S. Food and Drug Administration, or FDA, or analogous regulatory authorities outside the United States. In addition, some of our competitors may have ongoing clinical trials for product candidates that would treat the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates. Patient enrollment is also affected by other factors, including:

- severity of the disease under investigation;
- availability and efficacy of approved medications for the disease under investigation;
- eligibility criteria for the trial in question;
- perceived risks and benefits of the product candidate under study;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment; and
- proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing.

***If serious adverse effects or unexpected characteristics of our product candidates are identified during development, we may need to abandon or limit our development of some or all of our product candidates.***

CB-839 is our only product candidate in Phase 1 clinical trials, all our other programs are in preclinical development and their risk of failure is high. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans or will receive marketing approval. If our product candidates are associated with undesirable side effects or have characteristics that are unexpected, we may need to abandon their development or limit development to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Many agents that initially showed promise in early stage testing for treating cancer or other diseases have later been found to cause side effects that prevented further development of the agent.

We are in early clinical trials with CB-839 and we have seen several adverse events deemed possibly or probably related to CB-839. As of July 25, 2014, we had enrolled 24 patients in these trials and 21 Grade 1 adverse events, or AEs, (most commonly nausea, vomiting and fatigue), two Grade 2 AEs and two Grade 3 AEs had been reported. We have treated an insufficient number of patients to assess the safety of CB-839 and, as our trials progress, we may experience more frequent or more severe adverse events. Our ongoing trials for CB-839 may fail due to safety issues, and we may need to abandon development of CB-839. Our arginase inhibitor program may also fail due to preclinical safety issues, causing us to abandon or delay the development of a product candidate from this program.

***We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.***

We have limited financial and managerial resources. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

***Even if any of our product candidates receive marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, third party payors and others in the medical community necessary for commercial success.***

If any of our product candidates receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, third party payors and others in the medical community for us to achieve commercial success. For example, current cancer treatments like chemotherapy and radiation therapy for certain diseases and conditions are well established in the medical community, and doctors may continue to rely on these treatments. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenue to become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and potential advantages compared to alternative treatments;
- our ability to offer any approved products for sale at competitive prices;
- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- sufficient third-party coverage or reimbursement; and
- the prevalence and severity of any side effects.

***If, in the future, we are unable to establish sales and marketing capabilities or to selectively enter into agreements with third parties to sell and market our product candidates, we may not be successful in commercializing our product candidates if and when they are approved.***

We do not have a sales or marketing infrastructure and have no experience in the sale, marketing or distribution of pharmaceutical products. To achieve commercial success for any approved product for which we retain sales and marketing responsibilities, we must either develop a sales and marketing organization or outsource these functions to other third parties. In the future, we may choose to build a focused sales and marketing infrastructure to sell some of our product candidates if and when they are approved.



There are risks involved both with establishing our own sales and marketing capabilities and with entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our product candidates on our own include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future products; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenue or the profitability of these product revenue to us may be lower than if we were to market and sell any products that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market our product candidates or may be unable to do so on terms that are favorable to us. We may have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

***We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.***

The development and commercialization of new drug products is highly competitive. We face competition with respect to our current product candidates, and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of the cancer indications for which we are focusing our product development efforts. Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our approach and others are based on entirely different approaches. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

We are developing our product candidates for the treatment of various cancers. There are a variety of available drug therapies marketed for cancer. In many cases, these drugs are administered in combination to enhance efficacy. Some of the currently approved drug therapies are branded and subject to patent protection, and others are available on a generic basis. Many of these approved drugs are well-established therapies and are widely accepted by physicians, patients and third-party payors. Insurers and other third-party payors may also encourage the use of generic products. We expect that if our product candidates are approved, they will be priced at a significant premium over competitive generic products. This may make it difficult for us to achieve our business strategy of using our product candidates in combination with existing therapies or replacing existing therapies with our product candidates.

There are also a number of product candidates in preclinical and clinical development by third parties to treat cancer by targeting cellular metabolism. Our principal competitors in the field of tumor metabolism include Advanced Cancer Therapeutics, LLC, Agios Pharmaceutical, Inc., AstraZeneca plc, Cornerstone Pharmaceuticals, Inc., Eli Lilly and Company, Forma Therapeutics Holdings, LLC, GlaxoSmithKline plc, Novartis International AG, Pfizer, Inc., 3-V Biosciences, Inc., and Roche Holdings and its subsidiary Genentech Inc. Our principal competitors in the field of tumor immunology include AstraZeneca plc, Ono Pharmaceuticals, Co., Ltd., NewLink Genetics Corporation, Incyte Corporation, Merck & Co., Bristol-Myers Squibb Company, CureTech Ltd, and EMD Serono, Inc.

Our competitors may develop products that are more effective, safer, more convenient or less costly than any that we are developing or that would render our product candidates obsolete or non-competitive. In addition, our competitors may discover biomarkers that more efficiently measure metabolic pathways than our methods, which may give them a competitive advantage in developing potential products. Our competitors may also obtain marketing approval from the FDA or other regulatory authorities for their products sooner than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties may compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

***Even if we are able to commercialize any product candidates, these products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which would harm our business.***

The regulations that govern marketing approvals, pricing and reimbursement for new drugs vary widely from country to country. In the United States, new and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product-licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial marketing approval is granted. As a result, we might obtain marketing approval for a drug in a particular country, but then be subject to price regulations that delay its commercial launch, possibly for lengthy time periods, and negatively impact the revenue we are able to generate from the sale of the drug in that country. Adverse pricing limitations may hinder our ability to commercialize and generate revenue from one or more product candidates, even if our product candidates obtain marketing approval.

Our ability to commercialize any product candidates successfully also will depend in part on the extent to which reimbursement for these products and related treatments will be available from government health programs, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A significant trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of payment for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Reimbursement may not be available for any product that we commercialize and, if reimbursement is available, the level of reimbursement may not be sufficient. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining reimbursement for newly approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA or similar regulatory authorities outside the United States. Moreover, eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the medical circumstances under which it is used, may be based on reimbursement levels already set for lower cost products or procedures or may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policies and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable payment rates from both government-funded programs and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize our approved products and our overall financial condition.

***Product liability lawsuits against us could cause us to incur substantial liabilities and could limit the commercialization of any product candidates we may develop.***

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop after approval. If we cannot successfully defend ourselves against claims that our product candidates caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend any related litigation;

- substantial monetary awards to trial participants or patients;
- loss of revenue; and
- the inability to commercialize any products we may develop.

Although we maintain product liability insurance coverage in the amount of up to \$10.0 million per claim and in the aggregate, it may not be adequate to cover all liabilities that we may incur. We anticipate that we will need to increase our insurance coverage as we continue clinical trials and if we successfully commercialize any products. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

***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 harm 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 and radioactive 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. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees in our workplace, including those resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, chemical, hazardous or radioactive materials.

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.

#### **Risks Related to Our Dependence on Third Parties**

***We rely on third parties to conduct our clinical trials and some aspects of our research and preclinical testing, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research or testing.***

We currently rely and expect to continue to rely on third parties, such as contract research organizations, clinical data management organizations, medical institutions and clinical investigators, to conduct our clinical trials and to conduct some aspects of our research and preclinical testing. Any of these third parties may terminate their engagements with us at any time. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If we need to enter into alternative arrangements, it would delay our product development activities.

Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as Good Clinical Practices, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, available at [www.clinicaltrials.gov](http://www.clinicaltrials.gov), within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

We also rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our product candidates or commercialization of our product candidates, producing additional losses and depriving us of potential product revenue.

We do not have any manufacturing facilities. We currently rely, and expect to continue to rely, on third-party manufacturers for the manufacture of our product candidates for preclinical studies and clinical trials and for commercial supply of any of these product candidates for which we obtain marketing approval. To date, we have obtained materials for CB-839 for our Phase 1 trial from third-party manufacturers. We have engaged third party manufacturers to obtain the active ingredient for CB-839 for pre-clinical testing and clinical trials. We do not have a long-term supply agreement with any third-party manufacturers, and we purchase our required drug supply on a purchase order basis.

We may be unable to establish agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party; and
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

Third-party manufacturers may not be able to comply with current U.S. Good Manufacturing Practice requirements, or cGMPs, or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates, operating restrictions and criminal prosecutions, any of which could adversely affect supplies of our product candidates and harm our business and results of operations.

Any product that we may develop may compete with other product candidates and products for access to these manufacturing facilities. There are a limited number of manufacturers that operate under cGMPs and that might be capable of manufacturing for us.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply for bulk drug substances. If any one of our current contract manufacturers cannot perform as agreed, we may be required to replace that manufacturer. Although we believe that there are several potential alternative manufacturers who could manufacture our product candidates, we may incur added costs and delays in identifying and qualifying any such replacement.

Our current and anticipated future dependence upon others for the manufacture of our product candidates or products may adversely affect our future profit margins and our ability to commercialize any product candidates that receive marketing approval on a timely and competitive basis.

We also expect to rely on third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of these third parties could delay clinical development or marketing approval of our product candidates or commercialization of our drugs, producing additional losses and depriving us of potential revenue. Although we believe that there are several potential alternative third parties who could store and distribute drug supplies for our clinical trials, we may incur added costs and delays in identifying and qualifying any such replacement.

***We may seek to selectively establish collaborations, and, if we are unable to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.***

Our drug development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. For some of our product candidates, we may decide to collaborate with additional pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate.

***Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.***

If we decide to collaborate with a third party in connection with any of our development programs or product candidates, we may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development program or the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

***To the extent we enter into any collaborations, we may depend on such collaborations for the development and commercialization of our product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of our product candidates.***

We may selectively seek third-party collaborators for the development and commercialization of our product candidates. Our likely collaborators for any collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. If we enter into any such arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenue from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements.

Collaborations involving our product candidates pose many risks to us, including that:

- Collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations.
- Collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator's strategic focus or available funding or external factors such as an acquisition that diverts resources or creates competing priorities.
- Collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing.
- Collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates or products if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours.
- A collaborator with marketing and distribution rights to one or more product candidates or products may not commit sufficient resources to the marketing and distribution of such drugs.
- Collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation.
- Disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our product candidates or products or that result in costly litigation or arbitration that diverts management attention and resources.
- We may lose certain valuable rights under circumstances identified in our collaborations if we undergo a change of control.
- Collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates.
- Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If a future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished or terminated.

## Risks Related to Our Intellectual Property

### ***Recent laws and rulings by U.S. courts make it difficult to predict how patents will be issued or enforced in our industry.***

Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may have a significant impact on our ability to protect our technology and enforce our intellectual property rights. There have been numerous recent changes to the patent laws and to the rules of the United States Patent and Trademark Office, or the USPTO, which may have a significant impact on our ability to protect our technology and enforce our intellectual property rights. For example, the Leahy-Smith America Invents Act, which was signed into law in 2011, includes a transition from a “first-to-invent” system to a “first-to-file” system, and changes the way issued patents are challenged. Certain changes, such as the institution of *inter partes* review proceedings, came into effect on September 16, 2012. Substantive changes to patent law associated with the America Invents Act may affect our ability to obtain patents, and, if obtained, to enforce or defend them in litigation or post-grant proceedings, all of which could harm our business.

Furthermore, the patent positions of companies engaged in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. Two cases involving diagnostic method claims and “gene patents” have recently been decided by the Supreme Court. On March 20, 2012, the Supreme Court issued a decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, or *Prometheus*, a case involving patent claims directed to measuring a metabolic product in a patient to optimize a drug dosage amount for the patient. According to the Supreme Court, the addition of well-understood, routine or conventional activity such as “administering” or “determining” steps was not enough to transform an otherwise patent ineligible natural phenomenon into patent eligible subject matter. On July 3, 2012, the USPTO issued guidance indicating that process claims directed to a law of nature, a natural phenomenon or an abstract idea that do not include additional elements or steps that integrate the natural principle into the claimed invention such that the natural principle is practically applied and the claim amounts to significantly more than the natural principle itself should be rejected as directed to non-statutory subject matter. On June 13, 2013, the Supreme Court issued its decision in *Association for Molecular Pathology v. Myriad Genetics, Inc.*, or *Myriad*, a case involving patent claims held by Myriad Genetics, Inc. relating to the breast cancer susceptibility genes BRCA1 and BRCA2. *Myriad* held that isolated segments of naturally occurring DNA, such as the DNA constituting the BRCA1 and BRCA2 genes, is not patent eligible subject matter, but that complementary DNA, which is an artificial construct that may be created from RNA transcripts of genes, may be patent eligible.

We cannot assure you that our efforts to seek patent protection for our technology and products will not be negatively impacted by the decisions described above, rulings in other cases or changes in guidance or procedures issued by the USPTO. We cannot fully predict what impact the Supreme Court’s decisions in *Prometheus* and *Myriad* may have on the ability of life science companies to obtain or enforce patents relating to their products and technologies in the future.

Moreover, although the Supreme Court has held in *Myriad* that isolated segments of naturally occurring DNA are not patent-eligible subject matter, certain third parties could allege that activities that we may undertake infringe other gene-related patent claims, and we may deem it necessary to defend ourselves against these claims by asserting non-infringement and/or invalidity positions, or pay to obtain a license to these claims. In any of the foregoing or in other situations involving third-party intellectual property rights, if we are unsuccessful in defending against claims of patent infringement, we could be forced to pay damages or be subjected to an injunction that would prevent us from utilizing the patented subject matter. Such outcomes could harm our business.

### ***If we are alleged to infringe intellectual property rights of third parties, our business could be harmed.***

Our research, development and commercialization activities may be alleged to infringe patents, trademarks or other intellectual property rights owned by other parties. Certain of our competitors and other companies in the industry have substantial patent portfolios and may attempt to use patent litigation as a means to obtain a competitive advantage. We may be a target for such litigation. Even if our pending patent applications issue, they may relate to our competitors’ activities and may therefore not deter litigation against us. The risks of being involved in such litigation may also increase as we become more visible as a public company and move into new markets and applications for our product candidates. There may also be patents and patent applications that are relevant to our technologies or product candidates that are unknown to us. For example, certain relevant patent applications may have been filed but not published. If such patents exist, or if a patent issues on any of such patent applications, that patent could be asserted against us. Third parties could bring claims against us that would cause us to incur substantial expenses and, if the claims against us are successful, could cause us to pay substantial damages, including treble damages and attorneys’ fees for willful infringement. The defense of such a suit could also divert the attention of our management and technical personnel. Further, if an intellectual property infringement suit were brought against us, we could be forced to stop or delay research, development or sales of the product that is the subject of the suit.

As a result of infringement claims, or to avoid potential claims, we may choose or be compelled to seek intellectual property licenses from third parties. These licenses may not be available on acceptable terms, or at all. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us likely would be nonexclusive, which would mean that our competitors also could obtain licenses to the same intellectual property. Ultimately, we could be prevented from commercializing a product candidate and/or technology or be forced to cease some aspect of our business operations if, as a result of actual or threatened infringement claims, we are unable to enter into licenses of the relevant intellectual property on acceptable terms. Further, if we attempt to modify a product candidate and/or technology or to develop alternative methods or products in response to infringement claims or to avoid potential claims, we could incur substantial costs, encounter delays in product introductions or interruptions in sales.

***We may become involved in other lawsuits to protect or enforce our patents or other intellectual property, which could be expensive and time-consuming, and an unfavorable outcome could harm our business.***

In addition to the possibility of litigation relating to infringement claims asserted against us, we may become a party to other patent litigation and other proceedings, including *inter partes* review proceedings, post-grant review proceedings, derivation proceedings declared by the USPTO and similar proceedings in foreign countries, regarding intellectual property rights with respect to our current or future technologies or product candidates or products. The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Patent litigation and other proceedings may also absorb significant management time. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could impair our ability to compete in the marketplace.

Competitors may infringe or otherwise violate our intellectual property, including patents that may issue to or be licensed by us. As a result, we may be required to file claims in an effort to stop third-party infringement or unauthorized use. Any such claims could provoke these parties to assert counterclaims against us, including claims alleging that we infringe their patents or other intellectual property rights. This can be expensive, particularly for a company of our size, and time-consuming, and even if we are successful, any award of monetary damages or other remedy we may receive may not be commercially valuable. In addition, in an infringement proceeding, a court may decide that our asserted intellectual property is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our intellectual property does not cover its technology. An adverse determination in any litigation or defense proceedings could put our intellectual property at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

If the breadth or strength of our patent or other intellectual property rights is compromised or threatened, it could allow third parties to commercialize our technology or products or result in our inability to commercialize our technology and products without infringing third-party intellectual property rights. Further, third parties may be dissuaded from collaborating with us.

Interference or derivation proceedings brought by the USPTO or its foreign counterparts may be necessary to determine the priority of inventions with respect to our patent applications, and we may also become involved in other proceedings, such as re-examination proceedings, before the USPTO or its foreign counterparts. Due to the substantial competition in the pharmaceutical space, the number of such proceedings may increase. This could delay the prosecution of our pending patent applications or impact the validity and enforceability of any future patents that we may obtain. In addition, any such litigation, submission or proceeding may be resolved adversely to us and, even if successful, may result in substantial costs and distraction to our management.

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. Moreover, intellectual property law relating to the fields in which we operate is still evolving and, consequently, patent and other intellectual property positions in our industry are subject to change and are often uncertain. We may not prevail in any of these suits or other efforts to protect our technology, and the damages or other remedies awarded, if any, may not be commercially valuable. During the course of this type of litigation, there could 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, the market price for our common stock could be significantly harmed.

***We may not be able to protect our intellectual property rights throughout the world, which could impair our competitive position.***

Filing, prosecuting, defending and enforcing patents on all of our technologies, product candidates and products throughout the world would be prohibitively expensive. As a result, we seek to protect our proprietary position by filing patent applications in the United States and in select foreign jurisdictions and cannot guarantee that we will obtain the patent protection necessary to protect our competitive position in all major markets. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export infringing products to territories where we may obtain patent protection but where enforcement is not as strong as that in the United States. These products may compete with our current and future products in jurisdictions where we do not have any issued patents, and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so 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 and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or the marketing of competing products in violation of our proprietary rights generally. The legal systems of certain countries make it difficult or impossible to obtain patent protection for pharmaceutical products and services. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and could divert our efforts and attention from other aspects of our business.

***If we are unable to protect the confidentiality of our trade secrets, our business and competitive position could be harmed.***

In addition to seeking patents for some of our technologies and product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention assignment agreements with our employees and consultants that obligate them to assign to us any inventions developed in the course of their work for us. However, we cannot guarantee that we have executed these agreements with each party that may have or have had access to our trade secrets or that the agreements we have executed will provide adequate protection. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. As a result, we may be forced to bring claims against third parties, or defend claims that they bring against us, to determine ownership of what we regard as our intellectual property. Monitoring unauthorized disclosure is difficult and we do not know whether the procedures we have followed to prevent such disclosure are, or will be adequate. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States may be less willing or unwilling to protect trade secrets. If any of the technology or information that we protect as trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to, or independently developed by, a competitor, our competitive position would be harmed.

***If our trademarks and trade names are not adequately protected, we may not be able to build name recognition in our markets of interest, and our business may be harmed.***

Our trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be infringing on other marks. As a means to enforce our trademark rights and prevent infringement, we may be required to file trademark claims against third parties or initiate trademark opposition proceedings. This can be expensive and time-consuming, particularly for a company of our size. In addition, in an infringement proceeding, a court may decide that a trademark of ours is not valid or is unenforceable, or may refuse to stop the other party from using the trademark at issue. We may not be able to protect our rights to these and other trademarks and trade names which we need to build name recognition by potential partners or customers in our markets of interest. We do not currently have any registered trademarks in the United States. Any trademark applications in the United States and in other foreign jurisdictions where we may file may not be allowed or may subsequently be opposed. In addition, other companies in the biopharmaceutical space may be using trademarks that are similar to ours and may in the future allege that our use of the a trademark infringes or otherwise violates their trademarks. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be harmed.



***Third parties may assert ownership or commercial rights to inventions we develop.***

Third parties may in the future make claims challenging the inventorship or ownership of our intellectual property. We have written agreements with collaborators that provide for the ownership of intellectual property arising from our collaborations. In some instances, there may not be adequate written provisions to address clearly the resolution of intellectual property rights that may arise from a collaboration. If we cannot successfully negotiate sufficient ownership and commercial rights to the inventions that result from our collaborations, or if disputes otherwise arise with respect to the intellectual property developed in the course of a collaboration, we may be limited in our ability to capitalize on the market potential of these inventions.

In addition, we may face claims by third parties that our agreements with employees, contractors or consultants obligating them to assign intellectual property to us are ineffective or are in conflict with prior or competing contractual obligations of assignment, which could result in ownership disputes regarding intellectual property we have developed or will develop and interfere with our ability to capture the commercial value of such inventions. Litigation may be necessary to resolve an ownership dispute, and if we are not successful, we may be precluded from using certain intellectual property, or may lose our exclusive rights in that intellectual property. Either outcome could have an adverse impact on our business.

**Risks Related to Regulatory Approval of Our Product Candidates and Other Legal Compliance Matters**

***If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize, or will be delayed in commercializing, our product candidates, and our ability to generate revenue will be impaired.***

Our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. We have not received approval to market any of our product candidates from regulatory authorities in any jurisdiction. We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party contract research organizations to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals, both in the United States and elsewhere, is expensive, may take many years and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. We cannot assure you that we will ever obtain any marketing approvals in any jurisdiction. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations or changes in regulatory review for each submitted product application may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical or other studies, and clinical trials. In addition, varying interpretations of the data obtained from preclinical testing and clinical trials could delay, limit or prevent marketing approval of a product candidate. Additionally, any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

***Any product candidate for which we obtain marketing approval could be subject to marketing restrictions or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products.***

Any product candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements, quality assurance and corresponding maintenance of records and documents and requirements regarding the distribution of samples to physicians and recordkeeping. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the medicine. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure that they are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if we do not market our products for their approved indications, we may be subject to enforcement action for off-label marketing.

In addition, later discovery of previously unknown problems with our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling, marketing, distribution or use of a product;
- requirements to conduct post-approval clinical trials;
- warning or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenue;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure; and
- injunctions or the imposition of civil or criminal penalties.

***Our relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.***

Healthcare providers, physicians and third-party payors play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our medicines for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal healthcare anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid;
- the federal False Claims Act imposes criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;
- the federal transparency requirements under the Affordable Care Act requires manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests; and

- analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

***Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain.***

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or Medicare Modernization Act, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for physician-administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. Cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for any approved products. While the Medicare Modernization Act applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the Medicare Modernization Act may result in a similar reduction in payments from private payors.

More recently, in March 2010, President Obama signed into law the Affordable Care Act, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Effective October 1, 2010, the Affordable Care Act revises the definition of "average manufacturer price" for reporting purposes, which could increase the amount of Medicaid drug rebates to states. Further, the new law imposes a significant annual fee on companies that manufacture or import branded prescription drug products. Substantial new provisions affecting compliance have also been enacted, which may affect our business practices with health care practitioners. We will not know the full effects of the Affordable Care Act until applicable federal and state agencies issue regulations or guidance under the new law. Although it is too early to determine the effect of the Affordable Care Act, the new law appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

## **Risks Related to Employee Matters and Managing Growth**

***Our future success depends on our ability to retain our senior management team and to attract, retain and motivate qualified personnel.***

We are highly dependent upon our senior management team, as well as the other principal members of our research and development teams. All of our executive officers are employed “at will,” meaning we or they may terminate the employment relationship at any time. We do not maintain “key person” insurance for any of our executives or other employees. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors, may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

***We expect to expand our operations, and may encounter difficulties in managing our growth, which could disrupt our business.\****

We expect to expand the scope of our operations, particularly in the areas of drug development, regulatory affairs and sales and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. We may not be able to effectively manage the expected expansion of our operations or recruit and train additional qualified personnel. Furthermore, as our operations grow, we will need to enhance our information technology systems and security measures. Should we fail to effectively do so, we could be vulnerable to external or internal security breaches, acts of vandalism, computer viruses, misplaced or lost data, programming or human errors, or other similar events. A security breach or cyber attack of our computer systems could interrupt or damage our operations. Moreover, the expected expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

***We may engage in acquisitions that could disrupt our business, cause dilution to our stockholders or reduce our financial resources.***

In the future, we may enter into transactions to acquire other businesses, products or technologies. Because we have not made any acquisitions to date, our ability to do so successfully is unproven. If we do identify suitable candidates, we may not be able to make such acquisitions on favorable terms, or at all. Any acquisitions we make may fail to strengthen our competitive position, and these transactions may be viewed negatively by customers or investors. We may decide to incur debt in connection with an acquisition or issue our common stock or other equity securities to the stockholders of the acquired company, which would reduce the percentage ownership of our existing stockholders. We could incur losses resulting from undiscovered liabilities of the acquired business that are not covered by the indemnification we may obtain from the seller. In addition, we may not be able to successfully integrate the acquired personnel, technologies and operations into our existing business in an effective, timely and non-disruptive manner. Acquisitions may also divert management attention from day-to-day responsibilities, increase our expenses and reduce our cash available for operations and other uses. We cannot predict the number, timing or size of future acquisitions or the effect that any such transactions might have on our operating results.

## **Risks Related to Our Common Stock**

***An active trading market for our common stock may not develop or be sustainable, and investors may not be able to resell their shares at or above the initial public offering price.***

Prior to our initial public offering, there had been no public market for our common stock. An active trading market for our shares may never develop or be sustained. If an active market for our common stock does not develop, it may be difficult for investors to sell their shares of our common stock. We cannot predict the prices at which our common stock will trade and investors may not be able to resell their shares.

***The trading price of our common stock is likely to be volatile, and purchasers of our common stock could incur substantial losses.***

Our stock price is likely to be volatile. The stock market in general and the market in which we operate have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock. The market price for our common stock may be influenced by many factors, including:

- the success of competitive products or technologies;
- regulatory actions with respect to our product candidates or our competitors' product and product candidates;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- results of clinical trials of our product candidates or those of our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to in-license or acquire additional products or product candidates;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- inconsistent trading volume levels of our shares;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or our other stockholders;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other factors described in this "Risk Factors" section.

In addition, in the past, stockholders have initiated class action lawsuits against companies following periods of volatility in the market prices of these companies' stock. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources.

***Concentration of ownership of our common stock among our existing executive officers, directors and principal stockholders may prevent new investors from influencing significant corporate decisions.***

Based upon shares outstanding as of September 30, 2014, including shares sold in our initial public offering, our executive officers, directors and current beneficial owners of 5% or more of our common stock beneficially own approximately 59.4% of our outstanding common stock.

These stockholders, acting together, will be able to significantly influence all matters requiring stockholder approval, including the election and removal of directors and any merger or other significant corporate transactions. The interests of this group of stockholders may not coincide with the interests of other stockholders.

***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 and will be affected by numerous factors, including:

- our ability to successfully develop, obtain regulatory approvals, and market and sell CB-839 and our other product candidates;
- the success of competitive products or technologies;
- results of clinical trials of our product candidates or those of our competitors;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or medicines;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other factors described in this “Risk Factors” section.

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 securities or industry analysts do not publish research, or publish unfavorable research, about our business, our stock price and trading volume could decline.***

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business, our market and our competitors. We do not have any control over these analysts. If one or more of the analysts who cover us downgrade our shares or change their opinion of our shares, our share price would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline.

***We will incur costs and demands upon management as a result of complying with the laws and regulations affecting public companies in the United States, which may harm our operating results.***

As a public company listed in the United States, we will incur significant additional legal, accounting and other expenses. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including regulations implemented by the Securities and Exchange Commission, or SEC, and the NASDAQ Global Market, may increase legal and financial compliance costs and make some activities more time-consuming. These laws, regulations and standards are subject to varying interpretations, and as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management’s time and attention from revenue-generating activities to compliance activities. If, notwithstanding our efforts to comply with new laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us, and our business may be harmed.

Further, failure to comply with these laws, regulations and standards might also make it more difficult for us to obtain certain types of insurance, including director and officer liability insurance, and we might be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on committees of our board of directors or as members of senior management.

***We do not anticipate paying any cash dividends on our common stock, so any returns will be limited to changes in the value of our common stock.***

We have never declared or paid cash dividends on our common stock. We currently intend to retain our future earnings, if any, to fund the development and growth of our business. In addition, the terms of any existing or future credit facility may restrict our ability to pay dividends. Any return to stockholders will therefore be limited to the increase, if any, of our stock price.

***We are an “emerging growth company,” and we expect to comply with the reduced disclosure requirements applicable to emerging growth companies, which could make our common stock less attractive to investors.***

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act, or JOBS Act, enacted in April 2012, and for as long as we continue to be an “emerging growth company,” we expect to take advantage of exemptions from various reporting requirements applicable to other public companies but not to “emerging growth companies,” including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404, 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 and shareholder approval of any golden parachute payments not previously approved. We will continue to be an “emerging growth company” until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the closing 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 exceeds \$700 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. We cannot predict if investors will find our common stock less attractive if we choose to rely on these exemptions. If some investors find our common stock less attractive as a result of any choices to reduce future disclosure, there may be a less active trading market for our common stock, and our stock price may be more volatile.

***If we are unable to maintain proper and effective internal controls over financial reporting, the accuracy and timeliness of our financial reporting may be adversely affected.***

Effective internal controls are necessary for us to provide reliable financial reports and to protect from fraudulent, illegal or unauthorized transactions. If we cannot provide effective controls and reliable financial reports, our business and operating results could be harmed. We have in the past discovered, and may in the future discover, areas of our internal controls that need improvement. For example, in connection with the audit of our financial statements from inception through the year ended December 31, 2013, we and our independent public accounting firm identified a material weakness in our internal control over financial reporting. A “material weakness” is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. The material weakness related to a deficiency in the operation of our internal controls over the accounting for a non-routine, complex equity transaction, which resulted in material post-closing adjustments to the convertible preferred stock and additional paid-in capital balances in the financial statements for the years ended December 31, 2011 and 2012. Specifically, we did not properly account for a reduction in the liquidation preference amount the holders of our Series A preferred stock would be entitled to receive in the event we consummate a change in control.

If material weaknesses or control deficiencies occur in the future, we may be unable to report our financial results accurately on a timely basis, which could cause our reported financial results to be materially misstated and result in the loss of investor confidence and cause the market price of our common stock to decline.

We will be required, pursuant to Section 404 of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting for the fiscal year ending December 31, 2015. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. Our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting until our first annual report required to be filed with the SEC following the later of the date we are deemed to be an “accelerated filer” or a “large accelerated filer,” each as defined in the Securities Exchange Act of 1934, as amended, or the Exchange Act, or the date we are no longer an “emerging growth company,” as defined in the JOBS Act. We will be required to disclose changes made in our internal control and procedures on a quarterly basis. To comply with the requirements of being a public company, we may need to undertake various actions, such as implementing new internal controls and procedures and hiring accounting or internal audit staff. We have begun the costly and challenging process of compiling the system and processing documentation necessary to perform the evaluation needed to comply with Section 404, when applicable, and we may not be able to complete our evaluation, testing and any required remediation in a timely fashion.

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

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after the lock-up and legal restrictions on resale lapse, the trading price of our common stock could decline. Each of our directors and executive officers, and substantially all holders of our common stock and securities exercisable for or convertible into our common stock have entered into lock-up agreements with the underwriters that restrict their ability to sell or transfer their shares. The lock-up agreements pertaining to our initial public offering will expire 180 days after October 1, 2014. Citigroup Global Markets Inc. and Leerink Partners LLC, however, may, in their sole discretion, waive the contractual lock-up prior to the expiration of the lock-up agreements. During such 180-day period, our directors and executive officers may establish a trading plan pursuant to Rule 10b5-1 under the Exchange Act for the sale of shares of common stock to occur on or after the date of the lock-up agreements. After the lock-up agreements expire, based on shares outstanding as of September 30, 2014, 9,881,573 shares of common stock will be eligible for sale in the public market. These shares will become eligible for sale in the public market to the extent permitted by the provisions of various vesting agreements, the lock-up agreements and Rules 144 and 701 under the Securities Act of 1933, as amended, or the Securities Act. We have filed a registration statement on Form S-8 under the Securities Act covering all of the shares of common stock subject to options outstanding and reserved for issuance under our stock plans. This registration statement became effective immediately upon filing, and shares covered by this registration statement will be eligible for sale in the public markets, subject to Rule 144 limitations applicable to affiliates and any lock-up agreements described above. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

***Provisions in our corporate charter documents and under Delaware law may prevent or frustrate attempts by our stockholders to change our management or hinder efforts to acquire a controlling interest in us, and the market price of our common stock may be lower as a result.***

There are provisions in our certificate of incorporation and bylaws that may make it difficult for a third party to acquire, or attempt to acquire, control of our company, even if a change in control was considered favorable by our stockholders.

Our charter documents will also contain other provisions that could have an anti-takeover effect, such as:

- establishing a classified board of directors so that not all members of our board of directors are elected at one time;
- permitting the board of directors to establish the number of directors and fill any vacancies and newly created directorships;
- providing that directors may only be removed for cause;
- prohibits cumulative voting for directors;
- requiring super-majority voting to amend some provisions in our certificate of incorporation and bylaws;
- authorizing the issuance of “blank check” preferred stock that our board of directors could use to implement a stockholder rights plan;
- eliminating the ability of stockholders to call special meetings of stockholders; and stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibit a person who owns 15% or more of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. Any provision in our certificate of incorporation or our bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.



***Our amended and restated certificate of incorporation will provide that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.***

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation or our bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. The choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. If a court were to find the choice of forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business and financial condition.

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

### *Sales of Unregistered Securities*

Since July 1, 2014, we have made sales of the following unregistered securities (share and per share amounts give effect to a 1-for-48 reverse stock split of our common stock and preferred stock effected on September 19, 2014):

(1) Between July 1, 2014 and September 30, 2014, we granted stock options or restricted stock awards under our 2010 Equity Incentive Plan to purchase an aggregate of 306,559 shares of our common stock at exercise prices ranging between \$5.28 and \$7.20 per share to a total of 39 employees, directors and consultants.

(2) Between July 1, 2014 and September 30, 2014, we issued and sold to our employees, directors and consultants an aggregate of 48,789 shares of our common stock upon the exercise of options for aggregate proceeds of \$104,112.

The issuances and sales of the securities listed in (1) and (2) above were deemed to be exempt from registration under the Securities Act in reliance on Section 4(2) of the Securities Act or Rule 701 promulgated under Section 3(b) of the Securities Act, as transactions by an issuer not involving a public offering or transactions pursuant to compensatory benefit plans and contracts relating to compensation as provided under Rule 701.

### *Use of Proceeds from our Public Offering of Common Stock*

On October 7, 2014, we closed our IPO, in which we issued and sold 8,000,000 shares of our common stock at a public offering price of \$10.00 per share, for net proceeds of approximately \$71.7 million, after deducting underwriting discounts and commissions of \$5.6 million and estimated offering expenses of \$2.7 million payable by the Company. No payments for such expenses were made directly or indirectly to (i) any of our officers or directors or their associates, (ii) any persons owning 10% or more of any class of our equity securities, or (iii) any of our affiliates. The offer and sale of all of the shares in the IPO were registered under the Securities Act pursuant to a registration statement on Form S-1 (File No. 333-198355), which was declared effective by the SEC on October 1, 2014. Citigroup Global Markets and Leerink Partners acted as joint book-running managers for the offering. Wells Fargo Securities and JMP Securities acted as co-managers for the offering. Following the sale of the shares in connection with the closings of the IPO, the offering terminated.

There has been no material change in the planned use of proceeds from our IPO as described in our prospectus dated October 1, 2014, filed with the SEC pursuant to Rule 424(b) under the Securities Act of 1933, as amended.

### *Repurchases of Shares or of Company Equity Securities*

None.

## **Item 3. Defaults Upon Senior Securities.**

None.

## **Item 4. Mine Safety Disclosures.**

Not applicable.

**Item 5. Other Information.**

None.

**Item 6. Exhibits**

The documents listed in the Exhibit Index of this Quarterly Report on Form 10-Q are herein incorporated 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.

Date: November 13, 2014

Calithera Biosciences, Inc.

By: /s/ Susan M. Molineaux  
Susan M. Molineaux, Ph.D.  
President and Chief Executive Officer  
(Principal Executive Officer)

Date: November 13, 2014

Calithera Biosciences, Inc.

By: /s/ William D. Waddill  
William D. Waddill  
Senior Vice President, Chief Financial Officer, Treasurer  
and Secretary  
(Principal Financial and Accounting Officer)

**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Incorporation By Reference</b>			
		<b>Form</b>	<b>SEC File No.</b>	<b>Exhibit</b>	<b>Filing Date</b>
3.1	Amended and Restated Certificate of Incorporation of Calithera Biosciences, Inc.	8-K	001-36644	3.1	10/07/2014
3.2	Amended and Restated Bylaws of Calithera Biosciences, Inc.	S-1	333-198355	3.4	9/19/2014
4.1	Reference is made to Exhibits 3.1 through 3.2.				
4.2	Form of common stock certificate.	S-1	333-198355	4.1	9/25/2014
10.1	Amended and Restated Investor Rights Agreement, dated October 7, 2013, as amended.	S-1	333-198355	10.1	8/25/2014
31.1	Certifications of Principal Executive Officer pursuant to Rule 13a-14(a).				
31.2	Certifications of Principal Financial Officer pursuant to Rule 13a-14(a).				
32.1*	Certification of Principal Executive Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
32.2*	Certification of Principal Financial Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 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.				
*	The Certifications attached as Exhibits 32.1 and 32.2 that accompany this Quarterly Report on Form 10-Q are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of Calithera Biosciences, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Form 10-Q, irrespective of any general incorporation language contained in such filing.				
**	Attached as Exhibit 101 to this Quarterly Report on Form 10-Q for the quarter ended September 30, 2014 formatted in XBRL (Extensible Business Reporting Language): (i) Condensed Balance Sheets, (ii) Condensed Statements of Operations, (iii) Condensed Statements of Comprehensive Income (Loss), (iv) Condensed Statements of Cash Flows, and (v) Notes to Financial Statements, tagged as blocks of text and including detailed tags.				

## CERTIFICATIONS

I, Susan M. Molineaux, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Calithera Biosciences, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) 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)):
  - 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) 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
  - c) 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(s) 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 13, 2014

/s/ Susan M. Molineaux

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Susan M. Molineaux, Ph.D.  
*President and Chief Executive Officer*

## CERTIFICATIONS

I, William D. Waddill, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Calithera Biosciences, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) 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)):
  - 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) 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
  - c) 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(s) 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 13, 2014

/s/ William D. Waddill

William D. Waddill

*Senior Vice President, Chief Financial Officer, Treasurer and Secretary*

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

In connection with the Quarterly Report of Calithera Biosciences, Inc. (the "Company") on Form 10-Q for the quarter ended September 30, 2014, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Susan M. Molineaux, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Susan M. Molineaux

Susan M. Molineaux, Ph.D.  
*President and Chief Executive Officer*

November 13, 2014

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

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

In connection with the Quarterly Report of Calithera Biosciences, Inc. (the "Company") on Form 10-Q for the quarter ended September 30, 2014, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, William D. Waddill, Senior Vice President, Chief Financial Officer, Treasurer and Secretary of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ William D. Waddill  
William D. Waddill  
*Senior Vice President, Chief Financial Officer,  
Treasurer and Secretary*

November 13, 2014

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



