

CATABASIS PHARMACEUTICALS INC

Form 10-Q

August 13, 2015

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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, DC 20549

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**FORM 10-Q**

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(Mark One)

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

**For the quarterly period ended June 30, 2015**

**OR**

**o 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: 001-37467

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## Catabasis Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Its Charter)

**Delaware**

(State or Other Jurisdiction of  
Incorporation or Organization)

**26-3687168**

(IRS Employer  
Identification No.)

**One Kendall Square**

**Bldg. 1400E, Suite B14202**

**Cambridge, Massachusetts**

(Address of Principal Executive Offices)

**02139**

(Zip Code)

**(617) 349-1971**

(Registrant's Telephone Number, Including Area Code)

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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 during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). **Yes** ☒ **No** ☐

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

Large accelerated filer ☐

Accelerated filer ☐

Non-accelerated filer ☒ (Do not check if a smaller reporting company)

Smaller reporting company ☐

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

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As of August 1, 2015, there were 15,297,794 shares of the registrant's Common Stock, par value \$0.001 per share, outstanding.

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**CAUTIONARY NOTE CONCERNING FORWARD-LOOKING STATEMENTS**

This Quarterly Report on Form 10-Q contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Quarterly Report on Form 10-Q, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans and objectives of management and expected market growth are forward-looking statements. The words anticipate, believe, continue, could, estimate, expect, intend, may, plan, potential, should, target, would and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

These forward-looking statements include, among other things, statements about:

- our plans to identify, develop and commercialize novel small molecule drugs based on our SMART linker technology platform;
- ongoing and planned clinical trials for our product candidates, whether conducted by us or by any future collaborators, including the timing of initiation of these trials and of the anticipated results;
- our plans to enter into collaborations for the development and commercialization of product candidates;
- the potential benefits of any future collaboration;
- our ability to receive research and development funding and achieve anticipated milestones under our collaborations;
- the timing of and our ability to obtain and maintain regulatory approvals for our product candidates;
- the rate and degree of market acceptance and clinical utility of any products for which we receive marketing approval;

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- our commercialization, marketing and manufacturing capabilities and strategy;
- our intellectual property position and strategy;
- our ability to identify additional products or product candidates with significant commercial potential;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- developments relating to our competitors and our industry; and
- the impact of government laws and regulations.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this

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Quarterly Report on Form 10-Q, particularly in the Risk Factors section, that could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, collaborations, joint ventures or investments that we may make or enter into.

[Table of Contents](#)**PART I FINANCIAL INFORMATION****Item 1. Financial Statements****Catabasis Pharmaceuticals, Inc.****Condensed Balance Sheets**

(in thousands, except share and per share data)

*(Unaudited)*

	June 30, 2015	December 31, 2014
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 81,548	\$ 14,668
Prepaid expenses and other current assets	528	354
Total current assets	82,076	15,022
Property and equipment, net	230	288
Restricted cash	113	113
Other non-current assets	35	541
Total assets	\$ 82,454	\$ 15,964
<b>Liabilities and stockholders' equity (deficit)</b>		
Current liabilities:		
Accounts payable	\$ 2,486	\$ 1,132
Accrued expenses	2,563	2,793
Current portion of notes payable, net of discount	2,346	309
Total current liabilities	7,395	4,234
Deferred rent, net of current portion	42	67
Notes payable, net of current portion and discount	7,352	4,439
Other liability	77	23
Warrant liability		108
Total Liabilities	14,866	8,871
Commitments (Note 7)		
Convertible preferred stock:		
Series A convertible preferred stock, \$0.001 par value per share; 0 and 68,837,703 shares authorized, issued and outstanding at June 30, 2015 and December 31, 2014, respectively		47,898
Series B convertible preferred stock, \$0.001 par value per share; 0 and 37,830,473 shares authorized, and 0 and 34,129,571 shares issued and outstanding at June 30, 2015 and December 31, 2014, respectively		32,248
Stockholders' equity (deficit):		
Preferred stock, \$0.001 par value per share, 5,000,000 and 0 shares authorized at June 30, 2015 and December 31, 2014, respectively, 0 shares issued and outstanding		
Common stock, \$0.001 par value, 150,000,000 shares authorized at June 30, 2015 and 132,000,000 shares authorized at December 31, 2014; 15,297,794 and 493,200 shares issued	15	1



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and outstanding at June 30, 2015 and December 31, 2014, respectively				
Additional paid-in capital		157,493		2,326
Accumulated deficit		(89,920)		(75,380)
Total stockholders' equity (deficit)		67,588		(73,053)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	\$	82,454	\$	15,964

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

Table of Contents**Catabasis Pharmaceuticals, Inc.****Condensed Statements of Operations and Comprehensive Loss**

(in thousands, except share and per share data)

*(Unaudited)*

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2015</b>	<b>2014</b>	<b>2015</b>	<b>2014</b>
Operating expenses:				
Research and development	\$ 5,931	\$ 3,722	\$ 10,547	\$ 6,818
General and administrative	1,833	1,642	3,578	3,016
Total operating expenses	7,764	5,364	14,125	9,834
Loss from operations	(7,764)	(5,364)	(14,125)	(9,834)
Other (expense) income:				
Other income, net	4	1	13	1
Interest expense	(279)		(428)	
Total other (expense) income	(275)	1	(415)	1
Net loss and comprehensive loss	\$ (8,039)	\$ (5,363)	\$ (14,540)	\$ (9,833)
Net loss per share - basic and diluted	\$ (8.07)	\$ (13.42)	\$ (19.46)	\$ (24.72)
Weighted-average common shares outstanding				
used in net loss per share - basic and diluted	996,592	399,766	747,117	397,782

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

Table of Contents**Catabasis Pharmaceuticals, Inc.****Condensed Statements of Cash Flows**

(in thousands)

*(Unaudited)*

	<b>Six Months Ended June 30,</b>	
	<b>2015</b>	<b>2014</b>
<b>Operating activities</b>		
Net loss	\$ (14,540)	\$ (9,833)
Reconciliation of net loss to net cash used in operating activities:		
Depreciation and amortization	93	130
Stock-based compensation expense	655	373
Non-cash interest expense	123	
Changes in assets and liabilities:		
Prepaid expenses and other current assets	(174)	(454)
Accounts payable	649	522
Accrued expenses	(11)	(491)
Deferred rent	(18)	(10)
Net cash used in operating activities	(13,223)	(9,763)
<b>Investing activities</b>		
Purchases of property and equipment	(35)	(157)
Net cash used in investing activities	(35)	(157)
<b>Financing activities</b>		
Proceeds from initial public offering, net of issuance costs	62,763	
Proceeds from issuance of preferred stock, net of issuance costs	12,331	
Proceeds from exercise of common stock options	51	22
Proceeds from borrowings	5,000	
Debt issuance costs	(7)	
Net cash provided by financing activities	80,138	22
Net increase (decrease) in cash and cash equivalents	66,880	(9,898)
Cash and cash equivalents, beginning of period	14,668	30,747
Cash and cash equivalents, end of period	\$ 81,548	\$ 20,849
<b>Supplemental disclosure of cash flow information</b>		
Cash paid for interest	\$ 254	\$
<b>Non-cash financing activities</b>		
Warrants for the purchase of series B preferred stock issued in conjunction with credit facility	\$ 110	\$
Initial public offering costs in accounts payable and accrued liabilities	\$ 970	\$
Reclassification of deferred IPO costs from non-current assets to additional paid-in capital	\$ 1,787	\$
Reclassification of warrant liability to additional paid-in capital	\$ 206	\$

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



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**Catabasis Pharmaceuticals, Inc.**

**Notes to Condensed Financial Statements**

*(Unaudited)*

**1. Organization and Operations**

***The Company***

Catabasis Pharmaceuticals, Inc. (the "Company") is a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of novel therapeutics based on the Company's proprietary Safely Metabolized And Rationally Targeted, or SMART, linker technology platform. The Company's SMART linker technology platform is based on the concept of treating diseases by simultaneously modulating multiple biological targets in one or more related disease pathways. The Company engineers bi-functional product candidates that are conjugates of two molecules, or bioactives, each with known pharmacological activity, joined by one of the Company's proprietary SMART linkers. The SMART linker conjugates are designed for enhanced efficacy and improved safety and tolerability. The Company seeks to develop therapies that modulate multiple targets in the disease pathway. The Company targets therapeutic areas and specific diseases with significant unmet medical needs where it believes it will have a competitive advantage. The Company's focus is on treatment for rare diseases, such as Duchenne Muscular Dystrophy ("DMD"). The Company is also developing other product candidates for the treatment of serious lipid disorders. The Company was incorporated in the State of Delaware on June 26, 2008.

***Initial Public Offering***

In June 2015, the Company completed its Initial Public Offering (the "IPO"). All of the shares issued and sold in the IPO were registered pursuant to a registration statement on Form S-1, as amended. An aggregate of 5,750,000 shares of Common Stock registered pursuant to the registration statement were sold at a price to the public of \$12.00 per share (including 750,000 shares of Common Stock sold pursuant to the exercise of an overallotment option granted to the Company's underwriters in connection with the IPO). Net proceeds of the IPO were \$61.8 million, after deducting underwriting discounts, commissions and offering-related expenses payable by the Company of approximately \$7.2 million. In connection with the IPO, all shares of the Company's convertible preferred stock (the "Preferred Stock") were automatically converted into an aggregate of 9,029,549 shares of its Common Stock and its outstanding warrants to purchase 315,688 shares of Preferred Stock were automatically converted into warrants to purchase 24,566 shares of Common Stock.

As of June 30, 2015, the Company had an accumulated deficit of \$89.9 million. The Company has been primarily involved with research and development activities and has incurred operating losses and negative cash flows from operations since inception. The Company is subject to a number of risks similar to other life science companies, including, but not limited to, successful discovery and development of its drug candidates, raising additional capital, development by its competitors of new technological innovations, protection of proprietary technology and market acceptance of the Company's products. The Company anticipates that it will continue to incur significant operating losses for the next several years as it continues to develop its product candidates.

**2. Summary of Significant Accounting Policies**

***Reverse stock split***

In connection with the IPO, the Company's board of directors and stockholders approved a 1-for-12.85 reverse stock split of the Company's Common Stock which was effected on June 11, 2015. Stockholders entitled to fractional shares as a result of the reverse stock split received a cash payment in lieu of receiving fractional shares. All share, share equivalent and per share amounts presented herein have been adjusted to

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reflect the reverse stock split. The ratios by which shares of Preferred Stock are convertible into shares of Common Stock have been adjusted to reflect the effects of the reverse stock split. Shares of Common Stock reserved for future issuance have been presented on an as converted basis and the financial statements disclose the adjusted conversion ratios.

***Basis of Presentation***

The accompanying financial statements have been prepared in accordance with United States generally accepted accounting principles ( U.S. GAAP ) and include all adjustments necessary for the fair presentation of the Company's financial position for the periods presented.

The unaudited interim condensed financial statements of the Company included herein have been prepared, pursuant to the rules and regulations of the Securities and Exchange Commission (the SEC ). Certain information and footnote disclosures normally included in financial statements prepared in accordance with U.S. GAAP have been condensed or omitted from this report, as is permitted by such rules and regulations. Accordingly, these condensed financial statements should be read in conjunction with the financial statements as of and for the year ended December 31, 2014 and notes thereto, included in the Company's prospectus dated June 24, 2015, filed with the SEC pursuant to Rule 424(b)(4) on June 25, 2015 (the Prospectus ).

The unaudited interim condensed financial statements have been prepared on the same basis as the audited financial statements. In the opinion of the Company's management, the accompanying unaudited interim condensed financial statements contain all adjustments which are necessary to fairly present the Company's financial position as of June 30, 2015, the results of its operations for the three and six months ended June 30, 2015 and 2014 and its cash flows for the six months ended June 30, 2015 and 2014. Such adjustments are of a normal and recurring nature. The results for the six months ended June 30, 2015 are not necessarily indicative of the results for the year ending December 31, 2015, or for any future period.

***Use of Estimates***

The preparation of the Company's financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from such estimates.

The Company utilized significant estimates and assumptions in determining the fair value of its Common Stock prior to completion of the IPO. The board of directors determined the estimated fair value of the Common Stock based on a number of objective and subjective factors, including external market conditions affecting the biotechnology industry sector and the prices at which the Company sold shares of convertible preferred stock, the achievement of research and development milestones, the superior rights and preferences of securities senior to the Common Stock at the time and the likelihood of achieving a liquidity event, such as an initial public offering or sale of the Company.

The Company utilized various valuation methodologies in accordance with the framework of the American Institute of Certified Public Accountants ( AICPA ), Audit and Accounting Practice Aid Series: Valuation of Privately Held Company Equity Securities Issued as Compensation ( AICPA Practice Aid ), to estimate the fair value of its Common Stock. The methodologies included the Option Pricing Method

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utilizing the Backsolve Method (a form of the market approach defined in the AICPA Practice Aid) and the Probability-Weighted Expected Return Method based upon the probability of occurrence of certain future liquidity events such as an initial public offering or sale of the Company. Each valuation methodology includes estimates and assumptions



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that require the Company's judgment. Significant changes to the key assumptions used in the valuations could result in different fair values of Common Stock at each valuation date.

The Company utilizes certain estimates to record expenses relating to research and development contracts. These contract estimates, which are primarily related to the length of service of each contract, are determined by the Company based on input from internal project management, as well as from third-party service providers.

***Fair Value of Financial Instruments***

The fair value hierarchy prioritizes the inputs to valuation techniques used to measure fair value into three broad levels as follows: Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities; Level 2 inputs are inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly; and Level 3 inputs are unobservable inputs that reflect the Company's own assumptions about the assumptions market participants would use in pricing the asset or liability. Financial assets and liabilities are classified in their entirety based on the lowest level of input that is significant to the fair value measurement.

The carrying amounts reflected in the balance sheets for cash equivalents, restricted cash, prepaid expenses and other current assets, other assets, accounts payable and accrued expenses approximate their fair values at June 30, 2015 and December 31, 2014, due to their short-term nature. There have been no changes to the valuation methods during the year ended December 31, 2014 or the six months ended June 30, 2015. The Company evaluates transfers between levels at the end of each reporting period. There were no transfers of assets or liabilities between levels during the year ended 2014 or the six months ended June 30, 2015. At June 30, 2015, the carrying value of the Company's debt approximated fair value, which was determined using Level 3 inputs, including a quoted interest rate.

***Recent Accounting Pronouncements***

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ( FASB ) or other standard setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on its financial position or results of operations upon adoption.

In April 2015, the FASB issued ASU No. 2015-03, *Simplifying the Presentation of Debt Issuance Costs*. This standard amends existing guidance to require the presentation of debt issuance costs in the balance sheet as a deduction from the carrying amount of the related debt liability rather than as a deferred charge. It is effective for annual reporting periods beginning after December 15, 2015, but early adoption is permitted. The Company is currently evaluating the impact that this standard will have on its financial statements.

**3. Financial Instruments**

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The following tables present information about the Company's financial assets and liabilities that have been measured at fair value, and indicates the fair value hierarchy of the valuation inputs utilized to determine such fair value. The Company determines the fair value of the preferred stock warrants (Note 6) using Level 3 inputs. Below is a summary of assets and liabilities measured at fair value on a recurring basis (in thousands):

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	As of June 30, 2015			
	Quoted Prices in Active Markets (Level 1)	Significant Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:				
Cash Equivalents	17,005			17,005
Total	\$ 17,005	\$	\$	\$ 17,005

	As of December 31, 2014			
	Quoted Prices in Active Markets (Level 1)	Significant Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:				
Cash Equivalents	13,506			13,506
Total	\$ 13,506	\$	\$	\$ 13,506
Liabilities:				
Warrant Liability			108	108
Total	\$	\$	\$	\$ 108

As of June 30, 2015 and December 31, 2014, the Company's cash equivalents consisted principally of money market funds, which approximate their fair value due to their short-term nature. In connection with the completion of the IPO, warrants exercisable for Preferred Stock were automatically converted into warrants exercisable for Common Stock, resulting in the reclassification of the related warrant liability to additional paid-in capital as the warrants to purchase shares of Common Stock are accounted for as equity instruments (Note 6).

#### 4. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	June 30, 2015	December 31, 2014
Accrued compensation	\$ 752	\$ 796
Accrued contracted research costs	1,164	1,109
Accrued professional fees	369	791
Accrued other	278	97
Total	\$ 2,563	\$ 2,793

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**5. Notes Payable**

On August 27, 2014, the Company entered into the Credit Facility. The Credit Facility, as amended on March 31, 2015, provides for initial borrowings of \$5.0 million under a term loan ( Term Loan A ) and additional borrowings of up to \$20.0 million under other term loans, for a maximum of \$25.0 million. On August 27, 2014, the Company received proceeds of \$5.0 million from the issuance of promissory notes under Term Loan A. On March 31, 2015, the Company received proceeds of \$5.0 million from the issuance of promissory notes under another term loan ( Term Loan B ). Of the remaining borrowing capacity, (i) \$5.0 million was available to be drawn until May 31, 2015, subject to the completion of an equity financing with net cash proceeds of at least \$8.0 million and the issuance of warrants to purchase shares of the Company s stock equal in value to 3% of the amount drawn, and (ii) \$10.0 million was available until July 31, 2015, subject to the completion of an initial public offering with net cash proceeds to the Company of at least \$50.0 million and the issuance of warrants to purchase shares of the Company s common stock equal in value to 3% of the amount drawn. However, these amounts were not drawn. All amounts outstanding under the Credit Facility are due on October 1, 2018 and are collateralized by substantially all of the Company s personal property, other than its intellectual property.

Interest-only payments are due monthly on amounts outstanding under the Credit Facility until September 1, 2015 and, thereafter, interest and principal payments are due in 36 equal monthly installments from October 1, 2015 through September 1, 2018. Amounts due under the Credit Facility bear interest at an annual rate of 7.49%. In addition, a final payment equal to 3.48% of any amounts drawn under the Credit Facility is due upon the earlier of the maturity date, acceleration of the term loans or prepayment of all or part of the term loans. The final payment is being accrued as additional interest expense using the effective-interest method from the date of issuance through the maturity date, and is recorded within other long-term liabilities. In the event of prepayment, the Company is obligated to pay 1% to 3% of the amount of the outstanding principal depending upon the timing of the prepayment. The effective interest rate as of June 30, 2015 was 11.2%.

In conjunction with Term Loan A, the Company issued warrants to purchase 157,844 shares of series B convertible preferred stock at an exercise price of \$0.9503 per share (the 2014 Warrants ) to the lenders. In conjunction with Term Loan B, the Company issued warrants to purchase an additional 157,844 shares of series B convertible preferred stock at an exercise price of \$0.9503 per share (the 2015 Warrants ) to the lenders (see Note 6). The 2014 Warrants and 2015 Warrants were exercisable immediately and have seven-year lives. The 2014 Warrants and 2015 Warrants were initially valued at \$0.1 million and \$0.1 million, respectively, using the Black-Scholes option-pricing model. The Company recorded debt discounts of \$0.1 million and \$0.1 million upon issuance of the 2014 Warrants and 2015 Warrants, respectively, which are being accreted as interest expense using the effective-interest method over the remaining term of the loan.

There are no financial covenants associated with the Credit Facility; however, there are negative covenants restricting the Company s activities, including limitations on asset dispositions, mergers or acquisitions; encumbering or granting a security interest in its intellectual property; incurring indebtedness or liens; paying dividends; making certain investments; and entering into certain other business transactions.

Upon the occurrence and continuation of an event of default, the lenders have the right to exercise certain remedies against the Company and the collateral securing the loans under the Credit Facility, including cash. Events of default include, among other things, failure to pay amounts due under the Credit Facility, insolvency, the occurrence of a material adverse event, which includes a material adverse change in the business, operations or conditions (financial or otherwise) of the Company or a material impairment of the prospect of repayment of any portion of the obligations, the occurrence of any default under certain other indebtedness and a final judgment against the Company in an amount greater than \$250,000. The occurrence



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of a material adverse change could result in acceleration of the payment of the debt. At June 30, 2015 and December 31, 2014, the Company concluded that the likelihood of the acceleration of the debt was remote, as a material adverse change had not occurred and was unlikely to occur and therefore the debt was classified in current and long-term liabilities based on scheduled principal payments. Following the occurrence and during the continuance of an event of default, borrowings under the Credit Facility shall bear interest at a rate per annum, which is five hundred basis points, or 5.0%, above the rate that is otherwise applicable.

The Company accounted for the amendment to the Credit Facility, effective March 31, 2015, as a debt modification pursuant to ASC Topic 470-50 *Modifications and Extinguishments*.

Estimated future principal payments at June 30, 2015 are as follows (in thousands):

Six Months Ending June 30, 2015	Amount
Remainder 2015	\$ 834
2016	3,333
2017	3,333
2018	2,500
Total	\$ 10,000
Less: discount for warrants and costs paid to lender	(302)
Less: current portion	(2,346)
Note payable, net of current portion and discount	\$ 7,352

Estimated future principal payments at December 31, 2014 are as follows (in thousands):

Year Ending December 31, 2014	Amount
2015	\$ 416
2016	1,667
2017	1,667
2018	1,250
Total	\$ 5,000
Less: discount for warrants and costs paid to lender	(252)
Less: current portion	(309)
Note payable, net of current portion and discount	\$ 4,439

During the three and six months ended June 30, 2015, the Company recognized \$0.3 million and \$0.4 million, respectively, of interest expense related to the Credit Facility.

## 6. Warrants

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On August 27, 2014 and March 31, 2015, the Company issued the 2014 Warrants and 2015 Warrants to purchase an aggregate 315,688 shares of series B convertible preferred stock at an exercise price of \$0.9503 per share to the lenders in connection with the Credit Facility (Note 5). The 2014 Warrants and 2015 Warrants were exercisable immediately on issuance and have a seven-year life. The 2014 Warrants and 2015 Warrants were recorded as a liability and re-measured at each reporting date using the then-current assumptions. In connection with the completion of the IPO, the 2014 Warrants and the 2015 Warrants were automatically converted into warrants exercisable for Common Stock, resulting in the reclassification of the related warrant liability to

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additional paid-in capital as the warrants to purchase shares of Common Stock met the criteria to be accounted for as equity instruments. The warrant liability was re-measured to fair value prior to reclassification to additional paid-in capital. As of June 30, 2015, the Company had no outstanding warrant liability.

The following table provides a roll-forward of the fair value of the 2014 Warrants and 2015 Warrants determined by Level 3 inputs (in thousands):

	<b>Fair Value</b>
Balance at December 31, 2014	\$ 108
Issuance of warrants at fair value	107
Change in fair value, recorded as a component of other income, net	(9)
Reclassification to additional paid-in capital	(206)
Balance at June 30, 2015	\$

The fair value of warrants exercisable for 315,688 shares of series B convertible preferred stock, which were automatically converted into warrants exercisable for 24,566 shares of Common Stock with an exercise price of \$12.14, was estimated using the Black-Scholes option pricing model with the following weighted-average assumptions:

	<b>June 30, 2015 (1)</b>	<b>December 31, 2014</b>
Risk-free interest rate	1.97%	1.95%
Expected dividend yield	0.00%	0.00%
Expected term (in years)	6.5	6.7
Expected volatility	75.79%	78.16%

(1) Represents the date the warrants for series B convertible preferred stock converted to warrants for common stock

## 7. Commitments

In November 2010, the Company entered into a five-year, non-cancelable operating lease for office and laboratory space. In December 2011, the Company signed a lease amendment that expanded the leased premises beginning in the second quarter of 2012. The lease amendment also extended the term of the existing lease through June 30, 2017. The expansion lease includes a free rent period and escalating rent payments. The Company is recognizing rent expense on a straight-line basis over the lease term. The lease agreement provides for a five-year extension upon the completion of the lease term.

Future minimum payments required under the non-cancelable operating lease as of June 30, 2015 are summarized as follows (in thousands):



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Year Ending December 31,	Amount	
Remainder 2015	\$	382
2016		760
2017		378
Total minimum lease payments	\$	1,520

Rent expense for the three months ended June 30, 2015 and 2014 was \$0.2 million and \$0.2 million, respectively. Rent expense for the six months ended June 30, 2015 and 2014 was \$0.4 million and \$0.4 million, respectively.

Table of Contents**8. Convertible Preferred Stock**

Upon closing the Company's IPO on June 30, 2015, all outstanding shares of the Company's preferred stock were automatically converted into 9,029,549 shares of Common Stock. As of June 30, 2015, the Company has 5,000,000 shares of preferred stock authorized for issuance, \$0.001 par value per share, with none issued or outstanding.

Preferred stock may be issued from time to time in one or more series, each of such series to have such terms as stated or expressed in the resolutions providing for the issue of such series adopted by the board of directors of the Company. Preferred Stock which may be redeemed, purchased or acquired by the Corporation may be reissued except as otherwise provided by law.

**9. Common Stock Reserved for Future Issuance**

The Company has reserved for future issuance the following number of shares of Common Stock:

	<b>June 30, 2015</b>	<b>December 31, 2014</b>
Conversion of Series A Preferred Stock		5,356,996
Conversion of Series B Preferred Stock		2,655,992
Warrants for the purchase of Preferred Stock		12,283
Warrants for the purchase of Common Stock	59,405	34,839
Options to purchase Common Stock	2,572,959	1,385,341
Employee Stock Purchase Plan	182,352	
<b>Total</b>	<b>2,814,716</b>	<b>9,445,451</b>

**10. Stock-based compensation**

Prior to the Company's IPO, the Company granted awards to eligible participants under the 2008 equity incentive plan ( "2008 Plan" ). In June 2015, the Company's board of directors adopted and the Company's stockholders approved the 2015 Stock Incentive Plan ( "2015 Plan" ), which became effective immediately prior to the effectiveness of the Company's IPO. Subsequent to the Company's IPO, option grants are awards to eligible participants only under the 2015 Plan.

The 2015 Plan provides for the grant of incentive stock options, nonstatutory stock options, restricted stock awards, restricted stock units, stock appreciation rights and other stock-based awards. The Company's employees, officers, directors and consultants and advisors are eligible to receive awards under the 2015 Plan. The maximum number of shares of Common Stock that may be delivered in satisfaction of awards under the 2015 Plan is 1,068,287 shares, plus (1) 25,942 shares that were available for grant under the 2008 Plan immediately prior to the closing of the IPO, (2) the number of shares of Common Stock subject to outstanding awards under the 2008 Plan upon closing of the IPO that expire, terminate or are otherwise surrendered, cancelled, forfeited or repurchased by the Company at their original issuance price pursuant to a contractual repurchase right and (3) an annual increase, to be added the first day of each fiscal year, beginning with the fiscal year ending

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December 31, 2016 and continuing until, and including, the fiscal year ending December 31, 2025, equal to the lowest of 1,297,334 shares of Common Stock, 4% of the number of shares of Common Stock outstanding on the first day of the fiscal year and an amount determined by the Company's board of directors.

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As of June 30, 2015, the Company had reserved 1,478,731 shares of Common Stock under the 2008 Plan, of which none remained available for future issuance. As of June 30, 2015, the Company had reserved 1,094,228 shares of Common Stock under the 2015 Plan, of which 1,038,758 shares remained available for future issuance.

## Stock Options

A summary of the Company's stock option activity and related information follows:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (years)	Agregate Intrinsic Value (in 000 s)
Outstanding at December 31, 2014	1,226,140	\$ 4.14	8.15	\$ 6,579
Granted	360,530	10.64		
Exercised	(25,045)	2.05		
Cancelled or forfeited	(27,424)	4.09		
Outstanding at June 30, 2015	1,534,201	\$ 5.70	8.16	\$ 9,980
Exercisable at June 30, 2015	690,832	\$ 3.06	7.02	\$ 6,318
Vested or expected to vest at June 30, 2015	1,410,518	\$ 5.46	8.06	\$ 9,524

The total intrinsic value of options exercised for the three months ended June 30, 2015 and 2014 was \$0, and \$7,000, respectively. The total intrinsic value of options exercised for the six months ended June 30, 2015 and 2014 was \$0.2 million and \$28 thousand, respectively. The total fair value of options vested for the three months ended June 30, 2015 and 2014 was \$0.2 million and \$0.1 million, respectively. The total fair value of options vested for the six months ended June 30, 2015 and 2014 was \$0.8 million and \$0.3 million, respectively.

At June 30, 2015, the total unrecognized compensation expense related to unvested stock option awards, including estimated forfeitures, was \$4.2 million. The Company expects to recognize that cost over a weighted-average period of approximately 3.0 years.

## Stock-based compensation expense

Total stock-based compensation expense is recognized for stock options granted to employees and non-employees and has been reported in the Company's statements of operations as follows (in thousands):

	Three months ended June 30,		Six months ended June 30,	
	2015	2014	2015	2014
Research and development	\$ 165	\$ 109	\$ 333	\$ 189
General and administrative	189	119	322	184

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Total	\$	354	\$	228	\$	655	\$	373
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Table of Contents*Employee Stock Purchase Plan*

In June 2015, the Company's board of directors adopted and the Company's stockholders approved the 2015 Employee Stock Purchase Plan (the 2015 ESPP) which became effective upon closing of the Company's IPO. The 2015 ESPP authorizes the initial issuance of up to a total of 182,352 shares of Common Stock to participating eligible employees. The number of shares increases each January 1, commencing on January 1, 2016 and ending on December 31, 2026, by an amount equal to the lesser of one percent of the outstanding shares as of the end of the immediately preceding fiscal year, 364,705 shares and any lower amount determined by the Company's board of directors. As of June 30, 2015 there has been no activity under the 2015 ESPP.

**11. Net Loss Per Share**

Basic net loss per share is calculated by dividing net loss by the weighted average shares outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is calculated by adjusting weighted average shares outstanding for the dilutive effect of common stock equivalents outstanding for the period, determined using the treasury-stock method. For purposes of the dilutive net loss per share calculation, preferred stock, stock options, warrants to purchase Common Stock and warrants to purchase preferred stock are considered to be common stock equivalents but are excluded from the calculation of diluted net loss per share, as their effect would be anti-dilutive; therefore, basic and diluted net loss per share were the same for all periods presented.

The following common stock equivalents were excluded from the calculation of diluted net loss per share for the periods indicated because including them would have had an anti-dilutive effect:

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2015</b>	<b>2014</b>	<b>2015</b>	<b>2014</b>
Convertible preferred stock		8,012,987		8,012,987
Stock options	1,534,201	1,209,072	1,534,201	1,209,072
Common stock warrants	59,405	34,839	59,405	34,839
	1,593,606	9,256,898	1,593,606	9,256,898

**12. Subsequent Events**

We consider events or transactions that occur after the balance sheet date but prior to the issuance of the financial statements to provide additional evidence for certain estimates or to identify matters that require additional disclosure. Subsequent events have been evaluated as required. There were no material recognized subsequent events recorded in the condensed consolidated financial statements as of and for the three and six months ended June 30, 2015.

*Operating Lease*

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On July 16, 2015, the Company entered into a Second Amendment to the Lease (the "Second Lease Amendment") with DWF IV One Kendall, LLC (the "Landlord"), which amends certain terms of the Company's existing lease with the Landlord. The Second Lease Amendment expands the rentable square footage of the Company's leased premises from approximately 14,817 square feet to approximately 18,876 square feet. Pursuant to the Second Lease Amendment, the date on which the Company will become responsible for paying rent with respect to such additional square footage is September 1, 2015. The Second Lease Amendment will increase the future minimum payments described in Note 7 from approximately \$1,520,000 to approximately \$1,844,000.

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**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 together with the unaudited condensed financial statements and the related notes appearing elsewhere in this Quarterly Report on Form 10-Q.*

*Our actual results and timing of certain events may differ materially from the results discussed, projected, anticipated, or indicated in any forward-looking statements. We caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this Quarterly Report. In addition, even if our results of operations, financial condition and liquidity, and the development of the industry in which we operate are consistent with the forward-looking statements contained in this Quarterly Report, they may not be predictive of results or developments in future periods.*

**Overview**

We are a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of novel therapeutics based on our proprietary Safely Metabolized And Rationally Targeted, or SMART, linker technology platform. Our SMART linker technology platform is based on the concept of treating diseases by simultaneously modulating multiple biological targets in one or more related disease pathways. We engineer bi-functional product candidates that are conjugates of two molecules, or bioactives, each with known pharmacological activity, joined by one of our proprietary SMART linkers. Our SMART linker conjugates are designed for enhanced efficacy and improved safety and tolerability, and we seek to develop therapies that modulate multiple targets in the disease pathway. We target therapeutic areas and specific diseases with significant unmet medical need where we believe we will have a competitive advantage. Our focus is on treatments for rare diseases, such as Duchenne muscular dystrophy, or DMD. We are also developing other product candidates for the treatment of serious lipid disorders.

We have applied our SMART linker technology platform to build a development pipeline that includes three clinical-stage product candidates and multiple programs in preclinical development. Our current drug candidates are small molecules. CAT-1004 is an oral small molecule that we believe has the potential to be a disease-modifying therapy for the treatment of DMD that may be able to regenerate muscle in boys regardless of the underlying dystrophin mutation. DMD is an ultimately fatal genetic disorder involving progressive muscle degeneration. Our two other clinical-stage product candidates, CAT-2054 and CAT-2003, are members of our CAT-2000 series of molecules. We are initially developing CAT-2054 for the treatment of patients with hypercholesterolemia, or elevated low density lipoprotein cholesterol, or LDL-C, levels, for whom existing treatments are insufficient. Hypercholesterolemia is a disease that increases the risk of cardiovascular events. In January 2015, we initiated a Phase 1 clinical trial to assess the safety, tolerability and pharmacokinetics of CAT-2054 in healthy volunteers. In August 2015, we reported top-line data for the full range of doses tested in the single and multiple ascending dose portions of the trial. We have completed three Phase 2a trials of CAT-2003 in patient populations with elevated triglycerides or hypertriglyceridemia. CAT-4001 is in preclinical studies and is being developed for the treatment of severe, rare neurodegenerative diseases, such as Friedreich's ataxia and amyotrophic lateral sclerosis, two diseases of the central nervous system in which the Nrf2 and NF- $\kappa$ B pathways have been implicated.

Since our inception in June 2008, we have devoted substantially all of our resources to developing our proprietary platform technology, identifying potential product candidates, undertaking preclinical studies and conducting clinical trials for our three clinical-stage compounds, building our intellectual property portfolio,





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organizing and staffing our company, business planning, raising capital, and providing general and administrative support for these operations. To date, we have primarily financed our operations through private placements of our preferred stock, a secured debt financing, and our initial public offering, or IPO.

In June 2015, we completed our IPO, in which we sold an aggregate of 5,750,000 shares of our common stock, including 750,000 shares of common stock sold pursuant to the underwriters' exercise of their option to purchase additional shares of common stock, at a price to the public of \$12.00 per share. Net proceeds from the IPO were \$61.8 million, after deducting underwriting discounts, commissions and offering-related expenses of approximately \$7.2 million.

In connection with our IPO, all shares of our preferred stock were automatically converted into an aggregate of 9,029,549 shares of our common stock and our outstanding warrants to purchase 315,688 shares of preferred stock were automatically converted into warrants to purchase 24,566 shares of common stock.

In connection with the IPO, we also effected a one-for-12.85 reverse split of our common stock. All share, share equivalent and per share amounts presented herein have been adjusted to reflect the reverse stock split. The ratios by which shares of preferred stock are convertible into shares of Common Stock have been adjusted to reflect the effects of the reverse stock split.

We have not generated any revenue to date. We have incurred significant annual net operating losses in every year since our inception and expect to incur a net operating loss in 2015 and continue to incur net operating losses for the foreseeable future. As of June 30, 2015, we had an accumulated deficit of \$89.9 million. We expect to continue to incur significant expenses and increasing operating losses for the next several years. Our net losses may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase significantly if and as we continue to develop and conduct clinical trials with respect to our CAT-1004 and CAT-2054 product candidates; initiate and continue research, preclinical and clinical development efforts for our other product candidates and potential product candidates; maintain, expand and protect our intellectual property portfolio; establish a commercial infrastructure to support the marketing and sale of certain of our product candidates; hire additional personnel, such as clinical, regulatory, quality control and scientific personnel; and operate as a public company.

From our inception through June 30, 2015, we have raised an aggregate of \$172.1 million, composed of \$92.9 million from private placements of preferred stock, \$69.0 million in gross proceeds from our IPO, \$10 million from a secured debt financing and \$0.2 million from common stock option exercises.

**Financial Overview**

***Revenue***

To date, we have not generated any revenue from product sales or any other source and do not expect to generate any revenue from the sale of products in the near future. In the future, we will seek to generate revenue primarily from a combination of product sales and collaborations with

strategic partners.

***Research and Development Expenses***

Research and development expenses consist primarily of costs incurred for our research activities, including our drug discovery efforts, and the development of our product candidates, which include:

- employee-related expenses including salaries, benefits and stock-based compensation expense;

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- expenses incurred under agreements with third parties, including contract research organizations, or CROs, that conduct clinical trials and research and development and preclinical activities on our behalf;
- the cost of consultants;
- the cost of lab supplies and acquiring, developing and manufacturing preclinical study materials; and
- facilities and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance and other supplies.

Research and development costs are expensed as incurred. Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are deferred and capitalized. The capitalized amounts are expensed as the related goods are delivered or the services are performed.

The following summarizes our most advanced current research and development programs:

- CAT-1004 is an orally administered SMART linker conjugate of salicylate and the omega-3 fatty acid docosahexaenoic acid, or DHA, that we designed to enhance the activity of salicylate and DHA in modulating the NF- $\kappa$ B pathway at multiple points. NF- $\kappa$ B, or nuclear factor kappa- light-chain-enhancer of activated B cells, is a protein that coordinates cellular response to damage, stress and inflammation and plays an important role in muscle health. We initiated patient enrollment in a Phase 1/2 clinical trial of CAT-1004 for the treatment of DMD in June 2015 and, subject to patient enrollment, expect to report top-line Phase 2 data in late 2016. If the results from our Phase 1/2 clinical trial and discussions with regulatory authorities regarding a pivotal trial are positive, we intend to initiate a six-month Phase 3 pivotal clinical trial of CAT-1004 in 2017 and seek marketing approval based on this Phase 3 trial.
- CAT-2054 is an orally administered SMART linker conjugate of the omega-3 fatty acid eicosapentaenoic acid, or EPA, and nicotinic acid, designed to modulate the SREBP pathway in the liver. SREBP is a master regulator of lipid metabolism and controls levels of both LDL-C and triglycerides. We are initially developing CAT-2054 to treat patients with hypercholesterolemia for whom existing treatments are insufficient. In January 2015, we initiated a Phase 1 clinical trial to assess the safety, tolerability and pharmacokinetics of CAT-2054 in healthy volunteers. In August 2015, we reported top-line data for the full range of doses tested in the single and multiple ascending dose portions of the trial. We intend to initiate a Phase 2a clinical trial of CAT-2054 for the treatment of hypercholesterolemia in the fourth quarter of 2015 and would expect to report Phase 2a data in mid-2016. If the results of the planned Phase 2a clinical trial are positive, we intend to initiate a Phase 2b clinical trial of CAT-2054 in

the fourth quarter of 2016.

- CAT-2003 is an orally administered SMART linker conjugate of EPA and nicotinic acid that we designed to modulate the SREBP pathway. We have completed three Phase 2a trials of CAT-2003 in patient populations with elevated triglycerides or hypertriglyceridemia.

Other research and development programs include our CAT-4001 development program and activities related to exploratory efforts, target validation and lead optimization for our early stage programs and our proprietary platform technology.

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We typically use our employee, consultant and infrastructure resources across our development programs. We track outsourced development costs by product candidate or development program, but we do not allocate personnel costs, other internal costs or external consultant costs to specific product candidates or development programs. We record our research and development expenses net of any research and development tax incentives we are entitled to receive from government authorities.

The following table summarizes our research and development expenses by program (in thousands):

	Six Months Ended June 30,			
	2015		2014	
CAT-1004	\$	2,731	\$	213
CAT-2054		2,331		1,356
CAT-2003		542		1,375
Other research and platform programs		1,026		585
Costs not directly allocated to programs:				
Employee expenses including cash compensation, benefits and stock-based compensation		2,857		2,257
Facilities		411		358
Consultants and professional expenses, including stock-based compensation		406		431
Other		243		243
Total costs not directly allocated to programs	\$	3,917	\$	3,289
Total research and development expenses	\$	10,547	\$	6,818

The successful development of our product candidates is highly uncertain. Accordingly, at this time, we cannot reasonably estimate the nature, timing and costs of the efforts that will be necessary to complete the remainder of the development of these product candidates. We are also unable to predict when, if ever, material net cash inflows will commence from CAT-1004, CAT-2054 or any of our other current or potential product candidates. This is due to the numerous risks and uncertainties associated with developing medicines, including the uncertainties of:

- establishing an appropriate safety profile with investigational new drug application, or IND, enabling toxicology studies;
- successful enrollment in, and completion of clinical trials;
- 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 regulatory exclusivity for our product candidates;



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- launching commercial sales of the products, if and when approved, whether alone or in collaboration with others; and
- a continued acceptable safety profile of the products following approval.

A change in the outcome of any of these variables with respect to the development of any of our product candidates would significantly change the costs and timing associated with the development of that product candidate.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect research and development costs to increase significantly for the foreseeable future as our product candidate development programs progress. However, we do not believe that it is possible at this time to accurately project total program-specific expenses through commercialization. There are numerous factors associated with the successful commercialization of any of our product candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. Additionally, future commercial and regulatory factors beyond our control will impact our clinical development programs and plans.

***General and Administrative Expenses***

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation, for personnel in executive, finance, accounting, business development and human resources functions. Other significant costs include facility costs not otherwise included in research and development expenses, legal fees relating to patent and corporate matters, and fees for accounting and consulting services.

We anticipate that our general and administrative expenses will increase in the future to support continued research and development activities, potential commercialization of our product candidates and increased costs of operating as a public company. These increases will likely include increased costs related to the hiring of additional personnel and fees to outside consultants, lawyers and accountants, among other expenses. Additionally, we anticipate increased costs associated with being a public company including expenses related to services associated with maintaining compliance with exchange listing and Securities and Exchange Commission requirements, insurance costs and investor relations costs.

***Other (Expense) Income, Net***

Other (expense) income, net consists of interest expense incurred on debt instruments, amortized deferred financing costs and amortized debt discount, and changes in the fair value of the warrant liability, as offset by any interest income earned on our cash and cash equivalents. Upon completion of our IPO in June 2015, warrants to purchase preferred stock were converted to warrants to purchase common stock and as a result,



the Company no longer records fair value adjustment for its warrants.

#### **Critical Accounting Policies and Significant Judgments and Estimates**

We believe that several accounting policies are important to understanding our historical and future performance. We refer to these policies as critical because these specific areas generally require us to make judgments and estimates about matters that are uncertain at the time we make the estimate, and different estimates which also would have been reasonable could have been used. The preparation of financial

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statements in conformity with U.S. generally accepted accounting principles, or GAAP, requires us to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. On an ongoing basis, we evaluate estimates, which include, but are not limited to, estimates related to clinical trial accruals, stock-based compensation expense, warrants to purchase redeemable securities, and reported amounts of expenses during the reported period. We base our estimates on historical experience and other market-specific or other relevant assumptions that we believe to be reasonable under the circumstances. Actual results may differ materially from those estimates or assumptions.

There have been no material changes to our accounting policies from those described in our prospectus filed with the SEC pursuant to Rule 424(b)(4) on June 25, 2015, or the Prospectus. It is important that the discussion of our operating results that follows be read in conjunction with the critical accounting policies disclosed in our Prospectus.

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

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

	Three Months Ended June 30,		Period to Period	
	2015	2014	Change	
Operating expenses:				
Research and development	\$ 5,931	\$ 3,722	\$	2,209
General and administrative	1,833	1,642		191
Total operating expenses	7,764	5,364		2,400
Loss from operations	(7,764)	(5,364)		(2,400)
Other (expense) income, net	(275)	1		(276)
Net loss	\$ (8,039)	\$ (5,363)	\$	(2,676)

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### *Research and Development Expenses*

Research and development expenses increased by \$2.2 million to \$5.9 million for the three months ended June 30, 2015 from \$3.7 million for the three months ended June 30, 2014, an increase of 59%. The increase in research and development expenses was primarily attributable to a net increase of \$1.9 million in direct program costs, reflecting an increase of \$1.8 million for CAT-1004 driven by the start of a Phase 1/2 clinical trial, an increase of \$0.4 million for CAT-2054 driven by Phase 1 clinical trial progress, and an increase of \$0.3 million in our general research and platform programs, which were partially offset by a decrease of \$0.6 million in CAT-2003 clinical trial, manufacturing and preclinical development costs due to the completion of two Phase 2 clinical trials that were active in the three months ended June 30, 2014. In addition, the costs related to internal research and development increased by \$0.3 million, primarily attributable to increased stock-based compensation expense.

### *General and Administrative Expenses*

General and administrative expenses increased by \$0.2 million to \$1.8 million for the three months ended June 30, 2015 from \$1.6 million for the three months ended June 30, 2014, an increase of 13%. The increase in general and administrative expenses was primarily attributable to increased employee costs of \$0.2 million associated with salaries, benefits, and stock-based compensation expenses from hiring additional senior personnel.

### *Other (Expense) Income, Net*

Other (expense) income consists of interest expense, which increased by \$0.3 million for the three months ended June 30, 2015 due to the interest expense on our credit facility, which we entered into in August 2014.

### *Comparison of the Six Months Ended June 30, 2015 and 2014*

The following table summarizes our results of operations for the six months ended June 30, 2015 and 2014, together with the dollar change in those items (in thousands):

	Six Months Ended June 30,		Period to Period	
	2015	2014	Change	
Operating expenses:				
Research and development	\$ 10,547	\$ 6,818	\$ 3,729	
General and administrative	3,578	3,016	562	
Total operating expenses	14,125	9,834	4,291	
Loss from operations	(14,125)	(9,834)	(4,291)	
Other (expense) income, net	(415)	1	(416)	
Net loss	\$ (14,540)	\$ (9,833)	\$ (4,707)	

*Research and Development Expenses*

Research and development expenses increased by \$3.7 million to \$10.5 million for the six months ended June 30, 2015 from \$6.8 million for the six months ended June 30, 2014, an increase of 54%. The increase in research and development expenses was primarily attributable to a net increase of \$3.1 million in direct program costs, reflecting an increase of \$2.5 million in costs related to CAT-1004 primarily related to the

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initiation of a Phase 1/2 clinical trial, an increase of \$1.0 million in costs related to CAT-2054 primarily related to the initiation of a Phase 1 clinical trial, and an increase of \$0.4 million in our general research and platform programs, which were partially offset by a decrease of \$0.8 million in costs related to our CAT-2003 clinical trial, manufacturing and preclinical development costs due to the completion of two Phase 2 clinical trials that were active in the six months ended June 30, 2014. In addition, the costs related to internal research and development increased by \$0.6 million, primarily attributable to stock-based compensation expense.

*General and Administrative Expenses*

General and administrative expenses increased by \$0.6 million to \$3.6 million for the six months ended June 30, 2015 from \$3.0 million for the six months ended June 30, 2014, an increase of 20%. The increase in general and administrative expenses was primarily attributable to increased employee costs of \$0.4 million associated with hiring additional senior personnel, and an increase of \$0.1 million in consulting expense primarily due to recruiting for two senior business development positions. The remaining increase of \$0.1 million was spread in smaller amounts across several categories including insurance, facilities and general office expense.

*Other (Expense) Income, Net*

Other (expense) income consists of interest expense, which increased by \$0.4 million for the six months ended June 30, 2015 due to the interest expense on our credit facility, which we entered into in August 2014.

**Liquidity and Capital Resources**

*Overview*

From our inception through June 30, 2015, we have raised an aggregate of \$172.1 million, of which \$92.9 million consisted of gross proceeds from private placements of preferred stock, \$10.0 million consisted of gross proceeds from a secured debt financing, \$69.0 million consisted of gross proceeds from our IPO, and \$0.2 million resulted from common stock option exercises. As of June 30, 2015, we had \$81.6 million in cash and cash equivalents.

*Initial Public Offering*

In June 2015, we completed the sale of an aggregate of 5,750,000 shares of our common stock, including 750,000 shares of common stock sold pursuant to the underwriters' exercise of their option to purchase additional shares of common stock, in our IPO, at a price to the public of \$12.00 per share. Net proceeds from the IPO were \$61.8 million, after deducting underwriting discounts, commissions and offering-related expenses of approximately \$7.2 million.

*Credit Facility*

On August 27, 2014, we entered into a loan and security agreement with MidCap Financial Trust, Flexpoint MCLS Holdings, LLC and Square 1 Bank. On March 31, 2015, we entered into an amendment to the credit facility, as amended, the Credit Facility. The Credit Facility provides for initial borrowings of \$5.0 million and additional borrowings of up to \$20.0 million. Concurrently with entering into the Credit Facility in August 2014, we borrowed \$5.0 million under a term loan under the Credit Facility and we issued to the lenders warrants to purchase an aggregate of 157,844 shares of our series B preferred stock (24,566 shares of common stock on an as-converted basis) at an exercise price of \$0.9503 per share. Concurrently with the amendment to the Credit Facility, we drew down an additional \$5.0 million under our term loan under the Credit Facility and we issued to the lenders warrants to purchase an aggregate of 157,844 shares of our series B preferred stock

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(24,566 shares of common stock on an as-converted basis) at an exercise price of \$0.9503 per share. An additional \$5.0 million was available to us under the Credit Facility until May 31, 2015, subject to our completion of a series B preferred stock financing meeting certain conditions, including gross proceeds to us of at least \$8.0 million, and our issuance of warrants to purchase shares of our stock equal in value to 3% of the amount drawn. However, none of this \$5.0 million was drawn. The remaining \$10.0 million was available to us until July 31, 2015, subject to the completion of an initial public offering with net cash proceeds to us of at least \$50.0 million, and our issuance of warrants to purchase shares of our common stock equal in value to 3% of the amount drawn. However, none of this \$10.0 million was drawn. All borrowings under the Credit Facility are due on October 1, 2018 and are collateralized by substantially all of our personal property, other than our intellectual property.

There are no financial covenants associated with the Credit Facility; however, there are negative covenants that prohibit us from transferring any of our material assets, exclusively licensing our intellectual property (subject to certain exceptions), merging with or acquiring another entity, entering into a transaction that would result in a change of control, incurring additional indebtedness, creating any lien on our property, making investments in third parties or redeeming stock or paying dividends.

The Credit Facility also includes events of default, the occurrence and continuation of any of which provides the lenders the right to exercise remedies against us and the collateral securing the loans under the Credit Facility, including cash. These events of default include, among other things, failure to pay amounts due under the Credit Facility, insolvency, the occurrence of a material adverse event, which includes a material adverse change in our business, operations or conditions (financial or otherwise) or a material impairment of the prospect of repayment of any portion of the obligations, the occurrence of any default under certain other indebtedness and a final judgment against us in an amount greater than \$250,000. The occurrence of a material adverse change could result in acceleration of payment of the debt. At June 30, 2015 and December 31, 2014, we concluded that the likelihood of the acceleration of the debt was remote, as a material adverse change had not occurred and was unlikely to occur and therefore the debt was classified in current and long-term liabilities based on scheduled principal payments.

We are obligated to make monthly interest-only payments on any term loans borrowed under the Credit Facility until September 1, 2015 and, thereafter, to pay 36 consecutive, equal monthly installments of principal and interest from October 1, 2015 through September 1, 2018. Term loans under the Credit Facility bear interest at an annual rate of 7.49%. Following the occurrence and during the continuance of an event of default, borrowings under the Credit Facility will bear interest at an annual rate that is 5.00% above the rate that is otherwise applicable. In addition, a final payment equal to 3.48% of any amounts drawn under the Credit Facility is due upon the earlier of the maturity date, acceleration of the term loans or prepayment of all or part of the term loans.

***Preferred Stock Financing***

In March 2015, we raised \$12.4 million in gross proceeds from the sale of 13,062,965 shares of our series B preferred stock at a price per share of \$0.9503.

***Cash Flows***

The following table provides information regarding our cash flows for the six months ended June 30, 2015 and 2014 (in thousands):





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	Six Months Ended June 30,	
	2015	2014
Net cash used in operating activities	\$ (13,223)	\$ (9,763)
Net cash used in investing activities	(35)	(157)
Net cash provided by financing activities	80,138	22
Net increase (decrease) in cash and cash equivalents	\$ 66,880	\$ (9,898)

***Comparison of the Six Months Ended June 30, 2015 and 2014****Net Cash Used in Operating Activities*

Net cash used in operating activities was \$13.2 million for the six months ended June 30, 2015 and consisted primarily of a net loss of \$14.5 million adjusted for non-cash items, including stock-based compensation expense of \$0.7 million, non-cash interest expense of \$0.1 million and depreciation and amortization expense of \$0.1 million, and a net decrease in operating assets and liabilities of \$0.4 million, which resulted primarily from a net increase in accounts payable and accrued expenses of \$0.6 million partially offset by an increase in prepaid expenses and other current assets of \$0.2 million.

Net cash used in operating activities was \$9.8 million for the six months ended June 30, 2014 and consisted primarily of a net loss of \$9.8 million adjusted for non-cash items, including stock-based compensation expense of \$0.4 million and depreciation and amortization expense of \$0.1 million, and a net increase in operating assets of \$0.5 million, which resulted primarily from an increase in prepaid expenses and other current assets of \$0.4 million.

*Net Cash Used in Investing Activities*

Net cash used in investing activities was \$35 thousand during the six months ended June 30, 2015 compared to \$0.2 million during the six months ended June 30, 2014, a decrease of \$0.1 million, which resulted primarily from decreased laboratory equipment expenditures in the six months ended June 30, 2015.

*Net Cash Provided by Financing Activities*

Net cash provided by financing activities was \$80.1 million during the six months ended June 30, 2015 compared to \$22 thousand during the six months ended June 30, 2014. The cash provided by financing activities for the six months ended June 30, 2015 primarily consisted of net proceeds received from the IPO of \$62.8 million in June 2015, net proceeds of \$12.3 million from the issuance of 13,062,965 shares of our series B preferred stock in March 2015, and \$5.0 million from our borrowings under the Credit Facility in March 2015.

***Funding Requirements***

We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development of, and conduct clinical trials and seek marketing approval for, our product candidates. 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. Furthermore, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are

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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.

We expect that our cash and cash equivalents, including the proceeds from our recent IPO, will enable us to fund our operating expenses and capital expenditure requirements at least through 2016. We have based this estimate on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development of CAT-1004, CAT-2054 and our other current and potential product candidates, and because the extent to which we may enter into collaborations with third parties for the development of these product candidates is unknown, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the research and development of our product candidates. 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;
- the success of any future collaborations;
- the extent to which we acquire or in-license other medicines and technologies;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims; and
- our ability to establish and maintain collaborations on favorable terms, if at all.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of medicines that we do not expect to be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all.

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Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interests will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. Additional debt financing, if available, would result in increased fixed payment obligations and may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, that could adversely impact our ability to conduct our business.

If we raise funds through 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 when needed, we may be required to delay, limit, reduce or

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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.

**Off-Balance Sheet Arrangements**

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under applicable Securities and Exchange Commission, or SEC, rules.

**Contractual Obligations**

On July 16, 2015, the Company entered into a Second Amendment to the Lease (the "Second Lease Amendment") with DWF IV One Kendall, LLC (the "Landlord"), which amends certain terms of the Company's existing lease with the Landlord. The Second Lease Amendment expands the rentable square footage of the Company's leased premises from approximately 14,817 square feet to approximately 18,876 square feet. Pursuant to the Second Lease Amendment, the date on which the Company will become responsible for paying rent with respect to such additional square footage is September 1, 2015 (the "Expansion Space Rent Commencement Date"). The Second Lease Amendment will increase the future minimum payments described in Note 7 from approximately \$1,520,000 to approximately \$1,844,000.

There were no other material changes to our contractual obligations and commitments described under Management's Discussion and Analysis of Financial Condition and Results of Operations in the Prospectus.

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

The market risk inherent in our financial instruments and in our financial position represents the potential loss arising from adverse changes in interest rates. As of June 30, 2015, we had cash and cash equivalents of \$81.6 million and, as of December 31, 2014, we had cash and cash equivalents of \$14.7 million, consisting primarily of money market funds. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in short-term marketable securities. Our marketable securities are subject to interest rate risk and could fall in value if market interest rates increase. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our investment portfolio. We have the ability to hold our marketable securities until maturity, and therefore we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a change in market interest rates on our investments.

As of June 30, 2015 and December 31, 2014, we had no liabilities denominated in foreign currencies.

**Item 4. Controls and Procedures**

**Management's Evaluation of our Disclosure Controls and Procedures**

We maintain disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e) under the Exchange Act) that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is (1) recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and (2) accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

As of June 30, 2015, our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our principal executive officer and principal financial officer have concluded based upon the evaluation described above that, as of June 30, 2015, our disclosure controls and procedures were effective at the reasonable assurance level.

We continue to review and document our disclosure controls and procedures, including our internal controls and procedures for financial reporting, and may from time to time make changes aimed at enhancing their effectiveness and to ensure that our systems evolve with our business.

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

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During the six months ended June 30, 2015, there have been no changes in our internal control over financial reporting, as such term is defined in Rules 13a-15 (f) and 15(d)-15(f) promulgated under the Exchange Act, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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**PART II OTHER INFORMATION**

**Item 1A. Risk Factors**

*We operate in a dynamic and rapidly changing business environment that involves multiple risks and substantial uncertainty. The following discussion addresses risks and uncertainties that could cause, or contribute to causing, actual results to differ from expectations in material ways. In evaluating our business, investors should pay particular attention to the risks and uncertainties described below and in other sections of this Quarterly Report on Form 10-Q and in our subsequent filings with the SEC. These risks and uncertainties, or other events that we do not currently anticipate or that we currently deem immaterial also may affect our results of operations, cash flows and financial condition. The trading price of our common stock could also decline due to any of these risks, and you could lose all or part of your investment.*

**Risks Related to Our Financial Position and Need for Additional Capital**

*We have incurred significant losses since inception and expect to incur significant and increasing losses for at least the next several years. We may never achieve or maintain profitability.*

We have incurred significant annual net operating losses in every year since our inception. We expect to continue to incur significant and increasing operating losses for at least the next several years. Our net losses were \$18.1 million and \$21.9 million for the years ended December 31, 2013 and 2014, respectively, and \$14.5 million for the six months ended June 30, 2015. As of June 30, 2015, we had an accumulated deficit of \$89.9 million. We have not generated any revenues from product sales, have not completed the development of any product candidate and may never have a product candidate approved for commercialization. We have financed our operations to date primarily through private placements of our preferred stock and a debt financing, and have devoted substantially all of our financial resources and efforts to research and development, including preclinical studies and our clinical development programs. Our net losses may fluctuate significantly from quarter to quarter and year to year. Net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' (deficit) equity and working capital.

We anticipate that our expenses will increase substantially if and as we:

- continue to develop and conduct clinical trials with respect to our product candidates CAT-1004 and CAT-2054, including an ongoing Phase 1/2 clinical trial of CAT-1004 for which we initiated patient enrollment in June 2015 and an ongoing Phase 1 clinical trial of CAT-2054 that we initiated in January 2015;
- initiate and continue research and preclinical and clinical development efforts for our other product candidates;



- seek to identify and develop additional product candidates;
- seek regulatory and marketing approvals for our product candidates that successfully complete clinical trials, if any;
- establish sales, marketing, distribution and other commercial infrastructure in the future to commercialize various products for which we may obtain marketing approval, if any;
- require the manufacture of larger quantities of product candidates for clinical development and potentially commercialization;

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- maintain, expand and protect our intellectual property portfolio;
- hire and retain additional personnel, such as clinical, quality control and scientific personnel;
- add operational, financial and management information systems and personnel, including personnel to support our product development and help us comply with our obligations as a public company; and
- add equipment and physical infrastructure to support our research and development programs.

Our ability to become and remain profitable depends on our ability to generate revenue. We do not expect to generate significant revenue unless and until we are, or any future collaborator is, able to obtain marketing approval for, and successfully commercialize, one or more of our product candidates. This will require our, or any of our future collaborators', success in a range of challenging activities, including completing clinical trials of our product candidates, obtaining marketing approval for these product candidates, manufacturing, marketing and selling those products for which we, or any of our future collaborators, may obtain marketing approval, satisfying any post-marketing requirements and obtaining reimbursement for our products from private insurance or government payors. Because of the uncertainties and risks associated with these activities, we are unable to accurately predict the timing and amount of increased expenses, and if or when we might achieve profitability. We and any future collaborators may never succeed in these activities and, even if we do, or any future collaborators does, we may never generate revenues that are large enough for us to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our pipeline of product candidates or continue our operations. A decline in the value of our company could cause you to lose all or part of your investment.

***We have a limited operating history and no history of commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for our future viability.***

We began operations in 2008. Our operations to date have been limited to financing and staffing our company and developing our technology and conducting preclinical research and early-stage clinical trials for our product candidates. We have not yet demonstrated an ability to successfully conduct pivotal clinical trials, 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 product commercialization. Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by companies in the early stages of development, especially clinical-stage biopharmaceutical companies such as ours. Predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing pharmaceutical products.

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

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Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. We expect our expenses to increase in connection with our ongoing activities, particularly as we initiate new clinical trials of, initiate new research and preclinical development efforts for and seek marketing approval for, our product candidates. In addition, if we obtain marketing approval for any of our product candidates, we may incur significant

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commercialization expenses related to product sales, marketing, manufacturing and distribution to the extent that such sales, marketing, manufacturing and distribution are not the responsibility of a future collaborator. Furthermore, we expect to incur significant additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we may be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

We will be required to expend significant funds in order to advance the development of CAT-1004 and CAT-2054, as well as our other product candidates. In addition, while we may seek one or more collaborators for future development of our product candidates, and, in particular, expect that we would conduct any large Phase 3 clinical trial of CAT-2054 for the treatment of hypercholesterolemia in collaboration with one or more partners that would pay most of the associated costs, we may not be able to enter into a collaboration for any of our product candidates on suitable terms or at all. In any event, our existing cash and cash equivalents, including the net proceeds from our initial public offering of common stock, will not be sufficient to fund all of the efforts that we plan to undertake or to fund the completion of development of any of our product candidates. Accordingly, we will be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources. We do not have any committed external source of funds.

Adequate additional financing may not be available to us on acceptable terms, or at all. Further, our ability to obtain additional debt financing may be limited by covenants we have made under our loan and security agreement with MidCap, Flexpoint and Square 1, including our negative pledge with respect to intellectual property in favor of MidCap, Flexpoint and Square 1, as well as our pledge to MidCap, Flexpoint and Square 1 of substantially all of our assets, other than our intellectual property, as collateral. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy.

We believe that our existing cash and cash equivalents as of June 30, 2015, including the net proceeds from our recent initial public offering of common stock, will enable us to fund our operating expenses, debt service and capital expenditure requirements at least through 2016. Our estimate as to how long we expect our existing cash and cash equivalents to be able to fund our operations is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Further, changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned. Our future funding requirements, both short-term and long-term, will depend on many factors, including:

- the progress, timing, costs and results of clinical trials of, and research and preclinical development efforts for, our product candidates and potential product candidates, including current and future clinical trials;
- our ability to identify a collaborator for CAT-2054 and the terms and timing of any collaboration agreement that we may establish for the development and commercialization of CAT-2054;
- our ability to enter into and the terms and timing of any additional collaborations, licensing or other arrangements that we may establish;

- the number and characteristics of future product candidates that we pursue and their development requirements;

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- the outcome, timing and costs of seeking regulatory approvals;
- the costs of commercialization activities for any of our product candidates that receive marketing approval to the extent such costs are not the responsibility of any future collaborators, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities;
- subject to receipt of marketing approval, revenue, if any, received from commercial sales of our product candidates;
- our headcount growth and associated costs as we expand our research and development and establish a commercial infrastructure;
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending against intellectual property related claims; and
- the costs of operating as a public company.

***The audit opinion on our financial statements contains a going concern explanatory paragraph.***

Based on our cash balances, recurring losses, net capital deficiency and debt outstanding as of December 31, 2014 and our projected spending in 2015, which raise substantial doubt about our ability to continue as a going concern, the audit opinion on our audited financial statements as of and for the year ended December 31, 2014 contains a going concern explanatory paragraph. Given our planned expenditures for the next several years, including, without limitation, expenditures in connection with our clinical trials of CAT-1004 and CAT-2054, our independent registered public accounting firm may conclude, in connection with the audit of our financial statements for fiscal year 2015 or any other subsequent period, that there is substantial doubt regarding our ability to continue as a going concern. If we are unable to continue as a going concern, we might have to liquidate our assets and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our financial statements. Additionally, amounts due under our credit facility may become immediately due and payable upon the occurrence of a material adverse change, as defined under the loan agreement. In addition, the inclusion of a going concern explanatory paragraph by our auditors, our lack of cash resources and our potential inability to continue as a going concern may materially adversely affect our share price and our ability to raise new capital or to enter into critical contractual relations with third parties.

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

We expect that significant additional capital will be needed in the future to continue our planned operations. To the extent that we raise additional capital through the sale of common stock, convertible securities or other equity securities, our existing stockholders' ownership interest may be substantially diluted, and the terms of these securities could include liquidation or other preferences and anti-dilution protections that could adversely affect your rights as a common stockholder. Additional debt financing, if available, would result in increased fixed payment obligations and may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures, creating liens, redeeming stock or declaring dividends, that could adversely impact our ability to conduct our business. For example, our credit facility with MidCap, Flexpoint and Square 1 contains restrictive covenants that, among other things and subject to certain exceptions, prohibit us from transferring any of our material assets, exclusively licensing our intellectual property (subject to certain exceptions), merging with or acquiring another entity, entering into a

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transaction that would result in a change of control, incurring additional indebtedness, creating any lien on our property, making investments in third parties or redeeming stock or paying dividends. Future debt securities or other financing arrangements could contain similar or more restrictive negative covenants. In addition, securing additional financing could require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from day-to-day activities, which may adversely affect our management's ability to oversee the development of our product candidates.

If we raise additional funds through collaborations or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds 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 existing and any future indebtedness could adversely affect our ability to operate our business.***

As of June 30, 2015, we had \$10.0 million of outstanding borrowings under our credit facility with MidCap, Flexpoint and Square 1. We currently make monthly interest payments and, beginning in October 2015, will be required to repay principal and interest on these borrowings in monthly installments through October 2018. Subject to the restrictions in this existing credit facility, we could in the future incur additional indebtedness beyond our borrowings from MidCap, Flexpoint and Square 1.

Our outstanding indebtedness, including any additional indebtedness beyond our borrowings from MidCap, Flexpoint and Square 1, combined with our other financial obligations and contractual commitments could have significant adverse consequences, including:

- requiring us to dedicate a portion of our cash resources to the payment of interest and principal, reducing money available to fund working capital, capital expenditures, product development and other general corporate purposes;
- increasing our vulnerability to adverse changes in general economic, industry and market conditions;
- subjecting us to restrictive covenants that may reduce our ability to take certain corporate actions or obtain further debt or equity financing;
- limiting our flexibility in planning for, or reacting to, changes in our business and the industry in which we compete; and



- placing us at a competitive disadvantage compared to our competitors that have less debt or better debt servicing options.

We intend to satisfy our current and future debt service obligations with our existing cash and cash equivalents. However, we may not have sufficient funds, and may be unable to arrange for additional financing, to pay the amounts due under our existing debt instruments. Failure to make payments or comply with other covenants under our existing debt instruments could result in an event of default and acceleration of amounts due. Under our loan and security agreement with MidCap, Flexpoint and Square 1, the occurrence of an event that would reasonably be expected to have a material adverse effect on our business, operations, assets or condition is an event of default. If an event of default occurs and the lenders accelerate the amounts due, we may not be able to make accelerated payments, and the lenders could seek to enforce security interests in the collateral securing such indebtedness, which includes substantially all of our assets other than our intellectual

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property. In addition, the covenants under our credit facility, the pledge of our assets as collateral and the negative pledge with respect to our intellectual property could limit our ability to obtain additional debt financing.

**Risks Related to the Discovery, Development and Commercialization of Our Product Candidates**

*Our approach to the discovery and development of product candidates based on our SMART linker technology platform is unproven, and we do not know whether we will be able to develop any products of commercial value.*

We are focused on discovering and developing novel bi-functional small molecule drugs by applying our SMART linker technology platform. While we believe that applying our SMART linker technology platform may potentially enable drug research and clinical development that is more efficient than conventional small molecule drug research and development, this approach is unproven. We have not yet succeeded and may never succeed in demonstrating efficacy and safety for any of our product candidates in later stage clinical trials or in obtaining marketing approval thereafter. For example, although we have discovered and evaluated numerous compounds using our SMART linker technology platform, we have not yet advanced a compound into Phase 3 clinical development and no product created using the SMART linker technology platform has ever been approved for sale.

*We are dependent on the success of our product candidates CAT-1004 and CAT-2054. If we are unable to complete the clinical development of, obtain marketing approval for or successfully commercialize at least one of these product candidates, either alone or with a collaborator, or if we experience significant delays in doing so, our business could be substantially harmed.*

We currently have no products approved for sale and are investing a significant portion of our efforts and financial resources in the development of CAT-1004 for the treatment of Duchenne muscular dystrophy, or DMD, and CAT-2054 for the treatment of hypercholesterolemia. Our prospects are substantially dependent on our ability, or that of any future collaborator, to develop, obtain marketing approval for and successfully commercialize at least one of these product candidates.

The success of CAT-1004 and CAT-2054 will depend on several factors, including the following:

- successful completion of our ongoing clinical trials;
- initiation and successful enrollment and completion of additional clinical trials;
- safety, tolerability and efficacy profiles that are satisfactory to the U.S. Food and Drug Administration, or FDA, or any comparable foreign regulatory authority for marketing approval;

- timely receipt of marketing approvals from applicable regulatory authorities;
- the performance of our future collaborators, if any;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- establishment of supply arrangements with third-party raw materials suppliers and manufacturers;

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- establishment of arrangements with third-party manufacturers to obtain finished drug products that are appropriately packaged for sale;
- obtaining and maintaining patent, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- protection of our rights in our intellectual property portfolio;
- successful launch of commercial sales following any marketing approval;
- a continued acceptable safety profile following any marketing approval;
- commercial acceptance by patients, the medical community and third-party payors following any marketing approval; and
- our ability to compete with other therapies, including, in the case of CAT-1004, therapies targeting dystrophin, utrophin and myostatin and inflammatory mediators.

Many of these factors are beyond our control, including clinical development, the regulatory submission process, potential threats to our intellectual property rights and the manufacturing, marketing and sales efforts of any future collaborator. If we are unable to develop, receive marketing approval for and successfully commercialize at least one of CAT-1004 or CAT-2054, on our own or with any future collaborator, or experience delays as a result of any of these or other factors, our business could be substantially harmed.

***Our SMART linker technology platform may fail to help us discover and develop additional potential product candidates.***

A significant portion of the research that we are conducting involves the development of new compounds using our SMART linker technology platform. The drug discovery that we are conducting using our SMART linker technology platform may not be successful in creating compounds that have commercial value or therapeutic utility. Our SMART linker technology platform may initially show promise in identifying potential product candidates, yet fail to yield viable product candidates for clinical development or commercialization for a number of reasons, including:

- compounds created through our SMART linker technology platform may not demonstrate improved efficacy, safety or tolerability;
- potential product candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to receive marketing approval and achieve market acceptance;
- competitors may develop alternative therapies that render our potential product candidates non-competitive or less attractive; or
- a potential product candidate may not be capable of being produced at an acceptable cost.

Our research programs to identify new product candidates will require substantial technical, financial and human resources, and we may be unsuccessful in our efforts to identify new product candidates. If we are unable to identify suitable additional compounds for preclinical and clinical development, our ability to develop

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product candidates and obtain product revenues in future periods could be compromised, which could result in significant harm to our financial position and adversely impact our stock price.

***We have never obtained marketing approval for a product candidate and we may be unable to obtain, or may be delayed in obtaining, marketing approval for any of our product candidates.***

We have never obtained marketing approval for a product candidate. It is possible that the FDA may refuse to accept for substantive review any new drug applications, or NDAs, that we submit for our product candidates or may conclude after review of our data that our application is insufficient to obtain marketing approval of our product candidates. If the FDA does not accept or approve our NDAs for either of our most advanced product candidates, it may require that we conduct additional clinical, nonclinical or manufacturing validation studies and submit that data before it will reconsider our applications. Depending on the extent of these or any other FDA-required studies, approval of any NDA or application that we submit may be delayed by several years, or may require us to expend more resources than we have available. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA to approve our NDAs.

Any delay in obtaining, or an inability to obtain, marketing approvals would prevent us from commercializing our product candidates, generating revenues and achieving and sustaining profitability. If any of these outcomes occur, we may be forced to abandon our development efforts for our product candidates, which could significantly harm our business.

***Results of preclinical studies and early clinical trials may not be predictive of results of future clinical trials.***

The outcome of preclinical studies and early clinical trials may not be predictive of the success of later clinical trials, and interim results of clinical trials do not necessarily predict success in future clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in earlier development, and we cannot be certain that we will not face similar setbacks. The design of a clinical trial can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. We have limited experience in designing clinical trials and may be unable to design and execute a clinical trial to support marketing approval. In addition, preclinical and clinical data are often susceptible to varying interpretations and analyses. Many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for the product candidates. Even if we, or any future collaborators, believe that the results of clinical trials for our product candidates warrant marketing approval, the FDA or comparable foreign regulatory authorities may disagree and may not grant marketing approval of our product candidates.

In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the dosing regimen and other clinical trial protocols and the rate of dropout among clinical trial participants. If we fail to receive positive results in clinical trials of our product candidates, the development timeline and regulatory approval and commercialization prospects for our most advanced product candidates, and, correspondingly, our business and financial prospects would be negatively impacted.



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***Because we are developing CAT-1004 for the treatment of DMD, a disease for which regulatory authorities have not issued definitive guidance as to how to measure and demonstrate efficacy, there is increased risk that the outcome of our clinical trials will not be satisfactory for marketing approval.***

There is currently no approved therapy for DMD in the United States. In addition, there has been limited historical clinical trial experience for the development of drugs to treat the underlying cause of DMD. As a result, the design and conduct of clinical trials for this disease, particularly for drugs to address the underlying cause of this disease, is subject to increased risk. In particular, regulatory authorities in the United States and European Union have not issued definitive guidance as to how to measure and demonstrate efficacy. We anticipate that the primary endpoint in our Phase 1/2 clinical trial of CAT-1004 for the treatment of DMD will be change in muscle inflammation as measured by magnetic resonance imaging, or MRI, of leg muscles. MRI markers of leg muscle inflammation have been observed to increase with age but decrease with initiation of steroid therapy. We intend to include as exploratory endpoints the timed function tests best suited for this age group, specifically the 10 meter walk/run, time to stand and 4-stair climb tests. However, due to the age and development stage of the patients we intend to enroll in this clinical trial, these endpoints may not be sufficiently sensitive to demonstrate efficacy over the period of the trial.

***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.***

Because we have limited financial and managerial resources, we intend to focus on developing product candidates for specific indications that we identify as most likely to succeed, in terms of both their potential for marketing approval and commercialization. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that may 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 product candidates. 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 the product candidate.

***Clinical drug development involves a lengthy and expensive process with an uncertain outcome.***

Clinical testing is expensive, time-consuming and uncertain as to outcome. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, or at all. The clinical development of our product candidates is susceptible to the risk of failure at any stage of drug development, including failure to demonstrate efficacy in a clinical trial or across a broad population of patients, the occurrence of adverse events that are severe or medically or commercially unacceptable, failure to comply with protocols or applicable regulatory requirements and determination by the FDA or any comparable foreign regulatory authority that a product candidate may not continue development or is not approvable. For example, our IND for CAT-2003 was placed on partial clinical hold by the FDA in November 2012 because of the need for additional nonclinical work to support potential expansion of dosing and duration of our proposed Phase 1 multiple ascending dose trial. Although the partial clinical hold was removed in July 2013, it is possible that any of our development programs may be placed on full or partial clinical hold by regulatory authorities at any point, which would delay and possibly prevent further development of our product candidates. It is possible that even if one or more of our product candidates has a beneficial effect, that effect will not be detected during clinical evaluation as a result of one or more of a variety of factors, including the size, duration, design, measurements, conduct or analysis of our clinical trials. Conversely, as a result of the same factors, our clinical trials may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any. Similarly, in





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our clinical trials we may fail to detect toxicity of or intolerability caused by our product candidates, or mistakenly believe that our product candidates are toxic or not well tolerated when that is not in fact the case.

In addition to the risk of failure inherent in drug development, certain of the compounds that we are developing and may develop in the future using our SMART linker technology platform may be particularly susceptible to failure to the extent they are based on compounds that others have previously studied or tested, but did not progress in development due to safety, tolerability or efficacy concerns or otherwise. Our failure to successfully complete clinical trials of our product candidates and to demonstrate the efficacy and safety necessary to obtain regulatory approval to market any of our product candidates would significantly harm our business.

***If clinical trials of our product candidates fail to satisfactorily demonstrate safety and efficacy to the FDA and other comparable foreign regulators, we, or any future collaborators, may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of these product candidates.***

We, and any future collaborators, are not permitted to commercialize, market, promote or sell any product candidate in the United States without obtaining marketing approval from the FDA. Comparable foreign regulatory authorities, such as the European Medicines Agency, or the EMA, impose similar restrictions. We, and any future collaborators, may never receive such approvals. We, and any future collaborators, must complete extensive preclinical development and clinical trials to demonstrate the safety and efficacy of our product candidates in humans before we, or they, will be able to obtain these approvals.

Clinical testing is expensive, difficult to design and implement, can take many years to complete and is inherently uncertain as to outcome. We have not previously submitted an NDA to the FDA or similar drug approval filings to comparable foreign regulatory authorities for any of our product candidates. Any inability to complete preclinical and clinical development successfully could result in additional costs to us, or any future collaborators, and impair our ability to generate revenues from product sales, regulatory and commercialization milestones and royalties. Moreover, if (1) we, or any future collaborators, are required to conduct additional clinical trials or other testing of our product candidates beyond the trials and testing that we, or they contemplate, (2) we, or any future collaborators, are unable to successfully complete clinical trials of our product candidates or other testing, (3) the results of these trials or tests are unfavorable, uncertain or are only modestly favorable, or (4) there are unacceptable safety concerns associated with our product candidates, we, or any future collaborators, 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 significant safety warnings, including boxed warnings;

- be subject to additional post-marketing testing or other requirements; or
- be required to remove the product from the market after obtaining marketing approval.

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*Adverse events or undesirable side effects caused by, or other unexpected properties of, any of our product candidates may be identified during development that could delay or prevent their marketing approval or limit their use.*

Adverse events or undesirable side effects caused by, or other unexpected properties of, our product candidates could cause us, any future collaborators, an institutional review board or regulatory authorities to interrupt, delay or halt clinical trials of one or more of our product candidates and could result in a more restrictive label or the delay or denial of marketing approval by the FDA or comparable foreign regulatory authorities. For example, in our clinical trials of CAT-2003 we observed gastrointestinal tolerability issues, including nausea, diarrhea and vomiting, and in some cases these adverse events led to dose reductions or discontinuations. If any of our product candidates is associated with adverse events or undesirable side effects or has properties that are unexpected, we, or any future collaborators, may need to abandon development or limit development of that product candidate 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 compounds that initially showed promise in clinical or earlier stage testing have later been found to cause undesirable or unexpected side effects that prevented further development of the compound.

*If we, or any future collaborators, experience any of a number of possible unforeseen events in connection with clinical trials of our product candidates, potential marketing approval or commercialization of our product candidates could be delayed or prevented.*