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

Form 10-Q

☒ **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

☐ **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: 001-36829

Inotek Pharmaceuticals Corporation
(Exact name of registrant as specified in its charter)

Delaware	**04-3475813**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

131 Hartwell Avenue, Suite 105
Lexington, MA 02421
(Address of principal executive office) (Zip Code)

Registrant's telephone number, including area code:
(781) 676-2100

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

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

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

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

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

As of August 6, 2015, there were 20,197,716 shares of common stock, $0.01 par value per share, outstanding.

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements that involve risks and uncertainties, as well as assumptions that, if they never materialize or prove incorrect, could cause our results to differ materially from those expressed or implied by such forward-looking statements. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q are forward-looking statements. In some cases, you can identify forward-looking statements by words such as “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “seek,” “should,” “target,” “will,” “would,” or the negative of these words or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- our anticipated cash needs and our estimates regarding our capital requirements and our needs for additional financing;
- federal, state, and non-U.S. regulatory requirements, including regulation of our current or any other future product candidates by the U.S. Food and Drug Administration (the “FDA”);
- the success, timing and cost of our planned Phase 3 clinical trials and anticipated Phase 3 program for *trabodenoson* as a monotherapy and Phase 2 program for our fixed-dose combination (“FDC”) product candidate, including statements regarding the timing of initiation and completion of the trials;
- the timing of and our ability to submit regulatory filings with the FDA and to obtain and maintain FDA or other regulatory authority approval of, or other action with respect to, our product candidates;
- our commercialization, marketing and manufacturing capabilities and strategy, including with respect to our potential sales force in the United States and our partnering and collaboration efforts outside the United States;
- third-party payor reimbursement for our current product candidates or any other potential products;
- our expectations regarding the clinical efficacy of our product candidates and results of our clinical trials;
- the glaucoma patient market size and the rate and degree of market adoption of our product candidates by ophthalmologists, optometrists and patients;
- the timing, cost or other aspects of a potential commercial launch of our product candidates and potential future sales of our current product candidates or any other potential products if any are approved for marketing;
- our expectations regarding licensing, acquisitions and strategic operations;
- the potential advantages of our product candidates;
- our competitors and their product candidates, including our expectations regarding those competing product candidates;
- our ability to protect and enforce our intellectual property rights, including our patented and trade secret protected proprietary rights in our product candidates; and
- anticipated trends and challenges in our business and the markets in which we operate.

We caution you that the foregoing list may not contain all of the forward-looking statements made in this Quarterly Report on Form 10-Q.

Any forward-looking statements in this Quarterly Report on Form 10-Q reflect our current views with respect to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under Part II, Item 1A. Risk Factors in this Quarterly Report on Form 10-Q and elsewhere in this Quarterly Report on Form 10-Q. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

This Quarterly Report on Form 10-Q also contains estimates, projections and other information concerning our industry, our business, and the markets for certain diseases, including data regarding the estimated size of those markets, and the incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources.

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Inotek Pharmaceuticals Corporation

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PART I — FINANCIAL INFORMATION

Item 1. Financial Statements

Inotek Pharmaceuticals Corporation
Balance Sheets
(Unaudited)
(In thousands, except for share and per share amounts)

	June 30, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$ 49,012	$ 3,618
Prepaid expenses and other current assets	465	52
Total current assets	49,477	3,670
Property and equipment, net	29	—
Other assets	2,182	1,850
Total assets	$ 51,688	$ 5,520
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Notes payable, current portion	$ —	$ 3,063
Accounts payable	813	1,146
Accrued expenses and other current liabilities	1,273	992
Accrued interest	366	—
Convertible Bridge Notes	—	1,541
Convertible Bridge Notes redemption rights derivative	—	480
Total current liabilities	2,452	7,222
2020 Convertible Notes, net of debt discount of $12,074	8,926	—
Notes payable, net of current portion	—	2,550
Warrant liabilities	—	482
2020 Convertible Notes derivative liability	8,567	—
Other long-term liabilities	24	24
Total liabilities	19,969	10,278
Series AA redeemable convertible preferred stock, $0.001 par value; 0 shares authorized, issued and outstanding at June 30, 2015; 25,757,874 shares authorized and 24,057,013 shares issued and outstanding at December 31, 2014	—	46,253
Series X redeemable convertible preferred stock, $0.001 par value; 0 shares authorized, issued and outstanding at June 30, 2015; 2,902,050 shares authorized and 1,892,320 shares issued and outstanding at December 31, 2014	—	548
Total redeemable convertible preferred stock	—	46,801
Commitments and Contingencies (Note 7)		
Stockholders' equity (deficit):		
Preferred Stock, $0.001 par value: 5,000,000 shares authorized and 0 shares issued or outstanding	—	—
Common stock, $0.01 par value: 120,000,000 shares and 43,509,727 shares authorized at June 30, 2015 and December 31, 2014, respectively; 16,327,003 shares and 1,020,088 shares issued and outstanding at June 30, 2015 and December 31, 2014, respectively	163	10
Additional paid-in capital	163,446	76,472
Accumulated deficit	(131,890)	(128,041)
Total stockholders' equity (deficit)	31,719	(51,559)
Total Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)	$ 51,688	$ 5,520

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

Inotek Pharmaceuticals Corporation

Statements of Operations
(Unaudited)
(In thousands, except share and per share data)

	Three Months ended June 30,		Six Months ended June 30,	
	2015	2014	2015	2014
Operating expenses:				
Research and development	$ (1,954)	$ (1,862)	$ (3,023)	$ (3,412)
General and administrative	(1,728)	(332)	(3,708)	(494)
Loss from operations	(3,682)	(2,194)	(6,731)	(3,906)
Interest expense	(564)	(248)	(1,038)	(491)
Loss on extinguishment of debt	—	—	(683)	—
Change in fair value of warrant liabilities	—	(405)	267	(598)
Change in fair value of Convertible Bridge Notes redemption rights derivative	—	—	480	—
Change in fair value of 2020 Convertible Notes derivative liability	1,859	—	3,856	—
Net loss	$ (2,387)	$ (2,847)	$ (3,849)	$ (4,995)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.15)	$ (3.81)	$ (0.33)	$ (6.89)
Weighted-average number of shares outstanding—basic and diluted	16,327,003	1,020,088	12,026,183	1,020,088

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

Inotek Pharmaceuticals Corporation

Statements of Cash Flows
(Unaudited)
(In thousands)

	Six Months Ended June 30,	
	2015	2014
Cash flows from operating activities:		
Net loss	$ (3,849)	$ (4,995)
Adjustments to reconcile net loss to cash used in operating activities:		
Noncash interest expense	577	106
Loss on extinguishment of debt	522	—
Depreciation	1	—
Change in fair value of warrant liabilities	(267)	598
Change in fair value of Convertible Bridge Notes redemption rights derivative	(480)	—
Change in fair value of 2020 Convertible Notes derivative liability	(3,856)	—
Stock-based compensation	1,558	4
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(574)	26
Accounts payable	(333)	130
Accrued expenses and other current liabilities	651	219
Net cash used in operating activities	(6,050)	(3,912)
Cash flows from investing activities:		
Purchase of property and equipment	(30)	—
Net cash used in investing activities:	(30)	—
Cash flows from financing activities:		
Proceeds from issuance of common stock in initial public offering, net of issuance costs	38,115	—
Proceeds from issuance of 2020 Convertible Notes in initial public offering, net of underwriting discounts	21,000	—
Payments of 2020 Convertible Notes issuance costs	(1,841)	—
Principal payments on notes payable	(5,800)	—
Net cash provided by financing activities:	51,474	—
Net change in cash and cash equivalents	45,394	(3,912)
Cash and cash equivalents, beginning of period	3,618	12,793
Cash and cash equivalents, end of period	$ 49,012	$ 8,881
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 89	$ 385
Supplemental disclosure of noncash investing and financing activities:		
Accrual of Series AA preferred stock dividends	$ —	$ 1,611
Conversion of Series AA preferred stock into common stock upon initial public offering	$ 46,383	$ —
Conversion of Series X preferred stock into common stock upon initial public offering	$ 548	$ —
Conversion of Convertible Bridge Notes into common stock upon initial public offering	$ 2,028	$ —
Accretion of Series AA preferred stock to redemption value	$ 130	$ 419
Reclassification of fair value of warrant liability to equity upon initial public offering	$ 215	$ —
Reclassification of deferred public offering costs to stockholders' equity	$ 1,590	$ —
Reclassification of deferred public offering costs to other assets	$ 256	$ —

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

INOTEK PHARMACEUTICALS CORPORATION

Notes to Financial Statements
(Amounts in thousands, except share and per share data)

1. Organization and Operations

Inotek Pharmaceuticals Corporation (the "Company") is a clinical-stage biopharmaceutical company advancing molecules with novel mechanisms of action to address significant diseases of the eye. The Company's business strategy is to develop and progress its product candidates through human clinical trials. The Company's headquarters is located in Lexington, Massachusetts.

The Company has devoted substantially all of its efforts to research and development, including clinical trials of its product candidates. The Company has not completed the development of any product candidates. The Company has no current source of revenue to sustain present activities and does not expect to generate revenue until and unless the Company receives regulatory approval of and successfully commercializes its product candidates. The Company is subject to a number of risks and uncertainties similar to those of other life science companies developing new products, including, among others, the risks related to the necessity to obtain adequate additional financing, to successfully develop product candidates, to obtain regulatory approval of products candidates, to comply with government regulations, to successfully commercialize its potential products, to the protection of proprietary technology and to the dependence on key individuals.

In February 2015, the Company completed its initial public offering (the "IPO") of (i) 6,667,000 shares of common stock at a price of $6.00 per share and (ii) $20,000 aggregate principal amount of 5.0% Convertible Senior Notes due 2020 (the "2020 Convertible Notes"). In March 2015, the underwriters purchased 299,333 shares of common stock at $6.00 per share and $1,000 of the 2020 Convertible Notes pursuant to exercises of their overallotment options. The Company received net proceeds of $36,525 after deducting underwriting discounts and offering-related costs, from its equity issuances and $18,903 in net proceeds, after deducting underwriting discounts and offering-related costs, from its debt issuances (see Note 5). Prior to this, the Company has funded its operations primarily through the sale of preferred stock and issuance of convertible promissory notes and notes payable. As of June 30, 2015, the Company had an accumulated deficit of $131,890 and cash and cash equivalents of $49,012. The Company estimates that it has sufficient funding to sustain operations through 2016.

The Company will need to expend substantial resources for research and development, including costs associated with the clinical testing of its product candidates and will need to obtain additional financing to fund its operations and to conduct trials for its product candidates. If such products were to receive regulatory approval, the Company would need to prepare for the potential commercialization of its product candidates and fund the commercial launch and continued marketing of its products. The Company expects operating expenses will substantially increase in the future related to additional clinical testing and to support an increased infrastructure to support expanded operations and being a public company.

The Company will require additional funding in the future and may not be able to raise such additional funds. The Company expects losses will continue as it conducts research and development activities. The Company will seek to finance future cash needs through public or private equity offerings, license agreements, debt financings, collaborations, strategic alliances, or any combination thereof. The incurrence of indebtedness would result in increased fixed payment obligations and could also result in restrictive covenants, such as limitations on our ability to incur additional debt, limitations on the Company's ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact the ability of the Company to conduct its business. If adequate funds are not available, the Company would delay, reduce or eliminate research and development programs and reduce administrative expenses. The Company may seek to access the public or private capital markets whenever conditions are favorable, even if it does not have an immediate need for additional capital at that time. In addition, if the Company raises additional funds through collaborations, strategic alliances or licensing arrangements with third parties, it may have to relinquish valuable rights to its technologies, future revenue streams or product candidates or to grant licenses on terms that may not be favorable to it. If the Company is unable to raise sufficient funding, it may be unable to continue to operate. There is no assurance that the Company will be successful in obtaining sufficient financing on acceptable terms and conditions to fund continuing operations, if at all. The failure of the Company to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on the Company's business, results of operations and financial condition.

2. Significant Accounting Policies

Basis of Presentation—The Company's interim financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"). In the opinion of management, the Company has made all necessary adjustments, which include normal recurring adjustments necessary for a fair statement of the Company's financial position and results of operations for the interim periods presented. Certain information and disclosures normally included in the annual financial statements prepared in accordance with GAAP have been condensed or omitted. These interim financial statements should be

read in conjunction with the audited financial statements and accompanying notes for the year ended December 31, 2014 included in the Company's Annual Report on Form 10-K. The results for the three and six months ended June 30, 2015, are not necessarily indicative of the results to be expected for a full year, any other interim periods or any future year or period.

Use of Estimates—The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from these estimates. Significant items subject to such estimates and assumptions include the assumptions utilized for the calculation of stock-based compensation, fair value of warrant liabilities and other derivative financial instruments, and calculation of accruals related to research and clinical development.

Cash and Cash Equivalents—Cash and cash equivalents consists of bank deposits and money market accounts. Cash equivalents are carried at cost which approximates fair value due to their short-term nature and which the Company believes do not have a material exposure to credit risk. The Company considers all highly liquid investments with maturities of three months or less from the date of purchase to be cash equivalents.

The Company maintains its cash and cash equivalent balances in the form of money market, savings or operating accounts with financial institutions that management believes are creditworthy. The Company's cash and cash equivalent accounts, at times, may exceed federally insured limits. The Company has not experienced any losses in such accounts. The Company believes it is not exposed to any significant credit risk on cash and cash equivalents.

Deferred Public Offering Costs—Deferred public offering costs, which consist primarily of direct, incremental legal, accounting, Securities and Exchange Commission ("SEC") and NASDAQ Global Market ("NASDAQ") fees relating to the IPO and issuance of the 2020 Convertible Notes, were capitalized as a component of other assets in the accompanying balance sheet as of December 31, 2014. At December 31, 2014, the Company had $1,846 of deferred public offering costs. In the six months ended June 30, 2015, the Company incurred an additional $1,128 of public offering costs and allocated $2,347 of the aggregate public offering costs to the equity offering and $627 to the debt offering which were recorded as deferred financing costs and are being amortized to interest expense over the term of the 2020 Convertible Notes.

Deferred Financing Costs—Financing costs incurred in connection with the Company's notes payable, Convertible Bridge Notes and 2020 Convertible Notes were capitalized at the inception of the notes and are amortized over the term of the respective notes using the effective interest rate method. Amortization of deferred financing costs were $44 and $55 in the three months ended June 30, 2015 and 2014, respectively, and $92 and $106 in the six months ended June 30, 2015 and 2014, respectively.

Research and Development Costs—Research and development costs are charged to expense as incurred and include, but are not limited to:

- employee-related expenses including salaries, benefits, travel and stock-based compensation expense for research and development personnel;
- expenses incurred under agreements with contract research organizations that conduct clinical and preclinical studies, contract manufacturing organizations and consultants;
- costs associated with preclinical and development activities; and
- costs associated with regulatory operations.

Costs for certain development activities, such as clinical studies, are recognized based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations, and information provided to the Company by its vendors on their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the patterns of costs incurred, and are reflected in the financial statements as accrued expenses, or prepaid expenses and other current assets, if the related services have not been provided.

Stock-Based Compensation—The Company measures the cost of employee services received in exchange for an award of equity instruments based on the fair value of the award on the grant date. That cost is recognized on a straight-line basis over the period during which the employee is required to provide service in exchange for the award. The fair value of options on the date of grant is calculated using the Black-Scholes option pricing model based on key assumptions such as stock price, expected volatility and expected term. The Company's estimates of these assumptions are primarily based on third-party valuations, historical data, peer company data and judgment regarding future trends and factors.

The Company accounts for stock options issued to non-employees in accordance with the provisions of the Financial Accounting Standards Board ("FASB") Accounting Standard Codification ("ASC") 505-50, *Equity-Based Payments to Non-employees*, which requires valuing the stock options on their grant date and measuring such stock options at their current fair value as they vest.

Fair Value Measurements—The Company is required to disclose information on all assets and liabilities reported at fair value that enables an assessment of the inputs used in determining the reported fair values. ASC 820, *Fair Value Measurements and Disclosures* ("ASC 820"), establishes a hierarchy of inputs used when available. Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the asset or liability, and are developed based on the best information available in the circumstances. The fair value hierarchy applies only to the valuation inputs used in determining the reported fair value of the investments and is not a measure of the investment credit quality. The three levels of the fair value hierarchy are described below:

Level 1—Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date.

Level 2—Valuations based on quoted prices for similar assets or liabilities in markets that are not active or for which all significant inputs are observable, either directly or indirectly.

Level 3—Valuations that require inputs that reflect the Company's own assumptions that are both significant to the fair value measurement and unobservable.

To the extent that valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. The fair value of the Company's financial instruments, including cash and cash equivalents, accounts payable and accrued expenses approximate their respective carrying values due to the short-term nature of these instruments. The Company's assets and liabilities measured at fair value on a recurring basis include its warrant liabilities, convertible notes redemption rights derivative and 2020 Convertible Notes derivative liability (see Note 8).

Derivative Financial Instruments—All derivatives are recorded as assets or liabilities at fair value, and the changes in fair value are immediately included in earnings, as the derivatives had not been formally designated as hedges for accounting purposes. The Company's derivative financial instruments include bifurcated embedded derivatives that were identified within the 2020 Convertible Notes and the Convertible Bridge Notes (see Notes 5, 8 and 9).

Net loss per share—The Company calculates net loss per share in accordance with ASC 260, *Earnings per Share*. Basic earnings (loss) per share ("EPS") is calculated by dividing the net income or loss applicable to common stockholders by the weighted average number of common shares outstanding for the period, without consideration of unissued common stock equivalents. The net loss applicable to common stockholders is determined by the reported net loss for the period and deducting dividends accrued and accretion of preferred stock. Diluted EPS is calculated by adjusting the weighted average common shares outstanding for the dilutive effect of common stock options, warrants, and convertible preferred stock and accrued but unpaid convertible preferred stock dividends. In periods where a net loss is recorded, no effect is given to potentially dilutive securities, as their effect would be anti-dilutive.

The following table sets forth the computation of basic and diluted earnings (loss) per share attributable to the Company's common stockholders:

	For the three months ended June 30,		For the six months ended June 30,	
	2015	2014	2015	2014
	(in thousands, except share and per share data)			
Numerator:				
Net loss	$ (2,387)	$ (2,847)	$ (3,849)	$ (4,995)
Accretion and dividends on convertible preferred stock	—	(1,037)	(130)	(2,030)
Net loss applicable to common stockholders	(2,387)	(3,884)	(3,979)	(7,025)
Denominator:				
Weighted average common shares outstanding - basic and diluted	16,327,003	1,020,088	12,026,183	1,020,088
Net loss per share applicable to common stockholders - basic and diluted	$ (0.15)	$ (3.81)	$ (0.33)	$ (6.89)

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

	Three months ended June 30,		Six months ended June 30,	
	2015	2014	2015	2014
Series AA preferred stock	—	7,037,874	—	7,037,874
Series X preferred stock	—	466,319	—	466,319
Shares issuable upon conversion of the 2020 Convertible Notes	3,333,333	—	3,333,333	—
Warrants exercisable for common stock	56,408	266,428	56,408	266,428
Stock options	1,394,075	11,835	1,394,075	11,835
Total	4,783,816	7,782,456	4,783,816	7,782,456

Subsequent Events—The Company considers events or transactions that occur after the balance sheet date but prior to the issuance of the financial statements to provide additional evidence relative to certain estimates or to identify matters that require additional disclosure. The Company has completed an evaluation of all subsequent events through the date the financial statements were issued.

3. Property and Equipment, net

Property and equipment, net, at June 30, 2015 and December 31, 2014, consisted of the following:

	Useful lives	June 30, 2015	December 31, 2014
		(in thousands)	
Laboratory equipment	5 years	$ 16	$ —
Office equipment	5 years	14	—
		30	—
Less: accumulated depreciation		(1)	
Property and equipment, net		$ 29	$ —

Depreciation expense for property and equipment was $1 for the three and six month periods ended June 30, 2015, and $0 for the three and six month periods ended June 30, 2014, respectively.

4. Accrued Expenses

Accrued expenses at June 30, 2015 and December 31, 2014, consisted of the following:

	June 30, 2015	December 31, 2014
	(in thousands)	
Research and development	$ 110	$ 116
Government payable	436	421
Compensation and benefits	563	293
Professional fees	156	155
Other	8	7
Total	$1,273	$ 992

5. Debt

2020 Convertible Notes

On February 23, 2015, the Company issued an aggregate of $20,000 of the 2020 Convertible Notes pursuant to its IPO. On March 24, 2015, the Company issued an additional $1,000 of 2020 Convertible Notes pursuant to the exercise of the underwriters' overallotment option. The 2020 Convertible Notes mature on February 15, 2020 ("Maturity Date"), are unsecured and accrue interest at a rate of 5.0% per annum, payable semi-annually on February 15 and August 15 of each year. In connection with the issuance of the 2020 Convertible Notes, the Company incurred $2,097 of financing costs which were recorded in other assets on the balance sheet.

Each holder of a 2020 Convertible Note (the "Holder"), has the option to convert all or any portion of such note at an initial conversion rate of 158.7302 shares of the Company's common stock per $1 principal amount of 2020 Convertible Notes (the "Conversion Rate"). The Conversion Rate is subject to adjustment from time to time upon the occurrence of certain events, including the issuance of stock dividends and payment of cash dividends. For any conversion that occurs on or after July 23, 2015, the Company will, in addition to the other consideration payable, make an interest make-whole payment (the "Interest Make-Whole Payment") to such converting Holder equal to the sum of the present values of the scheduled payments of interest that would have been made on the notes to be converted had such notes remained outstanding from the date of the conversion (the "Conversion Date") through the earlier of (i) the date that is three years after the Conversion Date and (ii) the Maturity Date if the Notes had not been so converted or otherwise repurchased. Present values for the Interest Make-Whole Payment will be calculated using a discount rate equal to 2%. The Company may satisfy its obligation to pay any Interest Make-Whole Payment, at its election, in cash, shares of common stock or a combination thereof.

The 2020 Convertible Notes are convertible, at the holder's option, upon a fundamental change ("Fundamental Change"), as defined in the Indenture ("Indenture"). If a holder elects to convert its notes upon a Fundamental Change, the Company shall increase the Conversion Rate for the Notes so surrendered for conversion by a number of additional shares of common stock by which the Conversion Rate shall be increased per $1 principal amount of notes for each stock price and make-whole Fundamental Change effective date as set forth in the Indenture. The additional shares range from 7.9364 to 0.

Upon a Fundamental Change, each Holder shall have the right to require the Company to repurchase for cash all of such Holder's notes, or any portion thereof that is equal to $1 or an integral multiple of $1. The repurchase price of the notes will equal 100% of the principal amount thereof, plus accrued and unpaid interest thereon. However, if the repurchase occurs after a regular record date for an interest payment, but before the distribution date of that interest payment, the Holder will receive the regular interest payment and the repurchase price will only equal 100% of the principal amount of the notes to be repurchased.

The 2020 Convertible Notes can be redeemed at the holder's option upon an event of default ("Event of Default"). If an Event of Default (other than certain events of bankruptcy, insolvency or reorganization involving the Company) occurs and is continuing, the Trustee by notice to the Company, or the holders of at least 25% in principal amount of the outstanding notes by written notice to the Company and the Trustee, may declare 100% of the principal and accrued and unpaid interest, if any, on all of the notes to be due and payable immediately. Upon the occurrence of certain Events of Default relating to bankruptcy, insolvency or reorganization involving the Company, 100% of the principal and accrued and unpaid interest, if any, on all of the notes will become due and payable automatically.

The Indenture provides that, to the extent the Company elects and for up to 180 days, the sole remedy for an Event of Default relating to certain failures by the Company to comply with certain reporting covenants in the Indenture consists exclusively of the right to receive additional interest ("Additional Interest") on the notes. The Additional Interest consists of interest at an additional rate of 0.25% per annum for the first 90 days after the Event of Default. For the 91st to 180th day after the Event of Default the Additional Interest shall consist of interest at an additional rate of 0.50% per annum. After 180 days, if the Event of Default is not cured or waived, the notes are subject to acceleration as provided in Section 6.02 of the Indenture.

The Company determined that the conversion option, Interest Make-Whole Payments and the Additional Interest were embedded derivatives that require bifurcation and separate accounting under ASC 815, *Derivatives and Hedging*. Based on the characteristics of the (i) conversion option including make-whole provision, (ii) the Additional Interest, and (iii) the notes, the Company estimated the fair value of the conversion option including make-whole and the Additional Interest using the "with" and "without" method. Using this methodology, the Company first valued the notes with the conversion option including make-whole provision but excluding the Additional Interest (the "with" scenario) and subsequently valued the notes without the conversion option including make-whole provision and excluding the Additional Interest (the "without" scenario). The difference between the fair values of the notes in the "with" and "without" scenarios was the concluded fair value of the conversion option including make-whole provision as of the measurement date. The Company developed an estimate of fair value for the 2020 Convertible Notes excluding the Additional Interest using a binomial lattice model. The Company modeled the decision to convert or hold by considering the maximum of the conversion or hold value at every node of the lattice in which the notes are convertible and choosing the action that maximizes the return to the notes' holders. The significant assumptions used in the binomial model were: the market yield and the expected volatility.

The Company estimated the fair value of the Additional Interest using an income approach, specifically, the risk-neutral debt valuation method that is used to derive the value of a debt instrument using the expected cash flows and the risk-free rate. The significant assumptions used in estimating the expected cash flows were: the market yield used to determine the risk-neutral probability of default and the expected recovery rate upon default.

The Company recorded $11,850 as the fair value of the combined embedded derivative liability on February 23, 2015, with a corresponding amount recorded as a discount to the 2020 Convertible Notes, related to the initial issuance of the 2020 Convertible Notes. The Company recorded approximately $573 of additional derivative liability and discount to the 2020 Convertible Notes as the fair value of the combined embedded derivative on March 24, 2015 upon the issuance of additional 2020 Convertible Notes for the exercise of the underwriters' overallotment option. The deferred financing costs and the debt discount were recorded in other assets and are being amortized to interest expense over the life of the 2020 Convertible Notes using the effective interest method. Changes in the fair value of the combined embedded derivative liability are recorded in earnings in the period in which the changes occur.

As of June 30, 2015, the fair value of the combined embedded derivative liability was $8,567. The change in the estimated fair value of the combined embedded derivative liability for the three and six months ended June 30, 2015, was $1,859 and $3,856, respectively. Interest expense related to the 2020 Convertible Notes for the three months ended June 30, 2015, was $565, including $44 related to amortization of the issuance costs and $259 related to amortization of the debt discount. Interest expense related to the 2020 Convertible Notes for the six months ended June 30, 2015, was $774, including $59 related to amortization of the issuance costs and $349 related to amortization of the debt discount. As of June 30, 2015, the balance of debt discount and issuance costs were $12,074 and $2,038, respectively. At June 30, 2015, interest accrued on the 2020 Convertible Notes was $366 and is reflected in accrued interest on the balance sheet.

The following table summarizes how the 2020 Convertible Notes are reflected on the balance sheet at June 30, 2015:

	June 30, 2015 (in thousands)
Gross proceeds	$ 21,000
Initial value of embedded derivatives	(12,423)
Amortization of debt discount	349
Carrying value	$ 8,926

In July and August 2015, the 2020 Convertible Notes fully converted into shares of common stock (see Note 11).

Convertible Bridge Notes

In December 2014, the Company sold an aggregate of $2,000 of subordinated convertible promissory notes to existing stockholders (the "Convertible Bridge Notes"). The Convertible Bridge Notes mature on June 30, 2015, and accrue interest at the rate of 8% per annum and are subordinate to all other senior indebtedness of the Company. Upon the closing of an IPO of common stock of at least $40,000 in gross proceeds, all outstanding principal and accrued interest thereon will automatically convert into common stock at the IPO price.

Pursuant to the IPO in February 2015, the Convertible Bridge Notes were converted into 337,932 shares of common stock based upon the IPO common share offering price of $6.00. For the six months ended June 30, 2015, the Company reflected interest expense related to the Convertible Bridge Notes (i) $23 related to the 8% coupon rate and (ii) $128 of amortization of the initial fair value of the redemption rights derivative and issuance costs. In the six months ended June 30, 2015, in connection with the conversion of the Convertible Bridge Notes into common stock, the Company reflected a (i) a $480 gain in change in fair value of the of the Convertible Bridge Notes redemption rights derivative from the write off of the derivative and (ii) a loss on extinguishment of debt of $360 from the acceleration of the unamortized balance of the debt discount and issuance costs.

Notes Payable

On June 28, 2013, the Company entered into two Loan and Security Agreements (the "Loan Agreements" or "Loans") with two financial entities (the "Lenders") pursuant to which the Company issued Loans for $3,500 to each lender and received proceeds of $6,915 net of costs and fees payable to the lenders. The Loans bear interest at a rate per annum of 11.0%. The Loans mature on October 1, 2016 and required interest-only payments for the initial 12 months and thereafter required repayment of the principal balance with interest in 27 monthly installments. Also, upon full repayment or maturity of the Loans, the Lenders are due a termination payment of 3.0% of the initial principal amount of the Loans, or $210 (the "Loan Termination Payment").

In connection with the Loan Agreements, the Company issued to the Lenders fully-vested warrants to purchase either, at the election of the warrant holder, (i) 228,906 shares of the Company's Series AA preferred stock at an exercise price of $1.529 per share, or (ii) $350 of stock in the next round stock, as defined in the Loan Agreements, at a price that is the lowest effective price per share that is offered in the next round. The warrants expire on the earlier of (i) ten years after the date of grant, or (ii) immediately prior to an acquisition transaction, as defined in the warrants. The Company determined that the warrants should initially be classified as a liability based upon the nature of the underlying Series AA preferred stock.

In connection with the Company's IPO in February 2015, the Company exercised its right to terminate the Loan Agreements by paying the $5,347 principal balance due, the $210 Loan Termination Payment, a $160 prepayment fee calculated as 3% of the principal balance due at the time of the termination, plus $23 of interest accrued from February 1, 2015 through the payoff date. The Company made a scheduled principal payment of $243 in January 2015.

For the six months ended June 30, 2015, interest expense related to the Loan Agreements was $115, including $26 related to accretion of the debt discount and termination payment. Additionally in the six months ended June 30, 2015, the Company recorded a charge for loss on extinguishment of debt of $322 related to the write-off of the unamortized debt discount.

For the three months ended June 30, 2014, interest expense related to the Loan Agreements was $248, including $55 related to accretion of the debt discount and termination payment. For the six months ended June 30, 2014, interest expense related to the Loan Agreements was $491, including $106 related to accretion of the debt discount and termination payment.

Subsequent to the Company's IPO, the warrants issued to the lenders became exercisable for 56,408 shares of common stock at $6.204 per share. The Company calculated the fair value of the warrants at the IPO date using a Black Scholes model using the following assumptions: a fair value of $6.00 per share (the IPO price of the Company's common stock), 8.4 years to maturity, 1.70% risk-free rate, and 60% volatility. The Company determined the fair value of the warrant liability at the IPO date to be $215 and recorded a gain on change in fair value of warrant liabilities of $267 in the statement of operations for the six months ended June 30, 2015. The Company determined that subsequent to this change, the warrants were exercisable at a fixed price for a fixed number of shares of common stock and qualified for equity classification under the accounting guidance, and the fair value of $215 was reclassified to additional paid-in capital as of the IPO date during the six months ended June 30, 2015.

6. Equity

Authorized Shares

As of December 31, 2014, the authorized stock of the Company was 43,509,727 shares of common stock, $0.01 par value per share, and 28,659,924 shares of preferred stock, $0.001 par value per share, of which 25,757,874 shares are authorized Series AA redeemable convertible preferred stock (the "Series AA preferred stock") and 2,902,050 shares are authorized as Series X redeemable convertible preferred stock (the "Series X preferred stock") (collectively, the "Preferred Stock").

In February 2015, the Company's Board of Directors and stockholders approved an amendment of the Company's certificate of incorporation such that upon the closing of the IPO, the Company's authorized capital stock will consist of 120,000,000 shares of common stock, par value $0.01 per share, and 5,000,000 shares of undesignated preferred stock, par value $0.001 per share.

Reverse Stock Splits

In November 2014, the Board of Directors and the stockholders of the Company approved a 1-for-3.39 reverse stock split of the Company's outstanding common stock and in January 2015, the Board of Directors and the stockholders of the Company approved a 1-for-1.197 reverse stock split of the Company's outstanding common stock. Shares of common stock underlying outstanding stock options were proportionally reduced and the respective exercise prices were proportionally increased in accordance with the terms of the option agreements. The Company's historical share and per share information has been retroactively adjusted in the financial statements presented to give effect to these reverse stock splits, including reclassifying an amount equal to the reduction in par value to additional paid-in capital.

Preferred Stock

Pursuant to the IPO, all of the Company's outstanding 25,949,333 shares of Series AA and Series X preferred stock, including all accrued and unpaid dividends thereon, automatically converted into 8,002,650 shares of common stock. Pursuant to these conversions, the $46,383 carrying value of the Series AA preferred stock at the time of the IPO was reclassified as $75 to common stock par value and $46,308 additional paid-in capital and the $548 carrying value of the Series X preferred stock at the time of the IPO was reclassified as $5 to common stock par value and $543 additional paid-in capital.

During the year ended December 31, 2014, the Company modified the terms of 558,862 shares of Series X preferred stock such that the Company's repurchase right relative to those shares expired upon consummation of the IPO. The Company estimated the fair value of the modified award at the modification date to be $950 and recognized this amount as stock-based compensation expense in the six months ended June 30, 2015.

Common Stock

All preferences, voting powers, relative, participating, optional, or other specific rights and privileges, limitations, or restrictions of the common stock are expressly subject to those that may be fixed with respect to any shares of preferred stock. Common stockholders are entitled to one vote per share, and to receive dividends, when and if declared by the Board of Directors. At June 30, 2015 and December 31, 2014, there were 16,327,003 and 1,020,088 shares of common stock outstanding, respectively.

2014 Stock Option and Incentive Plan

In August 2014, the Company's Board of Directors adopted the 2014 Stock Option and Incentive Plan (the "2014 Plan") for the issuance of incentive and non-qualified stock options, restricted stock, and other equity awards, all for common stock, as determined by the Board of Directors to employees, officers, directors, consultants, and advisors of the Company and its subsidiaries. In November 2014, the Board of Directors increased the number of shares available for grant under the terms of the 2014 Plan to the number of shares that represents 13.7% of the outstanding common stock after giving effect to the issuance of shares relating to the Company's then-proposed IPO (not including any shares purchased by the underwriters pursuant to their overallotment option). Subsequent to the IPO in February 2015, there were 2,175,216 shares available for grant under the 2014 Plan. The 2014 Plan expires in August 2024.

On August 28, 2014, the Board of Directors granted 840,975, ten-year term, stock options to officers of the Company at an exercise price of $4.342 per share, the fair market value of the common stock as determined by the Board of Directors, on the condition that the options would be of no further force and effect if the Company had not consummated an IPO prior to the one-year anniversary of the grant date (the "IPO Condition"). The IPO Condition was met upon the Company's February 2015 IPO. These stock options will vest 25% on the one-year anniversary of the grant date and the remaining 75% will vest equally over the following 36 monthly anniversaries. Additionally on August 28, 2014, the Board of Directors granted an aggregate of 59,142 stock options to the directors that were fully vested on the date of the grant.

The fair value of the stock options granted during 2014 was estimated on the grant date using a Black-Scholes stock option pricing model based on the following assumptions: an expected term of 5 to 6.25 years; expected stock price volatility of 83.3% to 92.5%; a risk free rate of 1.63% to 1.84%; and a dividend yield of 0%. The Company will recognize $2,798 of stock-based compensation expense for these stock options on a straight-line basis commencing upon the grant date in August 2014 through the final vesting date in August 2018. As a result of the resolution of the IPO Condition, the six months ended June 30, 2015, reflects stock compensation expense calculated from the grant date in August 2014 through June 30, 2015.

During the three and six months ended June 30, 2015, the Board of Directors granted a total of 483,000, ten-year term, stock options to employees and directors of the Company. The fair value of each stock option granted was estimated on the grant date using a Black-Scholes stock option pricing model based on the following assumptions: an expected term of 5.31 to 6.08 years; expected stock price volatility of 97.6% to 101.1%; a risk free rate of 1.63% to 1.85%; and a dividend yield of 0%. The Company will recognize $1,983 of stock-based compensation expense for these stock options on a straight-line basis commencing upon the grant dates through the final vesting dates.

The following table summarizes activity for the six months ended June 30, 2015, under the 2014 Plan:

	Number of Shares	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value
Options outstanding at December 31, 2014	900,117	$ 4.342	$ 970
Granted during the period	483,000	5.190	—
Exercised during the period	—	—	—
Expired during the period	—	—	—
Options outstanding at June 30, 2015	1,383,117	$ 4.638	$ 502
Options exercisable at June 30, 2015	59,142	$ 4.342	$ 33
Weighted-average years remaining on contractual life	9.5		
Unrecognized compensation cost related to non-vested stock options	$ 4,176		

Aggregate intrinsic value is based on $4.90 per share, the closing price of common stock on June 30, 2015.

For the three months ended June 30, 2015, the Company recorded aggregate stock compensation expense of $194, of which $98 was recorded in general and administrative expense and $96 in research and development expense. For the six months ended June 30, 2015, the Company recorded aggregate stock compensation expense of $608, of which $316 was recorded in general and administrative expense and $292 in research and development expense.

2004 Stock Option and Incentive Plan

The Company has outstanding stock options pursuant to its 2004 Stock Option and Incentive Plan. The following table summarizes activity for the six months ended June 30, 2015, under the 2004 Plan:

	Number of Shares	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value
Options outstanding at December 31, 2014	10,958	$ 40.578	$ —
Granted during the period	—	—	—
Exercised during the period	—	—	—
Expired during the period	—	—	—
Options outstanding at June 30, 2015	10,958	$ 40.578	$ —
Options exercisable at June 30, 2015	10,958	$ 40.578	$ —
Weighted-average years remaining on contractual life	2.8		
Unrecognized compensation cost related to non-vested stock options	$ —		

The exercise price exceeds the $4.90 closing price of common stock on June 30, 2015, therefore there is no intrinsic value of the outstanding 2004 Plan stock options.

Employee Stock Purchase Plan

In November 2014, the Company's Board of Directors adopted and the stockholders approved the 2014 Employee Stock Purchase Plan ("ESPP"). The Company's Board of Directors has authorized the issuance of a number of shares of common stock issuable under the ESPP to the number that represents 1% of our outstanding common stock outstanding after the IPO, or 160,276 shares. The ESPP provides that the number of shares reserved and available for issuance under the ESPP shall be cumulatively increased each January 1, beginning on January 1, 2016, by the lesser of (i) 600,000 shares of common stock or (ii) the number of shares necessary to set the number of shares of Common Stock under the Plan at 1% percent of the outstanding number of shares as of January 1 of the applicable year. However, the Board of Directors reserves the right to determine that there will be no increase for any year or that any increase will be for a lesser number of shares. As of June 30, 2015, no shares have been issued pursuant to the ESPP.

7. Commitments and Contingencies

Operating leases

The Company leases office space in Lexington, Massachusetts under a lease agreement expiring in September 2015. Rent expense for the three and six months ended June 30, 2015, was $20 and $35, respectively. Rent expense for the three and six months ended June 30, 2014, was $12 and $27, respectively.

In May 2015, the Company entered into a lease agreement for 11,125 square feet for its new headquarters in Lexington, Massachusetts. The Company expects to occupy this space in September 2015, at which time its rental obligations will commence. The lease term is 90 months and the Company has the right to extend the term for one period of five years. Aggregate rental payments over the term of the lease are approximately $2,100, including approximately $209 due in the first twelve months of the lease. The lease also provides that the Company will be responsible for the operating expenses and real estate taxes, to the extent in excess of base-year amounts, and electricity attributable to the premises.

Indemnification Arrangements

As permitted under Delaware law, the Company's bylaws provide that the Company will indemnify any director, officer, employee or agent of the Company or anyone serving in these capacities. The maximum potential amount of future payments the Company could be required to pay is unlimited. The Company has insurance that reduces its monetary exposure and would enable it to recover a portion of any future amounts paid. As a result, the Company believes that the estimated fair value of these indemnification commitments is minimal.

Throughout the normal course of business, the Company has agreements with vendors that provide goods and services required by the Company to run its business. In some instances, vendor agreements include language that requires the Company to indemnify the vendor from certain damages caused by the Company's use of the vendor's goods and/or services. The Company has insurance that would allow it to recover a portion of any future amounts that could arise from these indemnifications. As a result, the Company believes that the estimated fair value of these indemnification commitments is minimal.

8. Fair Value of Financial Measurements

Items measured at fair value on a recurring basis are convertible preferred stock warrant liabilities, the Convertible Bridge Notes redemption rights derivative and the 2020 Convertible Notes derivative liability.

The following table sets forth the Company's financial instruments that were measured at fair value on a recurring basis by level within the fair value hierarchy:

	Fair Value Measurements at June 30, 2015			
	Total	Level 1	Level 2	Level 3
Liabilities:				
2020 Convertible Notes derivative liability	$8,567	$ —	$ —	$8,567

	Fair Value Measurements at December 31, 2014			
	Total	Level 1	Level 2	Level 3
Liabilities:				
Convertible preferred stock warrant liability	$482	$ —	$ —	$ 482
Convertible Bridge Notes redemption rights derivative	$480	$ —	$ —	$ 480

2020 Convertible Notes derivative liability

The fair value methodologies related to the 2020 Convertible Notes derivative liability are discussed in Note 5.

Convertible preferred stock warrant liability

As of December 31, 2013, June 30, 2014, and December 31, 2014, the Company had outstanding warrants to purchase Series AA preferred stock in connection with Series AA preferred stock issued in 2013 and the Loan Agreements. The Series AA warrant liabilities were recorded at their fair value on the date of issuance and are remeasured on each subsequent balance sheet date and as of the warrant exercise date, with fair value changes recognized as income (decrease in fair value) or expense (increase in fair value) in other income (expense) in the statements of operations.

As of December 31, 2013, June 30, 2014, and December 31, 2014, the Company used a hybrid valuation model in which a Monte Carlo simulation was used to calculate the fair value of the Company's equity securities under three scenarios including: (i) an IPO scenario, (ii) a merger or acquisition scenario or (iii) a stay private scenario. The Company then probability-weighted each equity value derived from the Monte Carlo simulation based upon the Company's estimate of the likelihood of the exit scenario occurring.

The assumptions used in calculating the estimated fair value of the warrants represent the Company's best estimates and include probabilities of settlement scenarios, enterprise value, time to liquidity, risk-free interest rates, discount for lack of marketability and volatility. The estimates are based, in part, on subjective assumptions and could differ materially in the future. Generally, increases or decreases in the fair value of the underlying convertible preferred stock would result in a directionally similar impact in the fair value measurement of the warrant liability. The following table details the assumptions used in the Monte Carlo simulation models used to estimate the fair value of the Series AA preferred stock warrants at December 31, 2013, June 30, 2014, and December 31, 2014:

	December 31, 2013	June 30, 2014	December 31, 2014
Volatility	60%	65%	65% - 70%
Expected term (years)	1.00 - 1.25	0.50 - 0.75	0.17 - 0.50
Expected dividend yield	0.00%	0.00%	0.00%
Risk-free rate	0.13 - 0.19%	0.06% - 0.09%	0.02% - 0.03%

In addition to the assumptions above, the Company's estimated fair value of the Series AA preferred stock warrant liabilities is calculated using other key assumptions including the probability of an exit event, the enterprise value as determined on an income approach, and a discount for lack of marketability. Management, with the assistance of an independent valuation firm, made these subjective determinations based on available current information.

Convertible Bridge Notes redemption rights derivative

The Convertible Bridge Notes redemption rights derivative required separate accounting and was valued using a single income valuation approach. The Company estimated the fair value of the redemption rights derivative using a ''with and without'' income valuation approach. Under this approach, the Company estimated the present value of the fixed interest rate debt based on the fair value of similar debt instruments excluding the embedded feature. This amount was then compared to the fair value of the debt instrument including the embedded feature using a probability weighted approach by assigning each embedded derivative feature a probability of occurrence, with consideration provided for the settlement amount including conversion discounts, prepayment penalties, the expected life of the liability and the applicable discount rate.

As of December 31, 2014, the Company ascribed a probability of occurrence to the Change in Control Redemption Feature of 25%. The expected life of the feature was the remaining term of the debt and the discount rate was 18.9%. The Company classified the liability within Level 3 of the fair value hierarchy as the probability factor and the discount rate are unobservable inputs and significant to the valuation model. As of December 31, 2014, the fair value of the embedded derivative was $480. Pursuant to the IPO, the Convertible Bridge Notes were redeemed.

During the periods presented, the Company has not changed the manner in which it values liabilities that are measured at fair value using Level 3 inputs. The Company recognizes transfers between levels of the fair value hierarchy as of the end of the reporting period. There were no transfers within the hierarchy during any of the years presented.

The following table reflects the change in the Company's Level 3 liabilities for the six months ended June 30, 2015 and 2014:

	Convertible preferred stock warrant liabilities	Convertible Bridge Notes redemption rights derivative	2020 Convertible Notes derivative liability
Balance at December 31, 2014	$ 482	$ 480	$ —
Issuance of 2020 Convertible Notes	—	—	12,423
Change in fair value	(267)	(480)	(3,856)
Reclassification to stockholders' equity	(215)	—	—
Balance at June 30, 2015	—	—	8,567

	Convertible preferred stock warrant liabilities	Convertible Bridge Notes redemption rights derivative	2020 Convertible Notes derivative liability
Balance at December 31, 2013	$ 1,888	$ —	$ —
Change in fair value	598	—	—
Balance at June 30, 2014	2,486	—	—

9. Derivative Financial Instruments

The Company determined that certain embedded features related to the 2020 Convertible Notes and the Convertible Bridge Notes are derivative financial instruments.

Fair values of derivative instruments not designated as hedging instruments consist of the following:

Liability derivative financial instruments	Balance Sheet Location	Fair Value
December 31, 2014:		
Convertible Bridge Notes redemption rights derivative	Convertible Bridge Notes redemption rights derivative	$ 480
June 30, 2015:		
2020 Convertible Notes derivative liability	2020 Convertible Notes derivative liability	$ 8,567

The effect of derivative instruments not designated as hedging instruments on the statement of operations for the three and six months ended June 30, 2015, consist of the following:

Derivative financial instruments not designated as hedging instruments	Location of gain or loss recognized in income on derivative financial instrument	Amount of gain or (loss) recognized in income on derivative financial instrument	
		For the three months ended June 30, 2015	For the six months ended June 30, 2015
2020 Convertible Notes derivative liability	Change in fair value of 2020 Convertible Notes derivative liability	$ 1,859	$ 3,856
Convertible Bridge Notes	Change in fair value of Convertible Bridge Notes redemption rights derivative	$ —	$ 480

See Notes 5 and 8 for additional discussion regarding the accounting for and valuation of these derivative financial instruments.

10. Management Incentive Plan

In August 2014, the Company adopted the Amended and Restated 2014 Management Incentive Plan (the “MIP”) in which certain of our named executive officers participate. Pursuant to the MIP, upon a “change in control” (as defined in the MIP), a bonus pool will be created from the proceeds received in connection with such change in control (ranging from 7 percent to 9.75 percent of transaction proceeds, depending upon the level of transaction proceeds received in the transaction), and each participant is entitled to receive a bonus equal to a certain percentage of such bonus pool. The MIP terminated automatically upon the IPO in February 2015.

11. Subsequent Events

2020 Convertible Notes

In July and August 2015, holders of $21.0 million principal amount of the 2020 Convertible Notes elected to convert the principal into approximately 3.33 million shares of common stock. In addition, the Make-Whole Interest Payment was settled with shares of common stock, at the election of the Company, resulting in the issuance of approximately 0.53 million additional shares of common stock.

S-1 Registration Statement

On July 31, 2015, the Company filed a registration statement with the SEC on Form S-1 to sell up to $57.5 million of our common stock.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our condensed financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K for the year ended December 31, 2014.

Overview

We are a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of therapies for glaucoma. Glaucoma is a disease of the eye that is typically characterized by structural evidence of optic nerve damage, vision loss and consistently elevated intraocular pressure ("IOP"). Our lead product candidate, *trabodenoson*, is a first-in-class selective adenosine mimetic that we rationally designed to lower IOP by restoring the eye's natural pressure control mechanism. Our product pipeline includes *trabodenoson* monotherapy delivered in an eye drop formulation, as well as a fixed-dose combination ("FDC") of *trabodenoson* with *latanoprost* given once-daily. Our completed Phase 2 trial of *trabodenoson* co-administered with *latanoprost*, a prostaglandin analogue ("PGA"), demonstrated IOP-lowering in patients who have previously had inadequate response to *latanoprost*. These patients represent PGA poor-responders, as evidenced by persistently elevated IOP at levels that typically require the addition of a second drug to further lower IOP.

We had an End-of-Phase 2 meeting with the U.S. Food and Drug Administration ("FDA") in the first half of 2015 to discuss our Phase 3 program for trabodenoson monotherapy and to confirm the design and endpoints for the Phase 3 pivotal trials. Our End-of-Phase 2 meeting was a critical milestone for advancing the development of *trabodenoson*. At the meeting, we reached agreement on the design of our initial Phase 3 trial, as well as the overall regulatory path for trabodenoson. For our first Phase 3 trial, we agreed to three doses of trabodenoson to be tested against placebo as the primary comparator for statistical purposes. We plan to start this trial for trabodenoson monotherapy in the fourth quarter of 2015.

In February 2015, we completed our initial public offering (the "IPO") of (i) 6,667,000 shares of common stock at a price of $6.00 per share and (ii) $20.0 million aggregate principal amount of 5.0% Convertible Senior Notes due 2020 (the "2020 Convertible Notes"). In March 2015 the underwriters purchased 299,333 shares of common stock at $6.00 per share and $1.0 million of the 2020 Convertible Notes pursuant to exercises of their overallotment options. We received net proceeds of $36.5 million after deducting underwriting discounts and offering-related costs, from its equity issuances and $18.9 million in net proceeds, after deducting underwriting discounts and offering-related costs, from its debt issuances (See Note 5 of Notes to Financial Statements). Prior to this we funded our operations primarily through the sale of preferred stock and issuance of convertible promissory notes and notes payable. As of June 30, 2015, the Company had an accumulated deficit of $131.9 million and cash and cash equivalents of $49.0 million. Pursuant to the IPO, all of our outstanding 25,949,333 shares of Series AA and Series X preferred stock, including all accrued and unpaid dividends thereon, automatically converted into 8,002,650 shares of common stock. We estimate we have sufficient funding to sustain operations through 2016. See "Liquidity and Capital Resources."

In July and August 2015, the $21.0 million principal amount of the 2020 Convertible Notes fully converted into shares of common stock (see Note 11).

Since our inception on July 7, 1999, we have devoted substantially all of our resources to business planning, raising capital, product research and development, applying for and obtaining government and private grants, recruiting management, research and technical staff and other personnel, acquiring operating assets, and undertaking preclinical studies and clinical trials of our lead product candidates.

We have not completed development of any product candidate and we have therefore not generated any revenues from product sales. Prior to 2012, we generated revenues primarily from research grants received from governmental agencies and private companies as well as revenue earned under licensing and research collaboration contracts. All previously recognized revenue was unrelated to our current development efforts focused on our lead product candidate, *trabodenoson*, for the treatment of glaucoma and other diseases of the eye.

Factors Affecting our Results of Operations

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we continue to invest in research and development and commence our Phase 3 program of *trabodenoson* in 2015. We also expect our expenses to increase as we complete formulation and manufacturing activities of our FDC product candidate which is expected to commence clinical trials in 2016. In addition, if we successfully launch *trabodenoson* as a monotherapy or any other product candidates, we expect to incur significant commercialization expenses related to sales, marketing, manufacturing and distribution of our products.

Furthermore, we expect to incur additional costs associated with operating as a public company. We expect operating expenses to increase substantially to support an increased infrastructure and expanded operations. Accordingly, we will need to obtain

additional funding in connection with our continuing operations. Adequate additional financing may not be available to us on acceptable terms, or at all. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or any potential future commercialization efforts. We will need to generate significant revenues to achieve profitability, and we may never do so. As a result, we expect to incur significant expenses and increasing operating losses for the foreseeable future.

Financial Overview

Revenue

We have not generated any revenue from product sales since our inception and do not expect to generate any revenue from the sale of products in the near future. Our ability to generate revenues will depend on the successful development, regulatory approval and commercialization of *trabodenoson* and any other future product candidates. Historically, we generated revenues primarily from research grants received from governmental agencies and private companies as well as revenue earned under licensing and research collaboration contracts that were unrelated to our current research and development programs.

Research and Development Expenses

Research and development expenses consist primarily of the costs associated with our research and development activities, conducting preclinical studies and clinical trials and activities related to regulatory filings. Our research and development expenses consist of:

- direct clinical and non-clinical expenses which include expenses incurred under agreements with contract research organizations (“CROs”), contract manufacturing organizations and costs associated with preclinical activities and development activities and costs associated with regulatory activities;
- employee and consultant-related expenses, including compensation, benefits, travel and stock-based compensation expense for research and development personnel as well as consultants that conduct and support clinical trials and preclinical studies; and
- facilities and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance and other supplies used in research and development activities.

We expense research and development costs as incurred. We record costs for some development activities, such as clinical trials, based on an evaluation of the progress to completion of specific tasks using data such as subject enrollment, clinical site activations or other information our vendors provide to us.

The following table summarizes our research and development expenses by type of activity for the three and six months ended June 30, 2015 and 2014:

	For the three months ended June 30,		For the six months ended June 30,	
	2015	2014	2015	2014
	(in thousands)			
Trabodenoson - direct clinical and non-clinical	$ 882	$ 1,650	$ 1,396	$ 2,873
Personnel and other expenses				
Employee and consultant-related expenses	974	195	1,464	468
Facility expenses	56	16	118	59
Other expenses	42	1	45	12
Total personnel and other expenses	1,072	212	1,627	539
Total research and development expenses	$ 1,954	$ 1,862	$ 3,023	$ 3,412

All research and development efforts and expenses for the three and six month periods ended June 30, 2015 and 2014 relate to the development of *trabodenoson*. We do not track *trabodenoson*-related expenses by product candidate. All expenses related to *trabodenoson* as a monotherapy also benefit the FDC product candidate *trabodenoson* with *latanoprost*. We have expended approximately $42 million for external development costs related to *trabodenoson* from inception through June 30, 2015.

The process of conducting the necessary clinical research to obtain regulatory approval is costly and time consuming and the successful development of our product candidates is highly uncertain. Our future research and development expenses will depend on the clinical success of our product candidates, as well as ongoing assessments of the commercial potential of such product candidates. In addition, we cannot forecast with any degree of certainty which product candidates may be subject to future

collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements. We expect our research and development expenses to increase in future periods for the foreseeable future as we seek to complete development of our lead product candidate, *trabodenoson*, further develop our other product candidates and expand our research and development personnel to focus on these product candidate development activities.

The successful development and commercialization of our product candidates is highly uncertain. This is due to the numerous risks and uncertainties associated with product development and commercialization, including the uncertainty of:

- the scope, progress, outcome and costs of our clinical trials and other research and development activities;
- the efficacy and potential advantages of our product candidates compared to alternative treatments, including any standard of care;
- the market acceptance of our product candidates;
- obtaining, maintaining, defending and enforcing patent claims and other intellectual property rights;
- significant and changing government regulation; and
- the timing, receipt and terms of any marketing approvals.

A change in the outcome of any of these variables with respect to the development of *trabodenoson* or any other product candidate that we may develop could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials or other testing beyond those that we currently contemplate for the completion of clinical development of *trabodenoson* or any other product candidate that we may develop or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development of that product candidate.

General and Administrative Expenses

General and administrative expenses consist of compensation and related benefit costs, including stock-based compensation for administrative personnel. Other significant general and administrative expenses include travel costs, professional fees for legal, patents, consulting, auditing and tax services as well as other direct and allocated expenses for rent and maintenance of facilities, insurance and other supplies used in general and administrative activities. We anticipate that our general and administrative expenses will increase in future periods to support increases in our research and development activities and as a result of increased headcount (especially in our accounting and finance departments), increased stock-based compensation charges, expanded infrastructure, increased costs for insurance, and increased legal, compliance, accounting and investor and public relations expenses associated with being a public company.

Results of Operations

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

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

	Three Months ended June 30,		Increase
	2015	2014	(Decrease)
	(in thousands)		
Operating expenses:			
Research and development	$ (1,954)	$ (1,862)	$ 92
General and administrative	(1,728)	(332)	1,396
Loss from operations	(3,682)	(2,194)	1,488
Interest expense	(564)	(248)	316
Change in fair value of warrant and derivative liabilities	1,859	(405)	(2,264)
Net loss	$ (2,387)	$ (2,847)	$ (460)

Research and Development Expenses

Research and development expenses increased $0.1 million to $2.0 million for the three months ended June 30, 2015, as compared to $1.9 million for the three months ended June 30, 2014. CRO and other direct clinical trial expenses decreased $1.6 million as a result of the completion of our Phase 2 trial in October 2014. This decrease was offset by increases in non-clinical expenses of $0.8 million primarily related to work in preparation for our upcoming Phase 3 trial, higher payroll-related and stock-based compensation expenses of $0.6 million and higher consulting expenses of $0.2 million.

General and Administrative Expenses

General and administrative expenses increased $1.4 million to $1.7 million for the three months ended June 30, 2015, as compared to $0.3 million for the three months ended June 30, 2014. This increase was related to higher payroll-related and stock-based compensation expenses of $0.4 million related to additional headcount, including our current CEO and VP of Finance, higher consulting and board of director fees of $0.3 million, higher professional fees of $0.2 million, higher recruiting fees of $0.2 million, and higher D&O insurance expenses of $0.2 million.

Interest Expense

Interest expense increased $0.3 million to $0.6 million for the three months ended June 30, 2015, as compared to $0.3 million for the three months ended June 30, 2014. Interest expense in the three months ended June 30, 2015, related to our 2020 Convertible Notes which were not outstanding in the three months ended June 30, 2014. Interest expense in the three months ended June 30, 2014, related to our notes payable which were paid and extinguished in the three months ended March 31, 2015.

Change in fair value of warrant and derivative liabilities

Change in fair value of warrant and derivative liabilities was a gain of $1.9 million in the three months ended June 30, 2015, and resulted from a $1.9 million decrease in the fair value of our 2020 Convertible Notes derivative liability. The change in fair value of warrant and derivative liabilities in the three months ended June 30, 2014, was a loss of $0.4 million and related to an increase in the value of our warrant liabilities related to warrants to purchase shares of Series AA Preferred Stock.

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

The following table summarizes the results of our operations for the six months ended June 30, 2015 and 2014:

	Six Months ended June 30,		Increase
	2015	2014	(Decrease)
	(in thousands)		
Operating expenses:			
Research and development	$ (3,023)	$ (3,412)	$ (389)
General and administrative	(3,708)	(494)	3,214
Loss from operations	(6,731)	(3,906)	2,825
Interest expense	(1,038)	(491)	547
Loss on extinguishment of debt	(683)	—	683
Change in fair value of warrant and derivative liabilities	4,603	(598)	(5,201)
Net loss	$ (3,849)	$ (4,995)	$ (1,146)

Research and Development Expenses

Research and development expenses decreased $0.4 million to $3.0 million for the six months ended June 30, 2015, as compared to $3.4 million for the six months ended June 30, 2014. CRO and other direct clinical trial expenses decreased $2.7 million as a result of the completion of our Phase 2 trial in October 2014. This decrease was partially offset by increases in non-clinical expenses of $1.2 million primarily related to work in preparation for our upcoming Phase 3 trial as well as animal toxicology studies, higher payroll-related expenses of $0.5 million related primarily to increased headcount, $0.3 million in stock-based compensation and $0.2 million in increased consulting expense.

General and Administrative Expenses

General and administrative expenses increased $3.2 million to $3.7 million for the six months ended June 30, 2015, as compared to $0.5 million for the six months ended June 30, 2014. This increase included $1.3 million in stock-based compensation of which $1.0 million related to the elimination of the Company's repurchase rights and final vesting related to the Series X preferred shares held by our former CEO and CFO pursuant to our IPO. The remaining increase was due primarily to higher payroll-related expenses of $0.5 million primarily related increased headcount, including our current CEO and VP of Finance, higher consulting and board fees of $0.4 million, higher professional fees of $0.3 million, higher recruiting fees of $0.2 million, and higher D&O insurance expenses of $0.2 million.

Interest Expense

Interest expense increased $0.5 million to $1.0 million for the six months ended June 30, 2015, as compared to $0.5 million for the six months ended June 30, 2014. The $1.0 million of expense for the six months ended June 30, 2015, was comprised of $0.8 million for coupon interest and amortization of our debt discount and deferred financing costs related to our 2020 Convertible Notes, $0.1 million related to our Convertible Bridge Notes and $0.1 million related to our notes payable. Interest expense in the six months ended June 30, 2014, related to our notes payable.

Loss on Extinguishment of Debt

The Company recorded a loss on extinguishment of debt of $0.7 million in the six months ended June 30, 2015, comprised of $0.4 million of unamortized debt discount and issuance costs related to our Convertible Bridge Notes and $0.3 million related to unamortized debt discount and issuance costs and prepayment fees related to our Notes Payable.

Change in fair value of warrant and derivative liabilities

Change in fair value of warrant and derivative liabilities was a gain of $4.6 million for the six months ended June 30, 2015, compared to a loss of $0.6 million for the six months ended June 30, 2014. The $4.6 million gain in the six months ended June 30, 2015, resulted from a $3.9 million decrease in the fair value of our 2020 Convertible Notes derivative liability, a $0.3 million decrease in our warrant liabilities related to warrants to purchase shares of Series AA Preferred Stock and a $0.5 million decrease in the value of our 2014 Bridge Notes redemption rights derivative. The $0.6 million loss in the six months ended June 30, 2014, related to the increase in the value of the warrant liabilities related to our Series AA Preferred Stock.

Liquidity and Capital Resources

Since inception, we have incurred accumulated net losses and negative cash flows from our operations. We incurred a net loss of $3.8 million for the six months ended June 30, 2015, and our accumulated deficit was $131.9 million at June 30, 2015. At June 30, 2015, we had $49.0 million of cash and cash equivalents. The Company estimates that it has sufficient funding to sustain operations through 2016.

On July 31, 2015, we filed a registration statement with the Securities and Exchange Commission on Form S-1 to sell up to $57.5 million of our common stock. We cannot predict if or when we will sell such common stock, or that it will be in this amount.

In July and August 2015, holders of $21.0 million principal amount of our 2020 Convertible Notes elected to convert the principal into approximately 3.33 million shares of common stock. In addition, the Make-Whole Interest Payment was settled with shares of common stock, at the election of the Company, resulting in the issuance of approximately 0.53 million additional shares of common stock. As a result of these conversions, we no longer have an obligation to repay the principal or make cash interest payments on these 2020 Convertible Notes.

In February 2015, we completed our IPO and concurrent note offering and in March 2015, the underwriters exercised common stock and notes overallotment options resulting in aggregate net proceeds to us of approximately $55.5 million. As of June 30, 2015, we had outstanding $21.0 million of 2020 Convertible Notes.

In December 2014, the Company sold an aggregate of $2.0 million of the Convertible Bridge Notes. In addition to other terms, the Convertible Bridge Notes had a maturity of June 30, 2015, accrued interest at the rate of 8% per annum and were subordinate to all other senior indebtedness of the Company. Upon the closing of our IPO, the Convertible Bridge Notes, including accrued interest, automatically converted into 337,932 shares of our common stock.

On June 28, 2013, we entered into notes payable agreements with two financial entities pursuant to which we issued a $3.5 million note to each lender and received net proceeds of $6.9 million. The notes bore interest at a rate of 11.0% per annum and had a maturity date of October 1, 2016. In February 2015, we paid the lenders with proceeds from our IPO a total of $5.7 million, which included $5.3 million for the remaining principal and $0.4 million for end of term and prepayment amounts and accrued interest. These notes payable agreements were then terminated.

The following table summarizes our sources and uses of cash for each of the periods presented:

	Six months ended June 30,	
	2015	2014
	(in thousands)	
Cash used in operating activities	$ (6,050)	$ (3,912)
Cash used in investing activities	(30)	—
Cash provided by financing activities	51,474	—
Net increase (decrease) in cash and equivalents	$ 45,394	$ (3,912)

Net cash used in operating activities

Net cash used in operating activities was $6.0 million for the six months ended June 30, 2015, and $3.9 million for the six months ended June 30, 2014. Net cash used in operating activities for the six months ended June 30, 2015, resulted primarily from a noncash gain related to the decrease in the fair value of our 2020 Convertible Notes derivative liability, warrant liabilities and convertible notes redemption rights derivative, aggregating to $4.6 million, our net loss of $3.8 million and a net change in operating assets and liabilities of $0.3 million. These decreases were partially offset by $1.6 million of noncash stock-based compensation, $0.6 million in noncash interest expense and a $0.5 million noncash loss on extinguishment of debt. Net cash used in operating activities for the six months ended June 30, 2014, principally resulted from our net loss of $5.0 million, partially offset by increases in noncash expenses related to changes in the fair value of our warrant liabilities of $0.6 million.

Net cash provided by financing activities

Net cash provided by financing activities was $51.5 million for the six months ended June 30, 2015, and reflects the net proceeds from the issuance of common stock in our IPO of $38.1 million and the net proceeds from our offering of 2020 Convertible Notes of $19.1 million. These net proceeds from our common stock and 2020 Convertible Notes in 2015 do not reflect an aggregate of $1.8 million of IPO-related costs incurred in 2014. Additionally in 2015, we made $5.8 million of payments related to the principal and termination of our notes payable.

Operating Capital Requirements

To date, we have not generated any revenue from product sales. We do not know when, or if, we will generate any revenue from product sales. We do not expect to generate significant revenue from product sales unless and until we obtain regulatory approval of and commercialize one of our current or future product candidates. We anticipate that we will continue to generate losses for the foreseeable future and we expect the losses to increase as we continue the development of, and seek regulatory approvals for, our product candidates and begin to commercialize any approved products. Since the closing of our IPO in February 2015, we are incurring additional costs associated with operating as a public company. In addition, subject to obtaining regulatory approval of any of our product candidates, we expect to incur significant commercialization expenses for product sales, marketing and manufacturing. Accordingly, we anticipate that we will need substantial additional funding in connection with our continuing operations.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. To the extent that we are able to raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our existing stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends and may require the issuance of warrants, which could cause potential dilution. If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or research programs 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 terminate our product development or future commercialization efforts or grant rights to develop and market products or product candidates that we would otherwise prefer to develop and market ourselves.

Contractual Obligations and Commitments

The following summarizes our significant contractual obligations as of June 30, 2015:

	Total	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years
			(in thousands)		
Current facilities lease (1)	$ 22	$ 22	$ —	$ —	$ —
2020 Convertible Notes (2)	26,239	1,039	2,100	23,100	—
New facilities lease (3)	2,145	209	509	615	812
Total	$28,406	$ 1,270	$2,609	$23,715	$ 812

(1) Amounts represent our minimum lease obligations related to our current corporate headquarters in Lexington, Massachusetts. The minimum lease payments in the table do not include related common area maintenance charges or real estate taxes, which costs are variable.

(2) Amounts represent principal and interest on our 2020 Convertible Notes. In July and August 2015, our 2020 Convertible Notes were fully converted and we no longer owe any principal or interest on the 2020 Convertible Notes.

(3) In May 2015, we entered into a lease agreement for our new headquarters in Lexington, Massachusetts. We expect to occupy our new headquarters and the lease term to commence approximately October 1, 2015. The amounts in this chart reflect this assumption.

We enter into contracts in the normal course of business with CROs and contract manufacturers to assist in the performance of our research and development activities and other services and products for operating purposes. To the extent that these contracts provide for termination on notice, and therefore are cancelable contracts, they are not included in the table of contractual obligations and commitments.

JOBS Act

Under Section 107(b) of the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"), an "emerging growth company" can delay the adoption of new or revised accounting standards until such time as those standards would apply to private companies. We have irrevocably elected not to avail ourselves of this exemption and, as a result, we will adopt new or revised accounting standards at the same time as other public companies that are not emerging growth companies. There are other exemptions and reduced reporting requirements provided by the JOBS Act that we are currently evaluating. For example, as an emerging growth company, we are exempt from Sections 14A(a) and (b) of the Exchange Act which would otherwise require us to (i) submit certain executive compensation matters to stockholder advisory votes, such as "say-on-pay," "say-on-frequency" and "golden parachutes" and (ii) disclose certain executive compensation related items such as the correlation between executive compensation and performance and comparisons of our Chief Executive Officer's compensation to our median employee compensation. We also intend to rely on an exemption from the rule requiring us to provide an auditor's attestation report on our internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and the rule requiring us to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board ("PCAOB") regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements as the auditor discussion and analysis. We will continue to remain an "emerging growth company" until the earliest of the following: December 31, 2020; the last day of the fiscal year in which our total annual gross revenue is equal to or more than $1 billion; the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

Critical Accounting Policies and Estimates

Accrued Research and Development Expenses

As part of the process of preparing our financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated costs incurred for the services when we have not yet been invoiced or otherwise notified of the actual costs. The majority of our service providers invoice us in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; however, some require advanced payments. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. Examples of estimated accrued research and development expenses include fees paid to:

- CROs in connection with performing research and development services on our behalf;
- investigative sites or other providers in connection with clinical trials;

- vendors in connection with non-clinical development activities; and
- vendors related to product manufacturing, development and distribution of clinical supplies.

We base our expenses related to clinical trials on our estimates of the services received and efforts expended pursuant to contracts with multiple CROs that conduct and manage non-clinical studies and clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the clinical expense. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed, enrollment of patients, number of sites activated and level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in us reporting expenses that are too high or too low in any particular period.

Fair Value Measurements

We are required to disclose information on all assets and liabilities reported at fair value that enables an assessment of the inputs used in determining the reported fair values. The Financial Accounting Standards Board ("FASB") Accounting Standard Codification ("ASC") Topic 820, *Fair Value Measurements and Disclosures*, establishes a hierarchy of inputs used when available. Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of our company. Unobservable inputs are inputs that reflect our assumptions about the inputs that market participants would use in pricing the asset or liability, and are developed based on the best information available in the circumstances. The fair value hierarchy applies only to the valuation inputs used in determining the reported fair value of the investments and is not a measure of the investment credit quality. The three levels of the fair value hierarchy are described below:

- Level 1—Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that we have the ability to access at the measurement date;
- Level 2—Valuations based on quoted prices for similar assets or liabilities in markets that are not active or for which all significant inputs are observable, either directly or indirectly;
- Level 3—Valuations that require inputs that reflect our own assumptions that are both significant to the fair value measurement and unobservable.

To the extent that valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by us in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

Our material financial instruments at June 30, 2015, consisted of cash and cash equivalents and the 2020 Convertible Notes derivative liability. Our material financial instruments at December 31, 2014 consisted of cash and cash equivalents, preferred stock warrant liabilities and a convertible debt redemption rights derivative. We have determined that all these liabilities are subject to Level 3 fair value measurements and account for them as liabilities based upon the characteristics and provisions of the underlying instruments. These liabilities were recorded at their fair value on the date of issuance and are re-measured on each subsequent balance sheet date, with fair value changes recognized as income (decreases in fair value) or expense (increases in fair value) in the statements of operations.

Stock-Based Compensation

We measure the cost of employee services received in exchange for an award of equity instruments based on the grant date fair value of the award. That cost is recognized on a straight-line basis over the period during which the employee is required to provide service in exchange for the award. The fair value of options on the date of grant is calculated using the Black-Scholes option pricing model based on key assumptions such as stock price, expected volatility and expected term. Our estimates of these assumptions are primarily based on third-party valuations, historical data, peer company data and judgment regarding future trends and factors.

We account for stock options issued to non-employees in accordance with the provisions of ASC Subtopic 505-50, *Equity-Based Payments to Non-employees*, which requires valuing the stock options using the Black-Scholes option pricing model and re-measuring such stock options at their current fair value as they vest.

Significant Factors, Assumptions and Methodologies Used in Determining Fair Value

Determining the fair value of our convertible preferred stock warrants, convertible debt derivatives and stock-based awards requires the use of subjective assumptions used in the valuations of our securities we performed as a private and public company.

Valuations conducted in 2015, 2014 and 2013

A third-party valuation consultant was engaged to advise and assist us in connection with the valuations of our (i) Series AA preferred stock warrants outstanding on December 31, 2013, March 31, 2014 and December 31, 2014, (ii) our convertible debt redemption rights derivative at issuance and at December 31, 2014, (iii) our common stock options issued in August 2014 and (iv) our 2020 Convertible Notes derivative liability at issuance and at June 30, 2015. Because our Series X preferred stock was entitled to a contingent liquidation preference which varies based on the total value of our equity, we were precluded from using a closed-form model, such as the Black-Scholes option pricing method, to value the Series AA preferred stock warrants. Therefore, we employed a Monte Carlo simulation methodology for all models used to determine the fair value of securities in our capital structure.

Common Stock and Preferred Stock Warrant Valuations

Our initial equity value ("EV") was determined by utilizing a risk-adjusted discounted cash flow model based upon market research and management's assessment thereof, which is an income approach and was corroborated with market data, coupled with a series of Monte Carlo simulations which projected various equity values under different possible liquidity events including (i) initial public offering ("IPO"), (ii) merger and acquisition ("M&A"), and (iii) stay-private ("SP") scenarios. The first two scenarios assume positive results from our recent Phase 2 clinical trial, while the third scenario considered unfavorable results for valuations performed prior to December 31, 2014 and, at December 31, 2014, no IPO or M&A transaction.

Key assumptions underlying the discounted cash flow model are described below:

- Based on the research and industry knowledge of our officers and consultants, we developed projections of market penetration, product selling prices and required infrastructure to estimate our future revenues and operating expenses to determine projected free cash flows from our two current product candidates containing *trabodenoson*, through patent expiration.
- *Probability of Success.* To determine the probability of success for the various phases of development required for submission in an NDA, we utilized the clinical trial success rates as published in certain reports.
- *Time to Liquidity*. All 2014 and 2013 valuations assumed liquidity events occurring between December 31, 2014 and April 1, 2015.
- *Risk Free rates*. Risk free rates are based on published or imputed government treasury rates as of each valuation date.
- *Volatilities*. Volatilities were derived from historical data from guideline publicly traded comparable companies. We used volatilities of 60% to 70% for the 2014 and 2013 valuations.

The Monte Carlo-simulated total equity values were then allocated to each type of security using a current value (waterfall) method under each scenario and were then probability-adjusted using probability weights by scenario.

As of date:	IPO	M&A	SP
December 31, 2013	5%	20%	75%
June 30, 2014	30%	20%	50%
December 31, 2014	70%	25%	5%

Valuation models require the input of highly subjective assumptions. Because our shares had characteristics significantly different from that of publicly traded common stock and because changes in the subjective input assumptions can materially affect the fair value estimate, in management's opinion, the existing models do not necessarily provide a reliable, single measure of the fair value of our Series AA preferred stock or Series X preferred stock. The foregoing valuation methodologies are not the only valuation methodologies available and are not expected to be used to value our securities after our IPO. We cannot make complete assurances as to any particular valuation for our securities. Accordingly, investors are cautioned not to place undue reliance on the foregoing valuation methodologies as an indicator of future stock prices.

Convertible Debt Redemption Rights Derivative

The Convertible Bridge Notes redemption rights derivative required separate accounting and was valued using a single income valuation approach. We estimated the fair value of the redemption rights derivative using a ‘‘with and without’’ income valuation approach. Under this approach, we estimated the present value of the fixed interest rate debt based on the fair value of similar debt instruments excluding the embedded feature. This amount was then compared to the fair value of the debt instrument including the embedded feature using a probability weighted approach by assigning each embedded derivative feature a probability of occurrence, with consideration provided for the settlement amount including conversion discounts, prepayment penalties, the expected life of the liability and the applicable discount rate.

As of the issuance of the Convertible Bridge Notes on December 22, 2014 and on December 31, 2014, the Company ascribed a probability of occurrence to the Change in Control Redemption Feature of 25%. The expected life of the feature was the remaining term of the debt and the discount rate was 18.9%. The Company classified the liability within Level 3 of the fair value hierarchy as the probability factor and the discount rate are unobservable inputs and significant to the valuation model. As of December 22, 2014 and December 31, 2014, the fair value of the embedded derivative was approximately $0.5 million.

2020 Convertible Notes derivative liability

Based on the characteristics of the (i) conversion option including make-whole provision, (ii) the Additional Interest, and (iii) the notes, we estimated the fair value of the conversion option including make-whole and the Additional Interest using the “with” and “without” method. Using this methodology, we first valued the notes with the conversion option including make-whole provision but excluding the Additional Interest (the “with” scenario) and subsequently valued the notes without the conversion option including make-whole provision and excluding the Additional Interest (the “without” scenario). The difference between the fair values of the notes in the “with” and “without” scenarios was the concluded fair value of the conversion option including make-whole provision as of the measurement date. We developed an estimate of fair value for the notes excluding the Additional Interest using a binomial lattice model. We modeled the decision to convert or hold by considering the maximum of the conversion or hold value at every node of the lattice in which the notes are convertible and choosing the action that maximizes the return to the notes’ holders. The significant assumptions used in the binomial model were: the market yield and the expected volatility.

We estimated the fair value of the Additional Interest using an income approach, specifically, the risk-neutral debt valuation method that is used to derive the value of a debt instrument using the expected cash flows and the risk-free rate. The significant assumptions used in estimating the expected cash flows were the market yield used to determine the risk-neutral probability of default and the expected recovery rate upon default.

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 SEC rules.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to market risks in the ordinary course of our business. These market risks are principally limited to interest rate fluctuations. We had cash and cash equivalents of $49.0 million at June 30, 2015, consisting of funds in operating cash accounts. The primary objective of our investment activities is to preserve principal and liquidity while maximizing income without significantly increasing risk. We do not enter into investments for trading or speculative purposes. Due to the short-term nature of our investment portfolio, we do not believe an immediate 1.0% increase in interest rates would have a material effect on the fair market value of our portfolio, and accordingly we do not expect a sudden change in market interest rates to affect materially our operating results or cash flows.

Until the 2020 Convertible Notes were converted in July and August 2015, they bore interest at a fixed rate, therefore a change in interest rates would not impact the amount of interest we would have paid on our indebtedness.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures pursuant to Rule 13a-15 under the Securities Exchange Act of 1934, as amended (Exchange Act), as of the end of the period covered by this Quarterly Report on Form 10-Q.

Based on this evaluation, our chief executive officer and principal financial officer concluded that, as of June 30, 2015, our disclosure controls and procedures are designed at a reasonable assurance level and are effective to provide reasonable assurance

that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our chief executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) that occurred during the quarter ended June 30, 2015, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1. Legal Proceedings

We are not currently a party to any legal proceedings.

Item 1. A. Risk Factors

We operate in an industry that involves numerous risks and uncertainties. You should carefully consider the following information about these risks, together with the other information appearing elsewhere in this Form 10-Q for the quarterly period ended June 30, 2015, and our Annual Report on Form 10-K for the year ended December 31, 2014, including our financial statements and related notes included therein. The occurrence of any of the following risks could have a material adverse effect on our business, financial condition, results of operations and future growth prospects. The risks and uncertainties described below may change over time and other risks and uncertainties, including those that we do not currently consider material, may impair our business. In these circumstances, the market price of our common stock could decline.

Risks Related to Our Financial Position and Need for Additional Capital

We currently have no source of revenue and may never become profitable.

We are a clinical-stage biopharmaceutical company with a limited operating history. Our ability to generate revenue and become profitable depends upon our ability to successfully complete the development of our product candidates for the treatment of glaucoma and obtain the necessary regulatory approvals for our product candidates. We have never been profitable, have no products approved for commercial sale and to date have not generated any revenue from product sales. Even if we receive regulatory approval for the sale of our product candidates, we do not know when such product candidates will generate revenue, if at all. Our ability to generate product revenue depends on a number of factors, including our ability to:

- successfully complete clinical development, and receive regulatory approval, for our product candidates, including *trabodenoson* monotherapy and *trabodenoson* with *latanoprost* as a fixed-dose combination (“FDC”);
- set an acceptable price for our product candidates and obtain coverage and adequate reimbursement from third-party payors;
- establish sales, marketing and distribution systems for our product candidates;
- add operational, financial and management information systems and personnel, including personnel to support our clinical, manufacturing and planned future commercialization efforts;
- have commercial quantities of our product candidates manufactured at acceptable cost levels;
- successfully market and sell our product candidates in the United States and enter into partnerships or other arrangements to commercialize our product candidates outside the United States; and
- maintain, expand and protect our intellectual property portfolio.

In addition, because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses, or when, or if, we will be able to achieve or maintain profitability. In addition, our expenses could increase beyond expectations if we are required by the U.S. Food and Drug Administration (“FDA”) and comparable non-U.S. regulatory authorities, or other regulatory authorities to perform studies or clinical trials in addition to those that we currently anticipate. Even if our product candidates are approved for commercial sale, we anticipate incurring significant costs associated with the commercial launch of these products.

Our ability to become and remain profitable depends on our ability to generate revenue. Even if we are able to generate revenues from the sale of our product candidates, we may not become profitable and may need to obtain additional funding to continue operations. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce our operations. 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 or continue our operations.

We have a history of net losses and anticipate that we will continue to incur net losses for the foreseeable future.

We have a history of losses and anticipate that we will continue to incur net losses for the foreseeable future. Our net losses were $9.5 million and $7.6 million for the years ended December 31, 2014 and 2013, respectively. Our net losses were $3.8 million for the six months ended June 30, 2015. As of June 30, 2015, we had an accumulated deficit of $131.9 million.

Investment in pharmaceutical product development is highly speculative because it entails substantial upfront expenditures and significant risk that a product candidate will fail to gain regulatory approval or become commercially viable. We have devoted most of

our financial resources to research and development, including our non-clinical development activities and clinical trials. We are not currently generating revenues, and we cannot estimate with precision the extent of our future losses. We do not currently have any products that are available for commercial sale and we may never generate revenue from selling products or achieve profitability. We expect to continue to incur substantial and increasing losses through the projected commercialization of our product candidates. None of our product candidates have been approved for marketing in the United States and may never receive such approval. As a result of these factors, we are uncertain when or if we will achieve profitability and, if so, whether we will be able to sustain it. Our ability to produce revenue and achieve profitability is dependent on our ability to complete the development of our product candidates, obtain necessary regulatory approvals, and have our products manufactured and successfully marketed. We cannot assure you that we will be profitable even if we successfully commercialize our products. Failure to become and remain profitable may adversely affect the market price of our common stock and our ability to raise capital and continue operations.

We have financed our operations with a combination of private and public grants and contracts and equity and preferred stock offerings. From 1997 to 2004, we have received non-dilutive funding totaling over $50 million through federal and private grants and contracts. Since 2004, we have raised additional equity capital with funding from biotechnology and pharmaceutical investors. In February 2004, we completed the sale of approximately $20 million of Series A preferred stock. In October 2005, we completed the sale of $35 million of Series B preferred stock. In October of 2007, we completed the sale of approximately $24 million of Series C preferred stock. In June 2011, we completed the sale of an aggregate of approximately $23.5 million of Series AA preferred stock in four separate closings during the preceding year. In February 2013, we completed the sale of approximately $3.5 million of convertible promissory notes in three separate closings during the preceding eight months. In July 2013, we completed the sale of an additional approximately $13.5 million of Series AA preferred stock, including the conversion of the convertible promissory notes, in two separate closings during the previous two months. In December 2014, we completed the issuance and sale of $2.0 million of subordinated convertible promissory notes. Our product candidates will require the completion of regulatory review, significant marketing efforts and substantial investment before they can provide us with any revenue.

In February 2015, we completed our initial public offering of 6,667,000 shares of our common stock at a price of $6.00 per share and a concurrent offering of $20.0 million aggregate principal amount of 5.0% Convertible Senior Notes due in 2020 (the “2020 Convertible Notes”). In March 2015, the underwriters exercised 299,333 shares of common stock at $6.00 per share and $1.0 million of the 2020 Convertible Notes pursuant to their overallotment options. We received net proceeds of approximately $36.5 million, after deducting underwriting discounts and offering-related costs, from our equity issuances and approximately $18.9 million in net proceeds, after deducting underwriting discounts and offering-related costs, from our debt issuances.

We expect our research and development expenses to continue to be significant in connection with our product development activities, including our planned Phase 2 clinical trials and our planned Phase 3 programs. In addition, if we obtain regulatory approval for our product candidates, we expect to incur increased sales and marketing expenses. As a result, we expect to continue to incur significant and increasing operating losses and negative cash flows for the foreseeable future. These losses have had and will continue to have a material adverse effect on our stockholders’ deficit, financial position, cash flows and working capital.

We will need to obtain additional financing to fund our operations and, if we are unable to obtain such financing, we may be unable to complete the development and commercialization of our primary product candidates.

Our operations have consumed substantial amounts of cash since inception. At June 30, 2015, our cash and cash equivalents were $49.0 million.

We believe that the net proceeds from our initial public offering and the 2020 Convertible Notes, together with existing cash and cash equivalents, will be sufficient to fund our projected operating requirements through 2016. We will need to obtain additional financing to conduct additional trials for the approval of our drug candidates as required by regulatory bodies, and complete the development of any additional product candidates we might acquire. Moreover, our fixed expenses such as rent, interest expense and other contractual commitments are substantial and are expected to increase in the future.

Adequate additional funding may not be available to us on acceptable terms, or at all. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or future potential commercialization efforts. Our forecast of the period of time through which our financial resources will be adequate to support our operating requirements is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this “Risk Factors” section. We have based this forecast on a number of assumptions that may prove to be wrong, and changing circumstances beyond our control may cause us to consume capital more rapidly than we currently anticipate.

Our future funding requirements will depend on many factors, including, but not limited to:

- the progress, timing, scope and costs of our clinical trials, including the ability to enroll patients in our planned and potential future clinical trials in a timely manner;
- the time and cost necessary to obtain regulatory approvals that may be required by regulatory authorities;
- our ability to successfully commercialize our product candidates;
- the amount of sales and other revenues from product candidates that we may commercialize, if any, including the selling prices for such product candidates and the availability of coverage and adequate reimbursement from third parties;
- selling and marketing costs associated with our product candidates, including the cost and timing of expanding our marketing and sales capabilities;
- the terms and timing of any potential future collaborations, licensing or other arrangements that we may establish;
- cash requirements of any future acquisitions and/or the development of other product candidates;
- the costs of operating as a public company;
- the time and cost necessary to respond to technological and market developments;
- the costs of maintaining and expanding our existing intellectual property rights; and
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

Until we can generate a sufficient amount of revenue, we may finance future cash needs through public or private equity offerings, license agreements, debt financings, collaborations, strategic alliances, marketing or distribution arrangements or a combination thereof. Additional funds may not be available when we need them on terms that are acceptable to us, or at all. General market conditions or the market price of our common stock may not support capital raising transactions such as an additional public or private offering of our common stock or other securities. In addition, our ability to raise additional capital may be dependent upon our stock being quoted on The NASDAQ Global Market ("NASDAQ") or upon obtaining shareholder approval. There can be no assurance that we will be able to satisfy the criteria for continued listing on NASDAQ or that we will be able to obtain shareholder approval if it is necessary. If adequate funds are not available, we may be required to delay or reduce the scope of or eliminate one or more of our research or development programs or our commercialization efforts.

We may seek to access the public or private capital markets whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time. In addition, if we raise additional funds through collaborations, strategic alliances 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 to grant licenses on terms that may not be favorable to us. Our inability to obtain additional funding when we need it could seriously harm our business.

Additional capital that we may need to operate or expand our business may not be available.

We may require additional capital to operate or expand our business. If we raise additional funds through the issuance of equity or convertible securities, the percentage ownership of holders of our common stock could be significantly diluted and these newly issued securities may have rights, preferences or privileges senior to those of holders of our common stock. Furthermore, volatility in the credit or equity markets may have an adverse effect on our ability to obtain debt or equity financing or the cost of such financing. If we do not have funds available to enhance our solution, maintain the competitiveness of our technology and pursue business opportunities, this could have an adverse effect on our business, operating results and financial condition.

Risks Related to Development, Regulatory Approval and Commercialization

We depend substantially on the success of our product candidates, particularly trabodenoson monotherapy and trabodenoson FDC, which are still in development. If we are unable to successfully develop and commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.

Our business and the ability to generate revenue related to product sales, if ever, will depend on the successful development, regulatory approval and commercialization of our product candidates *trabodenoson* monotherapy and *trabodenoson* FDC, which are still in development, and other potential products we may develop or license. We have invested a significant portion of our efforts and financial resources in the development of our existing product candidates. The success of our product candidates will depend on several factors, including:

- successful completion of clinical trials, and the supporting non-clinical toxicology, formulation development, and manufacturing of supplies for the clinical program in accordance with current Good Manufacturing Practice, or cGMP, requirements;
- receipt of regulatory approvals from the FDA and other applicable regulatory authorities outside the United States;
- establishment of arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity;
- protecting our rights in our intellectual property;

- launching commercial sales of our product candidates, if and when approved;
- acceptance of any approved product by the medical community and patients;
- obtaining coverage and adequate reimbursement from third-party payors for product candidates, if and when approved;
- effectively competing with other products; and
- achieving a continued acceptable safety profile for our product candidates following regulatory approval, if and when received.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully develop and commercialize our product candidates, which would materially harm our business and we may not be able to earn sufficient revenues and cash flows to continue our operations.

Our product candidates are *trabodenoson* as a monotherapy and as an FDC consisting of *trabodenoson* with a prostaglandin analog ("PGA"). We have no other product candidates in our near term product pipeline. As a result, we are substantially dependent on the successful development and commercialization of *trabodenoson*. If the results of our chronic toxicology program were to identify a safety problem, or if our upcoming pivotal trials of *trabodenoson* monotherapy or our upcoming continuing Phase 2 program for the FDC product candidate were to demonstrate lack of efficacy in lowering intraocular pressure ("IOP"), or any safety issues related to *trabodenoson*, our development strategy would be materially and adversely affected.

We have not obtained regulatory approval for any of our product candidates in the United States or in any other country.

We currently do not have any product candidates that have gained regulatory approval for sale in the United States or in any other country, and we cannot guarantee that we will ever have marketable products. Our business is substantially dependent on our ability to complete the development of, obtain regulatory approval for and successfully commercialize product candidates in a timely manner. We cannot commercialize product candidates in the United States without first obtaining regulatory approval to market each product from the FDA; similarly, we cannot commercialize product candidates outside of the United States without obtaining regulatory approval from comparable foreign regulatory authorities. We have completed a Phase 2 trial in which we tested *trabodenoson* co-administered with *latanoprost*. We attended an End-of-Phase 2 meeting with the FDA for *trabodenoson* monotherapy in the first half of 2015 and expect to initiate a pivotal Phase 3 program in the fourth quarter of 2015, which will consist of two Phase 3 pivotal trials and a long-term safety study. We cannot predict whether any of our future trials, including our planned long-term safety trial of *trabodenoson*, will be successful or whether regulators will agree with our conclusions regarding the preclinical studies and clinical trials we have conducted to date. Moreover, determination of the ultimate study design and its confirmation with the FDA could result in a significant range of costs for the Phase 3 pivotal trials.

Before obtaining regulatory approvals for the commercial sale of any product candidate for a target indication, we must demonstrate in preclinical studies and well-controlled clinical trials, and, with respect to approval in the United States, to the satisfaction of the FDA, that the product candidate is safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate. In the United States, we have not submitted a New Drug Application ("NDA") for any of our product candidates. An NDA must include extensive preclinical and clinical data and supporting information to establish the product candidate's safety and effectiveness for each desired indication. The NDA must also include significant information regarding the chemistry, manufacturing and controls for the product. Obtaining approval of an NDA is a lengthy, expensive and uncertain process, and approval may not be obtained. If we submit an NDA to the FDA, the FDA must decide whether to accept or reject the submission for filing. We cannot be certain that any submissions will be accepted for filing and review by the FDA.

Regulatory authorities outside of the United States, such as in Europe and Japan and in emerging markets, also have requirements for approval of drugs for commercial sale with which we must comply prior to marketing in those areas. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our product candidates. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and obtaining regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking non-U.S. regulatory approval could require additional non-clinical studies or clinical trials, which could be costly and time consuming. The non-U.S. regulatory approval process may include all of the risks associated with obtaining FDA approval. For all of these reasons, we may not obtain non-U.S. regulatory approvals on a timely basis, if at all.

The process to develop, obtain regulatory approval for and commercialize product candidates is long, complex and costly both inside and outside of the United States, and approval is never guaranteed. Even if our product candidates were to successfully obtain approval from the regulatory authorities, any approval might significantly limit the approved indications for use, or require that precautions, contraindications, or warnings be included on the product labeling, or require expensive and time-consuming post-approval clinical trials or surveillance as conditions of approval. Following any approval for commercial sale of our product candidates, certain changes to the product, such as changes in manufacturing processes and additional labeling claims, will be subject to additional FDA review and approval. Also, regulatory approval for any of our product candidates may be withdrawn. If we are unable to obtain regulatory approval for our product candidates in one or more jurisdictions, or any approval contains significant

limitations, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed. Furthermore, we may not be able to obtain sufficient funding or generate sufficient revenue and cash flows to continue the development of any other product candidate in the future.

Regulatory approval may be substantially delayed or may not be obtained for one or all of our product candidates if regulatory authorities require additional time or studies to assess the safety and efficacy of our product candidates.

We may be unable to initiate or complete development of our product candidates on schedule, if at all. To complete the studies for our product candidates, we will require additional funding. In addition, if regulatory authorities require additional time or studies to assess the safety or efficacy of our product candidates, we may not have or be able to obtain adequate funding to complete the necessary steps for approval for any or all of our product candidates. Preclinical studies and clinical trials required to demonstrate the safety and efficacy of our product candidates are time consuming and expensive and together take several years or more to complete. Delays in regulatory approvals or rejections of applications for regulatory approval in the United States, Europe, Japan or other markets may result from many factors, including:

- our inability to obtain sufficient funds required for a clinical trial;
- requests from regulatory authorities for additional analyses, reports, data, non-clinical and preclinical studies and clinical trials;
- questions from regulatory authorities regarding interpretations of data and results and the emergence of new information regarding our product candidates or other products;
- clinical holds, other regulatory objections to commencing or continuing a clinical trial or the inability to obtain regulatory approval to commence a clinical trial in countries that require such approvals;
- failure to reach agreement with the FDA or comparable non-US regulatory authorities regarding the scope or design of our clinical trials;
- our inability to enroll a sufficient number of patients who meet the inclusion and exclusion criteria in our clinical trials. For example, we are seeking patients with elevated levels of IOP for our clinical trials, which are more difficult to find;
- our inability to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- our inability to reach agreements on acceptable terms with prospective contract research organizations (“CROs”) and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- our inability to identify and maintain a sufficient number of sites, many of which may already be engaged in other clinical trial programs, including some that may be for the same indications targeted by our product candidates;
- any determination that a clinical trial presents unacceptable health risks;
- lack of adequate funding to continue the clinical trial due to unforeseen costs or other business decisions;
- our inability to obtain approval from Institutional Review Boards, or IRBs, to conduct clinical trials at their respective sites;
- our inability to manufacture in a timely manner or obtain from third parties sufficient quantities or quality of the product candidates or other materials required for a clinical trial;
- difficulty in maintaining contact with patients after treatment, resulting in incomplete data; and
- unfavorable or inconclusive results of clinical trials and supportive non-clinical studies, including unfavorable results regarding the effectiveness of product candidates during clinical trials.

Changes in regulatory requirements and guidance may also occur and we may need to amend clinical trial protocols submitted to applicable regulatory authorities to reflect these changes. Amendments may require us to resubmit clinical trial protocols to IRBs for re-examination, which may impact the costs, timing or successful completion of a clinical trial.

If the FDA requires us to change the design of our planned pivotal trials, the actual costs of these trials may be greater than what we estimated based on our current expectations regarding the design of these trials. If we are required to conduct additional clinical trials or other studies with respect to any of our product candidates beyond those that we initially contemplated, if we are unable to successfully complete our clinical trials or other studies or if the results of these studies are not positive or are only modestly positive, we may be delayed in obtaining regulatory approval for that product candidate, we may not be able to obtain regulatory approval at all or we may obtain approval for indications that are not as broad as intended. Our product development costs will also increase if we experience delays in testing or approvals and we may not have sufficient funding to complete the testing and approval process. Significant clinical trial delays could allow our competitors to bring products to market before we do and impair our ability to commercialize our products if and when approved. If any of this occurs, our business will be materially harmed.

We have not yet successfully formulated, and may be unable to formulate or manufacture our fixed-dose combination product candidate in a way that is suitable for clinical or commercial use. Any such delay or failure could materially harm our commercial prospects, result in higher costs and deprive us of product candidate revenues.

We recently completed a Phase 2 trial to evaluate the efficacy, tolerability and safety of *trabodenoson* when co-administered with commercially-available *latanoprost* eye drops. However, we have not yet formulated our FDC product candidate to include these two drugs in a single combination dose, and we may never be able to formulate or manufacture our FDC product candidate in a way that is

suitable for clinical or commercial use. Any delay or failure to develop a suitable product formulation or manufacturing process for our FDC product candidate could materially harm our commercial prospects, result in higher costs or deprive us of potential product revenues.

Failure can occur at any stage of clinical development. If the clinical trials for our product candidates are unsuccessful, we could be required to abandon development.

A failure of one or more clinical trials can occur at any stage of testing for a variety of reasons. The outcome of preclinical testing and early clinical trials may not be predictive of the outcome of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. In addition, adverse events may occur or other risks may be discovered in any clinical trials that will cause us to suspend or terminate our clinical trials. In some instances, there can be significant variability in safety and/or efficacy results between different trials of the same product candidate due to numerous factors, including changes in or adherence to trial protocols, differences in size and type of the patient populations and the rates of dropout among clinical trial participants. To date, we have only exposed 233 clinical trial subjects to *trabodenoson*. The FDA expects that a total of at least 1,300 patients will be exposed to at least a single dose of *trabodenoson* before submission of an NDA, and the complete NDA submission package must also contain safety data from at least 300 patients treated with *trabodenoson* for at least six months, and at least 100 patients treated for at least a year. Our future clinical trial results therefore may not demonstrate safety and efficacy sufficient to obtain regulatory approval for our product candidates. Moreover, we still need to evaluate the long-term safety effects of our product candidates, the results of which could adversely affect our clinical development program.

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 regulatory approval. In addition, clinical trials often reveal that it is not practical or feasible to continue development efforts. Further, we have never submitted an NDA for any product candidates.

We may voluntarily suspend or terminate our clinical trials if at any time we believe that they present an unacceptable risk to participants. Further, regulatory agencies and IRBs may at any time order or data safety monitoring boards may at any time recommend to the sponsor the temporary or permanent discontinuation of our clinical trials or request that we cease using investigators in the clinical trials if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements, or that they present an unacceptable safety risk to participants.

If the results of our clinical trials for our current product candidates or clinical trials for any future product candidates do not achieve the primary efficacy endpoints or demonstrate unexpected safety issues, the prospects for approval of our product candidates will be materially adversely affected. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have failed to achieve similar results in later clinical trials, including longer term trials, or have failed to obtain regulatory approval of their product candidates. Many compounds that initially showed promise in clinical trials or earlier stage testing have later been found to cause undesirable or unexpected adverse effects that have prevented further development of the compound. In addition, we have typically only tested our product candidates in a single eye, which may not accurately predict the efficacy or safety of our product candidates when dosed in both eyes. Our planned Phase 3 pivotal trials of *trabodenoson* monotherapy may not produce the results that we expect. Our planned clinical trials are also designed to test the use of *trabodenoson* in combination with *latanoprost* as an add-on therapy. Accordingly, the efficacy of our primary product candidates may not be similar or correspond directly to their efficacy when used as a monotherapy. Our current product candidates remain subject to the risks associated with clinical drug development as indicated above.

In addition to the circumstances noted above, we may experience numerous unforeseen events that could cause our clinical trials to be delayed, suspended or terminated, or which could delay or prevent our ability to receive regulatory approval or commercialize our product candidates, including:

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

- we may elect or be required to suspend or terminate clinical trials of our product candidates based on a finding that the participants are being exposed to health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate; and
- our product candidates may have undesirable adverse effects or other unexpected characteristics.

If we elect or are required to suspend or terminate a clinical trial of any of our product candidates, our commercial prospects will be adversely impacted and our ability to generate product revenues may be delayed or eliminated.

Our product candidates may have undesirable adverse effects, which may delay or prevent regulatory approval or, if approval is received, require our products to be taken off the market, require them to include safety warnings or otherwise limit their sales.

Unforeseen adverse effects from any of our product candidates could arise either during clinical development or, if approved, after the approved product has been marketed. In particular, we are aware of the known potential of adenosine and adenosine-like drugs to affect the heart if present in the systemic circulation at high enough levels.

Any undesirable adverse effects that may be caused by our product candidates could interrupt, delay or halt clinical trials and could result in the denial of regulatory approval by the FDA and comparable non-U.S. regulatory authorities for any or all targeted indications, and in turn prevent us from commercializing our product candidates and generating revenues from their sale. In addition, if any of our product candidates receives regulatory approval and we or others later identify undesirable adverse effects caused by the product, we could face one or more of the following consequences:

- regulatory authorities may require the addition of labeling statements, such as a “black box” warning or a contraindication, or other labeling changes;
- regulatory authorities may withdraw their approval of the product;
- regulatory authorities may seize the product;
- we may be required to change the way that the product is administered, conduct additional clinical trials or recall the product;
- we may be subject to litigation or product liability claims, fines, injunctions, or criminal penalties; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product or could substantially increase the costs and expenses of commercializing such product, which in turn could delay or prevent us from generating significant revenues from its sale.

Trabodenoson is an adenosine mimetic. Adenosine is used therapeutically to manage cardiovascular arrhythmias, such as paroxysmal supraventricular tachycardia, a type of accelerated heart rate. All of our data to date reflects that *trabodenoson* does not have systemic effects, including no impact on the cardiovascular system when dosed in the eye. However, we are still conducting additional trials for *trabodenoson* and systemic effects may arise in future trials. Furthermore, if *trabodenoson* has the perception of having potential adverse effects because it is an adenosine mimetic, it may be negatively viewed by ophthalmologists and optometrists, patients, patient advocacy groups, third-party payors and the medical community which would adversely affect the market acceptance of our product candidates. In addition, the use of our product candidates outside the indications approved for use, or off-label use, or the use of our product candidate in an inappropriate manner, may increase the risk of injury to patients. If approved, clinicians may use our products for off-label uses, as the FDA does not restrict or regulate a clinician’s choice of treatment within the practice of medicine. Off-label use of our products may increase the risk of product liability claims against us. Product liability claims are expensive to defend and could divert our management’s attention and result in substantial damage awards against us.

If our product candidates receive regulatory approval, we will be subject to ongoing regulatory requirements and we may face future development, manufacturing and regulatory difficulties.

Our product candidates, if approved, will also be subject to ongoing regulatory requirements for labeling, packaging, storage, advertising, promotion, sampling, record-keeping, submission of safety and other post-market approval information, importation and exportation. In addition, approved products, manufacturers and manufacturers’ facilities are required to comply with extensive FDA and European Medicines Agency (“EMA”) requirements and the requirements of other similar agencies, including ensuring that quality control and manufacturing procedures conform to cGMP requirements. As such, we and our potential future contract manufacturers will be subject to continual review and periodic inspections to assess compliance with cGMP. Accordingly, we and others with whom we work will be required to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. We will also be required to report certain adverse reactions and production problems, if any, to the FDA, EMA and other similar foreign agencies and to comply with certain requirements concerning advertising and

promotion for our product candidates. Promotional communications with respect to prescription drugs also are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved labeling. Accordingly, once approved, we may not promote our products, if any, for indications or uses for which they are not approved.

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

- issue warning letters or untitled letters;
- require product recalls;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
- require us or our potential future collaborators to enter into a consent decree or permanent injunction, which can include shutdown of manufacturing facilities, imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- impose other administrative or judicial civil or criminal penalties or pursue criminal prosecution;
- withdraw regulatory approval;
- refuse to approve pending applications or supplements to approved applications filed by us or by our potential future collaborators;
- impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products.

If we are unable to effectively establish a direct sales force in the United States, our business may be harmed.

We currently do not have an established sales organization and do not have a marketing or distribution infrastructure. To achieve commercial success for any approved product, we must either develop a sales and marketing organization or outsource these functions to third parties. If *trabodenoson* receives marketing approval in the United States, we plan to commercialize it by establishing a glaucoma-focused specialty sales force of approximately 150 people targeting high-prescribing ophthalmologists and optometrists throughout the United States. We will need to incur significant additional expenses and commit significant additional time and management resources to establish and train a sales force to market and sell our products. We may not be able to successfully establish these capabilities despite these additional expenditures.

Factors that may inhibit our efforts to successfully establish a sales force include:

- our inability to compete with other pharmaceutical companies to recruit, hire, train and retain adequate numbers of effective sales and marketing personnel with requisite knowledge of our target market;
- the inability of sales personnel to obtain access to adequate numbers of ophthalmologists and optometrists to prescribe any future approved products;
- unforeseen costs and expenses associated with creating an independent sales and marketing organization; and
- a delay in bringing products to market after efforts to hire and train our sales force have already commenced.

In the event we are unable to successfully market and promote our products, our business may be harmed.

We currently intend to explore the licensing of commercialization rights or other forms of collaboration outside of the United States, which will expose us to additional risks of conducting business in international markets.

The non-U.S. markets are an important component of our growth strategy. If we fail to obtain licenses or enter into collaboration arrangements with selling parties, or if these parties are not successful, our revenue-generating growth potential will be adversely affected. Moreover, international business relationships subject us to additional risks that may materially adversely affect our ability to attain or sustain profitable operations, including:

- efforts to enter into collaboration or licensing arrangements with third parties in connection with our international sales, marketing and distribution efforts may increase our expenses or divert our management's attention from the acquisition or development of product candidates;
- changes in a specific country's or region's political and cultural climate or economic condition;
- differing regulatory requirements for drug approvals and marketing internationally, which could result in our being required to conduct additional clinical trials or other studies before being able to successfully commercialize our product candidates in any jurisdiction outside the United States;
- difficulty of effective enforcement of contractual provisions in local jurisdictions;
- potentially reduced protection for intellectual property rights;
- potential third-party patent rights in countries outside of the United States;
- unexpected changes in tariffs, trade barriers and regulatory requirements;

- economic weakness, including inflation, or political instability, particularly in non-U.S. economies and markets, including several countries in Europe;
- compliance with tax, employment, immigration and labor laws for employees traveling abroad;
- the effects of applicable foreign tax structures and potentially adverse tax consequences;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incidental to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- the potential for so-called parallel importing, which is what happens when a local seller, faced with high or higher local prices, opts to import goods from a foreign market (with low or lower prices) rather than buying them locally;
- failure of our employees and contracted third parties to comply with Office of Foreign Asset Control rules and regulations and the Foreign Corrupt Practices Act;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters, including earthquakes, volcanoes, typhoons, floods, hurricanes and fires.

These and other risks may materially adversely affect our ability to attain or sustain revenue from international markets.

We face competition from established branded and generic pharmaceutical companies and if our competitors are able to develop and market products that are preferred over our products, our commercial opportunity will be reduced or eliminated.

The development and commercialization of new drug products is highly competitive. We face competition from established branded and generic pharmaceutical companies, smaller biotechnology and pharmaceutical companies, as well as from academic institutions, government agencies and private and public research institutions, which may in the future develop products to treat glaucoma. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Glaukos Corporation recently commercialized a trabecular micro-bypass stent that is implanted in the eye during cataract surgery and allows fluid to flow from the anterior of the eye into the collecting channels, bypassing the TM. In addition, early-stage companies that are also developing glaucoma treatments may prove to be significant competitors, such as Aerie Pharmaceuticals, Inc., which is developing a Rho kinase/norepinephrine transport inhibitor. We expect that our competitors will continue to develop new glaucoma treatments, which may include eye drops, oral treatments, surgical procedures, implantable devices or laser treatments. Other early-stage companies may also compete through collaborative arrangements with large and established companies. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Our commercial opportunity will be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer adverse effects, are more convenient or are less expensive than our product candidates. The market for glaucoma prescriptions is highly competitive and is currently dominated by generic drugs, such as *latanoprost* and *timolol*, and additional products are expected to become available on a generic basis over the coming years. If any of our product candidates are approved, we expect that they will be priced at a premium over competitive generic products and consistent with other branded glaucoma drugs.

If our competitors market products that are more effective, safer, have fewer side effects or are less expensive than our product candidates or that reach the market sooner than our potential future products, if any, we may not achieve commercial success.

The commercial success of our product candidates will depend on the degree of market acceptance among ophthalmologists and optometrists, patients, patient advocacy groups, third-party payors and the medical community.

Our product candidates may not gain market acceptance among ophthalmologists and optometrists, patients, patient advocacy groups, third-party payors and the medical community. There are a number of available therapies marketed for the treatment of glaucoma. Some of these drugs are branded and subject to patent protection, but most others, including *latanoprost* and many beta blockers, are available on a generic basis. Many of these approved drugs are well established therapies and are widely accepted by ophthalmologists and optometrists, patients and third-party payors. Insurers and other third-party payors may also encourage the use of generic products. Additionally, in patients with normal tension glaucoma whose IOP falls into the normal range, IOP is generally much more difficult to reduce. In these patients, *trabodenoson* may offer little or no clinical benefit, which may ultimately limit its utility in this subpopulation of glaucoma patients. The degree of market acceptance of our product candidates will depend on a number of factors, including:

- the market price, affordability and patient out-of-pocket costs of our product candidates relative to other available products, which are predominantly generics;
- the degree to which our product candidates obtain coverage and adequate reimbursement;
- the effectiveness of our product candidates as compared with currently available products and any products that may be approved in the future;
- patient willingness to adopt our product candidates in place of current therapies;

- varying patient characteristics including demographic factors such as age, health, race and economic status;
- changes in the standard of care for the targeted indications for any of our product candidates;
- the prevalence and severity of any adverse effects or perception of any potential side effects;
- limitations or warnings contained in a product candidate's FDA-approved labeling;
- limitations in the approved clinical indications for our product candidates;
- relative convenience and ease of administration;
- the strength of our selling, marketing and distribution capabilities;
- the quality of our relationship with patient advocacy groups;
- sufficient third-party coverage and reimbursement; and
- product liability claims.

In addition, the potential market opportunity for our product candidates is difficult to precisely estimate. Our estimates of the potential market opportunity for our product candidates include several key assumptions based on our industry knowledge, industry publications, third-party research reports and other surveys. If any of these assumptions proves to be inaccurate, then the actual market for our product candidates could be smaller than our estimates of our potential market opportunity. If the actual market for our product candidates is smaller than we expect, our product revenue may be limited, and it may be more difficult for us to achieve or maintain profitability. If we fail to achieve market acceptance of our product candidates in the United States and abroad, our revenue will be more limited and it will be more difficult to achieve profitability.

If we fail to obtain and sustain coverage and an adequate level of reimbursement for our product candidates by third-party payors, potential future sales would be materially adversely affected.

The course of treatment for glaucoma patients primarily includes older drugs, and the leading products for the treatment of glaucoma currently in the market, including *latanoprost* and *timolol*, are available as generic brands. There will be no commercially viable market for our product candidates without coverage and adequate reimbursement from third-party payors, and any coverage and reimbursement policy may be affected by future healthcare reform measures. We cannot be certain that coverage and adequate reimbursement will be available for our product candidates or any other future product candidates we develop. Additionally, even if there is a commercially viable market, if the level of reimbursement is below our expectations, our anticipated revenue and gross margins will be adversely affected.

Third-party payors, such as government or private healthcare insurers, carefully review and increasingly question and challenge the coverage of and the prices charged for drugs. Reimbursement rates from private health insurance companies vary depending on the company, the insurance plan and other factors. Reimbursement rates may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. A current trend in the U.S. healthcare industry is toward cost containment. Large public and private payors, managed care organizations, group purchasing organizations and other similar organizations are exerting increasing influence on decisions regarding the use of, and reimbursement levels for, particular treatments. Such third-party payors, including Medicare, may question the coverage of, and challenge the prices charged for, medical products and services, and many third-party payors limit coverage of or reimbursement for newly approved healthcare products. In particular, third-party payors may limit the covered indications. Cost-control initiatives could decrease the price we might establish for our product candidates, which could result in product revenues being lower than anticipated. We believe our drugs will be priced significantly higher than existing generic drugs and consistently with current branded drugs. Patients who are prescribed medications for the treatment of their conditions, and their prescribing physicians, generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. If we are unable to show a significant benefit relative to existing generic drugs, Medicare, Medicaid and private payors may not be willing to cover or provide adequate reimbursement for our drugs, which would significantly reduce the likelihood of them gaining market acceptance. In the United States, no uniform policy requirement for coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor.

We expect that private insurers will consider the efficacy, cost effectiveness, safety and tolerability of our product candidates in determining whether to approve coverage and set reimbursement levels for such products. Obtaining these approvals can be a time consuming and expensive process. Our business and prospects would be materially adversely affected if we do not receive approval for coverage and reimbursement of our product candidates from private insurers on a timely or satisfactory basis. Limitations on coverage and reimbursement could also be imposed by government payors, such as the local Medicare carriers, fiscal intermediaries, or Medicare Administrative Contractors. Further, Medicare Part D, which provides a pharmacy benefit to certain Medicare patients, does not require participating prescription drug plans to cover all drugs within a class of products. Our business could be materially adversely affected if private or governmental payors, including Medicare Part D prescription drug plans were to limit access to, or deny or limit reimbursement of, our product candidates or other potential products.

Reimbursement systems in international markets vary significantly by country and by region, and reimbursement approvals must be obtained on a country-by-country basis. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing

governmental control even after initial approval is granted. For example, reimbursement in the European Union must be negotiated on a country-by-country basis and in many countries the product cannot be commercially launched until reimbursement is approved. The negotiation process in some countries can exceed 12 months. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our products to other available therapies.

If the prices for our product candidates decrease or if governmental and other third-party payors do not provide coverage and adequate reimbursement levels, our revenue, potential for future cash flows and prospects for profitability will suffer.

Governments outside the United States tend to impose strict price controls, which may adversely affect our revenues, if any.

The pricing of prescription pharmaceuticals is also subject to governmental control outside of the United States. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidates to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially.

If we are found in violation of federal or state "fraud and abuse" laws or other healthcare laws, we may face penalties, which may adversely affect our business, financial condition and results of operation.

In the United States, we are subject to various federal and state healthcare "fraud and abuse" laws, including anti-kickback laws, false claims laws and other laws intended, among other things, to reduce fraud and abuse in federal and state healthcare programs. The Federal Anti-Kickback Statute makes it illegal for any person or entity, including a prescription drug manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer or pay any remuneration, directly or indirectly, in cash or in kind, that is intended to induce or reward the referral of business, including the purchase, lease, order or arranging for or recommending the purchase, lease or order of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as Medicare or Medicaid. Although we seek to structure our business arrangements in compliance with all applicable requirements, many healthcare fraud and abuse laws are broadly written, and it may be difficult to determine precisely how the law will be applied in specific circumstances. Accordingly, it is possible that our practices may be challenged under the Federal Anti-Kickback Statute. The federal false claims and civil monetary penalties laws, including the civil False Claims Act prohibits any individual or entity from, among other things, knowingly presenting or causing to be presented for payment to the government, including the federal healthcare programs, claims for reimbursed drugs or services that are false or fraudulent, or making a false statement to avoid, decrease, or conceal an obligation to pay money to the federal government. The civil False Claims Act has been interpreted to prohibit presenting claims for items or services that were not provided as claimed, or claims for medically unnecessary items or services. Cases have been brought under false claims laws alleging that off-label promotion of pharmaceutical products or the provision of kickbacks have resulted in the submission of false claims to governmental healthcare programs. In addition, private individuals have the ability to bring actions on behalf of the government under the civil False Claims Act as well as under the false claims laws of several states. Under the Health Insurance Portability and Accountability Act of 1996
("HIPAA"), we are prohibited from, among other things, knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private payors, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services to obtain money or property of any healthcare benefit program.

Additionally, the federal Physician Payments Sunshine Act within the Patient Protection and Affordable Care Act, as amended by the Health Care Education and Reconciliation Act (collectively, the "ACA"), and its implementing regulations, require that certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, report annually to the Centers for Medicare & Medicaid Services ("CMS") information related to certain payments or other transfers of value provided to physicians and teaching hospitals, and certain ownership and investment interests held by physicians and their immediate family members.

Many states have adopted laws similar to the aforementioned laws, including state anti-kickback and false claims laws, some of which apply to the referral of patients for healthcare services reimbursed by any source, not just governmental payors. In addition, some states have passed laws that require pharmaceutical companies to comply with the April 2003 U.S. Department of Health and Human Services Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and/or the Pharmaceutical Research and Manufacturers of America's Code on Interactions with Healthcare Professionals. Several states also impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state. There may be ambiguities as to what is required to comply with these state requirements and if we fail to comply with an applicable state law requirement we could be subject to penalties.

In addition, we may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH") and their respective implementing regulations, including the Final Omnibus Rule published on January 25, 2013, imposes specified requirements relating to the privacy, security and transmission of individually identifiable health information on certain types of

individuals and organizations. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to business associates, defined as independent contractors or agents of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, many state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other and from HIPAA in significant ways and may not have the same effect, thus complicating compliance efforts.

Law enforcement authorities are increasingly focused on enforcing these laws, and it is possible that some of our practices may be challenged under these laws. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that the government could allege violations of, or convict us of violating, these laws. If we are found in violation of one of these laws, we could be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from governmental funded federal or state healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations. Were this to occur, our business, financial condition and results of operations and cash flows may be materially adversely affected.

Recently enacted and future legislation may increase the difficulty and cost of commercializing our product candidates and may affect the prices we may obtain.

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

In March 2010, President Obama signed into law the ACA, a sweeping law intended to, among other things, broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against healthcare fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Among other changes that affect the pharmaceutical industry, the ACA increased manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate amount for both branded and generic drugs and revised the definition of average manufacturer price ("AMP") which may also increase the amount of Medicaid drug rebates manufacturers are required to pay to states. The legislation also expanded Medicaid drug rebates, which previously had been payable only on fee-for-service utilization, to Medicaid managed care utilization, and created an alternative rebate formula for certain new formulations of certain existing products that is intended to increase the rebates due on those drugs. Further, the ACA imposed a significant annual fee on companies that manufacture or import branded prescription drug products and requires manufacturers to provide a 50% point-of-sale discount off the negotiated price of applicable branded drugs dispensed to beneficiaries in the Medicare Part D coverage gap, referred to as the "donut hole." Substantial new provisions affecting compliance have also been enacted, including the Physician Payments Sunshine Act, as described above. Although it is too early to determine the full effect of the ACA, the new law appears likely to continue the downward pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2012 through 2021, was unable to reach the required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2024 unless additional Congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability.

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

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict whether future healthcare initiatives will be implemented at the federal or state level or in countries outside of the United States in which we may do business in the future, or the effect any future legislation or regulation will have on us.

If we face allegations of noncompliance with the law and encounter sanctions, our reputation, revenues and liquidity may suffer, and our products could be subject to restrictions or withdrawal from the market.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenues from our products. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected. Additionally, if we are unable to generate revenues from our product sales, our potential for achieving profitability will be diminished and the capital necessary to fund our operations will be increased.

We may not be able to identify additional therapeutic opportunities for our product candidates or to expand our portfolio of products.

We may explore other therapeutic opportunities with *trabodenoson* and seek to commercialize a portfolio of new ophthalmic drugs in addition to our product candidates that we are currently developing. We have no potential products in our research and development pipeline other than those potential products that are formulations of *trabodenoson* or that apply *trabodenoson* for the treatment of glaucoma, other neuropathies and degenerative retinal diseases.

Research programs to pursue the development of our product candidates for additional indications and to identify new potential products and disease targets require substantial technical, financial and human resources whether or not we ultimately are successful. Our research programs may initially show promise in identifying potential indications and/or potential products, yet fail to yield results for clinical development for a number of reasons, including:

- the research methodology used may not be successful in identifying potential indications and/or potential products;
- product candidates may, after further study, be shown to have harmful adverse effects or other characteristics that indicate they are unlikely to be effective drugs; or
- it may take greater human and financial resources to identify additional therapeutic opportunities for our product candidates or to develop suitable potential products through internal research programs and clinical trials than we will possess, thereby limiting our ability to diversify and expand our product portfolio.

Because we have limited financial and managerial resources, we focus on research programs and product candidates for specific indications. As a result, we may forego or delay pursuit of opportunities with other potential products or for other indications that later prove to have greater commercial potential or a greater likelihood of success. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities.

Accordingly, there can be no assurance that we will ever be able to identify additional therapeutic opportunities for our product candidates or to develop suitable potential products through internal research programs, which could materially adversely affect our future growth and prospects.

Risks Related to Our Reliance on Third Parties

We currently depend on third parties to conduct some of the operations of our clinical trials and other portions of our operations, and we may not be able to control their work as effectively as if we performed these functions ourselves.

We rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to oversee and conduct our clinical trials, and to perform data collection and analysis of our product candidates. We expect to rely on these third parties to conduct clinical trials of any other potential products that we develop. These parties are not our employees and we cannot control the amount or timing of resources that they devote to our program. In addition, any CRO that we retain will be subject to the FDA's regulatory requirements or similar foreign standards and we do not have control over compliance with these regulations by these providers. Our agreements with third-party service providers are on trial-by-trial and project-by-project bases. Typically, we may terminate the agreements with notice and occasionally the third party service provider may terminate the agreement without notice. Typically, we are responsible for the third party's incurred costs and occasionally we have to pay cancellation fees. If any of our relationships with our third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. We also rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or regulatory approval of our product candidates or commercialization of our product candidates, producing additional losses and depriving us of potential product revenue.

Our reliance on these third parties for clinical development activities reduces our control over these activities but does not relieve us of our responsibilities, and we remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan, the protocols for the trial and the FDA's regulations and international standards, referred to as Good

Clinical Practice ("GCP") requirements, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Preclinical studies must also be conducted in compliance with other requirements, such as Good Laboratory Practice ("GLP"), and the Animal Welfare Act. Managing performance of third-party service providers can be difficult, time consuming and cause delays in our development programs. We currently have a small number of employees, which limits the internal resources we have available to identify and monitor our third-party providers.

Furthermore, these third parties may conduct clinical trials for competing drugs or may have relationships with other entities, some of which may be our competitors. As such, the ability of these third parties to provide services to us may be limited by their work with these other entities. The use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated.

If these third parties do not successfully carry out their contractual duties or obligations and meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols according to regulatory requirements or for other reasons, our financial results and the commercial prospects for our current product candidates or our other potential products could be harmed, our costs could increase and our ability to obtain regulatory approval and commence product sales could be delayed.

We have no manufacturing capacity or experience and anticipate continued reliance on third-party manufacturers for the development and commercialization of our product candidates in accordance with manufacturing regulations.

We do not currently, nor currently intend to, operate manufacturing facilities for clinical or commercial production of our product candidates. We have no experience in drug formulation, and we lack the resources and the capabilities to manufacture our product candidates and potential products on a clinical or commercial scale. We do not intend to develop facilities for the manufacture of product candidates for clinical trials or commercial purposes in the foreseeable future. We currently rely on third-party manufacturers to produce the active pharmaceutical ingredient and final drug product for our clinical trials. We manage such production with all our vendors on a purchase order basis in accordance with applicable master service and supply agreements. We do not have long-term agreements with any of these or any other third-party suppliers. To the extent we terminate our existing supplier arrangements in the future and seek to enter into arrangements with alternative suppliers, we might experience a delay in our ability to obtain adequate supply for our clinical trials and commercialization. We also do not have any current contractual relationships for the manufacture of commercial supplies of any of our product candidates if and when they are approved. Our third-party manufacturers have made only a limited number of lots of our product candidates to date and have not made any commercial lots. The manufacturing processes for our product candidates have never been tested at commercial scale, and the process validation requirement has not yet been satisfied for any product candidate. These manufacturing processes and the facilities of our third-party manufacturers will be subject to inspection and approval by the FDA before we can commence the manufacture and sale of our product candidates, and thereafter on an ongoing basis. Some of our third-party manufacturers have never been inspected by the FDA and have not been through the FDA approval process for a commercial product. Some of our third-party manufacturers are subject to FDA inspection from time to time. Failure by these third-party manufacturers to pass such inspections and otherwise satisfactorily complete the FDA approval regimen with respect to our product candidates may result in regulatory actions such as the issuance of FDA Form 483 inspectional observations, warning letters or injunctions or the loss of operating licenses. Based on the severity of the regulatory action, our clinical or commercial supply of our product candidates could be interrupted or limited, which could have a material adverse effect on our business.

With respect to commercial production of our product candidates in the future, we plan on outsourcing production of the active pharmaceutical ingredients and final product manufacturing if and when approved for marketing by the applicable regulatory authorities. This process is difficult and time consuming and we can give no assurance that we will enter commercial supply agreements with any contract manufacturers on favorable terms or at all.

Reliance on third-party manufacturers entails risks, including:

- manufacturing delays if our third-party manufacturers give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of their agreements with us;
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us;
- the possible breach of the manufacturing agreement by the third party;
- product loss due to contamination, equipment failure or improper installation or operation of equipment or operator error;
- the failure of the third-party manufacturer to comply with applicable regulatory requirements; and
- the possible misappropriation of our proprietary information, including our trade secrets and know-how.

Our manufacturers may not perform as agreed or may not remain in the contract manufacturing business. In the event of a natural disaster, business failure, strike or other difficulty, we may be unable to replace a third-party manufacturer in a timely manner and the production of our product candidates and potential products could be interrupted, resulting in delays and additional costs. We may also have to incur other charges and expenses for products that fail to meet specifications and undertake remediation efforts.

If third-party manufacturers fail to comply with manufacturing regulations, our financial results and financial condition will be adversely affected.

Before a third party can begin the commercial manufacturing of our product candidates and potential products, their manufacturing facilities, processes and quality systems must be in compliance with applicable regulations. Due to the complexity of the processes used to manufacture pharmaceutical products and product candidates, any potential third-party manufacturer may be unable to initially pass federal, state or international regulatory inspections in a cost effective manner. If contract manufacturers fail to pass such inspection, our commercial supply of drug substance will be significantly delayed and may result in significant additional costs. In addition, pharmaceutical manufacturing facilities are continuously subject to inspection by the FDA and comparable non-U.S. regulatory authorities, before and after product approval, and must comply with cGMP. Our contract manufacturers may encounter difficulties in achieving quality control and quality assurance and may experience shortages in qualified personnel. In addition, contract manufacturers' failure to achieve and maintain high manufacturing standards in accordance with applicable regulatory requirements, or the incidence of manufacturing errors, could result in patient injury, product liability claims, product shortages, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could seriously harm our business. If a third-party manufacturer with whom we contract is unable to comply with manufacturing regulations, we may also be subject to fines, unanticipated compliance expenses, recall or seizure of our products, product liability claims, total or partial suspension of production and/or enforcement actions, including injunctions, and criminal or civil prosecution. These possible sanctions could materially adversely affect our financial results and financial condition.

Furthermore, changes in the manufacturing process or procedure, including a change in the location where the product is manufactured or a change of a third-party manufacturer, will require prior FDA review and/or approval of the manufacturing process and procedures in accordance with the FDA's regulations, or comparable foreign requirements. This review may be costly and time consuming and could delay or prevent us from conducting our clinical trials or launching a product. The new facility will also be subject to pre-approval inspection. In addition, we have to demonstrate that the product made at the new facility is equivalent to the product made at the former facility by physical and chemical methods, which are costly and time consuming. It is also possible that the FDA may require clinical testing as a way to prove equivalency, which would result in additional costs and delay.

Any collaboration arrangement that we may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize our current and future product candidates.

We plan to seek collaboration arrangements with pharmaceutical or biotechnology companies for the development or commercialization of our current and future product candidates outside of the United States. We will face, to the extent that we decide to enter into collaboration agreements, significant competition in seeking appropriate collaborators. Moreover, collaboration arrangements are complex and time consuming to negotiate, document and implement. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements should we choose to enter into such arrangements, and the terms of the arrangements may not be favorable to us. If and when we collaborate with a third party for development and commercialization of a product candidate, we can expect to relinquish some or all of the control over the future success of that product candidate to the third party. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations. To the extent such collaborators have programs that are competitive with our product candidates, they may decide to focus time and resources on development of those programs rather than our product candidates.

Disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters can lead to delays in the development process or commercializing the applicable product candidate and, in some cases, termination of the collaboration arrangement. These disagreements can be difficult to resolve if neither of the parties has final decision making authority. Collaborations with pharmaceutical or biotechnology companies and other third parties often are terminated or allowed to expire by the other party. Any such termination or expiration would adversely affect us financially and could harm our business reputation.

If we are not able to establish collaborations, we may have to alter our development and commercialization plans.

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

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

be restricted under future license agreements from entering into agreements on certain terms with potential collaborators. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

Risks Related to Intellectual Property

We may not be able to protect our proprietary technology in the marketplace.

We depend on our ability to protect our proprietary technology. We rely largely on trade secret and patent laws, and confidentiality, licensing and other agreements with employees and third parties, all of which offer only limited protection. Our success depends in large part on our ability and any future licensee's ability to obtain and maintain patent protection in the United States and other countries with respect to our proprietary technology and products. We believe we will continue to be able to obtain, through prosecution of our current pending patent applications, adequate patent protection for our proprietary drug technology. If we are compelled to spend significant time and money protecting or enforcing our patents or patent applications, designing around patents held by others or licensing or acquiring, potentially for large fees, patents or other proprietary rights held by others, our business and financial prospects may be harmed. If we are unable to effectively protect the intellectual property that we own, other companies may be able to offer the same or similar products for sale, which could materially adversely affect our competitive business position and harm our business prospects. Our patents may be challenged, narrowed, invalidated, or circumvented, which could limit our ability to stop competitors from marketing the same or similar products or limit the length of term of patent protection that we may have for our products.

The patent positions of pharmaceutical products are often complex and uncertain. The breadth of claims allowed in pharmaceutical patents in the United States and many jurisdictions outside of the United States is not consistent. For example, in many jurisdictions the support standards for pharmaceutical patents are becoming increasingly strict. Some countries prohibit method of treatment claims in patents. Changes in either the patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or create uncertainty. In addition, publication of information related to our current product candidates and potential products may prevent us from obtaining or enforcing patents relating to these product candidates and potential products, including, without limitation, composition-of-matter patents, which are generally believed to offer the strongest patent protection.

Our intellectual property consists of issued patents and pending patent applications related to our product candidates and other proprietary technology which cover compositions of matter, methods of use, combinations with other glaucoma products, formulations, polymorphs and the protection of the optic nerve. For *trabodenoson*, the composition patents are scheduled to expire in 2025 and 2026, in Europe and the United States, respectively. See "Business—Intellectual Property" included elsewhere in our Annual Report on Form 10-K for the year ended December 31, 2014 for further information about our issued patents and patent applications.

Patents that we own or may license in the future do not necessarily ensure the protection of our product candidates for a number of reasons, including without limitation the following:

- we may not have been the first to make the inventions covered by our patents or pending patent applications;
- we may not have been the first to file patent applications for these inventions;
- any patents issued to us may not cover our products as ultimately developed;
- our pending patent applications may not result in issued patents, and even if they issue as patents, they may not provide us with any competitive advantages, or may be challenged and invalidated by third parties;
- our patents may not be broad or strong enough to prevent competition from other products that are identical or similar to our product candidates;
- there can be no assurance that the term of a patent can be extended under the provisions of patent term extension afforded by U.S. law or similar provisions in foreign countries, where available;
- our patents, and patents that we may obtain in the future, may not prevent generic entry into the U.S. market for our *trabodenoson* and other product candidates;
- we may be required to disclaim part of the term of one or more patents;

- there may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim;
- there may be patents issued to third parties that will affect our freedom to operate;
- if our patents are challenged, a court could determine that they are invalid or unenforceable;
- there might be significant changes in the laws that govern patentability, validity and infringement of our patents that adversely affects the scope of our patent rights;
- a court could determine that a competitor's technology or product does not infringe our patents;
- our patents could irretrievably lapse due to failure to pay fees or otherwise comply with regulations or could be subject to compulsory licensing; and
- we may fail to obtain patents covering important products and technologies in a timely fashion or at all.

In addition, on September 16, 2011, the Leahy-Smith America Invents Act (the "Leahy-Smith Act"), was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The United States Patent Office is currently developing regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act have not yet become effective. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act, in particular the first-to-file provision, and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

If we encounter delays in our development or clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced.

Our competitors may seek to invalidate our patents.

Our competitors may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. Our competitors may seek to market generic versions of any approved products by submitting Abbreviated New Drug Applications ("ANDAs") to the FDA in which our competitors claim that our patents are invalid, unenforceable and/or not infringed. Alternatively, our competitors may seek approval to market their own products similar to or otherwise competitive with our products. In these circumstances, we may need to defend and/or assert our patents, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our patents invalid and/or unenforceable. We may also fail to identify patentable aspects of our research and development before it is too late to obtain patent protection. Even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

The issuance of a patent is not conclusive as to its inventorship, scope, ownership, priority, validity or enforceability. In that regard, third parties may challenge our patents in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidates. In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized.

A significant portion of our intellectual property portfolio currently includes pending patent applications that have not yet issued as patents. If our pending patent applications fail to issue our business will be adversely affected.

Our commercial success will depend significantly on maintaining and expanding patent protection for our product candidates, as well as successfully defending our current and future patents against third-party challenges. As of June 30, 2015, we own at least 50 issued patents and have at least 40 pending patent applications in the United States and a number of foreign jurisdictions relating to our current product candidates and proprietary technology. See "Business—Intellectual Property" included elsewhere in our Annual Report on Form 10-K for the year ended December 31, 2014 for further information about our issued patents and patent applications. Our intellectual property consists of patents and pending patent applications related to our product candidates and other proprietary technology which cover compositions of matter, methods of use, combinations with other glaucoma products, formulations, polymorphs and the protection of the optic nerve. For *trabodenoson*, the composition of matter patents are scheduled to expire in 2025 and 2026, in Europe and the United States, respectively.

There can be no assurance that our patent applications will issue as patents in the United States or foreign jurisdictions in which such applications are pending. Even if patents do issue on any of these applications, there can be no assurance that a third party will not challenge their validity or that we will obtain sufficient claim scope in those patents to prevent a third party from competing successfully with our products.

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

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to life sciences. To the extent we are able to obtain patents or other

intellectual property rights in any foreign jurisdictions, it may be difficult for us to prevent infringement of our patents or misappropriation of these intellectual property rights. For example, some foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit.

Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain adequate protection for our technology and the enforcement of intellectual property.

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

The United States Patent and Trademark Office ("USPTO") and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In this event, competitors might be able to enter the market earlier than would otherwise have been the case.

We may infringe the intellectual property rights of others, which may prevent or delay our product development efforts and stop us from commercializing or increase the costs of commercializing our products.

Our commercial success depends significantly on our ability to operate without infringing the patents and other intellectual property rights of third parties. For example, there could be issued patents of which we are not aware that our product candidates or potential products infringe. There also could be patents that we believe we do not infringe, but that we may ultimately be found to infringe.

Moreover, patent applications are in some cases maintained in secrecy until patents are accepted or issued. The publication of discoveries in the scientific or patent literature frequently occurs substantially later than the date on which the underlying discoveries were made and patent applications were filed. Because patents can take many years to issue, there may be currently pending applications of which we are unaware that may later result in issued patents that our product candidates or potential products infringe. For example, pending applications may exist that claim or can be amended to claim subject matter that our product candidates or potential products infringe. Competitors may file continuing patent applications claiming priority to already issued patents in the form of continuation, divisional, or continuation-in-part applications, in order to maintain the pendency of a patent family and attempt to cover our product candidates.

Third parties may assert that we are employing their proprietary technology without authorization and may sue us for patent or other intellectual property infringement. These lawsuits are costly and could adversely affect our results of operations and divert the attention of managerial and scientific personnel. If we are sued for patent infringement, we would need to demonstrate that our product candidates, potential products or methods either do not infringe the claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity or unenforceability is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could have a material adverse effect on us. In addition, we may not have sufficient resources to bring these actions to a successful conclusion. If a court holds that any third-party patents are valid, enforceable and cover our products or their use, the holders of any of these patents may be able to block our ability to commercialize our products unless we acquire or obtain a license under the applicable patents or until the patents expire. We may not be able to enter into licensing arrangements or make other arrangements at a reasonable cost or on reasonable terms. Any inability to secure licenses or alternative technology could result in delays in the introduction of our products or lead to prohibition of the manufacture or sale of products by us. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, in any such proceeding or litigation, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Any claims by third parties that we have misappropriated their confidential information or trade secrets could have a similar negative impact on our business. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

We may face claims of infringement, misappropriation or other violations of the rights of third-party intellectual property holders.

Pharmaceutical companies, biotechnology companies and academic institutions may compete with us in the commercialization of *trabodenoson* for use in ophthalmic indications and filing patent applications potentially relevant to our business. In order to contend with the strong possibility of third-party intellectual property conflicts, we periodically conduct freedom-to-operate studies, but such studies may not uncover all patents relevant to our business.

From time to time, we find it necessary or prudent to obtain licenses from third-party intellectual property holders. Where licenses are readily available at reasonable cost, such licenses are considered a normal cost of doing business. In other instances, however, we may use the results of freedom-to-operate studies to guide our early-stage research away from areas where we are likely to encounter obstacles in the form of third-party intellectual property. For example, where a third party holds relevant intellectual property and is a direct competitor, a license might not be available on commercially reasonable terms or available at all. We strive to identify potential third-party intellectual property issues in the early stages of research of our research programs, in order to minimize the cost and disruption of resolving such issues.

In spite of these efforts to avoid obstacles and disruptions arising from third-party intellectual property, it is impossible to establish with certainty that our products will be free of claims that we infringe, misappropriate or otherwise violate the rights of third-party intellectual property holders. Even with modern databases and online search engines, freedom-to-operate searches are imperfect and may fail to identify relevant patents and published applications. Even when a third-party patent is identified, we may conclude that we do not infringe the patent or that the patent is invalid. If the third-party patent owner disagrees with our conclusion and we continue with the business activity in question, patent litigation may result. We might decide to initiate litigation in an attempt to have a court declare the third-party patent invalid or non-infringed by our activity.

We may be subject to claims that we or our employees have misappropriated the intellectual property, including trade secrets, of a third party, or claiming ownership of what we regard as our own intellectual property.

Many of our employees were previously employed at universities, biotechnology companies or other pharmaceutical companies, including our competitors or potential competitors. Some of these employees, including each member of our senior management, executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees do not use the intellectual property and other proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed such intellectual property, including trade secrets or other proprietary information. Litigation may be necessary to defend against these claims. We are not aware of any threatened or pending claims related to these matters or concerning the agreements with our senior management, but litigation may be necessary in the future to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while we typically require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own, which may result in claims by or against us related to the ownership of such intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our management and scientific personnel.

We may be unable to adequately prevent disclosure of trade secrets and other proprietary information.

We rely on trade secrets to protect our proprietary know-how and technological advances, especially where we have not filed a patent application or where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to protect our trade secrets and other proprietary information. However, any party with whom we have executed such an agreement may breach that agreement and disclose our proprietary information, including our trade secrets. Accordingly, these agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights. In addition, others may independently discover our trade secrets and proprietary information. Further, the FDA, as part of its Transparency Initiative, a proposal by the FDA to increase disclosure and make data more accessible to the public, is currently considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future, if at all. Failure to obtain or maintain trade secret protection could enable competitors to use our proprietary information to develop products that compete with our products or cause additional, material adverse effects upon our competitive business position and financial results.

Detecting the disclosure or misappropriation of a trade secret and enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

Any lawsuits relating to infringement of intellectual property rights brought by or against us will be costly and time consuming and may adversely impact the price of our common stock.

We may be required to initiate litigation to enforce or defend our intellectual property. These lawsuits can be very time consuming and costly. There is a substantial amount of litigation involving patent and other intellectual property rights in the pharmaceutical industry generally. Such litigation or proceedings could substantially increase our operating expenses and reduce the resources available for development activities or any future sales, marketing or distribution activities.

In any infringement litigation, any award of monetary damages we receive may not be commercially valuable. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are resolved. Further, any claims we assert against a perceived infringer could provoke these parties to assert counterclaims against us alleging that we have infringed their patents. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

In addition, our patents and patent applications could face other challenges, such as interference proceedings, opposition proceedings, re-examination proceedings, and other forms of post-grant review. In the United States, for example, post-grant review has recently been expanded. Any of these challenges, if successful, could result in the invalidation of, or in a narrowing of the scope of, any of our patents and patent applications subject to challenge. Any of these challenges, regardless of their success, would likely be time consuming and expensive to defend and resolve and would divert our management and scientific personnel's time and attention.

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

We will need to obtain FDA approval of any proposed product names, and any failure or delay associated with such approval may adversely affect our business.

Any name we intend to use for our product candidates will require approval from the FDA regardless of whether we have secured a formal trademark registration from the USPTO. The FDA typically conducts a review of proposed product names, including an evaluation of the potential for confusion with other product names. The FDA may also object to a product name if it believes the name inappropriately implies certain medical claims or contributes to an overstatement of efficacy. If the FDA objects to any of our proposed product names, we may be required to adopt an alternative name for our product candidates. If we adopt an alternative name, we would lose the benefit of our existing trademark applications for such product candidate and may be required to expend significant additional resources in an effort to identify a suitable product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our product candidates.

If we do not obtain additional protection under the Hatch-Waxman Amendments and similar foreign legislation extending the terms of our patents and obtaining data exclusivity for our product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of FDA regulatory approval for our product candidates, one or more of our U.S. patents may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. Patent term restorations, however, cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval by the FDA.

The application for patent term extension is subject to approval by the USPTO, in conjunction with the FDA. It takes at least six months to obtain approval of the application for patent term extension. We may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product will be shortened and our competitors may obtain earlier approval of competing products, and our ability to generate revenues could be materially adversely affected.

Risks Related to Our Business Operations and Industry

We will need to significantly increase the size of our organization, and we may experience difficulties in managing growth.

We are currently a small company with eleven full-time employees as of July 31, 2015, and we outsource to consultants or other organizations substantially all of our operations, including accounting, finance, research and development and conduct of clinical trials. In order to commercialize our product candidates, we will need to substantially increase our operations. We plan to continue to build our compliance, financial and operating infrastructure to ensure the maintenance of a well-managed company. We expect to significantly expand our employment base when we reach the full commercial stages of our current product candidates' life cycle.

Future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees. In addition, to meet our obligations as a public company, we will need to increase our general and administrative capabilities. Our management, personnel and systems currently in place may not be adequate to support this future growth. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to:

- manage our clinical trials and the regulatory process effectively;
- manage the manufacturing of product candidates and potential products for clinical and commercial use;
- integrate current and additional management, administrative, financial and sales and marketing personnel;
- develop a marketing and sales infrastructure;
- hire new personnel necessary to effectively commercialize our product candidates;
- develop our administrative, accounting and management information systems and controls; and
- hire and train additional qualified personnel.

Product candidates that we may acquire or develop in the future may be intended for patient populations that are large. In order to continue development and marketing of these product candidates, if approved, we would need to significantly expand our operations. Our staff, financial resources, systems, procedures or controls may be inadequate to support our operations and our management may be unable to manage successfully future market opportunities or our relationships with customers and other third parties. In particular, we will need to build out our finance, accounting and reporting infrastructure to meet our reporting obligations as a public company. Because we have never had this infrastructure, there may be increased risk that we will not be able to adequately meet these reporting obligations in a timely manner.

In addition, we may in the future decide to move our primary office into a new facility to address our business needs. This potential relocation could disrupt our operations, resulting in slower realization of efficiencies and capacity which could be associated with our use of a new office space.

We are a clinical-stage company and it may be difficult for you to evaluate the success of our business to date and to assess our future viability.

We are a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of therapies for glaucoma. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, conducting research and developing our product candidates. We have not yet demonstrated our ability to successfully complete a pivotal Phase 3 clinical trial, obtain regulatory approval of a product candidate, 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. Consequently, any predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history and more experience with late stage development and commercialization of product candidates.

In addition, as a new business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to transition from a company with a product development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

We depend upon our key personnel and our ability to attract and retain employees.

Our future growth and success depend on our ability to recruit, retain, manage and motivate our employees. We are highly dependent on our senior management team and our scientific founders, as well as the other principal members of our management and scientific teams. Although we have formal employment agreements with our executive officers, these agreements do not prevent them from terminating their employment with us at any time. The loss of the services of any member of our senior management or scientific team or the inability to hire or retain experienced management personnel could adversely affect our ability to execute our business plan and harm our operating results.

Because of the specialized scientific and managerial nature of our business, we rely heavily on our ability to attract and retain qualified scientific, technical and managerial personnel. In particular, the loss of David P. Southwell, our President and Chief Executive Officer, Rudolf A. Baumgartner, M.D., our Executive Vice President and Chief Medical Officer, William K. McVicar, Ph.D., our Executive Vice President and Chief Scientific Officer or Dale Ritter, our Vice President—Finance, could be detrimental to

us if we cannot recruit suitable replacements in a timely manner. We do not currently carry "key person" insurance on the lives of members of executive management. The competition for qualified personnel in the pharmaceutical field is intense. Due to this intense competition, we may be unable to continue to attract and retain qualified personnel necessary for the development of our business or to recruit suitable replacement personnel. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission ("SEC"). We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

If we engage in acquisitions in the future, we will incur a variety of costs and we may never realize the anticipated benefits of such acquisitions.

We may attempt to acquire businesses, technologies, services, products or other product candidates in the future that we believe are a strategic fit with our business. We have no present agreement regarding any material acquisitions. However, if we do undertake any acquisitions, the process of integrating an acquired business, technology, service, product candidates or potential products into our business may result in unforeseen operating difficulties and expenditures, including diversion of resources and management's attention from our core business. In addition, we may fail to retain key executives and employees of the companies we acquire, which may reduce the value of the acquisition or give rise to additional integration costs. Future acquisitions could result in additional issuances of equity securities that would dilute the ownership of existing stockholders. Future acquisitions could also result in the incurrence of debt, actual or contingent liabilities or the amortization of expenses related to other intangible assets, any of which could adversely affect our operating results. In addition, we may fail to realize the anticipated benefits of any acquisition.

Our business is affected by macroeconomic conditions.

Various macroeconomic factors could adversely affect our business and the results of our operations and financial condition, including changes in inflation, interest rates and foreign currency exchange rates and overall economic conditions and uncertainties, including those resulting from current and future conditions in the global financial markets. For instance, if inflation or other factors were to significantly increase our business costs, it may not be feasible to pass through price increases to patients. Interest rates, the liquidity of the credit markets and the volatility of the capital markets could also affect the value of our investments and our ability to liquidate our investments in order to fund our operations.

Interest rates and the ability to access credit markets could also adversely affect the ability of patients, payors and distributors to purchase, pay for and effectively distribute our products. Similarly, these macroeconomic factors could affect the ability of our potential future contract manufacturers, sole-source or single-source suppliers or licensees to remain in business or otherwise manufacture or supply product. Failure by any of them to remain in business could affect our ability to manufacture products.

If product liability lawsuits are successfully brought against us, our insurance may be inadequate and we may incur substantial liability.

We face an inherent risk of product liability claims as a result of the clinical testing of our product candidates. We will face an even greater risk if we commercially sell our product candidates or any other potential products that we develop. We maintain product liability insurance with an aggregate limit of $10 million that cover our clinical trials and we plan to maintain insurance against product liability lawsuits for commercial sale of our product candidates. Historically, the potential liability associated with product liability lawsuits for pharmaceutical products has been unpredictable. Although we believe that our current insurance is a reasonable estimate of our potential liability and represents a commercially reasonable balancing of the level of coverage as compared to the cost of the insurance, we may be subject to claims in connection with our clinical trials and, in the future, commercial use of our product candidates, for which our insurance coverage may not be adequate, and the cost of any product liability litigation or other proceeding, even if resolved in our favor, could be substantial.

For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of

warranties. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Regardless of the merits or eventual outcome, liability claims may result in:

- reduced resources of our management to pursue our business strategy;
- decreased demand for our product candidates or potential products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- termination of clinical trial sites or entire trial programs;
- initiation of investigations by regulators;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- significant costs to defend resulting litigation;
- diversion of management and scientific resources from our business operations;
- substantial monetary awards to trial participants or patients;
- loss of revenue; and
- the inability to commercialize any products that we may develop.

We will need to increase our insurance coverage if our product candidates receive marketing approval and we begin selling them. However, the product liability insurance we will need to obtain in connection with the commercial sales of our product candidates, if and when they receive regulatory approval, may be unavailable in meaningful amounts or at a reasonable cost. In addition, insurance coverage is becoming increasingly expensive. If we are unable to obtain or maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against product liability claims, it could prevent or inhibit the development and commercial production and sale of our product candidates, if and when they obtain regulatory approval, which could materially adversely affect our business, financial condition, results of operations, cash flows and prospects.

Additionally, we do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include general liability, employment practices liability, auto, property, workers' compensation, products liability and directors' and officers' insurance. We do not know, however, if we will be able to maintain insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would materially adversely affect our financial position, cash flows and results of operations.

Business interruptions could delay us in the process of developing our products and could disrupt our sales.

Our headquarters is located in Lexington, Massachusetts. We are vulnerable to natural disasters, such as severe storms and other events that could disrupt our business operations. We do not carry insurance for natural disasters and we may not carry sufficient business interruption insurance to compensate us for losses that may occur. Any losses or damages we incur could have a material adverse effect on our business operations.

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

Despite the implementation of security measures, our internal computer systems, and those of our CROs and other third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed.

Our employees, independent contractors, principal investigators, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading, which could significantly harm our business.

We are exposed to the risk of fraud or other misconduct by employees and independent contractors, such as principal investigators, consultants, commercial partners and vendors. Misconduct by these parties could include failures to comply with the regulations of the FDA and comparable non-U.S. regulatory authorities, provide accurate information to the FDA and comparable non-U.S. regulatory authorities, comply with fraud and abuse and other healthcare laws in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and other business arrangements in the healthcare industry are subject to extensive laws intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws may restrict or prohibit a wide range of business activities, including, but not limited to, research, manufacturing, distribution, pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We adopted a code of ethics, but it is not always

possible to identify and deter employee and other third-party misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws. If any such actions are instituted against us resulting from such misconduct those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate.

We and our development partners, third-party manufacturers and suppliers use biological materials and may use hazardous materials, and any claims relating to improper handling, storage or disposal of these materials could be time consuming or costly.

We and our development partners, third-party manufacturers and suppliers may use hazardous materials, including chemicals and biological agents and compounds that could be dangerous to human health and safety or the environment. Our operations and the operations of our third-party manufacturers and suppliers also produce hazardous waste products. Federal, state and local laws and regulations govern the use, generation, manufacture, storage, handling and disposal of these materials and wastes. Compliance with applicable environmental laws and regulations may be expensive and current or future environmental laws and regulations may impair our product development efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended.

The availability of our common stock and securities linked to our common stock for sale in the future could reduce the market price of our common stock.

In the future, we may issue equity and equity-linked securities to raise cash for acquisitions or otherwise. We may also acquire interests in other companies by using a combination of cash and our common stock or just our common stock. We may also issue preferred stock or additional securities convertible into our common stock or preferred stock. Any of these events may dilute your ownership interest in our Company and have an adverse effect on the price of our common stock.

Risks Related to Ownership of Our Common Stock

The market price of our common stock may be highly volatile, and you may not be able to resell your shares at or above the offering price.

Our initial public offering was completed in February 2015. Therefore, there has only been a public market for our common stock for a short period of time. Our common stock is listed on NASDAQ. Since shares of our common stock were sold in our initial public offering in February 2015 at $6.00 per share, our closing stock price has reached a high of $19.45 and a low of $4.71 through August 6, 2015.

The trading price of our common stock is likely to continue to be volatile, and you can lose all or part of your investment in us. The following factors, in addition to other factors described in this “Risk Factors” section and elsewhere in our Annual Report on Form 10-K for the year ended December 31, 2014, may have a significant impact on the market price of our common stock:

- announcements of regulatory approval or a complete response letter, or specific label indications or patient populations for its use, or changes or delays in the regulatory review process;
- announcements of therapeutic innovations or new products by us or our competitors;
- adverse actions taken by regulatory agencies with respect to our clinical trials, manufacturing supply chain or sales and marketing activities;
- any adverse changes to our relationship with manufacturers or suppliers;
- the results of our testing and clinical trials;
- the results of our efforts to acquire or license additional product candidates;
- variations in the level of expenses related to our existing product candidates or preclinical and clinical development programs;
- any intellectual property infringement actions in which we may become involved;
- announcements concerning our competitors or the pharmaceutical industry in general;
- achievement of expected product sales and profitability;
- manufacture, supply or distribution shortages;
- actual or anticipated fluctuations in our quarterly or annual operating results;
- changes in financial estimates or recommendations by securities analysts;
- trading volume of our common stock;
- sales of our common stock by us, our executive officers and directors or our stockholders in the future;

- sales by us of securities linked to our common stock, such as the 2020 Convertible Notes;
- general economic and market conditions and overall fluctuations in the U.S. equity markets;
- changes in accounting principles; and
- the loss of any of our key scientific or management personnel.

In addition, the stock market, in general, and small pharmaceutical and biotechnology companies have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. Further, a significant decline in the financial markets and other related factors beyond our control may cause our stock price to decline rapidly and unexpectedly.

We may be subject to securities litigation, which is expensive and could divert management attention.

Our share price has been and may continue to be volatile, and in the past companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Litigation of this type could result in substantial costs and diversion of management's attention and resources, which could adversely impact our business. Any adverse determination in litigation could also subject us to significant liabilities.

Our existing principal stockholders, executive officers and directors own a significant percentage of our common stock and will be able to exert a significant control over matters submitted to our stockholders for approval.

As of June 30, 2015, our officers and directors, and stockholders who own more than 5% of our outstanding common stock, in the aggregate, beneficially owned approximately 75% of our common stock.

This significant concentration of share ownership may adversely affect the trading price for our common stock because investors often perceive disadvantages in owning stock in companies with controlling stockholders. As a result, these stockholders, if they acted together, could significantly influence all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions. These stockholders may be able to determine all matters requiring stockholder approval. The interests of these stockholders may not always coincide with our interests or the interests of other stockholders. This may also prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

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

Sales of a substantial number of shares of our common stock or any of our securities linked to our common stock, such as the 2020 Convertible Notes, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities or equity-linked securities. Substantially all of our stockholders prior to our initial public offering are subject to lock-up agreements with the underwriters of our initial public offering that restrict the stockholders' ability to transfer shares of our common stock for a period of 180 days after the date of the initial public offering, February 17, 2015 (the "IPO Lock Up Period"). Certain of our officers, directors and such directors' affiliates are subject to lock-up agreements with the underwriters of this offering that restrict their ability to transfer shares of our common stock for a period of 90 days after the date of our currently contemplated public offering, if such offering is consummated (the "Subsequent Lock-Up Period"). As of June 30, 2015, we had 16,327,003 outstanding shares of common stock, which excludes:

- 1,394,075 shares of common stock issuable upon the exercise of stock options outstanding as of June 30, 2015, at a weighted-average exercise price of $4.92 per share;
- 56,408 shares of common stock issuable upon the exercise of warrants outstanding as of June 30, 2015, which have an exercise price of $6.204 per share;
- approximately 3.86 million shares of common stock issued pursuant to the conversion of $21.0 million of the principal amount of the 2020 Convertible Notes through August 6, 2015, including approximately 3.33 million shares related to the underlying 2020 Convertible Notes and approximately 0.53 million shares issued pursuant to the interest make-whole provision, which the Company elected to settle in shares; and
- any shares sold in connection with our currently contemplated public offering.

Subject to limitations, approximately 3.3 million shares will become eligible for sale upon expiration of the IPO Lock-Up Period, and approximately 8.7 million shares will become eligible for sale upon the expiration of the Subsequent Lock-Up Period. In addition, shares issued or issuable upon exercise of options and warrants vested as of the expiration of the lock-up period will be eligible for sale at that time. Sales of stock by these stockholders could have a material adverse effect on the trading price of our common stock.

At June 30, 2015, holders of an aggregate of 8.8 million shares of our common stock will have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. Registration of these shares under the Securities Act of 1933, as amended, or the Securities Act, would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by our affiliates as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

If securities or industry analysts do not publish or cease publishing research or reports about us, our business or our market, or if they adversely change their recommendations or publish negative reports regarding our business or our stock, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts may publish about us, our business, our market or our competitors. We do not have any control over these analysts and we cannot provide any assurance that analysts will cover us or provide favorable coverage. If any of the analysts who may cover us adversely change

their recommendation regarding our stock, or provide more favorable relative recommendations about our competitors, our stock price could decline. If any analyst who may cover us were to cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

Because we do not intend to declare cash dividends on our shares of common stock in the foreseeable future, stockholders must rely on appreciation of the value of our common stock for any return on their investment.

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends in the foreseeable future. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, we expect that only appreciation of the price of our common stock, if any, will provide a return to holders of our securities for the foreseeable future.

If we are unable to substantially utilize our net operating loss carryforward, our financial results will be adversely affected.

As of December 31, 2014, we had federal and state net operating losses of approximately $77 million and $36 million, respectively, which may be utilized against future federal and state income taxes, respectively. In general, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change net operating losses ("NOLs") to offset future taxable income. In general, an ownership change occurs if the aggregate stock ownership of certain stockholders (generally 5% stockholders, applying certain look-through and aggregation rules) increases by more than fifty percentage points over such stockholders' lowest percentage ownership during the testing period (generally three years). Purchases of our common stock in amounts greater than specified levels, which are beyond our control, or prior issuances of our common stock, could create a limitation on our ability to utilize our NOLs for tax purposes in the future. Limitations imposed on our ability to utilize NOLs could cause federal and state income taxes to be paid earlier than would be paid if such limitations were not in effect and could cause such NOLs to expire unused, in each case reducing or eliminating the benefit of such NOLs. Furthermore, we may not be able to generate sufficient taxable income to utilize our NOLs before they expire. If any of these events occur or have occurred in the past, we may not derive some or all of the expected benefits from our NOLs. In addition, at the state level there may be periods during which the use of NOLs is suspended or otherwise limited, which would accelerate or may permanently increase state taxes owed.

The requirements associated with being a public company require significant company resources and management attention.

We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act of 2002, as amended (the "Sarbanes-Oxley Act"), the listing requirements of the securities exchange on which our common stock is traded and other applicable securities rules and regulations. The Exchange Act requires that we file annual, quarterly and current reports with respect to our business and financial condition and maintain effective disclosure controls and procedures and internal control over financial reporting. In addition, subsequent rules implemented by the SEC and NASDAQ may also impose various additional requirements on public companies. As a result, we incur substantial legal, accounting and other expenses. Further, the corporate infrastructure demanded of a public company may divert management's attention from implementing our growth strategy. We have made, and will continue to make, changes to our corporate governance standards, disclosure controls and financial reporting and accounting systems to meet our reporting obligations. However, the measures we take may not be sufficient to satisfy our obligations as a public company, which could subject us to delisting of our common stock, fines, sanctions and other regulatory action and potentially civil litigation.

We will incur increased costs as a result of operating as a public company, and our management team will be required to devote substantial time to new compliance initiatives.

Now that we are a public company, and particularly after we are no longer considered an "emerging growth company," we will incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act of 2002 and rules subsequently implemented by the Securities and Exchange Commission and The NASDAQ Stock Market have imposed various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 ("Section 404"), we will be required to furnish a report by our management on our internal control over financial reporting, including an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that neither we nor our independent registered public accounting firm will be able to conclude that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our consolidated financial statements.

The JOBS Act will allow us to postpone the date by which we must comply with some of the laws and regulations intended to protect investors and to reduce the amount of information we provide in our reports filed with the SEC, which could undermine investor confidence in our company and adversely affect the market price of our common stock.

For so long as we remain an "emerging growth company" as defined in the JOBS Act, we may take advantage of certain exemptions from various requirements that are applicable to public companies that are not "emerging growth companies" including:

- the provisions of Section 404(b) of the Sarbanes-Oxley Act requiring that our independent registered public accounting firm provide an attestation report on the effectiveness of our internal control over financial reporting;
- the "say on pay" provisions (requiring a non-binding stockholder vote to approve compensation of certain executive officers) and the "say on golden parachute" provisions (requiring a non-binding stockholder vote to approve golden parachute arrangements for certain executive officers in connection with mergers and certain other business combinations) of the Dodd-Frank Wall Street Reform and Consumer Protection Act ("Dodd-Frank Act"), and some of the disclosure requirements of the Dodd-Frank Act relating to compensation of its chief executive officer;
- the requirement to provide detailed compensation discussion and analysis in proxy statements and reports filed under the Exchange Act, and instead provide a reduced level of disclosure concerning executive compensation; and
- any rules that may be adopted by the Public Company Accounting Oversight Board requiring mandatory audit firm rotation or a supplement to the auditor's report on the financial statements.

We may take advantage of these exemptions until we are no longer an "emerging growth company." We would cease to be an "emerging growth company" upon the earliest of: (i) December 31, 2020; (ii) the last day of the first fiscal year in which our annual gross revenues are $1 billion or more; (iii) the date on which we have, during the previous three-year period, issued more than $1 billion in non-convertible debt securities; or (iv) as of the end of any fiscal year in which the market value of our common stock held by non-affiliates exceeded $700 million as of the end of the second quarter of that fiscal year.

Although we are still evaluating the JOBS Act, we currently intend to take advantage of some, but not all, of the reduced regulatory and reporting requirements that will be available to us so long as we qualify as an "emerging growth company." For example, we have irrevocably elected under Section 107 of the JOBS Act not to take advantage of the extension of time to comply with new or revised financial accounting standards available under Section 102(b) of the JOBS Act. Our independent registered public accounting firm will not be required to provide an attestation report on the effectiveness of our internal control over financial reporting so long as we qualify as an "emerging growth company," which may increase the risk that weaknesses or deficiencies in our internal control over financial reporting go undetected. Likewise, so long as we qualify as an "emerging growth company," we may elect not to provide you with certain information, including certain financial information and certain information regarding compensation of our executive officers, that we would otherwise have been required to provide in filings we make with the SEC, which may make it more difficult for investors and securities analysts to evaluate our company. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, and our stock price may be more volatile and may decline.

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

Provisions in our amended and restated certificate of incorporation and our bylaws as well as provisions of the Delaware General Corporation Law ("DGCL"), could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions include:

- establishing a classified Board of Directors such that not all members of the board are elected at one time;
- allowing the authorized number of our directors to be changed only by resolution of our Board of Directors;
- limiting the removal of directors by the stockholders;
- authorizing the issuance of "blank check" preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;
- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;
- eliminating the ability of stockholders to call a special meeting of stockholders;
- establishing advance notice requirements for nominations for election to the Board of Directors or for proposing matters that can be acted upon at stockholder meetings; and
- requiring the approval of the holders of at least 75% of the votes that all our stockholders would be entitled to cast to amend or repeal our bylaws.

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

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

Unregistered Sales of Equity Securities

None.

Use of Proceeds from Initial Public Offering of Common Stock

On February 17, 2015 we issued and sold 6,667,000 shares of our common stock and on March 19, 2015 we issued and sold 299,333 shares of common stock pursuant to the underwriters' partial exercise of their option to purchase additional shares, in our IPO at a public offering price of $6.00 per share, for aggregate gross proceeds of $41.8 million. In addition, on February 17, 2015 we issued and sold $20.0 million of our 2020 Convertible Notes and on March 19, 2015 we issued and sold an additional $1.0 million of our 2020 Convertible Notes pursuant to the underwriters' partial exercise of their option to purchase additional 2020 Convertible Notes, in our IPO at face value in a public offering for aggregate gross proceeds of $21.0 million. All of the shares and notes issued and sold in the IPO were registered under the Securities Act pursuant to a Registration Statement on Form S-1 (File No. 333-199859), which was declared effective by the SEC on February 17, 2015. Cowen and Company, LLC and Piper Jaffray & Co. acted as joint book-running managers of the common stock offering and Canaccord Genuity Inc. and Nomura Securities International, Inc. acted as co-managers of the common stock offering. Nomura Securities International, Inc., Cowen and Company, LLC and Piper Jaffray & Co. acted as joint book-running managers of the of the concurrent offering of the 2020 Convertible Notes and Canaccord Genuity Inc. acted as co-manager of the concurrent offering of 2020 Convertible Notes.

The net offering proceeds to us from the equity offering, after deducting underwriting discounts of $2.9 million and offering expenses paid by us totaling $2.3 million, were approximately $36.5 million. The net offering proceeds to us from the debt offering, after deducting underwriting discounts of $1.5 million and offering expenses paid by us totaling $0.6 million, were approximately $18.9 million. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning 10.0% or more of any class of our equity securities or to any other affiliates.

There has been no material change in our planned use of the balance of the net proceeds from the offering described in the Prospectus.

Item 3. Defaults upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

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

SIGNATURES

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

INOTEK PHARMACEUTICALS CORPORATION

August 6, 2015

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

August 6, 2015

By: /s/ Dale Ritter
Dale Ritter
Vice President–Finance
(Principal Financial and Accounting Officer)

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EXHIBIT INDEX

Exhibit No.	Description	Incorporated by Reference to: Form or Schedule	Exhibit No.	Filing Date with SEC	SEC File Number
3.1	Amended and Restated Certificate of Incorporation of the Registrant.	10-K	3.1	3/31/15	001-36829
3.2	Amended and Restated By-Laws of the Registrant.	10-K	3.2	3/31/15	001-36829
4.1	Specimen Common Stock Certificate of the Registrant.	10-K	4.1	3/31/15	001-36829
31.1*	Certification of Principal Executive Officer pursuant to Exchange Act rules 13a-14 or 15d-14.				
31.2*	Certification of Principal Financial Officer pursuant to Exchange Act rules 13a-14 or 15d-14.				
32.1*	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Exchange Act rules 13a-14(b) or 15d-14(b) and 18 U.S.C. Section 1350.				
101.INS	XBRL Instance Document.				
101.SCH	XBRL Taxonomy Extension Schema Document.				
101.CAL	XBRL Taxonomy Extension Calculation Document.				
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.				
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document.				
101.PRE	XBRL Taxonomy Extension Presentation Link Document.				

* Filed herewith.

Exhibit 31.1

Certification

I, David P. Southwell, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the period ended June 30, 2015, of Inotek Pharmaceuticals Corporation;

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

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

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

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

   b. (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

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

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

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

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

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

Date: August 6, 2015

/s/ David P. Southwell

David P. Southwell
President, Chief Executive Officer and Director
(Principal Executive Officer)

Exhibit 31.2

Certification

I, Dale Ritter, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the period ended June 30, 2015, of Inotek Pharmaceuticals Corporation;

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

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

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

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

   b. (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

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

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

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

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

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

Date: August 6, 2015

/s/ Dale Ritter

Dale Ritter
Vice President–Finance
(Principal Financial Officer)

Exhibit 32.1

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

In connection with the quarterly report on Form 10-Q of Inotek Pharmaceuticals Corporation (the "Company") for the period ended June 30, 2015, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers hereby certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350, that their knowledge:

1) the Report which this statement accompanies fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

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

Date: August 6, 2015

/s/ David. P. Southwell
David P. Southwell
President, Chief Executive Officer and Director
(Principal Executive Officer)

Date: August 6, 2015

/s/ Dale Ritter
Dale Ritter
Vice President–Finance
(Principal Financial Officer)