TOBIRA THERAPEUTICS, INC.

FORM 10-Q
(Quarterly Report)

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Symbol	TBRA
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Fiscal Year	12/31

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2015

OR

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

For the transition period from ____to ____

Commission File Number: 001-35953

TOBIRA THERAPEUTICS, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**03-0422069**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
701 Gateway Blvd., Suite 300 South San Francisco, CA	**94080**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (650) 741-6625

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 small reporting company)	Small 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 November 6, 2015, there were 18,809,993 shares of the Registrant's common stock outstanding.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report contains forward-looking statements that are based on our beliefs and assumptions and on information currently available to us. Forward-looking statements include information concerning our expectations for the timing of clinical study results, including the CENTAUR and ORION studies, and the timing and success of future development of CVC, our possible or assumed future results of operations and expenses, business strategies and plans, trends, market sizing, competitive position, industry environment and potential growth opportunities, among other things. Forward-looking statements include all statements that are not historical facts and, in some cases, can be identified by terms such as “anticipates,” “believes,” “could,” “estimates,” “expects,” “intends,” “may,” “plans,” “potential,” “predicts,” “projects,” “seeks,” “should,” “will,” “would” or similar expressions and the negatives of those terms.

Forward-looking statements 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 the forward-looking statements, including those described in “Risk Factors” and elsewhere in this report. Given these uncertainties, you should not place undue reliance on these forward-looking statements.

Any forward-looking statement made by us in this report speaks only as of the date on which it is made. Except as required by law, we disclaim any obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

As used in this report, the term “Private Tobira” refers to Tobira Development, Inc. (formerly known as Tobira Therapeutics, Inc.) prior to the consummation of the Merger described in this report and references to the terms the "combined company”, “Tobira”, the "Company”, “we”, “our” and “us” refer to Private Tobira, prior to the consummation of the Merger described in this report and Tobira Therapeutics, Inc. (formerly known as Regado Biosciences, Inc.) and its subsidiaries upon the consummation of the Merger described in this report. The term "Regado" refers to the Regado Biosciences, Inc. and its subsidiaries prior to the Merger described in this report.

TOBIRA THERAPEUTICS, INC.
FORM 10-Q
FOR THE QUARTER ENDED SEPTEMBER 30, 2015

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PART I. FINANCI AL INFORMATION

Item 1. Financial Statements (Unaudited).

TOBIRA THERAPEUTICS, INC.
CONDENSED BALANCE SHEETS
(In thousands, except share and per share data)

	September 30, 2015 (Unaudited)	December 31, 2014 (Note 2)
Assets		
Current assets:		
Cash and cash equivalents	$ 68,624	$ 6,178
Prepaid expenses and other current assets	886	1,013
Total current assets	69,510	7,191
Property and equipment, net	416	474
Restricted cash	334	334
Other assets	1,560	347
Total assets	$ 71,820	$ 8,346
Liabilities, convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 1,283	$ 1,887
Accrued expenses and other liabilities	3,898	6,503
Capital lease obligations	23	21
Deferred rent	53	57
Convertible notes, related party	—	29,770
Total current liabilities	5,257	38,238
Capital lease obligations	23	40
Deferred rent	194	219
Term loan	15,013	14,789
Preferred stock warrant liabilities	—	2,460
Total liabilities	20,487	55,746
Commitments and contingencies (Note 11)		
Convertible preferred stock	—	61,982
Stockholders' equity (deficit):		
Preferred stock, par value $0.001; 1,000,000 and no shares authorized at September 30, 2015 and December 31, 2014, respectively; no shares issued and outstanding at September 30, 2015 and December 31, 2014	—	—
Common stock, par value $0.001; 500,000,000 shares authorized and 18,809,993 shares issued and outstanding at September 30, 2015; common stock, par value $0.0001; 8,456,867 shares authorized and 403,539 shares issued and outstanding at December 31, 2014	19	—
Additional paid-in capital	205,304	4,378
Accumulated other comprehensive income (loss)	—	—
Accumulated deficit	(153,990)	(113,760)
Total stockholders' equity (deficit)	51,333	(109,382)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 71,820	$ 8,346

See accompanying notes to unaudited condensed financial statements.

TOBIRA THERAPEUTICS, INC.
CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Unaudited)
(In thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Operating expenses				
Research and development	$ 6,092	$ 3,511	$ 18,379	$ 8,274
General and administrative	2,826	12	8,097	2,754
Impairment of intangible assets	17,315	—	17,315	—
Total operating expenses	26,233	3,523	43,791	11,028
Loss from operations	(26,233)	(3,523)	(43,791)	(11,028)
Other income (expense), net				
Interest expense	(335)	(1,514)	(2,770)	(3,795)
Change in fair value of preferred stock warrant liabilities	—	2,097	1,939	1,408
Loss before income tax benefit (expense)	(26,568)	(2,940)	(44,622)	(13,415)
Income tax benefit (expense)	4,357	—	4,392	(271)
Net loss and comprehensive loss	$ (22,211)	$ (2,940)	$ (40,230)	$ (13,686)
Net loss per share, basic and diluted	$ (1.22)	$ (7.29)	$ (4.05)	$ (33.91)
Weighted-average common shares outstanding, basic and diluted	18,184,146	403,539	9,929,260	403,539

See accompanying notes to unaudited condensed financial statements.

TOBIRA THERAPEUTICS, INC.
CONDENSED STATEMENTS OF CASH FLOWS
(Unaudited)
(In thousands)

	Nine Months Ended September 30,	
	2015	**2014**
Operating activities		
Net loss	$ (40,230)	$ (13,686)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	89	21
Stock-based compensation	1,474	528
Loss on disposal of assets	—	3
Amortization of debt discount	422	834
Change in fair value of preferred stock warrant liabilities	(1,939)	(1,408)
Noncash interest expense on convertible notes	1,068	1,740
Amortization of beneficial conversion feature	429	895
Amortization of debt issuance costs	66	14
Deferred income taxes	(4,392)	—
Impairment of intangible assets	17,315	—
Change in assets and liabilities:		
Prepaid expenses and other assets	302	(761)
Restricted cash	—	(334)
Accounts payable and accrued expenses	232	1,428
Deferred rent	(33)	26
Net cash used in operating activities	(25,197)	(10,700)
Investing activities		
Cash received from merger transaction	33,232	—
Purchase of property and equipment	(31)	(130)
Net cash provided by (used in) investing activities	33,201	(130)
Financing activities		
Proceeds from issuance of common stock, net	41,504	—
Proceeds from borrowings — term loans, net	—	14,822
Proceeds from convertible notes, net	12,954	7,984
Payments on term loan	—	(1,833)
Payments on capital lease obligations	(16)	—
Costs paid in connection with preparations for initial public offering	—	(2,423)
Net cash provided by financing activities	54,442	18,550
Net increase in cash and cash equivalents	62,446	7,720
Cash and cash equivalents at beginning of period	6,178	4,088
Cash and cash equivalents at end of period	$ 68,624	$ 11,808
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 786	$ 223
Noncash activities:		
Conversion of promissory notes and interest to common stock	$ 48,221	$ —
Conversion of Series A and B preferred stock to common stock	$ 61,982	$ —
Conversion of Series F preferred stock to common stock	$ 24,832	$ —
Financing costs in accounts payable and accrued expenses	$ 130	$ —
Beneficial conversion feature related to promissory notes	$ 396	$ —
Reclassification of preferred stock warrant liability to additional paid-in capital	$ 521	$ —
Issuance of common stock to financial advisors — Merger transaction	$ 852	$ —
Issuance of warrants — term loan and convertible notes, related party	$ —	$ 868
Reclassification of stock award liability from equity upon modification	$ —	$ 399
Accrued deferred initial public offering costs	$ —	$ 1,147
Landlord paid leasehold improvements	$ —	$ 259
Equipment purchased under capital lease	$ —	$ 70
Accrued debt issuance costs	$ —	$ 25
Fair value of assets acquired and liabilities assumed in the Merger:		
Fair value of assets acquired	$ 18,723	$ —
Fair value of liabilities assumed	(5,832)	—
Fair value of net assets acquired in the Merger	$ 12,891	$ —

See accompanying notes to unaudited condensed financial statements.

1. DESCRIPTION OF BUSINESS

Tobira Therapeutics, Inc., or Tobira or the Company, is a clinical-stage biopharmaceutical company focused on the development and commercialization of therapeutics to treat NASH, or nonalcoholic steatohepatitis, which is a form of liver disease affecting 3-5% of the U.S. population and is becoming the leading cause of liver transplant. The Company's lead product candidate, cenicriviroc, or CVC, is a proprietary immunomodulator that can potentially be used to treat a number of disease states with high unmet medical need such as NASH, fibrosis, inflammation and human immunodeficiency virus, or HIV. CVC is a once-daily pill with well-established safety and tolerability in approximately 600 subjects dosed in completed Phase 1 and Phase 2 trials, including a pharmacokinetics, or PK, and safety study in subjects with liver cirrhosis and 115 HIV infected subjects on treatment for up to 48 weeks.

Tobira is developing CVC for NASH, for which the Company recently completed enrollment of a Phase 2b clinical trial of CVC in 289 subjects with confirmed NASH and liver fibrosis entitled CENTAUR. The Company expects to announce CENTAUR primary endpoint results in the third quarter of 2016 and the study design incorporates surrogate endpoints that may form the basis for demonstrating efficacy required for accelerated approval. The U.S. Food and Drug Administration, or the FDA, Accelerated Approval Program allows for earlier approval of drugs that treat serious conditions and fill an unmet medical need based on a surrogate endpoint. CVC has been granted Fast Track designation by the FDA for the treatment of NASH in patients with liver fibrosis. Tobira is developing CVC both as a standalone, as well as a cornerstone for combination therapies for NASH and fibrosis and expects to present initial clinical combination data in 2015.

Reverse Merger

On May 4, 2015, Regado Biosciences, Inc., or Regado, completed its business combination with Private Tobira in accordance with the terms of an Agreement and Plan of Merger and Reorganization, dated as of January 14, 2015, as amended on January 23, 2015, or the Merger Agreement. Pursuant to the Merger Agreement, a newly formed wholly-owned subsidiary was established that merged with and into Private Tobira, with Private Tobira surviving the merger and becoming a wholly-owned subsidiary of Regado, or the Merger. In connection with the Merger, the name of Private Tobira was changed to Tobira Development, Inc., or Tobira Development. In connection with, and immediately prior to, the completion of the Merger, Regado filed an amended and restated certificate of incorporation with the Secretary of State of the State of Delaware to effect a one for nine reverse stock split of Regado's common stock. In connection with and immediately following the consummation of the Merger, Regado filed an amendment to the amended and restated certificate of incorporation with the Secretary of State of the State of Delaware to change its name to Tobira Therapeutics, Inc. On June 29, 2015, a Certificate of Ownership and Merger was filed with the Secretary of State of the State of Delaware to effect the merger of Tobira Development with and into Tobira Therapeutics, Inc. As a result, Tobira Therapeutics, Inc. is the sole entity.

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

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying unaudited condensed financial statements have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP, for interim financial information and instructions to Form 10-Q and Article 10 of Regulation S-X set forth by the Securities and Exchange Commission, or the SEC, for interim reporting. As permitted under these rules, certain footnotes or other financial information normally required by GAAP may be condensed or omitted. These financial statements have been prepared on the same basis as the Company's annual financial statements and, in the opinion of management, reflect all adjustments including normal and recurring adjustments which the Company considers necessary for the fair presentation of financial information. The results of operations and comprehensive loss for the three and nine months ended September 30, 2015 are not necessarily indicative of expected results for the full fiscal year or any other period. The condensed balance sheet as of December 31, 2014 has been derived from audited financial statements but does not include all information required by U.S. GAAP for complete financial statements.

The accompanying unaudited condensed financial statements and notes should be read in conjunction with the audited financial statements and accompanying notes for the year ended December 31, 2014 included in the Current Report, as amended, on Form 8-K/A filed on June 2, 2015. There have been no significant and material changes in our critical accounting policies and significant judgments and estimates during the three and nine months ended September 30, 2015, except as described below.

Reverse Stock Splits

On May 4, 2015, Regado effected a one for nine reverse stock split of its outstanding common stock and options for common stock. The par value was not adjusted as a result of the reverse stock split.

On July 28, 2014, Private Tobira effected a one for 26.4065866 reverse stock split of Private Tobira's common stock, convertible preferred stock, preferred stock warrants and options for common stock, or the Private Tobira Reverse Split. The par value was not adjusted as a result of the Private Tobira Reverse Split. On February 23, 2015, in connection with the Private Tobira Reverse Split, Private Tobira filed a correction to its amended articles of incorporation to effect a one for 26.4065866 reverse stock split of its authorized shares of common stock, Series A preferred stock and Series B preferred stock.

The accompanying condensed financial statements and notes to the condensed financial statements give retroactive effect to the Private Tobira Reverse Split for all periods presented.

Deferred Offering Costs

Deferred offering costs, which primarily consist of direct incremental legal and accounting fees relating to an initial public offering, are capitalized and offset against initial public offering proceeds upon the consummation of an offering. In the event an offering is terminated, deferred offering costs are expensed. The Company capitalized deferred offering costs related to a planned initial public offering as of September 30, 2014 that were subsequently expensed as of December 31, 2014 upon its termination.

Business Combinations

Accounting for acquisitions requires extensive use of estimates and judgment to measure the fair value of the identifiable tangible and intangible assets acquired, including in-process research and development and liabilities assumed. Additionally, the Company must determine whether an acquired entity is considered a business or a set of net assets because the excess of the purchase price over the fair value of net assets acquired can only be recognized as goodwill in a business combination. The Company accounted for the Merger with Regado as a business combination under the acquisition method of accounting. Consideration paid to acquire Regado was measured at fair value and included the exchange of Regado's common stock, Series F preferred stock and vested stock options. The allocation of the purchase price resulted in recognition of intangible assets related to in-process research and development and goodwill. The key assumptions in determining the fair value of intangible assets were assessing the timing and estimated costs to complete the in-process projects, projecting regulatory approvals, developing an appropriate discount rate and the estimated future cash flows.

As a result of the Merger, historical common stock, stock options and additional paid-in capital, including share and per share amounts, have been retroactively adjusted to reflect the equity structure of the Company including the effect of the exchange ratio of 1.4302 and the Company's common stock par value of $0.001 per share.

In-Process Research and Development

In-process research and development, or IPR&D, represents the fair value assigned to research and development assets that were not fully developed as of the completion of the Merger. IPR&D acquired in a business combination is capitalized on the Company's balance sheet at its acquisition-date fair value. Until the project is completed, the asset is accounted for as an indefinite-lived intangible asset subject to impairment testing. Upon completion of a project, the carrying value of the related IPR&D is reclassified to intangible assets and is amortized over the estimated useful life of the asset. The Company evaluates the potential impairment of intangible assets if events or changes in circumstances indicate that the carrying amount of the asset may not be fully recoverable.

IPR&D consists of intellectual property related to Regado's aptamer platform and is valued based on the estimated net present value of future cash flows expected to be generated from commercialization. Through September 30, 2015, the Company engaged in discussions with several third parties to divest or license the aptamer platform but was unsuccessful in securing an agreement. The Company's board of directors agreed to discontinue investment in developing the intellectual property. As a result of this indicator of impairment, as of September 30, 2015, management calculated and compared the fair value of the IPR&D to the carrying value to assess the recoverability of the asset. As of September 30, 2015, the Company recorded an impairment of the IPR&D of $12.2 million which is included under the caption "Impairment of intangible assets" in the accompanying Condensed Statements of Operations and Comprehensive Loss.

Goodwill

Goodwill represents the difference between the consideration transferred and the fair value of the net assets acquired under the acquisition method of accounting. Goodwill is not amortized but is evaluated for impairment during the last fiscal quarter of the year or if indicators of impairment exist that would, more likely than not, reduce the fair value from its carrying amount.

The Company recorded goodwill related to the Merger on May 4, 2015. As noted above under In-Process Research and Development, the Company was unable to divest or license the aptamer platform and plans to discontinue investment in the Regado business. The Company determined the fair value was less than the carrying value and impaired the IPR&D associated with its acquisition of Regado as of September 30, 2015. Further, the Company determined the Regado operations acquired in the Merger had not been integrated with the Company and thus no benefit was realized. As a result, the Company recorded an impairment of goodwill of $5.1 million in accordance with the applicable guidance as of September 30, 2015, which is included under the caption "Impairment of intangible assets" in the accompanying Condensed Statements of Operations and Comprehensive Loss.

Stock-Based Compensation Expense

For stock options granted to employees, the Company recognizes compensation expense for all stock-based awards based on the grant date estimated fair value. The value of the portion of the award that is ultimately expected to vest is recognized as expense ratably over the requisite service period. The fair value of stock options is determined using the Black-Scholes option pricing model net of estimated forfeitures. The determination of fair value for stock-based awards on the date of grant using an option pricing model requires management to make certain assumptions regarding subjective variables.

Stock-based compensation expense related to stock options granted to non-employees is recognized based on the fair value of the stock options, determined using the Black-Scholes option pricing model, as the options are vested. The awards generally vest over the time period the Company expects to receive services from non-employees. Stock options granted to non-employees are subject to periodic revaluation over their vesting terms.

Net Loss Per Share

Basic net loss per common share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding during the period, without consideration for potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common shares and potentially dilutive securities outstanding for the period determined using the treasury-stock and if-converted methods. The calculation of diluted loss per share also requires that, to the extent the average market price of the underlying shares for the reporting period exceeds the exercise price of the warrants and the presumed exercise of such securities are dilutive to earnings (loss) per share for the period, adjustments to net income or net loss used in the calculation are required to remove the change in fair value of the warrants for the period. Likewise, adjustments to the denominator are required to reflect the related dilutive shares. For purposes of the diluted net loss per share calculation, convertible preferred stock, convertible notes and accrued interest, stock options and preferred stock warrants are considered to be potentially dilutive securities and are excluded from the calculation of diluted net loss per share because their effect would be anti-dilutive. Therefore, basic and diluted net loss per share was the same for the periods presented due to the Company's net loss position.

The following table sets forth the outstanding potentially dilutive securities, as adjusted retroactively reflecting the exchange for Regado shares, that have been excluded in the calculation of diluted net loss per share because including such would be anti-dilutive (in common stock equivalent shares):

	Three and Nine Months Ended September 30,	
	2015	2014
Common stock options	2,373,996	1,324,297
Warrants to purchase preferred stock	64,657	901,987
Convertible preferred stock	—	5,559,977
Convertible notes	—	3,304,252
Total	2,438,653	11,090,513

Recent Accounting Pronouncements

In April 2015, the Financial Accounting Standards Board, or the FASB, issued Accounting Standard Update, or ASU, 2015-03, *Interest — Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs* , which amends the presentation of debt issuance costs as a direct deduction from the face amount of a liability rather than an asset. Amortization of debt

issuance costs is to be reported as interest expense. Additionall y, amortization of a discount or premium is to be reported as interest expense in the case of liabilities or interest income in the case of assets. For public business entities, the guidance is effective for fiscal years beginning after December 15, 2015 a nd interim periods within those fiscal years. For all other entities, the guidance is effective for fiscal years beginning after December 15, 2015 and interim periods with fiscal years beginning after December 15, 2016. Earlier adoption of the amendments i s permitted for financial statements that have not been previously issued, and the new guidance shall be applied retrospectively to comparative balance sheets presented. The Company expects to adopt this guidance for its 2016 fiscal year commencing on Janu ary 1, 2016 and does not expect adoption to have a material impact on its financial statements.

In August 2014, the FASB issued ASU No. 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern* , which requires management to evaluate, in connection with preparing financial statements for each annual and interim reporting period, whether there are conditions or events, considered in the aggregate, that raise substantial doubt about an entity's ability to continue as a going concern within one year after the date that the financial statements are issued and provide related disclosures. This guidance is effective for annual periods ending after December 15, 2016, and, as such, will be applicable to the Company in 2017. Early adoption is permitted. The Company does not expect this standard to have a material impact on its financial statements.

In April 2014, the FASB issued ASU No. 2014-08, *Presentation of Financial Statements (Topic 205) and Property, Plant, and Equipment (Topic 360): Reporting Discontinued Operations and Disclosures of Disposals of Components of an Entity* , which changed the requirements for reporting disposals as discontinued operations. A disposal that represents a strategic shift that has a major effect on the Company's operations and financial results, such as a major line of business, should be presented as a discontinued operation with additional financial disclosures. This guidance is effective for reporting periods beginning on or after December 15, 2014. As of September 30, 2015, the Company adopted this guidance. The decision to discontinue investment in the aptamer platform does not represent a strategic shift as prescribed by this guidance. Thus, there is no impact to the Condensed Financial Statements resulting from adopting this guidance.

3. REVERSE MERGER

The Company completed its Merger with Regado on May 4, 2015. Based on the terms of the Merger, Private Tobira was deemed the acquiring company for accounting purposes, and the transaction has been accounted for as a reverse acquisition under the acquisition method of accounting for business combinations in accordance with U.S. GAAP. Accordingly, the assets and liabilities of Regado have been recorded as of the Merger closing date at estimated fair value.

Immediately prior to the effective date of the Merger, the principal and accrued interest of outstanding convertible notes of Private Tobira converted into shares of Series B preferred stock of Private Tobira. Further, all outstanding shares of preferred stock of Private Tobira converted into shares of common stock of Private Tobira. Each Private Tobira warrant issued to Square 1 Bank in connection with a Loan and Security Agreement between Square 1 Bank and Private Tobira dated as of November 9, 2011 and Oxford Finance LLC in connection with a Loan and Security Agreement between Oxford Finance LLC and Tobira dated as of June 30, 2014 that were outstanding and unexercised as of and immediately prior to the effective date of the Merger were exchanged for warrants to purchase Regado common stock. All other Private Tobira warrants were terminated and cancelled in full. At the effective date of the Merger, each outstanding share of common stock of Private Tobira was converted into the right to receive 1.4302 shares of Regado common stock as adjusted for the one for nine reverse stock split, or the Exchange Ratio, as determined pursuant to the terms of the Merger Agreement, and all outstanding options, warrants, or other rights to purchase shares of capital stock of Private Tobira were exchanged for rights to acquire Regado common stock, as renamed Tobira. No fractional shares of Regado common stock were issued in connection with the Merger, and holders of Private Tobira capital stock were entitled to receive cash for any fractional share ownership in lieu of stock thereof.

After consummation of the Merger, Private Tobira stockholders owned a majority of the fully diluted common stock of Tobira.

Purchase Consideration

The purchase price for Regado on May 4, 2015, the closing date of the Merger, was as follows (in thousands):

Fair value of Regado common stock outstanding (1)	$	40,667
Fair value of Regado Series F convertible preferred stock outstanding (2)		2,420
Fair value of Regado vested stock options (3)		3,036
Total purchase price	$	46,123

(1) Comprised of 3,734,536 shares of common stock outstanding at the date of the Merger based on the closing price of $10.89 per share as adjusted for the one for nine reverse stock split on May 4, 2015;
(2) Comprised of 222,222 shares of common stock equivalents, as converted, at the date of the Merger based on the closing price of $10.89 per share as adjusted for the one for nine reverse stock split on May 4, 2015; and
(3) Consideration transferred includes 551,363 Regado vested equity awards assumed and deemed attributable to pre-combination services to Regado.

Allocation of Purchase Consideration

Under the acquisition method of accounting, the total purchase price was allocated to tangible and identifiable intangible assets acquired and liabilities assumed of Regado on the basis of their estimated fair values as of the transaction closing date on May 4, 2015. The Company engaged a third party valuation firm to assist management in its analysis of the fair value of Regado. All estimates, key assumptions, and forecasts were either provided by or reviewed by management. While the Company chose to utilize a third party valuation firm, the fair value analysis and related valuations represent the conclusions of management and not the conclusions or statements of any third party. The excess of the total purchase price over the fair value of assets acquired and liabilities assumed was allocated to goodwill.

The following table summarizes the allocation of the purchase consideration to the assets acquired and liabilities assumed based on their fair values as of May 4, 2015 (in thousands):

Cash, cash equivalents and restricted cash	$	33,232
Prepaid expenses and other assets acquired		1,408
In-process research and development		12,205
Goodwill		5,110
Deferred tax liability		(4,393)
Other liabilities		(1,439)
Total	$	46,123

The Company believes that the historical values of Regado's current assets and current liabilities approximate fair value based on the short-term nature of such items.

IPR&D consists of intellectual property related to Regado's aptamer platform and is valued based on the estimated net present value of future cash flows expected to be generated from commercialization. The valuation of the aptamer platform technology was valued using the income approach which values the asset by estimating the present value of future economic benefits that the asset is expected to produce. The Company will not amortize IPR&D until research and development is complete and the asset is reclassified to a definite-lived amortizable asset. Subsequently, as discussed in Note 2, the Company recorded an impairment of IPR&D as of September 30, 2015.

Goodwill is calculated as the difference between the fair value of the consideration expected to be transferred and the values assigned to the identifiable tangible and intangible assets acquired and liabilities assumed. Goodwill is not expected to be deductible for tax purposes. Subsequently, as discussed in Note 2, the Company recorded an impairment of goodwill as of September 30, 2015.

The deferred tax liability of $4.4 million relates to the temporary difference associated with the $12.2 million value of IPR&D. The deferred tax liability was recorded based on an effective tax rate of 35.99%. As of September 30, 2015, the deferred tax liability was reduced to $0 and recorded as an income tax benefit of $4.4 million in the accompanying Condensed Statements of Operations and Comprehensive Loss following the impairment of the associated IPR&D.

Other liabilities include $0.9 million liability for the settlement of common stock for Merger relate d fees to financial advisors that were settled by the issuance of 78,213 shares of common stock. The fair value of the liability was determined based upon the fair value of Regado common stock using the closing price of $10.89 per share, as adjusted for th e one for nine reverse stock split on May 4, 2015.

The Company's operating results include operating expenses attributable to the former Regado business activities for the period of May 5, 2015 to September 30, 2015 and were $0.3 million and $0.6 million for the three and nine months ended September 30, 2015, respectively.

The unaudited financial information in the following table summarizes the combined results of operations of the Company and Regado, on a pro forma basis, as if the Merger had occurred at the beginning of the periods presented (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Net loss	$ (22,211)	$ (24,950)	$ (46,064)	$ (70,059)
Deemed dividend	—	—	—	(14,840)
Net loss attributable to stockholders	$ (22,211)	$ (24,950)	$ (46,064)	$ (84,899)
Net loss attributable to preferred stockholders	$ —	$ (416)	$ —	$ (1,442)
Net loss attributable to common stockholders, basic and diluted	$ (22,211)	$ (24,534)	$ (46,064)	$ (83,457)
Net loss per share, basic and diluted	$ (1.49)	$ (1.88)	$ (3.10)	$ (6.49)

The above unaudited pro forma information was determined based on historical GAAP results of the Company and Regado. The unaudited pro forma combined results are not necessarily indicative of what the Company's combined results of operations would have been if the acquisition was completed on January 1, 2014. The unaudited pro forma combined net loss includes pro forma adjustments primarily relating to the following non-recurring items directly attributable to the business combination:

- Elimination of transaction costs of $0 and $5.2 million for the three and nine months ended September 30, 2015, respectively;
- Elimination of stock-based compensation expense of $0 and $1.8 million related to the acceleration of vesting and modification of post-termination exercise periods of Regado stock option awards in connection with the Merger for the three and nine months ended September 30, 2015;
- Elimination of $0 and $1.4 million expense related to severance agreements and transaction bonuses directly attributable to the Merger for the three and nine months ended September 30, 2015;
- Elimination of interest expense of $0 and $1.7 million for the three and nine months ended September 30, 2015, respectively, and $1.2 million and $3.4 million for the three and nine months ended September 30, 2014, respectively, related to the conversion of Private Tobira's convertible notes in connection with the Merger; and
- Elimination of the change in fair value of preferred stock warrant liabilities of $0 and $1.9 million of income for the three and nine months ended September 30, 2015, respectively, and $2.1 million and $1.4 million of income for the three and nine months ended September 30, 2014, respectively to reflect 1) the net exercise and cancellation of warrants issued in connection with the convertible notes payable and 2) the conversion of the Oxford Finance LLC, Square 1, and Comerica warrants from warrants on preferred stock to warrants on common stock eliminating the terms that caused the preferred stock warrants to be classified as a liability.

The combined transaction costs of the Company were $6.8 million which were expensed as incurred.

4. FAIR VALUE MEASUREMENTS

The following tables and disclosure present information about the Company's financial assets and liabilities measured at fair value on a recurring basis as of September 30, 2015 and December 31, 2014 and indicate the fair value hierarchy of the valuation techniques utilized by the Company to determine such fair value (in thousands):

	As of September 30, 2015			
	Level 1	Level 2	Level 3	Total
Assets				
Cash equivalents	$ 67,493	$ —	$ —	$ 67,493
Total	$ 67,493	$ —	$ —	$ 67,493

	As of December 31, 2014			
	Level 1	Level 2	Level 3	Total
Assets				
Cash equivalents	$ 4,800	$ —	$ —	$ 4,800
Total	$ 4,800	$ —	$ —	$ 4,800
Liabilities				
Preferred stock warrant liabilities	$ —	$ —	$ 2,460	$ 2,460
Total	$ —	$ —	$ 2,460	$ 2,460

The carrying amounts of the Company's financial instruments, including cash, restricted cash, deposits, accounts payable, and accrued expenses and other liabilities, approximate fair value due to their short maturities. The Company's lease obligations, term loan and convertible notes have fair values that approximate their carrying value based on prevailing borrowing rates available to the Company for loans with similar terms. Financial assets and liabilities, which are measured or disclosed at fair value on a recurring basis and are classified within the Level 3 designation, consist of preferred stock warrant liabilities. On May 4, 2015, the preferred stock warrants outstanding were converted to warrants to purchase common stock eliminating the terms that caused the preferred stock warrants to be accounted for as a liability and revalued at each reporting date.

The Company acquired IPR&D in connection with its Merger. IPR&D consists of intellectual property related to Regado's aptamer platform and is valued based on the estimated net present value of future cash flows expected to be generated from commercialization. The valuation of the aptamer platform technology was valued using the income approach which values the asset by estimating the present value of future economic benefits that the asset is expected to produce. There was no carrying value of IPR&D for the periods presented.

None of the Company's non-financial assets or liabilities is recorded at fair value on a non-recurring basis for the periods presented. There were no transfers between levels within the fair value hierarchy during the periods presented.

The following table provides a reconciliation of liabilities measured at fair value using Level 3 significant unobservable inputs (in thousands) for the nine months ended September 30, 2015 and the year ended December 31, 2014:

	Nine Months Ended September 30, 2015	Year Ended December 31, 2014
Balance, beginning of period	$ 2,460	$ 2,773
Issuance of preferred stock warrants	—	868
Reclassification of stock award liability from equity upon modification	—	399
Reclassification of stock award liability to equity upon expiration	—	(292)
Change in fair value of stock award liability	—	(107)
Reclassification of preferred stock warrant liability to equity upon conversion to common stock	(521)	—
Change in fair value of preferred stock warrant liabilities (1)	(1,939)	(1,181)
Balance, end of period	$ —	$ 2,460

(1) Changes in fair value of the preferred stock warrant liabilities are recorded in other income (expense), net on the accompanying Statements of Operations and Comprehensive Loss.

As of September 30, 2015, there were no Level 3 liabilities measured at fair value outstanding. As of December 31, 2014, the significant unobservable inputs used to determine the fair value of preferred stock warrant liabilities using an option-pricing model and the weighted average assumptions used in determining the fair value of the outstanding preferred stock warrant liabilities were as follows: risk-free interest rate of 0.13%, no expected dividend yield, expected price volatility of 107%, and expected term (in years) of 0.8.

5. RESTRICTED CASH

The Company held restricted cash of $0.3 million as of September 30, 2015 and December 31, 2014 consisting of a cash secured letter of credit required by the landlord associated with the May 2014 headquarters lease.

6. ACCRUED EXPENSES AND OTHER LIABILITIES

Accrued expenses and other liabilities consist of the following (in thousands):

	As of September 30, 2015	As of December 31, 2014
Clinical trial expenses	$ 2,069	$ 478
Research and development	490	235
Compensation expense	913	928
Professional services	426	709
Loan interest	—	4,153
Total accrued expenses and other liabilities	$ 3,898	$ 6,503

7. DEBT AND WARRANTS

Convertible Notes and Warrants

On May 4, 2015, Private Tobira's convertible notes of $43.0 million and accrued interest of $5.2 million were converted into 3,532,756 shares of Series B preferred stock of Private Tobira immediately followed by conversion on a one for one basis into shares of Private Tobira common stock. The following table presents convertible notes, including principal and accrued interest, that were converted to shares of common stock (in thousands):

Convertible Notes	Principal	Accrued Interest
July 2012	$ 10,000	$ 2,368
January 2013	7,000	1,342
October 2013	5,000	617
March 2014	8,000	726
March 2015	13,000	168
Total	$ 43,000	$ 5,221

In connection with the conversion of the March 2015 notes, the Company recorded a contingent beneficial conversion feature of $0.4 million equal to the difference between the conversion price of $11.81 and the fair value of the underlying Series B preferred stock on the date of issuance. The contingent beneficial conversion feature was immediately expensed to interest expense and recorded in other income (expense), net, on the accompanying statement of operations and comprehensive loss.

On May 4, 2015, warrants issued to holders of the July 2012 notes, January 2013 notes, October 2013 notes and March 2014 notes expired unexercised. No warrants were issued in connection with the March 2015 notes.

Oxford Finance Term Loan

On June 30, 2014, and as amended on May 5, 2015 to address the Merger, the Company entered into an aggregate $15.0 million, four year term loan with Oxford Finance LLC, or the Oxford Loan. The Oxford Loan bears interest at a fixed rate of 6.954% per annum with interest only payments through December 31, 2015 followed by 30 equal payments of principal and interest until maturity at June 1, 2018. At the time of final payment, the Company is required to pay an exit fee of 4.0% of the original principal balance of the Oxford Loan, which the Company recorded as a liability and debt discount at the origination of the term loan. In addition, the

Company incurred loan originati on fees of $0.1 million which were recorded as a loan discount and debt issuance costs of $0.1 million which were recorded as a n other asset.

On August 10, 2015, the Company amended the terms of the Oxford Loan to extend the interest only period through December 31, 2016 and the maturity date to June 1, 2019. The exit fee was increased from 4.0% to approximately 5.0% of the original principal balance. The Oxford Loan continues to bear interest at a fixed rate of 6.954% per annum. The Company accounted for the amended terms as a debt modification. No additional fees or other consideration were paid to Oxford Finance LLC. Costs incurred with third parties were expensed as incurred.

In connection with the Oxford Loan, the Company granted a security interest in all of its assets, except intellectual property, provided that a judicial authority could require the Company's intellectual property to be part of the collateral package to the extent necessary to satisfy repayment if the company's other secured assets are insufficient. The Oxford Loan restricts the Company from issuing dividends and contains customary affirmative and negative covenants. At September 30, 2015, the Company was in compliance with all loan covenants.

The Company is permitted to make voluntary prepayments of the Oxford Loan with a prepayment fee equal to (i) 3.0% of the loan prepaid during the first 12 months, (ii) 2.0% of the loan prepaid in months 13-24 and (iii) 1.0% of the loan thereafter. The Company is required to make mandatory prepayments of the outstanding loan upon the acceleration by the lenders following the occurrence of an event of default, along with a payment of the final payment, the prepayment fee and any other obligations that are due and payable at the time of prepayment.

The Company evaluated the Oxford Loan in accordance with accounting guidance for derivatives and determined there was de minimis value to the identified derivative features at issuance and at subsequent reporting periods through September 30, 2015.

The Company accounts for the debt discount and deferred issuance costs utilizing the effective interest method. The Company recorded interest expense and amortization of the debt discount of $0.3 million and $1.0 million for the three and nine months ended September 30, 2015, respectively, and $0.3 million and $0.3 million for the three and nine months ended September 30, 2014, respectively.

Long-term debt and unamortized discount balances are as follows (in thousands):

	As of September 30, 2015	As of December 31, 2014
Face value of term loan	$ 15,000	$ 15,000
Exit fee	755	600
Unamortized debt discount associated with issuance of preferred stock warrants, exit fee, and loan origination fees	(742)	(811)
Term loan, net	$ 15,013	$ 14,789

As of September 30, 2015, future minimum payments under the Oxford Loan were as follows (in thousands):

Year ending December 31,	
2015 (remaining three months)	$ 261
2016	1,043
2017	6,554
2018	6,554
2019	4,031
Total future minimum payments	18,443
Less: unamortized interest	(2,688)
Less: exit fee	(755)
Present value of loan payments	$ 15,000

Warrants

In connection with the Oxford Loan, the Company issued warrants to the lenders to purchase an aggregate of 51,783 of Series B preferred stock at a purchase price of $10.14 per share after giving effect for the Exchange Ratio.

In November 2011, the Company entered into a loan and security agreement with Square 1 Bank for a $4.0 million three-year loan, or the Square 1 Loan. The Square 1 Loan was paid in full and terminated in June 2014. In connection with the Square 1 Loan, the Company issued to Square 1 Ba nk a warrant to purchase 11,835 shares of Series B preferred stock with an exercise price of $10.14 per share after giving effect for the Exchange Ratio.

Prior to the Merger, Regado secured a venture debt loan with Comerica Bank for $4.5 million, or the Comerica Loan. The Comerica Loan was paid in full and was terminated in March 2015. In connection with the Comerica Loan, Regado issued to Comerica Bank a warrant to purchase 1,039 shares of common stock with an exercise price of $108.18 per share after giving effect to the one for nine reverse stock split.

Prior to May 4, 2015, the Company accounted for these warrants as a liability, which were revalued to fair value at each reporting period. On May 4, 2015, in connection with the Merger, the warrants to purchase shares of Series B preferred stock converted to warrants to purchase common stock, and the associated preferred stock warrant liability was revalued to fair value and reclassified to additional paid-in capital.

The Company had the following shares of common stock warrants outstanding as of September 30, 2015 after giving effect for the Exchange Ratio:

Issuance Date	Expiration Date	Per Share Exercise Price	Shares Outstanding as of September 30, 2015
November 2011	November 2018	$ 10.14	11,835
May 2013	May 2023	$ 108.18	1,039
June 2014	June 2021	$ 10.14	51,783
			64,657

8. CONVERTIBLE PREFERRED STOCK

Prior to May 4, 2015, Private Tobira's convertible preferred stock was classified as temporary equity on the accompanying condensed balance sheets. The preferred stock was not redeemable; however, upon certain change in control events that were outside of the Company's control, including liquidation, sale or transfer of control of the Company, holders of the convertible preferred stock had the right to receive its liquidation preference under the terms of the Company's certificate of incorporation.

Immediately prior to the Merger, Private Tobira's convertible notes and accrued interest were converted to 3,532,756 shares of Series B preferred stock. Immediately thereafter, Private Tobira's Series A and B preferred stock was converted to 3,916,772 shares of Private Tobira common stock at a conversion rate of 1.7742 for Series A preferred stock and a one for one basis for Series B preferred stock. Upon the close of the Merger, all resultant Private Tobira common stock was exchanged for 10,654,460 shares of Regado common stock, as renamed Tobira, at the Exchange Ratio.

The following table summarizes the Company's convertible preferred stock balances as of September 30, 2015 and December 31, 2014 (in thousands, except share and per share amounts):

	September 30, 2015	December 31, 2014
Series A, noncumulative convertible preferred stock, par value $0.0001; zero and 1,043,011 shares authorized at September 30, 2015 and December 31, 2014, respectively; zero and 994,866 shares issued and outstanding at September 30, 2015 and December 31, 2014, respectively; liquidation value of $0 and $31,000 at September 30, 2015 and December 31, 2014, respectively	—	30,908
Series B, noncumulative convertible preferred stock, par value $0.0001; zero and 5,133,477 shares authorized at September 30, 2015 and December 31, 2014, respectively; zero and 2,151,722 shares issued and outstanding at September 30, 2015 and December 31, 2014, respectively; liquidation value of $0 and $54,600 at September 30, 2015 and December 31, 2014, respectively	—	31,074

Following the completion of the Merger, on May 15, 2015, the holders of Series F convertible preferred stock elected to convert all 10,000 shares of outstanding preferred stock into 222,222 shares of common stock. No remaining convertible preferred stock balances were outstanding as of September 30, 2015.

9. STOCKHOLDERS' EQUITY (DEFICIT)

Common Stock

Immediately prior to the effective date of the Merger, the principal and accrued interest under Private Tobira's outstanding convertible notes converted into shares of Series B Preferred Stock of Private Tobira. Immediately thereafter, all outstanding preferred stock of Private Tobira converted into common stock of Private Tobira.

At the effective date of the Merger, each outstanding share of Private Tobira's common stock was converted into the right to receive 1.4302 shares of Regado common stock, as renamed Tobira, with cash paid in lieu of any fractional shares.

On May 4, 2015, Tobira entered into the 2015 Purchase Agreement with certain Private Tobira stockholders and other institutional investors which provided for the sale and issuance, promptly after the consummation of the Merger, of 2,542,365 shares of Tobira in the Private Placement at a purchase price of $10.62 per share (which price is equal to the closing price of Tobira's common stock on April 30, 2015, as adjusted by the one for nine reverse split effected on May 4, 2015) for aggregate gross proceeds of $27.0 million. Issuance costs of $0.2 million were recorded as a reduction to proceeds received in additional paid-in capital.

On June 3, 2015, the Company entered into a sales agreement with Cowen and Company, LLC, or Cowen, to issue shares of common stock at-the-market having an aggregate offering price of up to $40.0 million. Cowen will earn a commission equal to 3.0% of the gross proceeds from the sale of common stock pursuant to the terms of the sales agreement. The agreement may be terminated with advance notice by either party. During August 2015, the Company sold an aggregate of 1,141,970 shares of common stock for gross proceeds of $15.1 million. Issuance costs of $0.7 million were recorded as a reduction to proceeds received in additional paid-in capital.

The Company issued common stock during the nine months ended September 30, 2015 as follows:

	Common Stock Issued and Outstanding (in shares)
Balance at December 31, 2014	403,539
Conversion of convertible notes and accrued interest	3,532,756
Conversion of Series A and B preferred stock	3,916,772
Conversion of Series F preferred stock	222,222
Issuance of shares in connection with the Merger	6,939,282
Issuance of shares for banker fees	78,213
Issuance of shares in connection with the Private Placement	2,542,365
Issuance of shares at-the-market	1,141,970
Issuance of shares from options exercised	32,874
Balance at September 30, 2015	18,809,993

10 . STOCK-BASED COMPENSATION EXPENSE

The Company adopted two stock compensation plans prior to the Merger, the 2007 Stock Option Plan, or the 2007 Plan, adopted in August 2007, and the 2010 Stock Option Plan, or the 2010 Plan, adopted in March 2010. The Company ceased granting awards under the 2007 Plan when it adopted the 2010 Plan. Options remain outstanding under both the 2007 Plan and the 2010 Plan. In connection with the Merger, all such options converted into options to purchase shares of Regado common stock, as renamed Tobira, and the applicable exercise prices were adjusted to reflect the Exchange Ratio. The Company assumed the 2010 Plan under the terms of the Merger and may grant awards under this plan to certain employees. No additional grants can be made from the 2007 Plan, and shares subject to awards granted under this plan that cancel or expire unexercised do not revert to or become available for re-grant under any other Company stock compensation plan.

Prior to the Merger, Regado adopted two stock compensation plans, the 2004 Plan and 2013 Plan. Options remain outstanding under both the 2004 and the 2013 Plan. The number of shares subject to and the exercise prices applicable to these outstanding options were adjusted in connection with the one for nine reverse stock split. No additional grants may be made from the 2004 Plan. However, shares subject to awards granted under this plan that cancel or expire unexercised do revert to and become available for re-grant under the 2013 Plan pool. On July 9, 2015, the Company's stockholders approved amendments to material terms of the Company's 2013 Plan, including an increase by 1.2 million shares reserved for issuance and increases in, or imposition of, certain share limits under the 2013 Plan. The Company intends that the 2013 Plan will be its primary stock compensation plan in the future.

Because the Company is considered to be the acquirer for accounting purposes, the pre-Merger vested stock options granted by Regado under the 2004 Plan and the 2013 Plan are deemed to have been exchanged for equity awards of the Company and as such the por tion of the acquisition date fair value of these equity awards attributable to pre-Merger service to Regado were accounted for as a component of the consideration transferred.

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

The following table summarizes stock option activity under the Company's stock-based compensation plan during the nine months ended September 30, 2015:

	Number of Options	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Life (in Years)	Weighted-Average Grant Date Fair Value
Outstanding at December 31, 2014	1,110,744	$ 4.59	8.72	
Granted	761,382	$ 15.08		$ 10.95
Options assumed in the Merger	551,363	$ 30.11		
Exercised	(32,874)	$ 3.51		
Canceled	(16,619)	$ 20.30		
Outstanding at September 30, 2015	2,373,996	$ 14.00	8.51	
Vested and expected to vest at September 30, 2015	2,310,312	$ 14.08		
Vested and exercisable at September 30, 2015	1,090,000	$ 17.77		

As of September 30, 2015 and December 31, 2014, the total intrinsic value of vested and exercisable options was $3.2 million and $1.3 million, respectively. Under our stock-based compensation plan, option awards generally vest over a four-year period contingent upon continuous service and expire ten years from the date of grant (or earlier upon termination of continuous service). The fair value-based measurement of each option is estimated on the date of grant using the Black-Scholes option valuation model.

Stock-based compensation expense related to options granted was recorded as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Research and development	$ 240	$ 31	$ 375	$ 121
General and administrative	620	(712)	1,099	407
Total	$ 860	$ (681)	$ 1,474	$ 528

In February 2014, the Board of Directors approved an extension to the post-termination exercise period for vested stock options held by the former chief executive officer from April 2014 to October 2014. This modification, which was made subsequent to his employment with the Company, was treated as a new award and was accounted for as a liability. The stock award liability was adjusted to its estimated fair value each reporting period using the Black-Scholes option-pricing model with the change in fair value of the liability recorded to stock-based compensation expense through October 31, 2014, the date of expiration. Stock-based compensation expense for this modification was a reduction of expense of $0.9 million and $0 for the three and nine months ended September 30, 2014.

1 1 . COMMITMENTS AND CONTINGENCIES

Legal Proceedings

On February 2, 2015, a purported stockholder of Regado filed a putative class-action lawsuit (captioned *Maiman v. Regado Biosciences, Inc.* , C.A. No. 10606-CB) in the Court of Chancery for the State of Delaware, or the Court, challenging the proposed stock-for-stock merger of Regado with Tobira, or the Proposed Merger. On February 25, 2015, a second, related putative class action (captioned *Gilboa v. Regado Biosciences, Inc.* , C.A. No. 10720-CB) was filed in the Court challenging the Proposed Merger. On May 4, 2014, the Proposed Merger was consummated and Tobira became a wholly-owned subsidiary of Regado and changed its name to Tobira Development, Inc. The complaints name as defendants: (i) each member of Regado's Board of Directors, (ii) Regado, (iii) Private Tobira, and (iv) Landmark Merger Sub Inc. Plaintiffs allege that Regado's directors breached their fiduciary duties to Regado's stockholders by, among other things, (a) agreeing to merge Regado with Private Tobira for inadequate consideration, (b) implementing a process that was distorted by conflicts of interest, and (c) agreeing to certain provisions of the Merger Agreement that are alleged to favor Private Tobira and deter alternative bids. Plaintiffs also generally allege that the entity defendants aided and abetted the purported breaches of fiduciary duty by the directors. On March 25, 2015, the Court consolidated the two actions and assigned lead counsel for plaintiffs (captioned *In re Regado Biosciences, Inc. Stockholder Litigation* , Consolidated C.A. No. 10606-CB). On March 27, 2015, plaintiffs filed a consolidated amended complaint, a motion for expedited proceedings and a motion for preliminary injunction. On April 20, 2015, the parties agreed in principle to resolve the litigation (subject to approval by the Court) and signed a memorandum of understanding setting forth the terms of a proposed settlement to provide additional disclosures related to the Merger Agreement and to cover Court-awarded fees. On April 23, 2015, as part of the proposed settlement, Regado provided additional disclosures to its stockholders. Since then, the parties have engaged in confirmatory discovery and will prepare a stipulation of settlement to be submitted to the Court for approval. As of September 30, 2015, the Company is unable to reasonably estimate an amount and/or a range of loss until the Company is made aware of the fees awarded by the Court to the plaintiffs under the proposed settlement, if any, as administered under settlement law. The Company maintains D&O insurance and tail coverage with deductibles of $2.0 million and $1.5 million, respectively.

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

The interim financial statements and this Management's Discussion and Analysis of Financial Condition and Results of Operations should be read together with our audited financial statements and accompanying notes for the year ended December 31, 2014 included in Exhibit 99.2 of our Current Report on Form 8-K/A filed on June 2, 2015 and with the financial statements and notes thereto for the year ended December 31, 2014, and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K for the year ended December 31, 2014 . In addition to historical information, this discussion and analysis contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Please see Risk Factors beginning on page 31 for a discussion of certain risk factors applicable to our business, financial condition, and results of operations. Operating results are not necessarily indicative of results that may occur for the full fiscal year or any other future period. The term "Private Tobira" refers to Tobira Development, Inc. (formerly known as Tobira Therapeutics, Inc.) prior to the consummation of the Merger. Unless otherwise indicated, references to the terms the "combined company", "Tobira", the "Company", "we", "our" and "us" refer to Private Tobira, prior to the consummation of the Merger and Tobira Therapeutics, Inc. (formerly known as Regado Biosciences, Inc.) and its subsidiaries upon the consummation of the Merger described herein. The term "Regado" refers to the Regado Biosciences, Inc. and its subsidiaries prior to the Merger.

ABOUT TOBIRA THERAPEUTICS

We are a clinical-stage biopharmaceutical company focused on the development and commercialization of therapies to treat liver disease, inflammation, fibrosis and HIV. Our lead product candidate, cenicriviroc, or CVC, is a first-in-class immunomodulator and dual inhibitor of two chemokine receptors, CCR2 and CCR5, that is being evaluated for the treatment of non-alcoholic steatohepatitis, or NASH.

CVC is an oral, once-daily, potent immunomodulator that blocks CCR2 and CCR5, which are intricately involved in the inflammatory and fibrogenic pathways in NASH that cause liver damage and often lead to cirrhosis, liver cancer or liver failure. We believe this novel approach will establish CVC as both a single-agent and a cornerstone treatment in multi-therapy regimens for NASH for which there is currently no approved drug.

CVC is currently being evaluated in our fully enrolled global Phase 2b CENTAUR study and we expect to announce the study's primary endpoint in the third quarter of 2016. CENTAUR is comparing CVC to placebo in 289 patients with NASH and liver fibrosis. CVC has been granted Fast Track status in patients with NASH and liver fibrosis, the patient population at highest risk of progression to cirrhosis. The CENTAUR study includes surrogate endpoints identified as suitable for registrational studies in findings of an FDA-AASLD workshop reported in Hepatology. To date, approximately 600 subjects have been dosed in completed studies with CVC including 115 HIV infected subjects on treatment for up to 48 weeks.

Reverse Merger

On May 4, 2015, Regado Biosciences, Inc. (Regado) completed its business combination with Tobira Therapeutics, Inc., or prior to the completion of the Merger described below, Private Tobira or, after the completion of the Merger described below, Public Tobira, in accordance with the terms of an Agreement and Plan of Merger and Reorganization, dated as of January 14, 2015, as amended on January 23, 2015, or the Merger Agreement. Pursuant to the Merger Agreement, a newly formed wholly-owned subsidiary was established that merged with and into Private Tobira, with Private Tobira surviving the merger and becoming a wholly-owned subsidiary of Regado, or the Merger. In connection with the Merger, the name of Private Tobira was changed to Tobira Development, Inc., or Tobira Development. In connection with, and immediately prior to, the completion of the Merger, Regado filed an amended and restated certificate of incorporation with the Secretary of State of the State of Delaware to effect a one for nine reverse stock split of Regado's common stock. In connection with and immediately following the consummation of the Merger, Regado filed an amendment to the amended and restated certificate of incorporation with the Secretary of State of the State of Delaware to change its name to Tobira Therapeutics, Inc. On June 29, 2015, a Certificate of Ownership and Merger was filed with the Secretary of State of the State of Delaware to effect the merger of Tobira Development with and into Tobira Therapeutics, Inc. As a result, Tobira Therapeutics, Inc. is the sole entity.

BASIS OF PRESENTATION

Research and Development Expenses

Research and development expenses primarily consist of costs associated with our research activities, including the preclinical and clinical development of our product candidates. We expense research and development expenses as incurred. We contract with clinical research organizations to manage our clinical trials under agreed upon budgets for each study, with oversight by our clinical program managers. We account for nonrefundable advance payments for goods and services that will be used in future research and development activities as expenses when the service has been performed or when the goods have been received. Manufacturing

expense includes costs associated with drug formulation development and clinical drug production. We do not track our employee and facility related research and development costs by project, as we typical ly use our employee and infrastructure resources across multiple research and development programs. We believe that the allocation of such costs would be arbitrary and would not be meaningful. Our research and development costs are controlled through our i nternal budget and forecast process.

Our research and development expenses consist primarily of:

- salaries and related expenses for employee personnel, including benefits, travel and expenses related to stock-based compensation granted to personnel in development functions;
- external expenses paid to clinical trial sites, contract research organizations and consultants that conduct our clinical trials;
- expenses related to drug formulation development and the production of nonclinical and clinical trial supplies, including fees paid to contract manufacturers;
- expenses related to preclinical studies;
- expenses related to compliance with drug development regulatory requirements; and
- other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities, depreciation of equipment, and other supplies.

We expect to continue to incur substantial expenses related to our development activities for the foreseeable future as we conduct our Phase 2b CENTAUR study and expand our clinical program beyond CENTAUR. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. Our research and development expenses increased in the three and nine month period ended September 30, 2015 as compared to the similar period in 2014, and we expect that our research and development expenses will continue to increase in the future. The process of conducting preclinical studies and clinical trials necessary to obtain regulatory approval is costly and time consuming. The probability of success for each product candidate is affected by numerous factors, including preclinical data, clinical data, competition, manufacturing capability and commercial viability. Accordingly, we may never succeed in achieving marketing approval for any of our product candidates.

Successful development of current and future product candidates is highly uncertain. Completion dates and costs for our clinical development programs as well as our research program can vary significantly for each current and future product candidate and are difficult to predict. As a result, we cannot estimate with any degree of certainty the costs we will incur in connection with development of our product candidates. We anticipate we will make determinations as to which programs and product candidates to pursue and how much funding to direct to each program and product candidate on an ongoing basis in response to the scientific success of early research programs, results of ongoing and future clinical trials, our ability to enter into collaborative agreements with respect to programs or potential product candidates, as well as ongoing assessments as to each current or future product candidate's commercial potential.

Research and development expenses by major programs or categories were as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Phase 2b CENTAUR study	$ 3,533	$ 1,513	$ 11,759	$ 1,913
Other clinical studies (1)	389	218	1,426	1,282
Preclinical studies	375	102	612	313
Contract manufacturing	326	347	943	1,071
Internal and unallocated research and development expense	1,469	1,331	3,639	3,695
Total research and development expense	$ 6,092	$ 3,511	$ 18,379	$ 8,274

(1) Other clinical studies primarily reflect expenditures for drug interaction and bioavailability studies, the Phase 2a Orion study, a Phase 1 pioglitazone safety combination study and a Phase 1 hepatic impairment study.

Certain research and development expenses by major programs or categories have been reclassified to reflect their current nature.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries, benefits and stock-based compensation expense for employees in executive, finance, business development and support functions. Other significant general and administrative expenses include the costs associated with obtaining and maintaining our patent portfolio, professional fees for accounting, auditing, consulting and legal services, travel and allocated overhead expenses.

We expect that our general and administrative expenses may increase in the future as we expand our operating activities, maintain and expand our patent portfolio and incur additional costs associated with being a public company and maintaining compliance with exchange listing and SEC requirements. We expect these potential increases will likely include compensation, legal fees, accounting fees, directors' and officers' liability insurance premiums and expenses associated with investor relations.

Impairment of Intangible Assets

Impairment of intangible assets consists of impairment of IPR&D and goodwill resulting from the decision to discontinue investment in developing the intellectual property related to Regado's aptamer platform.

Other Income (Expense), Net

Other income (expense), net consists primarily of interest expense and gains and losses resulting from remeasurement of our preferred stock warrant liabilities.

Interest expense consists of cash interest expense on our outstanding loan with Oxford Finance LLC, or the Oxford Loan, and non-cash interest expense for stated interest on our convertible notes, amortization of debt discount, beneficial conversion features and debt issuance costs on our convertible notes and the Oxford Loan.

In connection with the Merger, the preferred stock warrants converted from warrants on preferred stock to warrants on common stock resulting in the reclassification of the preferred stock warrant liability to additional paid-in capital. As a result, we will no longer record any revaluation adjustments.

CRITICAL ACCOUNTING POLICIES AND SIGNIFICANT JUDGMENTS AND ESTIMATES

Our management's discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these financial statements require us to make estimates and judgments that affect the reported amount of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities as of the date of the financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued research and development expenses, warrant liabilities and stock-based compensation expense. We base our estimates on historical experience, known trends and events, and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ materially from these estimates under different assumptions or conditions. There have been no significant and material changes in our critical accounting policies and significant judgments and estimates during the three and nine months ended September 30, 2015, as compared to those disclosed in our Current Report filed on Form 8-K/A filed on June 2, 2015, except as described below.

Business Combinations

Accounting for acquisitions requires extensive use of estimates and judgment to measure the fair value of the identifiable tangible and intangible assets acquired, including in-process research and development and liabilities assumed. Additionally, we must determine whether an acquired entity is considered a business or a set of net assets because the excess of the purchase price over the fair value of net assets acquired can only be recognized as goodwill in a business combination. We accounted for the Merger with Regado as a business combination under the acquisition method of accounting. Consideration paid to acquire Regado was measured at fair value and included the exchange of Regado's common stock, Series F preferred stock and vested stock options. The allocation of the purchase price resulted in recognition of intangible assets related to in-process research and development and goodwill. The key assumptions in determining the fair value of intangible assets were assessing the timing and estimated costs to complete the in-process projects, projecting regulatory approvals, developing an appropriate discount rate and the estimated future cash flows.

In-Process Research and Development

In-process research and development, or IPR&D, represents the fair value assigned to research and development assets that were not fully developed as of the completion of the Merger. IPR&D acquired in a business combination is capitalized on our balance sheet at

its acquisition-date fair value. Until a project is completed, the asset is accounted for as an indefinite-lived intangible asset subject to impairment testing. Upon completion of a project, the carrying value of the related IPR&D is recla ssified to intangible assets and is amortized over the estimated useful life of the asset. We evaluate the potential impairment of intangible assets if events or changes in circumstances indicate that the carrying amount of the asset may not be fully recov erable.

IPR&D consists of intellectual property related to Regado's aptamer platform and is valued based on the estimated net present value of future cash flows expected to be generated from commercialization. Through September 30, 2015, we engaged in discussions with several third parties to divest or license the aptamer platform but were unsuccessful in securing an agreement. Our board of directors agreed to discontinue investment in developing the intellectual property. As a result of this indicator of impairment, as of September 30, 2015, we calculated and compared the fair value of the IPR&D to the carrying value to assess the recoverability of the asset. As of September 30, 2015, we recorded an impairment of the IPR&D of $12.2 million which is included under the caption "Impairment of intangible assets" in the accompanying Condensed Statements of Operations and Comprehensive Loss.

Goodwill

Goodwill represents the difference between the consideration transferred and the fair value of the net assets acquired under the acquisition method of accounting. Goodwill is not amortized but is evaluated for impairment during the last fiscal quarter of the year or if indicators of impairment exist that would, more likely than not, reduce the fair value from its carrying amount.

We recorded goodwill related to the Merger on May 4, 2015. As noted above under In-Process Research and Development, we were unable to divest or license the aptamer platform and plan to discontinue investment in the Regado business. We determined the fair value was less than the carrying value and impaired the IPR&D associated with our acquisition of Regado as of September 30, 2015. Further, we determined the Regado operations acquired in the Merger had not been integrated with the Company and thus no benefit was realized. As a result, we recorded an impairment of goodwill of $5.1 million in accordance with the applicable guidance as of September 30, 2015, which is included under the caption "Impairment of intangible assets" in the accompanying Condensed Statements of Operations and Comprehensive Loss.

RESULTS OF OPERATIONS

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

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

	Three Months Ended September 30,		Increase/ (Decrease)
	2015	2014	
Research and development	$ 6,092	$ 3,511	$ 2,581
General and administrative	2,826	12	2,814
Impairment of intangible assets	17,315	—	17,315
Other income (expense), net	(335)	583	(918)

Research and Development Expenses

Our research and development expenses were $6.1 million for the three months ended September 30, 2015 compared to $3.5 million for the three months ended September 30, 2014. Research and development expenses increased in the 2015 period primarily due to $2.0 million of increased clinical trial expenses for our Phase 2b CENTAUR study as the study was fully enrolled in 2015 whereas the study was in the initiation stages in the comparable 2014 period, $0.3 million for our Phase 2a Orion study which commenced during the quarter, $0.3 million in preclinical combination and toxicology studies, and $0.1 million in compensation related expenses for increased headcount and benefits. These increases were offset by a decrease of $0.1 million due to completion of our Phase 1 study in patients with hepatic impairment.

General and Administrative Expenses

Our general and administrative expenses were $2.8 million for the three months ended September 30, 2015 compared to $12,000 for the three months ended September 30, 2014. General and administrative expenses increased in the 2015 period primarily due to $1.3 million of increased expenses consisting of salaries, benefits and overhead as a result of increased headcount, directors and officers insurance and investor relations expenses which are reflective of our growth as a public company, $0.4 million of legal and accounting services for general corporate purposes and $0.2 million in patent maintenance costs primarily due to incremental costs associated with the aptamer patents acquired from Regado in the Merger. The three months ended September 30, 2014 included a $0.9 million reduction of general and administrative expense due to the change in fair value of a stock award liability related to the termination of the former chief executive officer.

Impairment of Intangible Assets

We recorded an impairment of intangible assets related to our IPR&D and goodwill of $17.3 million during the three months ended September 30, 2015, following the decision to discontinue investment in developing the intellectual property related to Regado's aptamer platform.

Other Income (Expense), Net

Changes in components of other income (expense), net were as follows:

Interest Expense

Interest expense was $0.3 million for the three months ended September 30, 2015 compared with $1.5 million for the same period in 2014. The decrease was primarily driven by $1.2 million in interest expense on our convertible notes recorded in 2014 as a result of conversion to equity in connection with the Merger on May 4, 2015.

Change in Fair Value of Preferred Stock Warrant Liabilities

The change in fair value of preferred stock warrant liabilities for the three months ended September 30, 2014 resulted in an increase in other income (expense), net of $2.1 million. We did not incur a change in fair value of preferred stock warrant liabilities for the three months ended September 30, 2015 as the preferred stock warrants outstanding were converted to warrants to purchase common stock in connection with the Merger eliminating the terms that caused the preferred stock warrants to be accounted for as a liability subject to revaluation each reporting period.

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

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

	Nine Months Ended September 30,		Increase/ (Decrease)
	2015	2014	
Research and development	$ 18,379	$ 8,274	$ 10,105
General and administrative	8,097	2,754	5,343
Impairment of intangible assets	17,315	—	17,315
Other income (expense), net	(831)	(2,387)	(1,556)

Research and Development Expenses

Our research and development expenses were $18.4 million for the nine months ended September 30, 2015 compared to $8.3 million for the nine months ended September 30, 2014. Research and development expenses increased in the 2015 period primarily due to $9.8 million of increased clinical trial expenses for our Phase 2b CENTAUR study as our study became fully enrolled in 2015, $1.1 million for other clinical studies including the initiation of our Phase 2a Orion study and completion of a Phase 1 pioglitazone safety combination study and $0.3 million in preclinical combination studies. These increases were partially offset by decreases of $1.0 million due to the completion of our Phase 1 study in patients with hepatic impairment and $0.1 million in manufacturing expenses.

General and Administrative Expenses

Our general and administrative expenses were $8.1 million for the nine months ended September 30, 2015 compared to $2.8 million for the nine months ended September 30, 2014. General and administrative expenses increased in the 2015 period primarily due to $2.7 million of merger related expenses consisting of legal and accounting services and $2.8 million of increased expenses primarily consisting of salaries, benefits and overhead as a result of increased headcount, directors and officers insurance and investor relations expenses which are reflective of our growth as a public company. These increases were partially offset by $0.2 million for severance expense related to the termination of the former chief executive officer.

Impairment of Intangible Assets

We recorded an impairment of intangible assets related to our IPR&D and goodwill of $17.3 million during the nine months ended September 30, 2015, following the decision to discontinue investment in developing the intellectual property related to Regado's aptamer platform.

Other Income (Expense), Net

Changes in components of other income (expense), net were as follows:

Interest Expense

Interest expense was $2.8 million for the nine months ended September 30, 2015 compared with $3.8 million for the same period in 2014. The decrease was primarily driven by $1.7 million in interest expense on our convertible notes as a result of conversion to equity in connection with the Merger on May 4, 2015. This decrease was partially offset by a $0.7 million increase in stated interest and debt discount accretion on the Oxford Loan that commenced in June 2014.

Change in Fair Value of Preferred Stock Warrant Liabilities

The change in fair value of preferred stock warrant liabilities for the nine months ended September 30, 2015 resulted in an increase in other income (expense), net of $1.9 million from $1.4 million for the same period in 2014.

LIQUIDITY AND CAPITAL RESOURCES

As of September 30, 2015, we had cash and cash equivalents including restricted cash of $69.0 million. To date, our operations have been financed primarily by net proceeds from the sale of preferred and common stock, the Merger with Regado, issuance of convertible promissory notes, and the issuance of senior term loans. We believe our cash and cash equivalents will be sufficient to fund our operations for at least the next twelve months.

On March 6, 2015, we issued convertible notes for $13.0 million, or the March 2015 Notes, which converted into common stock on May 4, 2015.

On May 4, 2015, we completed our Merger with Regado which provided $33.2 million in cash and cash equivalents. Immediately following the Merger, we raised $27.0 million in aggregate gross proceeds from our Private Placement.

On June 3, 2015, we filed a shelf registration on Form S-3 with the SEC for the issuance and sale of up to an aggregate offering price of $150.0 million of shares of our common stock, preferred stock, warrants to purchase common stock, and units comprised of any combination of the foregoing. Included in the shelf registration, we may issue and sell up to an aggregate offering price of up to $40.0 million of our common stock through an at-the-market sales agreement with Cowen. During August 2015, the Company sold an aggregate of 1,141,970 shares of common stock for gross proceeds of $15.1 million pursuant to the sales agreement.

Our primary uses of capital are, and we expect will continue to be, funding research efforts and the development of our product candidates, compensation and related expenses, hiring additional staff, including clinical, scientific, operational, financial, and management personnel, and costs associated with operating as a public company. We expect to incur substantial expenditures in the foreseeable future for the development and potential commercialization of our product candidates. Specifically, we have incurred and we expect to continue to incur substantial expenses in connection with our Phase 2b CENTAUR clinical trial of CVC in patients with NASH and liver fibrosis.

We plan to continue to fund losses from operations and capital funding needs through future equity and/or debt financings, as well as potential additional collaborations or strategic partnerships with other companies. The sale of additional equity or convertible debt could result in additional dilution to our stockholders. The incurrence of indebtedness would result in debt service obligations and

could result in operating an d financing covenants that would restrict our operations. We can provide no assurance that financing will be available in the amounts we need or on terms acceptable to us, if at all. If we are not able to secure adequate additional funding we may be forced to delay, make reductions in spending, extend payment terms with suppliers, liquidate assets where possible, and/or suspend or curtail planned programs. Any of these actions could materially harm our business.

Cash Flows

The following table provides a summary of our net cash flow activity (in thousands):

	Nine Months Ended September 30,	
	2015	2014
Net cash used in operating activities	$ (25,197)	$ (10,700)
Net cash provided by (used in) investing activities	33,201	(130)
Net cash provided by financing activities	54,442	18,550
Net increase in cash and cash equivalents	62,446	7,720

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

Net cash used in operating activities was $25.2 million for the nine months ended September 30, 2015 compared to $10.7 million for the nine months ended September 30, 2014. Net cash used in operating activities for the nine months ended September 30, 2015 consisted primarily of our net loss of $40.2 million offset by non-cash items consisting of interest expense on our convertible notes of $1.1 million, the amortization of the debt discount associated with the fair value of our preferred stock warrants of $0.4 million, the amortization of the beneficial conversion feature on our convertible notes of $0.4 million, and stock-based compensation expense of $1.5 million, a decrease in the fair value of our preferred stock warrant liabilities of $1.9 million, a decrease of $4.4 million in the deferred tax liability and an impairment in intangible assets of $17.3 million following the decision to discontinue investment in developing the intellectual property related to Regado's aptamer platform. Additionally, cash used in operating expenses for the nine months ended September 30, 2015 reflected an increase from net operating assets of $0.5 million primarily due to an increase in our accounts payable and accrued expenses relating to our clinical expenses for our Phase 2b CENTAUR clinical trial and decreases in our prepaid expenses associated with our Phase 2b CENTAUR clinical trial. Net cash used in operating activities for the nine months ended September 30, 2014 consisted primarily of our net loss of $13.7 million which was offset by non-cash items consisting of interest expense on our convertible notes of $1.7 million, the amortization of the debt discount associated with the fair value of our preferred stock warrants of $0.8 million, the amortization of the beneficial conversion feature on our convertible notes of $0.9 million, stock-based compensation expense of $0.5 million and a decrease in the fair value of our preferred stock warrant liabilities of $1.4 million. Cash used in operating expenses for the nine months ended September 30, 2014 also reflected an increase from net operating assets of $0.4 million primarily due to increases in accounts payable and accrued expenses related to the initiation of our Phase 2b CENTAUR clinical trial and related clinical manufacturing activities, our Phase 1 hepatic impairment study, 2014 annual performance bonuses, an increase in prepaid expenses supporting our Phase 2b CENTAUR clinical trial, and an increase in restricted cash securing a letter of credit associated with our leased corporate headquarters.

Net cash provided by investing activities was $33.2 million for the nine months ended September 30, 2015 compared to cash used in investing activities of $0.1 million for the nine months ended September 30, 2014. Net cash provided by investing activities for the nine months ended September 30, 2015 consisted primarily of cash received from the Merger of $33.2 million. Net cash used in investing activities for the nine months ended September 30, 2014 consisted of property and equipment purchased for $0.1 million.

Net cash provided by financing activities was $54.4 million for the nine months ended September 30, 2015 primarily reflecting net proceeds of $26.8 million from the Private Placement, net proceeds of $14.6 million from the issuance of shares at-the-market, net of issuance costs paid, $13.0 million of net proceeds from the issuance of convertible notes and $0.1 million from stock option exercises. Net cash provided by financing activities was $18.6 million for the nine months ended September 30, 2014 reflecting net proceeds of $14.8 million from the Oxford Loan and $8.0 million from the issuance of convertible notes partially offset by $1.8 million used to make payments on our term loan with Square 1 Bank and $2.4 million in costs paid in connection with preparations for an initial public offering.

CONTRACTUAL OBLIGATIONS AND COMMITMENTS

Contractual Arrangements

Other than the Oxford Loan amendment discussed below, no significant changes to contractual obligations and commitments occurred during the three months ended September 30, 2015.

Oxford Finance Term Loan

On June 30, 2014, and as amended on May 5, 2015 to address the Merger, we entered into the Oxford Loan. The Oxford Loan bears interest at a fixed rate of 6.954% per annum with interest only payments through December 31, 2015 followed by 30 equal monthly payments of principal and interest until maturity at June 1, 2018. At the time of final payment, we are required to pay an exit fee of 4.0% of the original principal balance of the Oxford Loan. In addition, we issued Oxford warrants to purchase an aggregate of 51,783 shares of common stock at an exercise price of $10.14 per share, subject to adjustment for stock splits, recapitalizations and certain other events. The warrants are exercisable for seven years from the date of issuance. We used approximately $0.8 million of the proceeds of this loan to pay off its existing term loan with Square 1 Bank. We granted a security interest in all of its assets, except intellectual property.

On August 10, 2015, the Company amended the terms of the Oxford Loan to extend the interest only period through December 31, 2016 and the maturity date to June 1, 2019. The exit fee was increased from 4.0% to approximately 5.0% of the original principal balance. The Oxford Loan continues to bear interest at a fixed rate of 6.954% per annum.

The Oxford Loan restricts us from issuing dividends and contains customary affirmative and negative covenants. At September 30, 2015, we were in compliance with all loan covenants.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements as defined in the rules and regulations of the SEC.

Item 3. Quantitative and Qualitati ve Disclosures About Market Risk.

Interest Rate Risk

Our cash and cash equivalents as of September 30, 2015 consisted of readily available checking and money market funds. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. However, because of the short-term nature of the instruments in our portfolio, a sudden change in market interest rates would not be expected to have a material impact on Tobira's financial condition and/or results of operations. We do not believe that our cash or cash equivalents has significant risk of default or illiquidity. While we believe our cash and cash equivalents do not contain excessive risk, we cannot provide absolute assurance that in the future its investments will not be subject to adverse changes in market value. In addition, we maintain significant amounts of cash and cash equivalents at one or more financial institutions that are in excess of federally insured limits.

Effects of Inflation

Inflation generally affects us with increased cost of labor and clinical trial costs. We do not believe that inflation and changing prices had a significant impact on our results of operations for any periods presented herein.

Item 4. Controls and Procedures.

Definition and limitations of disclosure controls

Our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act) are controls and other procedures that are designed to ensure that information required to be disclosed in our reports filed under the Exchange Act, such as this report, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures are also designed to ensure that such information is accumulated and communicated to our management, including the chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure. Our management evaluates these controls and procedures on an ongoing basis.

There are inherent limitations to the effectiveness of any system of disclosure controls and procedures. These limitations include the possibility of human error, the circumvention or overriding of the controls and procedures and reasonable resource constraints. In addition, because we have designed our system of controls based on certain assumptions, which we believe are reasonable, about the likelihood of future events, our system of controls may not achieve its desired purpose under all possible future conditions. Accordingly, our disclosure controls and procedures provide reasonable assurance, but not absolute assurance, of achieving their objectives.

Evaluation of disclosure controls and procedures

Our chief executive officer and our chief financial officer, after evaluating the effectiveness of our disclosure controls and procedures, believe that as of the end of the period covered by this report, our disclosure controls and procedures were effective in providing the requisite reasonable assurance that material information required to be disclosed in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding the required disclosure.

Changes in internal control over financial reporting

There has been no change in our internal control over financial reporting identified in connection with our evaluation that occurred during our most recent fiscal quarter that has materially affected or is reasonably likely to materially affect our internal control over financial reporting.

PART II – OTHE R INFORMATION

Item 1. Legal Proceedings.

On February 2, 2015, a purported stockholder of Regado filed a putative class-action lawsuit (captioned *Maiman v. Regado Biosciences, Inc.* , C.A. No. 10606-CB) in the Court of Chancery for the State of Delaware, or the Court, challenging the proposed stock-for-stock merger of Regado with Tobira, or the Proposed Merger. On February 25, 2015, a second, related putative class action (captioned *Gilboa v. Regado Biosciences, Inc.* , C.A. No. 10720-CB) was filed in the Court challenging the Proposed Merger. On May 4, 2014, the Proposed Merger was consummated and Tobira became a wholly-owned subsidiary of Regado and changed its name to Tobira Development, Inc. The complaints name as defendants: (i) each member of Regado's Board of Directors, (ii) Regado, (iii) Private Tobira, and (iv) Landmark Merger Sub Inc. Plaintiffs allege that Regado's directors breached their fiduciary duties to Regado's stockholders by, among other things, (a) agreeing to merge Regado with Private Tobira for inadequate consideration, (b) implementing a process that was distorted by conflicts of interest, and (c) agreeing to certain provisions of the Merger Agreement that are alleged to favor Private Tobira and deter alternative bids. Plaintiffs also generally allege that the entity defendants aided and abetted the purported breaches of fiduciary duty by the directors. On March 25, 2015, the Court consolidated the two actions and assigned lead counsel for plaintiffs (captioned *In re Regado Biosciences, Inc. Stockholder Litigation* , Consolidated C.A. No. 10606-CB). On March 27, 2015, plaintiffs filed a consolidated amended complaint, a motion for expedited proceedings and a motion for preliminary injunction. On April 20, 2015, the parties agreed in principle to resolve the litigation (subject to approval by the Court) and signed a memorandum of understanding setting forth the terms of a proposed settlement to provide additional disclosures related to the Merger Agreement and to cover Court-awarded fees. On April 23, 2015, as part of the proposed settlement, Regado provided additional disclosures to its stockholders. Since then, the parties have engaged in confirmatory discovery and will prepare a stipulation of settlement to be submitted to the Court for approval. As of September 30, 2015, the Company is unable to reasonably estimate an amount and/or a range of loss until the Company is made aware of the fees awarded by the Court to the plaintiffs under the proposed settlement, if any, as administered under settlement law. The Company maintains D&O insurance and tail coverage with deductibles of $2.0 million and $1.5 million, respectively.

From time to time, we may be involved in other legal proceedings and subject to claims incident to the ordinary course of business. Although the results of such legal proceedings and claims cannot be predicted with certainty, we believe we are not currently a party to any legal proceedings, other than as set forth above, the outcome of which, if determined adversely to us, would individually or taken together have a material adverse effect on our business, operating results, cash flows or financial position. Regardless of the outcome, such proceedings can have an adverse impact on us because of defense and settlement costs, diversion of resources and other factors, and there can be no assurances that favorable outcomes will be obtained.

Item 1A. Ri sk Factors.

You should carefully consider the risks described below, together with all of the other information included in or incorporated by reference into this prospectus, before making an investment decision. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we do not currently believe are important to an investor may also harm our business operations. If any of the events, contingencies, circumstances or conditions described in the following risks actually occurs, our business, financial condition or our results of operations could be seriously harmed. If that happens, the trading price of our common stock could decline and you may lose part or all of the value of any of our shares held by you.

Risks Related to our Business

We have limited operating history, have incurred significant operating losses since inception and we expect to incur significant losses for the foreseeable future. We may never become profitable or, if achieved, be able to sustain profitability.

We have incurred significant operating losses since inception and expect to incur significant losses for the foreseeable future as we continue our clinical trial and development programs for cenicriviroc, or CVC, and other future product candidates. As of September 30, 2015, we had an accumulated deficit of $154.0 million. Losses have resulted principally from costs incurred in our clinical trials, research and development programs and from our general and administrative expenses. As of September 30, 2015, we had cash and cash equivalents including restricted cash of $69.0 million. In the future, we intend to continue to conduct research and development, clinical testing, regulatory compliance activities and, if CVC or other future product candidates is approved, sales and marketing activities that, together with anticipated general and administrative expenses, will likely result in our incurring further significant losses for the foreseeable future.

We currently generate no revenue from product sales, and we may never be able to commercialize CVC or other future product candidates. We do not currently have the required regulatory approvals to market CVC or any other future product candidates, and we may never receive them. We may not be profitable even if we or any of our potential future development partners succeed in commercializing any of our product candidates. Because of the numerous risks and uncertainties associated with developing and commercializing our product candidates, we are unable to predict the extent of any future losses or when we will become profitable, if at all.

Our business depends on the success of CVC, which is still under development. If we are unable to obtain regulatory approval for or successfully commercialize CVC, our business will be materially harmed.

CVC, a dual inhibitor of chemokine receptor type 2, or CCR2, and type 5, or CCR5, with anti-fibrotic effects in liver disease models and antiviral effects on HIV-1 has been the sole focus of our product development. Successful continued development and ultimate regulatory approval of CVC for nonalcoholic steatohepatitis, or NASH, is critical to the future success of our business. We have invested, and will continue to invest, a significant portion of our time and financial resources in the development of CVC. We will need to raise sufficient funds for, and successfully enroll and complete, our ongoing clinical development program for CVC in NASH. The future regulatory and commercial success of this product candidate is subject to a number of risks, including the following:

- we may not have sufficient financial and other resources to complete the necessary clinical trials for CVC;
- we may not be able to obtain adequate evidence of efficacy and safety for CVC in NASH, HIV or any other indication;
- we do not know the degree to which CVC will be accepted as a therapy, even if approved;
- in our clinical programs, we may experience variability in patients, adjustments to clinical trial procedures and the need for additional clinical trial sites, which could delay our clinical trial progress;
- the results of our clinical trials may not meet the level of statistical or clinical significance required by the U.S. Food and Drug Administration, or FDA, or comparable foreign regulatory bodies for marketing approval;
- patients in our clinical trials may die or suffer other adverse effects for reasons that may or may not be related to CVC, which could delay or prevent further clinical development;
- the standards implemented by clinical or regulatory agencies may change at any time;
- the FDA and other foreign regulatory agencies have not issued guidance on development standards or endpoints for commercial approval of drugs for NASH and, if issued in the future, that guidance may call for additional or different clinical trials or endpoints than those included in our program;
- the FDA or foreign regulatory agencies may require efficacy endpoints for a Phase 3 clinical trial for the treatment of NASH that differ from the endpoints of our planned current or future trials, which may require us to conduct additional clinical trials;

- the mechanism of action of CVC is complex and we do not know the degree to which it will translate into a medical benefit in NASH;
- if approved for NASH, CVC will likely compete with the off-label use of currently marketed products and other therapies in development; and
- we may not be able to obtain, maintain or enforce our patents and other intellectual property rights.

Of the large number of drugs in development in the pharmaceutical industry, only a small percentage result in the submission of applications for marketing authorization to regulatory authorities and even fewer are approved for commercialization. Furthermore, even if we do receive regulatory approval to market CVC, any such approval may be subject to limitations on the indicated uses or patient populations for which we may market the product. Accordingly, even if we are able to obtain the requisite financing to continue to fund our development programs, we cannot assure you that CVC will be successfully developed or commercialized. If we or any of our potential future development partners are unable to develop, or obtain regulatory approval for, or, if approved, successfully commercialize CVC, we may not be able to generate sufficient revenue to continue our business.

We do not intend to progress CVC as an anti-retroviral therapy for HIV unless we raise significant non-dilutive financing and/or identify a strategic partner who will fund this program, which we might not achieve. We may not be able to secure such a strategic partner or non-dilutive financing.

We anticipate that future cash requirements to advance our HIV program will be significant and we only plan to advance it in collaboration with a strategic partner or with non-dilutive financing. If we are not able to collaborate with a strategic partner or secure non-dilutive financing, we may be unable to initiate further clinical studies for this program and may never be able to commercialize CVC in HIV. If we are unable to commercialize CVC in HIV or if we experience significant delays in advancing the program, our business may be adversely affected.

We are planning to discontinue the aptamer program unless we raise significant non-dilutive financing and/or identify a strategic partner who will fund this program, which we are unlikely to achieve.

We anticipate that future cash requirements to advance the aptamer program will be significant and we are planning to discontinue any development of or investment in the aptamer program. In conjunction with the discontinuation of the program there may still be other unknown expenses associated with the technology. It is unlikely that further clinical studies are undertaken for this program and it will likely never achieve commercialization.

The results of preclinical studies and early clinical trials are not always predictive of future results. Any product candidate we or any of our future development partners advance into clinical trials, including CVC, may not have favorable results in later clinical trials, if any, or receive regulatory approval.

Drug development has inherent risk. We or any of our potential future development partners will be required to demonstrate through adequate and well-controlled clinical trials that our product candidates are safe and effective, with a favorable benefit-risk profile, for use in their target indications before we can seek regulatory approvals for their commercial sale. Clinical studies are expensive, difficult to design and implement, can take many years to complete and are uncertain as to outcome. Delay or failure can occur at any stage of development, including after commencement of any of our clinical trials. In addition, success in early clinical trials does not mean that later clinical trials will be successful, because later-stage clinical trials may be conducted in broader patient populations and involve different study designs. Furthermore, our future trials will need to demonstrate sufficient safety and efficacy in larger patient populations for approval by regulatory authorities. Companies frequently suffer significant setbacks in advanced clinical trials, even after earlier clinical trials have shown promising results. In addition, only a small percentage of drugs under development result in the submission of applications for marketing authorization to regulatory authorities and even fewer are approved for commercialization.

We cannot be certain that any of our ongoing or future clinical trials will be successful, and any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of our product candidates in those and other indications.

Because CVC has not yet received regulatory approval, it is difficult to predict the time and cost of development and our ability to successfully complete clinical development and obtain the necessary regulatory approvals for commercialization.

CVC has not yet received regulatory approval for the treatment of NASH, and unexpected problems may arise that can cause us to delay, suspend or terminate our development efforts. Further, CVC has not yet demonstrated efficacy in humans for NASH, and the long-term safety consequences of dual inhibition of CCR2 and CCR5 receptors is not known. Regulatory approval of new product candidates such as CVC can be more expensive and take longer than approval for candidates for the treatment of more well

understood diseases with previously approved products. While we have received Fast Track designati on for CVC for the treatment of NASH with liver fibrosis, we may not benefit from any accelerated timelines or other regulatory benefits from this designation.

Any termination or suspension of, or delays in the commencement or completion of, our ongoing and planned clinical trials could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.

In order to continue development of CVC, we will need to submit the results of clinical and preclinical testing to the FDA and other regulatory bodies, along with other information including information about product candidate chemistry, manufacturing and controls, clinical results and potential clinical trial protocols. We may rely in part on preclinical, clinical and quality data generated by contract research organizations, or CROs, and other third parties for regulatory submissions for our product candidates. If these third parties do not provide us with data in a timely manner, we will not be able to make timely regulatory submissions for our product candidates, which may delay our plans for our clinical trials and potential product approvals. Furthermore, if those third parties do not make this data available to us, we will likely have to develop all necessary preclinical and clinical data on our own, which will lead to significant delays and increase development costs of the product candidate. Delays in the commencement or completion of our ongoing or future clinical trials for CVC or other future product candidates could significantly affect our product development costs. We do not know whether our current or planned trials will begin on time or be completed on schedule, if at all. The commencement and completion of clinical trials can be delayed for a number of reasons, including delays related to:

- regulatory agencies failing to grant permission to proceed or placing the clinical trial on hold;
- subjects failing to enroll or remain in our trial at the rate we expect;
- subjects choosing an alternative treatment for the indication for which we are developing the product candidates, or participating in competing clinical trials;
- lack of adequate funding to continue the clinical trial;
- subjects experiencing severe or unexpected drug-related adverse effects;
- a facility manufacturing our product candidate or any of its components being ordered by the FDA or other government or regulatory authorities to temporarily or permanently suspend operations due to violations of current good manufacturing practices, or GMP, regulations, or other applicable requirements;
- any changes to our manufacturing process that may be necessary or desired;
- third-party clinical investigators losing the licenses or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, GMP regulations or other regulatory requirements, or our CROs or other third parties not performing data collection or analysis in a timely or accurate manner;
- inspections of clinical trial sites by regulatory authorities or the finding of regulatory violations by regulatory authorities or an institutional review board, or IRB, that require us to undertake corrective action, that results in suspension or termination of one or more sites or the imposition of a clinical hold on the entire trial or that prohibits us from using some or all of the data in support of our marketing applications;
- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications; or
- one or more IRBs refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects or withdrawing its approval of the trial.

Product development costs will increase if we have delays in testing or approval of CVC or if we need to perform more or larger clinical trials than planned. Additionally, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the cost, timing or successful completion of a clinical trial. If we experience delays in completion of our clinical trials, or if we, the FDA or other regulatory authorities, IRBs, other reviewing entities or any of our clinical trial sites suspend or terminate any of our clinical trials, the commercial prospects for a product candidate may be harmed and our ability to generate product revenues will be delayed. In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. Further, if one or more clinical trials are delayed, our competitors may be able to bring products to market before we do, and the commercial viability of CVC or other future product candidates could be significantly reduced.

We have not yet determined the details of any potential Phase 3 trial designs, including identification of a primary endpoint that the FDA or other regulatory authorities woul d deem acceptable in a study for the treatment of NASH. If the FDA or other regulatory authorities determine that Phase 3 studies would require substantially different endpoints than those addressed in our ongoing or future clinical trials, we may need to conduct additional Phase 2 clinical trials of CVC.

If we encounter difficulties enrolling and retaining patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

Patient enrollment and retention, both significant factors in the timing of clinical trials, are affected by many factors including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, patient willingness to undergo a liver biopsy in our NASH trials, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages and disadvantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. Potential patients for CVC may not be adequately diagnosed or identified with the diseases which we are targeting or may not meet the entry criteria for our studies.

We will be required to identify and enroll a sufficient number of patients with NASH for each of our ongoing and planned clinical trials of CVC in this indication, which we may fail to do. Also, we may encounter difficulties in identifying and enrolling NASH patients with a stage of disease appropriate for our ongoing or future clinical trials. We may not be able to initiate or continue clinical trials if we are unable to locate a sufficient number of eligible patients to participate in the clinical trials required by the FDA or other foreign regulatory agencies. In addition, the process of finding and diagnosing patients may prove costly. Our inability to enroll a sufficient number of patients for any of our clinical trials would result in significant delays or may require us to abandon one or more clinical trials.

Any product candidate in our current or future clinical trials may cause unacceptable adverse events or have other properties that may delay or prevent its regulatory approval or commercialization or limit its commercial potential.

Unacceptable adverse events caused by any of our product candidates in current or future clinical trials could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications and markets. This in turn could prevent us from completing development or commercializing the affected product candidate and generating revenue from its sale. If any of our product candidates cause unacceptable adverse events in clinical trials, we may not be able to obtain regulatory approval or commercialize such product candidate.

Our product candidates are subject to extensive regulation, compliance with which is costly and time consuming, and such regulation may cause unanticipated delays in, or prevent the receipt of the required approvals for, commercialization of our product candidates.

The clinical development, manufacturing, labeling, storage, record-keeping, advertising, promotion, import, export, marketing and distribution of our product candidates are subject to extensive regulation by the FDA in the United States and by comparable foreign regulatory agencies. We are not permitted to market our product candidates until we receive regulatory approval from the FDA or comparable foreign regulatory bodies. The process of obtaining regulatory approval is expensive, often takes many years and can vary substantially based upon the type, complexity and novelty of the products involved, as well as the target indications and patient populations. Regulatory agencies may change their approval policies or regulations and have substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. Despite the time and expense invested in clinical development of product candidates, regulatory approval is never guaranteed.

The FDA or comparable foreign regulatory authorities can delay, limit or deny approval of a product candidate for many reasons, including the following:

- such authorities may disagree with the design or implementation of our or any of our potential future development partners' clinical trials;
- we or any of our potential future development partners may be unable to demonstrate to the satisfaction of the FDA or other regulatory authorities that a product candidate is safe and effective for any indication;
- the results of clinical trials may not demonstrate the appropriateness of the dose or the safety or efficacy required by such authorities for approval;
- we or any of our potential future development partners may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- such authorities may disagree with our interpretation or the quality of data from preclinical studies or clinical trials;

- such authorities may find deficiencies in the manufacturing processes or fa cilities of third-party manufacturers with which we or any of our potential future development partners contract for clinical and commercial supplies; or
- the approval policies or regulations of such authorities may significantly change in a manner rendering our or any of our potential future development partners' clinical data insufficient for approval.

With respect to foreign markets, approval procedures vary among countries and, in addition to the aforementioned risks, can involve additional product testing, administrative review periods and agreements with pricing authorities. In addition, events raising questions about the safety of certain marketed pharmaceuticals may result in increased cautiousness by the FDA and comparable foreign regulatory authorities in reviewing new drugs based on safety, efficacy or other regulatory considerations and may result in significant delays in obtaining regulatory approvals. Any delay in obtaining, or inability to obtain, applicable regulatory approvals would prevent us or any of our potential future development partners from commercializing our product candidates.

Coverage and reimbursement may be limited or unavailable in certain market segments for CVC and other future product candidates, which could make it difficult for us to sell our product candidates.

Market acceptance and sales of CVC and other future product candidates will depend significantly on the availability of adequate insurance coverage and reimbursement from third-party payors for any of our product candidates and may be affected by existing and future healthcare reform measures. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs they will pay for and establish reimbursement levels. Reimbursement by a third-party payor may depend upon a number of factors including the third-party payor's determination that use of a product candidate is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining coverage and reimbursement approval for a product candidate from a government or other third-party payor is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost effectiveness data for the use of the applicable product candidate. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. We cannot be sure that coverage or adequate reimbursement will be available for any of our product candidates. Further, reimbursement amounts may not support the demand for, or the price of, our product candidates. If reimbursement is not available or is available only in limited levels, we may not be able to commercialize certain of our product candidates profitably, or at all, even if approved.

As a result of legislative proposals and the trend toward managed healthcare in the United States, third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement of new drugs. They may also refuse to provide coverage of approved product candidates for medical indications other than those for which the FDA has granted market approvals. As a result, significant uncertainty exists as to whether and how much third-party payors will reimburse patients for their use of newly approved drugs, which in turn may put pressure on the pricing of drugs or force prescribers to use generic drugs. We expect to experience pricing pressures in connection with the sale of our product candidates, if approved, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative proposals as well as country, regional or local healthcare budget limitations.

Even if we obtain marketing approval for CVC or any other product candidate, it could be subject to restrictions or withdrawal from the market and will be subject to post-marketing requirements, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our product candidates, when and if any of them are approved.

Even if regulatory approval is obtained, the FDA or comparable regulatory authorities may still impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly and time consuming post-approval studies, post-market surveillance or clinical trials. Following approval, if any, of CVC or any other product candidate, such candidate will also be subject to ongoing FDA and comparable foreign regulatory agency requirements governing labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, recordkeeping, reporting of safety and other post-market information, import and export. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with GMP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents. If we or a regulatory agency discovers previously unknown problems with a

product, such as adverse events of unanticipated severity or frequency, or problems with the facilit y where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requesting a recall or withdrawal of the product from the market or suspension of manufacturing.

If we or the manufacturing facilities for CVC, or any other product candidate that may receive regulatory approval, if any, fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or untitled letters;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements or any subsequent applications or supplements we may file;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products, refuse to permit the import or export of products or request us to initiate a product recall.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue.

The FDA has the authority to require a risk evaluation and mitigation strategy, or REMS, as part of a NDA or after approval, which may impose further requirements or restrictions on the distribution or use of a drug, such as limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria and requiring treated patients to enroll in a registry.

In addition, if CVC or any other future product candidate is approved, our product labeling, advertising and promotion would be subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about prescription products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. If we receive marketing approval for a product candidate, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. However, if we are found to have promoted such off-label uses, we may become subject to significant liability. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we are deemed by the FDA to have engaged in the promotion of our products for off-label use, we could be subject to FDA prohibitions on the sale or marketing of our products or significant fines and penalties, and the imposition of these sanctions could also affect our reputation and position within the industry.

Even if we receive regulatory approval for CVC or any other product candidate, we still may not be able to successfully commercialize it, and the revenue that we generate from its sales, if any, could be limited.

Even if CVC or any other future product candidates receive regulatory approval, they may not gain market acceptance among physicians, patients, healthcare payors or the medical community. Coverage and reimbursement of our product candidates by third-party payors, including government payors, is also generally necessary for commercial success. The degree of market acceptance of our product candidates will depend on a number of factors, including:

- demonstration of clinical efficacy and safety compared to other products;
- the limitation of our targeted patient population and other limitations or warnings contained in any approved product labeling;
- acceptance of a new formulation by healthcare providers and their patients;
- the prevalence and severity of any adverse effects;
- new procedures or methods of treatment that may be more effective in treating or may reduce the incidences of NASH or other conditions for which our products are intended to treat;
- pricing and cost-effectiveness;
- the effectiveness of our or any future collaborators' sales and marketing strategies;

- our ability to obtain and maintain sufficient third-party coverage or reimbursement from government healt hcare programs, including Medicare and Medicaid, private health insurers and other third-party payors;
- unfavorable publicity relating to the product candidate; and
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage.

If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors or patients, we may not generate sufficient revenue from that product candidate and may not become or remain profitable. Our efforts to educate the medical community and third-party payors on the benefits of CVC or any other future product candidates may require significant resources and may never be successful. In addition, our ability to successfully commercialize our product candidate will depend on our ability to manufacture our products, differentiate our products from competing products and defend and enforce our intellectual property rights relating to our products.

If the market opportunity for CVC for the treatment of NASH is smaller than we believe it is, our future revenue may be adversely affected, and our business may suffer.

If the size of the market opportunity for CVC in NASH is smaller than we anticipate, we may not be able to achieve profitability and growth. While we are initially targeting CVC for the treatment of NASH, a disease we believe to be one of the most prevalent chronic liver diseases worldwide, our projections of the number of people who have NASH, as well as the subset of people with the disease who have the potential to benefit from treatment with CVC, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including the scientific literature, surveys of clinics, patient foundations and market research and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of this disease. The number of patients may turn out to be lower than expected. The effort to identify patients with the diseases we seek to treat is in early stages, and we cannot accurately predict the number of patients for whom treatment might be possible. For example, NASH is often undiagnosed and may be left undiagnosed for a long time. A definitive diagnosis of NASH is currently based on a histological assessment of a liver biopsy, which impacts the ability to easily identify patients. If improved diagnostic techniques for identifying NASH patients who will benefit from treatment are not developed, our market opportunity may be smaller than we currently anticipate. Additionally, the potentially addressable patient population may be limited or may not be amenable to treatment with CVC, and new patients may become increasingly difficult to identify or gain access to, which would adversely affect our results of operations and our business.

If we fail to develop and commercialize other product candidates, we may be unable to grow our business.

Although the development and commercialization of CVC is our primary focus, as part of our longer-term growth strategy, we plan to evaluate the development and commercialization of other therapies related to immune-mediated, inflammatory, orphan and other diseases. We will evaluate internal opportunities from our compound libraries, and also may choose to in-license or acquire other product candidates as well as commercial products to treat patients suffering from immune-mediated or orphan or other disorders with high unmet medical needs and limited treatment options. These other product candidates will require additional, time-consuming development efforts prior to commercial sale, including preclinical studies, clinical trials and approval by the FDA and/or applicable foreign regulatory authorities. All product candidates are prone to the risks of failure that are inherent in pharmaceutical product development, including the possibility that the product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot assure you that any such products that are approved will be manufactured or produced economically, successfully commercialized or widely accepted in the marketplace or be more effective than other commercially available alternatives.

We rely on third parties to conduct our clinical trials. If these third parties do not meet our deadlines and budget or otherwise conduct the trials as required, our clinical development programs could be delayed or unsuccessful and we may not be able to obtain regulatory approval for or commercialize our product candidates when expected or at all.

We are dependent on third parties to conduct all of our clinical trials. Accordingly, the timing of the initiation and completion of these trials is controlled by such third parties and may occur at times substantially different from our estimates. Specifically, we use CROs to conduct our clinical trials and rely on medical institutions, clinical investigators, CROs and consultants to conduct our trials in accordance with our clinical protocols and regulatory requirements. Our CROs, investigators, and other third parties play a significant role in the conduct of these trials and subsequent collection and analysis of data.

There is no guarantee that any CROs, investigators, or other third parties on which we rely for administration and conduct of our clinical trials will devote adequate time and resources to such trials or perform as contractually required or within the estimated budget. If any of these third parties fails to meet expected deadlines, fails to adhere to our clinical protocols or otherwise performs in a substandard manner, our clinical trials may be extended, delayed or terminated. If any of these third parties do not complete their contracted activities or have delays or unexpected costs, we may incur significant additional costs to complete our clinical studies. If

any of our clinical trial sites terminates for any reason, we may experience the loss of follow-up information on subjects enrolled in our ongoing clinical trials unless we are able to transfer thos e subjects to another qualified clinical trial site. In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such se rvices. If these relationships and any related compensation result in perceived or actual conflicts of interest, or if we fail to adequately disclose such compensation pursuant to FDA regulations, the integrity of the data generated at the applicable clini cal trial site may be jeopardized.

We also regularly allow independent clinical investigators to conduct studies with our products that may not be completely under our control. Such investigator initiated studies may be conducted in a manner that results in unexpected data or events that are damaging to the value of our programs.

We rely on third parties to supply the components of and manufacture CVC for our clinical trials and commercialization, which is a complex process. Our dependence on third parties could adversely impact our business.

We are dependent on third-parties to supply the components of and manufacture CVC. If these third-party suppliers do not supply sufficient quantities of materials to us on a timely basis and in accordance with applicable specifications, GMP regulations and other regulatory requirements, there could be a significant interruption of our supplies, which would adversely affect clinical development of the product candidate. Furthermore, if any of our contract manufacturers cannot successfully manufacture material that conforms to our specifications and within regulatory requirements, we will not be able to secure and/or maintain regulatory approval, if any, for our product candidates.

We will also rely on our contract manufacturers to purchase from third-party suppliers the materials necessary to produce our product candidates for our anticipated clinical trials. We have limited control over the process or timing of the acquisition of raw materials by our contract manufacturers. Moreover, we currently do not have agreements in place for the commercial production of these raw materials. Any significant delay in the supply of a product candidate or the raw material components thereof for an ongoing clinical trial could considerably delay completion of that clinical trial, product candidate testing and potential regulatory approval of that product candidate.

We do not expect to have the resources or capacity to commercially manufacture CVC or any other future product candidates, if approved, and will likely continue to be dependent on third-party manufacturers. Our dependence on third parties to manufacture and supply us with clinical trial materials and any approved product candidates may adversely affect our ability to develop and commercialize our product candidates on a timely basis.

The process of drug manufacturing is complex, highly regulated and subject to several risks, including:

- the manufacturing of compounds is complex, and only a limited number of manufacturers will be capable of manufacturing CVC and other future product candidates;
- the manufacturing of compounds is susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment or vendor or operator error. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our products or in the manufacturing facilities in which our products are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination;

- the manufacturing facilities in which CVC and other future pro duct candidates are made could be adversely affected by labor shortages, natural disasters, power failures and numerous other factors; and
- we and our contract manufacturers must comply with GMP regulations and guidelines. Although we are ultimately responsible for ensuring that our product candidates are manufactured in accordance with GMP regulations and guidance, we are not involved in the day-to-day operations of our contract manufacturers. We and our contract manufacturers may encounter difficulties in achieving quality control and quality assurance and may experience shortages in qualified personnel. We and our contract manufacturers are subject to inspections by the FDA and comparable agencies in other jurisdictions to confirm compliance with applicable regulatory requirements. Any failure to follow GMP or other regulatory requirements or any delay, interruption or other issues that arise in the manufacture, fill-finish, packaging or storage of our products as a result of a failure of our facilities or the facilities or operations of third parties to comply with regulatory requirements or pass any regulatory authority inspection could significantly impair our ability to develop and commercialize our product candidates, including leading to significant delays in the availability of product candidates for our clinical studies or the termination or hold on a clinical study or the delay or prevention of filing or approval of marketing applications for our product candidates. Significant noncompliance could also result in the imposition of sanctions, including warning or untitled letters, fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approvals for our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could be costly and damage our reputation. If we are not able to maintain regulatory compliance, we may not be permitted to market our product candidates and/or may be subject to product recalls, seizures, injunctions, or criminal prosecution.

Any adverse developments affecting manufacturing operations for our products may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of our products. We may also have to take inventory write-offs and incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives.

We may not be successful in establishing and maintaining of development or other strategic partnerships, which could adversely affect our ability to develop and commercialize product candidates.

We may choose to enter into development or other strategic partnerships in the future, including collaborations with major biotechnology or pharmaceutical companies. The negotiation process for collaborations is time consuming and complex. We may not be successful in our efforts to establish a development partnership or other alternative arrangements for any of our product candidates and programs. Even if we are successful in our efforts to establish development partnerships, the terms that we agree upon may not be favorable to us, and we may not be able to maintain such development partnerships if, for example, development or approval of a product candidate is delayed or sales of an approved product candidate are disappointing. Any delay in entering into development partnership agreements related to our product candidates could delay the development and commercialization of our product candidates and reduce their competitiveness if they reach the market.

In addition, our strategic partners may terminate any agreements they enter into with us, and we may not be able to adequately protect our rights under these agreements. Furthermore, our strategic partners will likely negotiate for certain rights to control decisions regarding the development and commercialization of our product candidates, if approved, and may not conduct those activities in the same manner as we do.

Moreover, if we fail to maintain development or other strategic partnerships related to our product candidates that we may choose to enter into, then:

- the development of certain of our current or future product candidates may be terminated or delayed;
- our cash expenditures related to development of certain of our current or future product candidates would increase significantly, and we may need to seek additional financing;
- we may be required to hire additional employees or otherwise develop expertise, such as sales and marketing expertise, for which we have not budgeted; and
- we will bear all of the risk related to the development of any such product candidates.

We may form strategic alliances in the future, and we may not realize the benefits of such alliances.

We may form strategic alliances, create joint ventures or collaborations or enter into licensing arrangements with third parties that we believe will complement or augment our existing business, including for the continued development or commercialization of CVC or other future product candidates. These relationships or those like them may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and

business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consu ming and complex. We cannot be certain that, following a strategic transaction or license, we will achieve the revenues or specific net income that justifies such transaction.

If our competitors develop treatments for the target indications of our product candidates that are approved more quickly than ours, marketed more successfully or demonstrated to be safer or more effective than our product candidates, our commercial opportunity will be reduced or eliminated.

We operate in highly competitive segments of the biotechnology and biopharmaceutical markets. We face competition from many different sources, including commercial pharmaceutical and biotechnology enterprises, academic institutions, government agencies and private and public research institutions. Our product candidates, if successfully developed and approved, may compete with established therapies as well as with new treatments that may be introduced by our competitors. Many of our competitors have significantly greater financial, product candidate development, manufacturing and marketing resources than we do. Large pharmaceutical and biotechnology companies have extensive experience in clinical testing and obtaining regulatory approval for drugs. In addition, universities and private and public research institutes may be active in research in our target indications, and they or their licensees could be in direct competition with us. We also may compete with these organizations to recruit management, scientists and clinical development personnel. We will also face competition from these third parties in establishing clinical trial sites, registering subjects for clinical trials and in identifying and in-licensing new product candidates. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Additionally, we may face competition from developing countries, where costs may be cheaper.

New developments, including the development of other pharmaceutical technologies and methods of treating disease, occur in the pharmaceutical and life sciences industries at a rapid pace. Developments by competitors may render our product candidates obsolete or noncompetitive. Competition in drug development is intense. We anticipate that we will face intense and increasing competition as new treatments enter the market and advanced technologies become available.

There are currently no therapeutic products approved for the treatment of NASH. There are several commercially available products that are currently used off label for NASH, such as vitamin E (an antioxidant), diabetes medications (such as pioglitazone), antihyperlipidemic agents (such as gemfibrozil), pentoxifylline, ursodeoxycholic acid and others. In addition, there are numerous drugs in development for the treatment of NASH. We are aware of several companies that have product candidates in clinical development for the treatment of NASH, including Boehringer Ingelheim GmbH, Bristol-Myers Squibb Company, Conatus Pharmaceuticals Inc., Galectin Therapeutics Inc., Galmed Medical Research Ltd., Genfit Corp., Gilead Sciences, Inc., Immuron Ltd., Intercept Pharmaceuticals, Inc., NGM Biopharmaceuticals, Inc., Nimbus Therapeutics Inc, Novartis AG, Novo Nordisk A/S, Shire plc, Takeda, Zydus Cadilla, and there are other companies with candidates in earlier stage development.

In HIV, we are aware of several companies that market therapies, including single tablet regimen Atripla, Complera, Stribild and Triumeq (commercialized by Bristol-Myers Squibb Company, Gilead Sciences Inc., Janssen Pharmaceuticals Inc. and ViiV Healthcare), NRTI backbones Truvada and Epzicom (commercialized by Gilead Sciences Inc. and ViiV Healthcare) and multiple single agent products in the integrase inhibitor, protease inhibitor and NNRTI class, as well as CCR5 inhibitor maraviroc (commercialized by ViiV Healthcare). Other companies are also developing novel HIV therapies and vaccines.

Even if we obtain regulatory approval for our product candidates, the availability and price of our competitors' products could limit the demand or the price we are able to charge, for our product candidates. Several generic products are already available and more will become available for the indications we are targeting with our product candidates. Our business will be harmed if the acceptance of our product candidates is inhibited by price competition or the reluctance of physicians to switch from existing methods of treatment to our product candidates, or if physicians switch to other new drug products or choose to reserve our product candidates for use in limited circumstances. Our inability to compete with existing or subsequently introduced drug products would have a material adverse impact on our business.

We have no sales, marketing, reimbursement or distribution capabilities, and we will have to invest significant resources to develop these capabilities.

We have no internal sales, marketing, reimbursement or distribution capabilities. If CVC or any other future product candidates ultimately receives regulatory approval, we may not be able to effectively market and distribute the product candidate. We will have to invest significant amounts of financial and management resources to develop internal sales, distribution and marketing capabilities, some of which will be committed prior to any confirmation that CVC or any other future product candidates will be approved, if at all. We may not be able to hire consultants or external service providers to assist us in sales, marketing, reimbursement and distribution functions on acceptable financial terms or at all. Even if we decide to establish sales, marketing, reimbursement and distribution functions, we could face a number of additional related risks, including the following:

- we may not be able to attract and build an effective marketing department or sales force;
- the cost of establishing a marketing department or sales force may exceed our available financial resources and the revenues generated by CVC or any other product candidates that we may develop, in-license or acquire; and
- our direct sales, reimbursement and marketing efforts may not be successful.

If we lose key scientists or management personnel, or if we fail to recruit additional highly skilled personnel, our ability to identify, develop and commercialize products will be impaired.

We are highly dependent on principal members of our management team and scientific staff, including our Chief Executive Officer, Laurent Fischer, M.D., and our Chief Medical Officer, Éric Lefebvre, M.D. These executives each have significant pharmaceutical industry experience. The loss of any member of our management team or scientific staff, including Drs. Fischer and Lefebvre, would impair our ability to identify, develop and market new products. Our management and other employees may voluntarily terminate their employment with us at any time. The loss of the services of these or other key personnel, or the inability to attract and retain additional qualified personnel, could result in delays to development or approval, loss of sales and diversion of management resources. In addition, we depend on our ability to attract and retain other highly skilled personnel. Competition for qualified personnel is intense, and the process of hiring and integrating such qualified personnel is often lengthy. We may be unable to recruit such personnel on a timely basis, if at all, which would negatively impact our development and commercialization programs.

Additionally, we do not currently maintain “key person” life insurance on the lives of our executives or any of our employees. This lack of insurance means that we may not receive adequate compensation for the loss of the services of these individuals.

We may encounter difficulties in managing our growth and expanding our operations successfully.

As of November 6, 2015, we had 20 full-time employees. We will need to grow our organization substantially to continue development and pursue the potential commercialization of CVC and other future product candidates, as well as function as a public company. As we seek to advance CVC and other product candidates, we will need to expand our financial, development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various strategic partners, suppliers and other third parties. Future growth will impose significant added responsibilities on members of management and require us to retain additional internal capabilities. 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 development efforts and clinical trials effectively and hire, train and integrate additional management, clinical and regulatory, financial, administrative and sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to so accomplish could prevent us from successfully growing our company.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize 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 healthcare systems that could prevent or delay marketing approval for our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell our product candidates.

Legislative and regulatory proposals have been made 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 or other agency 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 United States Congress of the FDA’s approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

In the United States, the Medicare Modernization Act of 2003, or MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for outpatient prescription drug purchases by the el derly with a new Part D program. In addition, this legislation authorized Medicare Part D prescription drug plans to use formulas where they can limit the number of drugs that will be covered in any therapeutic class. Notwithstanding the expansion of feder al coverage of drug products, there is pressure to contain and reduce costs.

More recently, in March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the Affordable Care Act, which is a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The Affordable Care Act, among other things:

- imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell "branded prescription drugs";
- increased the minimum level of Medicaid rebates payable by manufacturers of brand-name drugs from 15.1% to 23.1%;
- expanded the 340B drug discount program;
- required collection of rebates for drugs paid by Medicaid managed care organizations;
- revised the definition of "average manufacturer price" for Medicaid drug rebate reporting purposes, which could increase the amount of Medicaid drug rebates due to states;
- required manufacturers to participate in a coverage gap discount program, under which they must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; and
- mandated a further shift in the burden of Medicaid payments to the states.

Although it is too early to determine the full effect of the Affordable Care Act on our business, the law appears likely to continue the pressure on pharmaceutical pricing, especially under Medicare, and may also increase our regulatory burdens and operating costs.

Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. On August 2, 2011, the President signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee did not achieve its targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reductions to several government programs. These reductions include aggregate reductions to Medicare payments to providers, managed care organizations, and prescription drug plan sponsors, of 2% per fiscal year, which went into effect on April 1, 2013.

There likely will continue to be legislative and regulatory proposals at the federal and state levels directed at containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future or their full impact. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may adversely affect:

- the demand for any product candidates for which we may obtain regulatory approval;
- our ability to set a price that we believe is fair for our product candidates;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

If we fail to comply with healthcare regulations, we could face substantial penalties and our business, results of operations and financial condition could be adversely affected.

Certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. We could be subject to healthcare fraud and abuse and patient privacy laws and regulations by both the federal government and the states in which we conduct our business. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of these laws. The regulations that may affect our ability to operate include, without limitation:

- the federal False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false claims, or knowingly using false statements, to obtain payment from the federal government, and which may apply to entities that provide coding and billing advice to customers;
- the federal Anti-Kickback Statute, which prohibits, among other things, any person from knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formula managers on the other;
- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and its implementing regulations, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

Although there are several statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution under the Anti-Kickback Statute, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exemption or safe harbor. We have consulting arrangements with physicians who provide various services to us. Payment for some of these consulting services is not made on a per-hour basis. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability.

Recent legislation has strengthened the above laws. The Affordable Care Act, among other things, amends the intent requirement of the Federal Anti-Kickback Statute and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

The Affordable Care Act also imposes new reporting and disclosure requirements on drug manufacturers for any "transfer of value" made or distributed to prescribers and other healthcare providers. In addition, drug manufacturers will also be required to report and disclose any investment interests held by physicians and their immediate family members during the preceding calendar year. Failure to submit required information may result in civil monetary penalties of up to an aggregate of $150,000 per year (and up to an aggregate of $1.0 million per year for "knowing failures"), for all payments, transfers of value or ownership or investment interests not reported in an annual submission.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians for marketing. Some states mandate implementation of compliance programs and/or the tracking and reporting of gifts, compensation, and other remuneration to physicians. The need to build and maintain a robust compliance program with different compliance and/or reporting requirements increases the possibility that a healthcare company may violate one or more of the requirements.

If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, imprisonment, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

Governments may impose price controls, which may adversely affect our future profitability.

We intend to seek approval to market our product candidates in both the United States and in foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions, we will be subject to rules and regulations in those jurisdictions relating to our product candidates. In many foreign countries the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product candidate. If reimbursement of our future products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of CVC or other future product candidates.

We face an inherent risk of potential product liability as a result of the clinical testing of CVC and other future product candidates and will face an even greater risk if we commercialize our product candidates. For example, we may be sued if CVC or our other product candidates allegedly cause injury or are found to be otherwise unsuitable during product 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 candidate, negligence, strict liability and a breach of warranties. 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 or cease the commercialization of our product candidates. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for CVC or our other product candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- the inability to commercialize CVC or our other product candidates; and
- a decline in our stock price.

We maintain clinical trial insurance with $10.0 million in coverage in the United States and local policies in other countries of various amounts based on local requirements, which we believe is sufficient to cover foreseeable claims that may be made against us and is customary for similarly situated companies in our industry. However, we cannot be certain that such insurance will be sufficient to cover all claims that may be made against us and any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions, and we may be subject to a claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Furthermore, our inability to obtain and retain sufficient clinical trial insurance at an acceptable cost to protect against potential liability claims could prevent or inhibit the commercialization of CVC or our other product candidates.

Our term loan with Oxford contains restrictions that may limit our flexibility in operating our business.

In June 2014, and as amended in May 2015 and August 2015, we entered into a loan and security agreement with Oxford Finance LLC, or Oxford, pursuant to which we borrowed an aggregate principal amount of $15.0 million. Amounts outstanding under the term loan are secured by all of our existing and future assets, excluding intellectual property unless otherwise determined by applicable judicial authority. The agreement contains various covenants that require Oxford's approval to engage in specified types of transactions. These covenants require approval to, among other things:

- incur or assume certain debt;
- merge or consolidate;

- change the nature of our business;
- dispose of certain assets;
- grant liens on our assets including our intellectual property;
- make certain investments;
- pay dividends; and
- enter into material transactions with affiliates.

A breach of any of these covenants or a material adverse change to our business could result in a default under the loan. In the case of an event of default under the loan, Oxford could elect to declare all amounts outstanding to be immediately due and payable, commence and prosecute bankruptcy and/or other insolvency proceedings, or proceed against the collateral granted to Oxford as security for the loan.

We and any of our future development partners will be required to report to regulatory authorities if any approved products cause or contribute to adverse events, and any failure to do so would result in sanctions that would materially harm our business.

If we and any of our future development partners are successful in commercializing our products, the FDA and foreign regulatory authorities would require that we and any of our future development partners report certain information about adverse medical events if those products may have caused or contributed to those adverse events. The timing of our obligation to report would be triggered by the date we become aware of the adverse event as well as the nature of the event. We and any of our future development partners may fail to report adverse events we become aware of within the prescribed timeframe or we may fail to receive notice of such events from our CROs within the prescribed time period. We and any of our future development partners may also fail to appreciate that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of our products. If we and any of our future development partners fail to comply with our reporting obligations, the FDA or a foreign regulatory authority could take action, including criminal prosecution, the imposition of civil monetary penalties, seizure of our products or delay in approval of future products.

Our internal computer systems, or those of our development partners, third-party CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs.

Despite the implementation of security measures, our internal computer systems and those of our current and any future CROs and other contractors, consultants and collaborators are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties to manufacture our product candidates and conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidate could be delayed. We plan to update the financial systems technology associated with our general ledger accounting in 2016. Should the new systems not be implemented successfully, or if the systems do not perform in a satisfactory manner once the update is complete, our business and operations could be adversely affected.

Business disruptions could seriously harm our future revenues and financial condition and increase our costs and expenses.

Our operations could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, fires, extreme weather conditions, medical epidemics and other natural or manmade disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce CVC and our other product candidates. Our ability to obtain clinical supplies of CVC or our other product candidates could be disrupted if the operations of these suppliers are affected similarly.

Risks Relating to Our Intellectual Property

Our rights to develop and commercialize our product candidates are subject in part to the terms and conditions of a license to CVC granted to us by Takeda.

CVC is based in part on patents that we have licensed on an exclusive basis and other intellectual property licensed from Takeda Pharmaceutical Company Limited, or Takeda. Takeda holds certain rights with respect to CVC in the license agreement. This license imposes various commercial, contingent payment, royalty, insurance, indemnification, and other obligations on us. If we fail to comply with these obligations, the licensor may have the right to terminate the license, in which event we would lose valuable rights under our collaboration agreements and our ability to develop product candidates.

Either party may terminate the license agreement under certain circumstances, including a material breach of the agreement by the other. In the event we terminate our license, or if Takeda terminates our license due to our breach, all rights to CVC, including any intellectual property we develop with respect to CVC or licensed or developed by us under this agreement will revert or otherwise be licensed back to Takeda on an exclusive basis. Any termination or reversion to Takeda of our rights to develop or commercialize CVC, including any reacquisition by Takeda of our rights, will have a material adverse effect on our business.

We may fail to comply with any of our obligations under existing agreements pursuant to which we license rights or technology, which could result in the loss of rights or technology that are material to our business.

We are a party to a license agreement with Takeda that is important to our business, and we may enter into additional licenses in the future. Under our agreement from Takeda, Takeda has assigned and licensed to us certain patents and know-how relating to CVC. This license agreement imposes various commercial, contingent payment, royalty, insurance, indemnification, and other obligations on us. If we fail to comply with these obligations, Takeda may have the right to terminate the license agreement, in which event we would lose valuable rights to CVC and would be unable to develop or market CVC.

With respect to certain patents under our license agreement with Takeda and in some cases with respect to any license we may enter into in the future, patent prosecution of our licensed technology is controlled solely by the licensor. If our licensors fail to obtain and maintain patent or other protection for the proprietary intellectual property we license from them, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, and our competitors could market competing products using the intellectual property. In certain cases, including with respect to the patents assigned to us from Takeda, we control the prosecution of patents resulting from licensed or assigned technology. In the event we breach any of our obligations related to such prosecution, we may incur significant liability to our licensing partners. Licensing of intellectual property is of critical importance to our business and involves complex legal, business, and scientific issues. Disputes may arise regarding intellectual property subject to a licensing agreement, including but not limited to:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our collaborators; and
- the priority of invention of patented technology.

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

Our success depends on our ability to protect our intellectual property and our proprietary technologies.

Our commercial success depends in part on our ability to obtain and maintain patent protection and trade secret protection for our product candidates, proprietary technologies, and their uses as well as our ability to operate without infringing upon the proprietary rights of others. We can provide no assurance that our patent applications or those of our licensors will result in additional patents being issued or that issued patents will afford sufficient protection against competitors with similar technology, nor can there be any assurance that the patents issued will not be infringed, designed around or invalidated by third parties. Even issued patents may later be found unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. The degree of future protection for our proprietary rights is uncertain. Only limited protection may be available and may not

adequately protect our rights or permit us to gain or keep any competitive advantage. This failure to properly protect the intellectual prop erty rights relating to our product candidates could have a material adverse effect on our financial condition and results of operations.

Composition-of-matter patents on the biological or chemical active pharmaceutical ingredient are generally considered to be the strongest form of intellectual property and provide the broadest scope of patent protection for pharmaceutical products, as such patents provide protection without regard to any method of use. While we have issued composition-of-matter patents in the United States and other countries for CVC, we cannot be certain that the claims in our issued composition-of-matter patents will not be found invalid or unenforceable if challenged. We cannot be certain that the claims in our patent applications covering composition-of-matter or formulations of our other product candidates will be considered patentable by the United States Patent and Trademark Office, or USPTO, and courts in the United States or by the patent offices and courts in foreign countries, nor can we be certain that the claims in our issued composition-of-matter patents will not be found invalid or unenforceable if challenged. Even if our patent applications covering formulations of our product candidates issue as patents, the formulation patents protect a specific formulation of a product and may not be enforced against competitors making and marketing a product that has the same active pharmaceutical ingredient in a different formulation. Method-of-use patents protect the use of a product for the specified method or for treatment of a particular indication. This type of patent may not be enforced against competitors making and marketing a product that has the same active pharmaceutical ingredient but used for a method not included in the patent. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products "off-label." Although off-label prescriptions may infringe or contribute to the infringement of method-of-use patents, the practice is common and such infringement is difficult to prevent or prosecute.

Our issued composition of matter patents for CVC are expected to expire in the United States as early as 2023. Our additional patents and pending patent applications that cover formulations, combination products and use of CVC to treat various indications are expected to expire at various times that range from 2023 (for issued patents) to potentially 2036 (for currently-filed provisional patent applications if patents were to issue on non-provisional applications filed thereon).

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our future development partners will be successful in protecting our product candidates by obtaining and defending patents. These risks and uncertainties include the following:

- the 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 such an event, competitors might be able to enter the market earlier than would otherwise have been the case;
- patent applications may not result in any patents being issued;
- patents that may be issued or in-licensed may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;
- our competitors, many of whom have substantially greater resources than we do and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use, and sell our potential product candidates;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns;
- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates; and
- companies may also disregard intellectual property rights and manufacture counterfeit products that could reduce sales of our products.

In addition, we rely on the protection of our trade secrets and proprietary know-how. Although we have taken steps to protect our trade secrets and unpatented know-how, including entering into confidentiality agreements with third parties, and confidential information and inventions agreements with employees, consultants and advisors, we cannot provide any assurances that all such agreements have been duly executed, and third parties may still obtain this information or may come upon this or similar information independently. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating our trade secrets. If any of these events occurs or if we otherwise lose protection for our trade secrets or proprietary know-how, our business may be harmed.

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

On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. In particular, under the Leahy-Smith Act, the United States transitioned in March 2013 to a ''first inventor to file'' system in which the first inventor to file a patent application will be entitled to the patent. Third parties are allowed to submit prior art before the issuance of a patent by the USPTO, in which case a patent may become subject to post-grant proceedings including opposition, derivation, reexamination, *inter partes* review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position.

Claims by third parties that we infringe their proprietary rights may result in liability for damages or prevent or delay our developmental and commercialization efforts.

The biotechnology industry has been characterized by frequent litigation regarding patent and other intellectual property rights. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates. As the biotechnology industry expands and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties. Because patent applications are maintained in secrecy until the application is published, we may be unaware of third party patents that may be infringed by commercialization of CVC or our other product candidates. Moreover, because patent applications can take many years to issue, there may be currently-pending patent applications that may later result in issued patents that our product candidates may infringe. In addition, identification of third party patent rights that may be relevant to our technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. Any claims of patent infringement asserted by third parties would be time consuming and could likely:

- result in costly litigation;
- divert the time and attention of our technical personnel and management;
- cause development delays;
- prevent us from commercializing CVC or our other product candidates until the asserted patent expires or is held finally invalid or not infringed in a court of law;
- require us to develop non-infringing technology, which may not be possible on a cost-effective basis; or
- require us to enter into royalty or licensing agreements.

Although no third party has asserted a claim of patent infringement against us as of the date of this prospectus, others may hold proprietary rights that could prevent CVC or our other product candidates from being marketed. Any patent-related legal action against us claiming damages and seeking to enjoin commercial activities relating to our product candidate or processes could subject us to potential liability for damages and require us to obtain a license to continue to manufacture or market CVC or our other product candidates. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. In addition, we cannot be sure that we could redesign our product candidate or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing CVC or our other product candidates, which could harm our business, financial condition and operating results.

Moreover, we may be subject to a third party preissuance submission of prior art to the USPTO or in addition to interference proceedings, may become involved in opposition, derivation, reexamination, *inter partes* review, post-grant review or other post-grant proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming, and unsuccessful. Further, our issued patents could be found invalid or unenforceable if challenged in court.

If we or any of our future development partners were to initiate legal proceedings against a third party to enforce a patent directed at one of our product candidates, or one of our future product candidates, the defendant could counterclaim that our patent is invalid

and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requ irements, including lack of novelty, obviousness, non-enablement or insufficient written description. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. Third parties may also raise similar claims before the USPTO, even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. W ith respect to the validity question, for example, we cannot be certain that there is no invalidating prior art of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or un enforceability, we would lose at least part, and perhaps all, of the patent protection on such product candidate. Such a loss of patent protection would have a material adverse impact on our business.

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

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

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA and other regulatory authority regulations, provide accurate information to these regulatory authorities, comply with federal and state healthcare fraud and abuse laws and regulations, report financial information or data accurately, disclose unauthorized activities to us, or comply with securities laws. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, including for illegal insider trading activities, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a Code of Business Conduct and Ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

We may not be successful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in-licenses.

We currently have rights to the intellectual property, through licenses from third parties and under patents that we own, to develop our product candidates. Because our programs may require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license, or use these proprietary rights. For example, our product candidates may require specific formulations to work effectively and efficiently and the rights to these formulations may be held by others. We may be unable to acquire or in-license any compositions, methods of use, processes, or other third-party intellectual property rights from third parties that we identify as necessary for our product candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources, and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment.

We may collaborate with U.S. and foreign academic institutions to accelerate our preclinical or clinical research. Typically, these institutions provide us with an option to negotiate a license to any of the institution’s rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our program.

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

As of September 30, 2015, we recorded an impairment of intangible assets related to our IPR&D and goodwill of $17.3 million following the decision to discontinue investment in developing the intellectual property related to Regado's aptamer platform.

We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers.

As is common in the biotechnology and pharmaceutical industry, we engage the services of consultants, in addition to our employees, to assist us in the development of our product candidates. Many of these employees and consultants, and many of our employees, were previously employed at, or may have previously provided or may be currently providing consulting services to, other biotechnology or pharmaceutical companies including our competitors or potential competitors. We may become subject to claims that our company, our employees or a consultant inadvertently or otherwise used or disclosed trade secrets or other information proprietary to their former employers or their former or current clients. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team.

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

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

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

If we do not obtain protection under the Hatch-Waxman Amendments by extending the patent terms for CVC or our other product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of FDA marketing approval of CVC or other product candidates, one or more of our United States 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. However, 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, our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets o f interest and our business may be adversely affected.

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely impact our financial condition or results of operations.

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

While we have issued composition-of-matter patents directed at CVC in the United States and other countries, filing, prosecuting and defending patents on CVC and our other product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries may not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but enforcement is not as strong as that in the United States. These products may compete with our product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. For example, India and China have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. Although we currently do not have issued patents in these particular jurisdictions, to the extent we are able to obtain such patents, we may have limited remedies if our patents are infringed or if we are compelled to grant a license to a third party. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Risks Related to Our Financial Position and Need for Capital

If we fail to obtain the capital necessary to fund our operations, we will be unable to successfully develop and commercialize CVC and other future product candidates.

Although we believe that our existing cash and cash equivalents will be sufficient to fund our current operations through at least the next twelve months, we will require substantial future capital in order to complete the remaining clinical development for CVC and our other product candidates and to potentially commercialize these product candidates. We expect our spending levels to increase in connection with our clinical trials of CVC, as well as other corporate activities. The amount and timing of any expenditure needed to implement our development and commercialization programs will depend on numerous factors, including:

- the type, number, scope, progress, expansion costs, results of and timing of our ongoing or future clinical trials or the need for additional clinical trials of CVC for NASH or any of our other product candidates which we are pursuing or may choose to pursue in the future;
- the costs of obtaining, maintaining and enforcing our patents and other intellectual property rights;
- the costs and timing of obtaining or maintaining manufacturing for CVC for NASH and any of our other product candidates, including commercial manufacturing if any product candidate is approved;

- the costs and timing of establishing sales marketing, and reimbursement capabilities and enhanced internal controls over financial reporti ng;
- the terms and timing of establishing and maintaining collaborations, license agreements and other partnerships;
- costs associated with any new product candidates that we may develop, in-license or acquire;
- the effect of competing technological and market developments; and
- the costs associated with being a public company.

Some of these factors are outside of our control. We do not expect our existing capital resources together with the net proceeds from this offering to be sufficient to enable us to fund the completion of our clinical trials and commercialization of our product candidates. We expect that we will need to raise additional funds in the future.

We have not sold any products, and we do not expect to sell or derive revenue from any product sales for the foreseeable future. We may seek additional funding through future debt and equity financing, as well as potential additional collaborations or strategic partnerships with other companies or through non-dilutive financings. Additional funding may not be available to us on acceptable terms or at all. In addition, the terms of any financing may adversely affect the holdings or the rights of our stockholders. In addition, the issuance of additional shares by us, or the possibility of such issuance, may cause the market price of our shares to decline.

If we are unable to obtain funding on a timely basis, we will be unable to complete ongoing and planned clinical trials for CVC for NASH and any of our other product candidates and we may be required to significantly curtail some or all of our activities. We also could be required to seek funds through arrangements with collaborative partners or otherwise that may require us to relinquish rights to our product candidates or some of our technologies or otherwise agree to terms unfavorable to us.

Our ability to use net operating loss and tax credit carryforwards and certain built-in losses to reduce future tax payments may be limited by provisions of the Internal Revenue Code.

As of December 31, 2014, Tobira Development, Inc. had U.S. federal and state net operating loss carryforwards of approximately $90.8 million and $44.9 million, respectively, and Tobira (formerly known as Regado Biosciences, Inc.) had U.S. federal and state net operating loss carryforwards of approximately $205.6 million and $257.9 million, respectively, available to reduce future taxable income, which expire 2016 through 2026.

These net operating losses have been fully offset by a valuation allowance due to uncertainties surrounding our ability to realize these tax benefits. Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an “ownership change” (generally defined as a greater than 50% change (by value) in its equity ownership over a three year period), the corporation’s ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. Similar rules may apply under state tax laws. We have not performed a detailed analysis to determine whether an ownership change under Section 382 of the Code, or similar state provisions, has previously occurred or will occur as a result of the Merger. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards to offset U.S. federal taxable income may become subject to limitations, which could potentially result in increased future tax liability to us and may be substantial.

Risks Relating to Ownership of Our Common Stock

The price of our common stock has been, and may continue to be, volatile.

Historically, the market price of our common stock has fluctuated over a wide range, and it is likely that the price of our common stock will continue to be volatile in the future. The market price of our common stock could be impacted due to a variety of factors, including, in addition to global and industry-wide events:

- the losses we may incur;
- developments in patent or other proprietary rights owned or licensed by us, our collaborative partners or our competitors;
- public concern as to the safety and efficacy of products developed by us or others; and
- litigation.

In addition, due to one or more of the foregoing factors in one or more future quarters, our results of operations may fall below the expectations of securities analysts and investors. In that event, the market price of our common stock could materially decline.

Our executive officers, directors and principal stockholders will have the ability to control all matters submitted to our stockholders for approval.

Our executive officers, directors and stockholders who beneficially owned more than 5% of our common stock, in the aggregate, beneficially own shares representing approximately 71.4% of our common stock as estimated as of September 30, 2015. As a result, if these stockholders were to choose to act together, they would be able to control all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, will control the election of directors and approval of any merger, consolidation, sale of all or substantially all of our assets or other business combination or reorganization. This concentration of voting power could delay or prevent an acquisition of us on terms that other stockholders may desire. The interests of this group of stockholders may not always coincide with your interests or the interests of other 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.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult 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 amended and restated bylaws may delay or prevent a merger, acquisition or other change of control that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions include:

- classifying our board of directors into three classes;
- authorizing the issuance of "blank check" convertible preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;
- limiting the removal of directors by the stockholders;
- requiring a supermajority vote of stockholders to amend our certificate of incorporation or bylaws;
- 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
- establishing Delaware as the exclusive jurisdiction for certain stockholder litigation against us.

In addition, 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, who are responsible for appointing the members of our management team. In addition, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits, with some exceptions, stockholders owning in excess of 15% of our outstanding voting stock from merging or combining with us. Although we believe these provisions together provide for an opportunity to receive higher bids by requiring potential acquirers to negotiate with our board of directors, they would apply even if the offer may be considered beneficial by some stockholders.

Your investment may be diluted by exercises of outstanding options and warrants.

As of September 30, 2015, we had outstanding options to purchase an aggregate of 2,373,996 shares of our common stock at a weighted average exercise price of $14.00 per share and warrants to purchase an aggregate of 64,657 shares of our common stock at a weighted average exercise price of $11.72 per share. The exercise of such outstanding options and warrants will result in dilution of your investment. In addition, as described below, you may experience additional dilution if we issue common stock in the future. As a result of this dilution, you may receive significantly less than the full purchase price you paid for the shares in the event of liquidation.

Future sales and issuances of our common stock or rights to purchase common stock could result in additional dilution of the percentage ownership of our stockholders and could cause our share price to fall.

We expect that significant additional capital will be needed in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. Such future sales may be through Cowen and Company, LLC and may be made in sales deemed to be at-the-market equity offerings as defined in Rule 415 promulgated under the Securities Act of 1933, as discussed in more detail in our Registration Statement on

Form S-3 and the prospectus included t herein, filed with the Securities and Exchange Commission on June 4, 2015. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

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

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur, could significantly reduce the market price of our common stock and impair our ability to raise adequate capital through the sale of additional equity securities.

If we are unable to satisfy the continued listing requirements of The NASDAQ Stock Market, or NASDAQ, our common stock could be delisted and the price and liquidity of our common stock may be adversely affected.

Our common stock may lose value and our common stock could be delisted from NASDAQ due to several factors or a combination of such factors. While our common stock is currently listed on The NASDAQ Stock Market, there can be no assurance that we will be able to maintain such listing. To maintain the listing of our common stock on The NASDAQ, we are required to meet certain listing requirements, including, among others, a requirement to maintain a minimum closing bid price of $1.00 per share. If our common stock trades below the $1.00 minimum closing bid price requirement for 30 consecutive business days or if we do not meet other listing requirements, we may be notified by NASDAQ of non-compliance. There can be no assurance that the per share trading price of our common stock will remain above $1.00 per share or that we will be able to continue to meet other listing requirements. If our common stock is delisted, market liquidity for our common stock could be severely affected, and our stockholders' ability to sell their shares of our common stock could be limited. In addition, our common stock could be subject to "penny stock" rules which impose additional disclosure requirements on broker-dealers and could further negatively impact our market liquidity for our common stock and our stockholders' ability to sell their shares of our common stock. Accordingly, a delisting of our common stock from NASDAQ would negatively affect the value of our common stock. Delisting could also have other negative results, including, but not limited to, the loss of institutional investor interest.

We are incurring significantly increased costs and devote substantial management time as a result of operating as a public company and such costs are likely to increase particularly after we are no longer an "emerging growth company."

As a public company, we are incurring significant legal, accounting and other expenses that we did not incur as a private company. For example, we are required to comply with certain of the requirements of the Sarbanes-Oxley Act and the Dodd-Frank Wall Street Reform and Consumer Protection Act, as well as rules and regulations subsequently implemented by the Securities and Exchange Commission, and NASDAQ, our stock exchange, including the establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Compliance with these requirements has increased and will continue to increase our legal and financial compliance costs and will make some activities more time consuming and costly. In addition, our management and other personnel need to divert attention from operational and other business matters to devote substantial time to these public company requirements. In particular, we expect to incur significant expenses and devote substantial management effort toward ensuring compliance with the requirements of Section 404 of the Sarbanes-Oxley Act.

However, for as long as we remain an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or JOBS Act, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We intend to take advantage of these reporting exemptions until we are no longer an "emerging growth company."

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

After we are no longer an "emerging growth company," we expect to incur additional management time and cost to comply with the more stringent reporting requirements applicable to companies that are deemed accelerated filers or large accelerated filers, including complying with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act.

We are an "emerging growth company," and will be able take advantage of reduced disclosure requirements applicable to "emerging growth companies," which could make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act, and, for as long as we continue to be an "emerging growth company," we intend to take advantage of certain exemptions from various reporting requirements applicable to other public companies but not to "emerging growth companies," including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an "emerging growth company" for up to five years, or until the earliest of (i) the last day of the first fiscal year in which our annual gross revenues exceed $1 billion, (ii) the date that we become a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common stock that is held by non-affiliates exceeds $700.0 million as of the last business day of our most recently completed second fiscal quarter, or (iii) the date on which we have issued more than $1 billion in non-convertible debt during the preceding three year period. We cannot predict if investors will find our common stock less attractive if we choose to rely on these exemptions. If some investors find our common stock less attractive as a result of any choices to reduce future disclosure, there may be a less active trading market for our common stock and our stock price may be more volatile.

If we fail to maintain proper and effective internal control over financial reporting in the future, our ability to produce accurate and timely financial statements could be impaired, which could harm our operating results, investors' views of us and, as a result, the value of our common stock.

Pursuant to Section 404 of the Sarbanes-Oxley Act, our management will be required to report upon the effectiveness of our internal control over financial reporting beginning with the annual report for our fiscal year ending December 31, 2015. When and if we are a "large accelerated filer" or an "accelerated filer" and are no longer an "emerging growth company," each as defined in the Exchange Act, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. However, for so long as we remain an emerging growth company, we intend to take advantage of an exemption available to emerging growth companies from these auditor attestation requirements. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing, and possible remediation. To comply with the requirements of being a reporting company under the Exchange Act, we will need to upgrade our systems including information technology; implement additional financial and management controls, reporting systems, and procedures; and hire additional accounting and finance staff. If we or, if required, our auditors are unable to conclude that our internal control over financial reporting is effective, investors may lose confidence in our financial reporting, and the trading price of our common stock may decline.

We do not anticipate paying cash dividends on our common stock, and accordingly, stockholders must rely on stock appreciation for any return on their investment.

We have never declared or paid any cash dividend on our common stock and do not anticipate paying cash dividends on our common stock in the future. Our loan and security agreement with Oxford prohibits us from paying cash dividends. As a result, the only return to stockholders will be appreciation in the price of our common stock, which may never occur. Investors seeking cash dividends should not invest in our common stock.

We are now subject to and may in the future be subject to securities litigation, which is expensive and could divert management attention.

Our stock price has fluctuated in the past and may be volatile in the future, and in the past, companies that have experienced volatility in the market price of their stock have been subject to an increased incidence of securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business. For example, in February 2015, two putative class action lawsuits were filed in the Court of Chancery for the State of Delaware against us and certain of our directors on alleging that certain of our directors breached their fiduciary duties in connection with the Merger. For more information, see "Part II. Other Information, Item 1. Legal Proceedings".

Risks Relating to the Merger

The integration of Tobira and Tobira Development will require significant resources and may not be successful.

There is no history of Tobira (formerly known as Regado Biosciences, Inc.) and Tobira Development as a combined company. As a result, there can be no guarantee that the two companies will operate together successfully as a combined company. Integration of the companies and consolidation of their operations will require considerable management time, which could result in the diversion of management resources from other important matters.

The failure to integrate successfully the merged businesses in the expected timeframe could adversely affect the combined company's future results.

The failure to integrate successfully and to manage successfully the challenges presented by the integration process may result in the combined company's failure to achieve some or all of the anticipated benefits of the Merger.

Potential difficulties that may be encountered in the integration process include the following:

- using the combined company's cash and other assets efficiently to develop the business of the combined company;
- appropriately managing the liabilities of the combined company;
- potential unknown or currently unquantifiable liabilities associated with the Merger and the operations of the combined company; and
- performance shortfalls at one or both of the companies as a result of the diversion of management's attention caused by integrating the companies' operations.

The operations of the combined company may be adversely affected by the integration.

The combined company will be subject to various risks following the consummation of the Merger, including:

- interruption of the operations of the combined companies; and
- anticipated and unanticipated costs relating to additional administrative or operating expenses of each business.

These and other factors could adversely affect the combined business and operating results.

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

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

None.

Item 5. Other Information.

None.

Item 6. Exhibits.

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

SIGNAT URES

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.

Tobira Therapeutics, Inc.

Date: November 10, 2015 By: /s/ Laurent Fischer, M.D.

Laurent Fischer, M.D.
Chief Executive Officer and Director

Date: November 10, 2015 By: /s/ Christopher Peetz

Christopher Peetz
Chief Financial Officer

Exhibit Index

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 of the Current Report on Form 8-K filed by the registrant on May 7, 2015).
3.2	Certificate of Amendment of Seventh Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.2 of the Current Report on Form 8-K filed by the registrant on May 7, 2015).
4.1	Registration Rights Agreement, dated May 4, 2015 by and among Registrant and the Investors (as defined therein) (incorporated by reference to Exhibit 10.1 of the Current Report on Form 8-K filed by the registrant on May 7, 2015).
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith.

Exhibit 31.1

Certification of Chief Executive Officer Pursuant to
Securities Exchange Act Rules 13a-14(a) and 15d-14(a)
as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Laurent Fischer, M.D., certify that:

1. I have reviewed this quarterly report on Form 10-Q of Tobira Therapeutics, Inc.;

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

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

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

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

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

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

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

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

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

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

November 10, 2015

/s/ Laurent Fischer, M.D.
Laurent Fischer, M.D.
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

Certification of Chief Financial Officer Pursuant to
Securities Exchange Act Rules 13a-14(a) and 15d-14(a)
as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Christopher Peetz, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Tobira Therapeutics, Inc.;

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

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

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

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

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

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

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

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

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

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

November 10, 2015

/s/ Christopher Peetz
Christopher Peetz
Chief Financial Officer
(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 of Tobira Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2015 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Laurent Fischer, M.D., the Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

November 10, 2015

/s/ Laurent Fischer, M.D.
Laurent Fischer, M.D.
Chief Executive Officer
(Principal Executive Officer)

A signed original of this written statement required by Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. Section 1350), has been provided to Tobira Therapeutics, Inc. and will be retained by Tobira Therapeutics, Inc. and furnished to the Securities and Exchange Commission or its staff upon request. This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Tobira Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.

Exhibit 32.2

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

In connection with the Quarterly Report of Tobira Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2015 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Christopher Peetz, the Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

November 10, 2015

/s/ Christopher Peetz
Christopher Peetz
Chief Financial Officer
(Principal Financial Officer)

A signed original of this written statement required by Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. Section 1350), has been provided to Tobira Therapeutics, Inc. and will be retained by Tobira Therapeutics, Inc. and furnished to the Securities and Exchange Commission or its staff upon request. This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Tobira Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.