TOBIRA THERAPEUTICS, INC.

FORM 10-Q
(Quarterly Report)

Filed 08/11/14 for the Period Ending 06/30/14

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

FORM 10-Q

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

For the quarterly period ended June 30, 2014

OR

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

Commission File Number: 001-35953

REGADO BIOSCIENCES, INC.
(Exact name of registrant as specified in its charter)

Delaware	**No. 03-0422069**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

106 Allen Road, 4 th Floor
Basking Ridge, New Jersey 07920
(Address of principal executive offices) (Zip Code)

(908) 580-2100
(Registrant's telephone number, including area code)

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

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

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

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

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

As of August 11, 2014, 33,609,212 shares of common stock, $0.001 par value per share, were outstanding.

Table of Contents

REGADO BIOSCIENCES, INC.

FORM 10-Q

Quarter Ended June 30, 2014

Table of Contents

Table of Contents

PART I

Cautionary Statement Regarding Forward-Looking Statements

This quarterly report on Form 10-Q includes 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. For this purpose, any statements contained herein, other than statements of historical fact, including statements regarding the progress and timing of our product development programs and related trials; our future opportunities; our strategy, future operations, anticipated financial position, future revenues and projected costs; our management's prospects, plans and objectives; and any other statements about management's future expectations, beliefs, goals, plans or prospects constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. We may, in some cases, use words such as "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "plan," "project," "should," "target," "will," "would" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including our "critical accounting estimates"; the progress of our REGULATE-PCI trial, our single, open-label 13,200 subject Phase 3 trial of Revolixys™ Kit, formerly known as REG1; the Data Safety Monitoring Board's analysis and recommendations with respect to the REGULATE-PCI trial; the ultimate decision of the FDA regarding whether to remove the clinical hold from the REGULATE-PCI trial; the outcome of the pending lawsuits against us; our ability to satisfy domestic and international regulatory requirements with respect to Revolixys and our other product candidates, many of which are new and still evolving, and the labeling under any approval we may obtain; the performance of contract research organizations who conduct our clinical trials for us; the performance of third-party manufacturers who supply or manufacture our products; our ability to develop commercialization and marketing capabilities or to enter into strategic partnerships to develop and commercialize Revolixys or any of our other product candidates; the timing and success of the commercialization of Revolixys or any of our other product candidates; the rate and degree of market acceptance of Revolixys; the size and growth of the potential markets for Revolixys and our ability to serve those markets; our plans to expand the indications of Revolixys; our ability to discover, develop and commercialize novel and innovative therapies using our proprietary technology platform; regulatory developments in the United States and foreign countries; competition from existing antithrombotic drugs or new antithrombotic drugs that may emerge; potential product liability claims; our ability to attract and retain a sufficient number of scientists, clinicians, sales personnel and other key personnel; our ability to obtain, maintain, defend and enforce intellectual property rights protecting our product candidates; the accuracy of our estimates regarding expenses and capital requirements and our ability to adequately support future growth; and the risk factors listed in our Annual Report on Form 10-K and in this report under the heading "Risk Factors". All forward-looking statements are expressly qualified in their entirety by this cautionary notice. You are cautioned not to place undue reliance on any forward-looking statements, which speak only as of the date of this report or the date of the document incorporated by reference into this report. We have no obligation, and expressly disclaim any obligation, to update, revise or correct any of the forward-looking statements, whether as a result of new information, future events or otherwise. We have expressed our expectations, beliefs and projections in good faith and we believe they have a reasonable basis. However, we cannot assure you that our expectations, beliefs or projections will result or be achieved or accomplished.

Table of Contents

Item 1. FINANCIAL STATEMENTS

Regado Biosciences, Inc.
CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)

	June 30, 2014 (Unaudited)	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	$ 72,720	$ 30,688
Restricted cash	1,082	82
Prepaid expenses	1,520	2,147
Other assets	9,462	6,211
Total current assets	84,784	39,128
Property and equipment, net	209	108
Intangible assets, net	2,042	1,823
Other non-current assets	4,541	4,694
Total assets	$ 91,576	$ 45,753
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,761	$ 1,557
Accrued expenses	10,934	5,524
Warrant liability	30	19
Current portion of long-term debt	4,543	2,000
Total current liabilities	17,268	9,100
Long-term debt	—	2,452
Total liabilities	17,268	11,552
Commitments and contingencies		
Stockholders' equity:		
Series F convertible preferred stock; stated value of $1,000, 1,000,000 shares authorized, 10,000 and 0 shares issued and outstanding at June 30, 2014 and December 31, 2013, respectively	24,832	—
Common stock, $0.001 par value; 500,000,000 shares authorized; 33,609,212 and 21,310,614 shares issued and outstanding at June 30, 2014 and December 31, 2013, respectively	34	21
Additional paid-in-capital	231,700	179,159
Accumulated Deficit	(182,258)	(144,979)
Total stockholders' equity	74,308	34,201
Total liabilities and stockholders' equity	$ 91,576	$ 45,753

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

Table of Contents

Regado Biosciences, Inc.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(Unaudited)
(In thousands, except share and per share data)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2014	2013	2014	2013
Total revenue	$ —	$ —	$ —	$ —
Operating expenses:				
Research and development	(18,505)	(4,314)	(31,621)	(6,047)
General and administrative	(2,838)	(1,133)	(5,386)	(2,576)
Total operating expenses	(21,343)	(5,447)	(37,007)	(8,623)
Loss from operations	(21,343)	(5,447)	(37,007)	(8,623)
Other (expense) income:				
Interest income	47	68	50	69
Interest expense	(136)	(283)	(323)	(398)
Other income	—	60	—	60
Total other expense	(89)	(155)	(273)	(269)
Net loss	$ (21,432)	$ (5,602)	$ (37,280)	$ (8,892)
Deemed dividend related to beneficial conversion feature of Series F convertible preferred stock	—	—	(14,840)	—
Net loss attributable to stockholders	(21,432)	(5,602)	(52,120)	(8,892)
Net loss attributable to preferred stockholders	1,269	—	2,032	—
Net loss attributable to common stockholders – basic and diluted	$ (20,163)	$ (5,602)	$ (50,088)	$ (8,892)
Comprehensive loss applicable to all stockholders	(21,432)	(5,602)	(52,120)	(8,892)
Loss per share – basic and diluted	$ (0.63)	$ (24.24)	$ (1.81)	$ (39.31)
Weighted-average common shares – basic and diluted	31,777,266	231,161	27,659,526	226,221

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

Table of Contents

Regado Biosciences, Inc.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)
(In thousands)

	For the Six Months Ended June 30,	
	2014	2013
Cash flows used in operating activities:		
Net loss	$ (37,280)	$ (8,892)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	49	23
Amortization of patents and licenses	73	36
Impairment of patents	33	10
Accrued final bank fee	43	12
Amortization of debt discount	48	13
Amortization of debt issuance costs	8	90
Change in fair value of warrant liability	11	(65)
Stock-based compensation	1,152	205
Gain on sale of Patent	—	(60)
Changes in operating assets and liabilities:		
Prepaid expenses	627	(1,885)
Other assets	(3,251)	(97)
Other non-current assets	145	83
Accounts payable	204	1,386
Accrued expenses	5,410	621
Net cash used in operating activities	(32,728)	(8,520)
Cash flows used in investing activities:		
Change in restricted cash	(1,000)	—
Purchase of property and equipment	(150)	(43)
Patent and license acquisition costs	(325)	(303)
Proceeds received from sale of patents	—	89
Net cash used in investing activities	(1,475)	(257)
Cash flows from financing activities:		
Proceeds from borrowings on bank loan	—	4,500
Repayment of borrowings on bank loan	—	(4,500)
Payment of bank origination fee	—	(85)
Payment of debt issuance costs	—	(35)
Proceeds from issuance of common stock, net of underwriting discounts and fees	76,723	—
Payment of offering costs	(541)	(1,533)
Proceeds from sale of preferred stock, net of issuance costs	—	10,163
Proceeds from issuance of common stock from exercise of options and warrants	53	—
Proceeds from exercise of warrants	—	2
Net cash provided by financing activities	76,235	8,512
Net increase (decrease) in cash and cash equivalents	$ 42,032	$ (265)
Cash and cash equivalents, beginning of period	30,688	14,764
Cash and cash equivalents, end of period	$ 72,720	$ 14,499
Supplemental disclosures of cash flow information:		
Cash paid for interest	$ 165	$ 382
Supplemental disclosure of non-cash investing and financing activities :		
Deferred Offering costs of $502 were included in accounts payable and accrued expenses as of June 30, 2013	$ —	$ 502
Exchange of common stock for convertible preferred stock, net of issuance costs	$ 24,832	$ —
Fair value of Series F Preferred Stock beneficial conversion feature	$ 14,840	$ —
Accretion of deemed dividend on Series F Convertible Preferred Stock	$ (14,840)	$ —
Stock issued for cash held in escrow	$ —	$ 5,155

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

Regado Biosciences, Inc.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

1. Organization and Description of Business

Regado Biosciences, Inc. (the "Company" or "we" or "our" or "us") is a development stage enterprise incorporated in the State of Delaware on December 19, 2001, operating primarily in Basking Ridge, New Jersey and Durham, North Carolina. We are focused on the discovery and development of novel, first-in-class, actively controllable antithrombotic drug systems for acute and sub-acute cardiovascular indications. Each of our product candidates consists of a two-component system: an antithrombotic aptamer and its specific active control agent. Our lead product candidate, Revolixys™ Kit, formerly known as REG1, is a two-component system consisting of pegnivacogin, an anticoagulant aptamer specifically targeting coagulation Factor IXa, and its complementary oligonucleotide active control agent, anivamersen. Revolixys is being developed for use in patients with a wide variety of acute coronary syndromes, or ACS, undergoing a percutaneous coronary intervention, or PCI, a hospital-based procedure used to mechanically open or widen obstructed coronary arteries. Our actively controllable product candidates have the potential to improve patient outcomes, enhance the patient experience and reduce overall treatment costs. In September 2013, we commenced our single, open-label, 13,200 subject Phase 3 trial of Revolixys in patients undergoing PCI (excluding ST elevated myocardial infarction, or STEMI), or the REGULATE-PCI trial. This development program has been granted Fast Track designation by the FDA. On July 2, 2014, the Company announced that the Data Safety Monitoring Board, or DSMB, in agreement with the Company, was initiating a complete review of efficacy and safety data from the REGULATE-PCI trial. This review was initiated as a result of various serious adverse events, or SAEs, that were reported by certain site investigators at several sites around the world. As a result, the Company voluntarily suspended patient enrollment in the REGULATE-PCI trial until the DSMB completes its analysis and communicates its recommendations. In addition, on July 9, 2014 the United States Food and Drug Administration, or the FDA, informed the company that a clinical hold was placed on all patient enrollment and dosing of either study drug in the REGULATE-PCI trial. According to the FDA, this action was taken to formalize the involvement of the FDA in any decision to re-initiate enrollment and dosing in the trial in the future. During this period of data collection and analysis the Company and the principal investigators of the trial remain blinded. It is anticipated that the DSMB will complete their analysis by early September 2014.

2. Basis of Presentation

Principles of Consolidation

In March 2013, we incorporated Regado Biosciences Europe Limited, a wholly owned subsidiary registered in England and Wales, in order to establish a legal presence in the European Union (the "EU") for the purpose of conducting clinical trials in the EU. Regado Biosciences Europe Limited had no operations during the three or six months ended June 30, 2014 and 2013.

The accompanying consolidated financial statements include the accounts of Regado Biosciences, Inc. and its wholly owned subsidiary, Regado Biosciences Europe Limited. All intercompany balances and transactions have been eliminated in consolidation.

Unaudited Interim Financial Data

The accompanying interim consolidated financial statements are unaudited. These unaudited consolidated financial statements have been prepared in accordance with the rules and regulations of the United States Securities and Exchange Commission ("SEC") for interim financial information under Article 210.8-03 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by U.S. generally accepted accounting principles, or GAAP, for complete financial statements. These unaudited interim consolidated financial statements should be read in conjunction with the audited financial statements and the accompanying notes for the year ended December 31, 2013 contained in the Company's Annual Report on Form 10-K. The unaudited interim consolidated financial statements have been prepared on the same basis as the annual financial statements and, in the opinion of management, reflect all adjustments (consisting of normal recurring adjustments) necessary to state fairly our financial position as of June 30, 2014, the results of our operations for the three and six months ended June 30, 2014 and 2013, and our cash flows for the six months ended June 30, 2014 and 2013. The results of operations for the three and six months ended June 30, 2014 are not necessarily indicative of the operating results for the full year or any other interim period.

Going Concern Uncertainty

Our financial statements have been prepared on a going-concern basis, which contemplates the realization of assets and settlement of liabilities and commitments in the normal course of business. Operations since inception have consisted primarily of developing and acquiring product technologies and securing financing.

The accompanying financial statements have been prepared assuming that we will operate as a going concern. We have had negative cash flows from operating activities of $32.7 million during the six months ended June 30, 2014. Prior to our initial public offering ("IPO"), we were funded primarily through the issuance of preferred stock and debt. We will require additional capital until such time that we can generate operating revenue in excess of operating expenditures. Our plans include continued product development and a move toward completion of clinical trials. We will continue to closely monitor and analyze expenses and make adjustments as necessary to prioritize business operations. We believe that the net proceeds from our recent common stock offerings to new and existing investors (see Note 8), will be sufficient for us to fund the REGULATE-PCI trial and operations through the first quarter of 2015. We will need to raise additional financing to fund projected operations through the remainder of 2015 and we can provide no assurances that such additional financing will be available on favorable terms, or at all. Actual results may differ from estimates and the financial statements do not include any adjustments that might be necessary if we are unable to fund operations.

Reclassifications

We have reclassified certain costs associated with research and development activities, including all laboratory and clinical indirect costs, laboratory and clinical personnel stock compensations costs, and patent and product license amortization and patent impairment costs for the quarter ended June 30, 2013 from general and administrative expense to research and development expense in the accompanying consolidated statements of comprehensive loss. These reclassifications did not have any impact on our loss from operations or net loss for the quarter ended June 30, 2013.

The aforementioned reclassifications were made to conform to the current year presentation.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Clinical Trial Supplies

We capitalize materials that will be used in our REGULATE-PCI clinical trial that also have an alternative future use in either ongoing or future clinical research or development projects. Clinical trial supplies may comprise material used to manufacture active pharmaceutical ingredients ("API") used to develop our product candidates, in-process or completed API, in-process or completed unlabeled finished drug product and labeled finished drug product. Clinical trial supplies are stated at cost, using the first-in, first-out method ("FIFO"), and are reported in the accompanying consolidated balance sheets in other current assets. Clinical trial supplies that are determined to be unsuitable for future use are immediately expensed; otherwise clinical trial supplies are expensed when shipped to clinical sites for use in clinical studies or when used in other research and development projects.

We utilize CMOs to produce API and finished drug product for use in clinical trials. As we do not have facilities that meet the requisite regulatory requirements for storage of API or finished drug product produced, we use a third-party facility for storage. Upon release from the manufacturer, API is shipped to a third-party storage facility. For production of finished drug product, API is shipped from the storage facility to the finished drug product manufacturing site. Unlabelled finished drug product is either shipped from the manufacturer back to the third-party storage facility or directly to the third-party labeling site. Labeled finished drug product is held by the third-party labeling site until it is shipped to the clinical sites for trial use.

As of June 30, 2014 clinical trial supplies included in other current assets were $7.3 million. Included in the $7.3 million is $2.3 million of raw material, $2.6 million of in-process API held at a manufacturer, $0.7 million of in process drug product held at a manufacturer and $1.7 million of drug product located at depots. As of December 31, 2013, clinical trial supplies included in other current assets were $4.6 million of which $1.6 million and $3.0 million represented API held at the third party storage facility and drug product located at depots, respectively.

Clinical Agreements

We enter into various clinical trial agreements with academic research organizations ("AROs") and clinical research organizations ("CROs") for the planning, management and execution of clinical trials. The financial terms of these agreements are subject to negotiation, vary from contract to contract, and may result in uneven payment flows. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. Costs for ARO and CRO contracts are recognized based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations, or information provided by vendors on their actual costs incurred; such costs are charged to research and development expense in the accompanying consolidated statements of comprehensive loss. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the research and development expense. Upfront contract signing fees are amortized over the life of the respective contract; unamortized contract signing fees are included in other non-current assets. Cumulative amortization costs are $0.7 million as of June 30, 2014.

In the accompanying consolidated balance sheet as of June 30, 2014, prepaid expenses include $0.5 million related to clinical agreements, and other non-current assets include $4.1 million of upfront payments of which $2.8 million will be applied to final invoices as required under the respective contract, and $1.3 million will be amortized as contract signing costs over the remaining life of the respective contract, or approximately three years. By comparison, prepaid expenses on the December 31, 2013 consolidated balance sheet included $1.1 million related to clinical agreements. Other non-current assets on December 31, 2013 included $4.5 million of upfront payments of which $2.8 million were be applied to final invoices as required under the respective contract, and $1.7 million were to be amortized as contract signing costs over the remaining life of the respective contract, or approximately three years.

In general, our ARO and CRO service agreements permit either party to terminate at will, although we would continue to be responsible for payment of all services completed (or pro-rata completed) at the time of notice of termination, plus any non-cancellable expenses that have been entered into by the ARO and CRO on the Company's behalf. Accordingly, such expenses would be accrued at time of contract termination and any prepaid expenses and unamortized advance payments would be expensed, accordingly.

Restricted Cash

The Company has accrued $1.0 million for license obligations to Archemix. The funds are classified in restricted cash and are on deposit in an interest-bearing escrow account pending payment.

Intangible Assets

The Company's policy is to file patent application(s) to protect technology, inventions and improvements that are considered important to the development of its business. The patent positions of technology companies, including the Company, are uncertain and involve complex legal and factual questions for which important legal principles are largely unresolved. Upon receipt of a patent grant, respective costs are amortized over the remaining life of the patent.

The Company amortizes license agreements over the stated contractual life.

Research and Development

Research and development ("R&D") expenses include direct and indirect R&D costs. Direct R&D consists principally of external costs, such as fees paid to investigators, license and patent amortization and related impairment, consultants central laboratories and clinical research organizations, including costs incurred in connection with our clinical trials, and related clinical trial fees and all employee-related expenses for those employees working in research and development functions, including stock-based compensation for R&D personnel. Indirect R&D costs include overhead costs related to facilities, depreciation, insurance, and small supplies that are not allocated to specific product candidates or indications. R&D costs are expensed as incurred.

Stock-based Compensation

In accordance with ASC Topic 718, Stock Compensation, as modified or supplemented, we measure compensation cost for share-based payment awards granted to employees and non-employee directors at fair value using the Black-Scholes option-pricing model. We recognize compensation expense on a straight-line basis over the service period for awards expected to vest. Share-based compensation cost related to share-based payment awards granted to non-employees is adjusted each reporting period for changes in the fair value of our common stock until the measurement date. The measurement date is generally considered to be the date when all services have been rendered or the date that options are fully vested.

Series F Convertible Preferred Stock

The Series F convertible preferred stock was deemed to have a beneficial conversion feature (a "BCF"). See Note 8 for further detail regarding the accounting for the Series F convertible preferred stock and this feature.

Net Loss per Share

Basic net loss per share is calculated by dividing the net loss by the weighted average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted net loss per share is calculated by dividing the net loss by the weighted-average number of common stock equivalents outstanding for the period determined using the treasury-stock method. Dilutive common stock equivalents are comprised of convertible preferred stock, options outstanding under our stock option plan and warrants.

3. Recently Issued Accounting Pronouncements

In June of 2014 the Financial Accounting Standards Board issued Accounting Standards Update ASU 2014-10, Development Stage Entities (Topic 915) "Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation" ("ASU 2014-10"). The amendments in ASU 2014-10 remove the definition of a development stage entity from the master glossary of the Accounting Standards Codification, thereby removing the financial reporting distinction between development stage entities and other reporting entities from U.S. GAAP. In addition, the amendments eliminate the requirements for development stage entities to (1) present inception-to-date information in the statements of comprehensive loss, cash flows, and changes in stockholders' equity, (2) label the financial statements as those of a development stage entity, (3) disclose a description of the development stage activities in which the entity is engaged, and (4) disclose in the first year in which the entity is no longer a development stage entity that in prior years it had been in the development stage. The amendments in ASU 2014-10 will be effective prospectively for annual reporting periods beginning after December 15, 2014, and interim periods within those annual periods, however early adoption is permitted. We have elected to early adopt the provisions of ASU 2014-10 for the current period presented. Other than the changes in presentation noted above, the adoption of ASU 2014-10 did not have significant impact on our results of operations, financial condition or cash flows.

4. Fair Value of Financial Instruments

The following table (in thousands) sets forth our assets and liabilities that were measured at fair value on a recurring basis at June 30, 2014 and at December 31, 2013 by level within the fair value hierarchy. Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. Our assessment of the significance of a particular input to the fair value measurement in its entirety requires judgment and considers factors specific to the asset or liability.

	As of June 30, 2014				As of December 31, 2013			
Assets and Liabilities	Quoted Prices In Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance as of June 30, 2014	Quoted Prices In Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance at December 31, 2013
Assets:								
Money market funds	$ 73,539	$ —	$ —	$ 73,539	$ 30,325	$ —	$ —	$ 30,325
Total assets at fair value	$ 73,539	$ —	$ —	$ 73,539	$ 30,325	$ —	$ —	$ 30,325
Liabilities:								
Warrant liability	$ —	$ —	$ 30	$ 30	$ —	$ —	$ 19	$ 19
Total liabilities at fair value	$ —	$ —	$ 30	$ 30	$ —	$ —	$ 19	$ 19

The change in the fair value measurement using significant unobservable inputs (Level 3) is summarized below (in thousands):

Balance at December 31, 2013	$ 19
Change in fair value recorded as interest income	(40)
Change in fair value recorded as interest expense	51
Balance at June 30, 2014	$ 30

The warrant liability represents our allocation of a portion of the proceeds from the May 2013 Comerica Loan (as defined in Note 6). The allocation of the proceeds from the Comerica Loan was based on the fair value of the warrant liability on the date of grant. We accounted for equity contracts not indexed to the issuer's own stock and not meeting the definition of a derivative as an asset or liability. We utilized the Binomial pricing model to determine the fair value of the warrant liability. We record changes in the fair value of the warrant liability as interest expense or interest income, as applicable.

We used significant assumptions in estimating the fair value of the warrant liability including the estimated volatility, risk free interest rate, estimated fair value of the preferred shares, and the estimated life of the warrant. These assumptions were used to establish an expected set of cash flows which were probability-weighted and discounted to present value to determine a fair value.

5 . Accrued Expenses

The components of accrued expenses are as follows (in thousands):

	June 30, 2014	December 31, 2013
Accrued license milestones	$ 1,000	$ 1,000
Accrued obligations under clinical contracts	7,013	1,957
Accrued legal and professional services	237	152
Accrued VAT expenses	780	780
Accrued interest	23	24
Accrued compensation and benefits	1,450	1,225
Accrued expenses, other	431	386
Total accrued expenses	$ 10,934	$ 5,524

6. Long-term Debt

In May 2011, we entered into a loan and security agreement with MidCap Financial SBIC, LP pursuant to which we borrowed a total of $6.0 million, at the stated rate of LIBOR, at a 2% rate floor, plus 8% spread per annum. The loan was payable in monthly installments beginning September 2013 through August 2014. Our assets (including intellectual property) were collateral for the borrowings, and we were required to pay a 3% final payment of $180,000 regardless of when the loan was paid in full.

On May 13, 2013, we secured a venture debt loan with Comerica Bank (the "Comerica Loan"). We borrowed $4.5 million ("Tranche One"), and the proceeds of the loan were utilized to repay all amounts due to MidCap Financial SBIC, LP. The Comerica Loan bears interest at Comerica's Prime Reference Rate (as defined in the Loan Agreement) subject to a floor of 30 day LIBOR plus 250 basis points plus 4.0%, or 7.25% as of June 30, 2014. The terms allow for an interest only period of 15 months, and the remaining principal and interest will be repaid starting September 2014 over a nine-month period (24 months in total). Maturities for 2014 and 2015 are $4.5million and $0, respectively. Upon (i) Comerica's receipt of evidence satisfactory to Comerica that the 1,000 patient interim analysis in the REGULATE-PCI study is successful and performed by April 30, 2014 and (ii) our completion of the IPO and receipt of net proceeds of at least $50.0 million prior to June 30, 2013, we had the option to borrow an additional $4.0 million in the second tranche, or ("Tranche Two"). Since the latter of the Tranche Two conditions was not satisfied, Tranche Two is solely at the discretion of Comerica.

Charges recorded as interest expense related to the Comerica Loan, including interest expense charges for changes in fair value related to the warrant liability, were $163,000 for the six months ended June 30, 2014. Interest expense recorded related to the Comerica Loan was $81,000 and $45,000 for the three months ended June 30, 2014 and June 30, 2013, respectively and $163,000 and $45,000 for the six months ended June 30, 2014 and 2013, respectively. Interest expense recorded related to the MidCap Loan was $0 and $30,000 for the three months ended June 30, 2014 and 2013, respectively and $0 and $132,000 for the six months ended June 30, 2014 and 2013, respectively.

In connection with the funding of Tranche One, we issued to Comerica a warrant to purchase 156,250 shares of the Series E Preferred Stock at a price of $0.72 per share, or the Warrant Price, subject to adjustment for stock splits, combinations, reclassifications or exchanges and certain dilutive issuances. After giving effect to our IPO and reverse stock split, the warrant was adjusted to a warrant to purchase 9,356 shares of our common stock at a price of $12.02 per share (see Note 3).

The Loan Agreement does not contain any ongoing financial covenants.

Scheduled maturities of long-term debt are as follows (in thousands):

	June 30, 2014
Year ending December 31:	
2014	$ 4,500
2015	—
Total	$ 4,500
Less: unamortized discount	(55)
Less – current portion	(4,543)
Plus – fees due at closing(1)	98
Long-term debt, net	$ 0

(1) On the date that all of the principal and interest of the Comerica Loan become due and payable, we must pay an end of term fee of $173,000 (the "Final Fee"). The Final Fee is being accreted to interest expense over the term of the Comerica Loan.

In accounting for the Comerica Loan, the loan was separated into debt and warrant liability components. We utilized the Binomial pricing model to determine the fair value of the warrant liability component (see Note 4). The carrying amount of the debt component was determined by deducting the fair value of the warrant liability component from the par value of the Comerica Loan as a whole. The excess of the principal amount of the Comerica Loan component over its carrying amount, referred to as the debt discount, is amortized to interest expense over the term of the loan. The warrant liability component is re-measured at each reporting date and changes in the fair value of the warrant liability are recorded as interest expense or interest income, as applicable.

In accounting for the transaction costs related to the issuance of the Comerica Loan, we allocated the total costs incurred to the debt and warrant liability components of the Comerica Loan based on their relative values. Transaction costs totaling $85,000 attributable to the debt component are amortized to interest expense over the term of the Comerica Loan using the effective interest rate method, and transaction costs attributable to the warrant liability component were immediately expensed.

7. Commitments and Contingencies

On July 10, 2014, the first of two purported securities class action lawsuits was commenced in the United States District Court for the District of New Jersey, naming as defendants us and certain of our officers and directors. The lawsuits allege violations of the Securities Act of 1933 and the Securities Exchange Act of 1934 in connection with allegedly false and misleading statements made by us related to our Phase 3 trial of Revolixys in patients undergoing certain percutaneous coronary intervention procedures. Plaintiffs allege, among other things, that we failed to disclose facts related to the potential risk of several allergic reactions following the administration of Revolixys and therefore made false or misleading statements about Revolixys' safety. Plaintiffs seek damages and an award of reasonable costs and expenses, including attorney's fees. It is possible that additional suits will be filed, or allegations received from stockholders, with respect to these same or other matters and also naming us and/or our officers and directors as defendants. These lawsuits and any other related lawsuits are subject to inherent uncertainties, and the actual defense and disposition costs will depend upon many unknown factors. The outcome of these lawsuits is necessarily uncertain. We could be forced to expend significant resources in the defense of these suits and we may not prevail. In addition, we may incur substantial legal fees and costs in connection with these lawsuits. We currently are not able to estimate the possible cost to us from these matters, as these lawsuits are currently at an early stage, and we cannot be certain how long it may take to resolve these matters or the possible amount of any damages that we may be required to pay. We have not established any reserve for any potential liability relating to these lawsuits. It is possible that we could, in the future, incur judgments or enter into settlements of claims for monetary damages. A decision adverse to our interests on these actions could result in the payment of substantial damages, or possibly fines, and could have a material adverse effect on our cash flow, results of operations and financial position.

In April 2014, we entered into a 6-year lease agreement for 18,467 square feet of administrative office space at 106 Allen Road in Basking Ridge, NJ. The terms of the lease require $0 base rent from August 1, 2014 through January 31, 2015 with the remaining payment schedule noted below:

Start Date	End Date	Per Square Foot	Annual Base Rent	Monthly Base Rent
August 1, 2014	January 31, 2015	$ 0.00	$ 0.00	$ 0.00
February 1, 2015	January 31, 2016	$ 25.00	$ 300,000.00	$ 25,000.00
February 1, 2016	January 31, 2017	$ 25.50	$ 382,500.00	$ 31,875.00
February 1, 2017	January 31, 2018	$ 26.00	$ 480,142.00	$ 40,011.83
February 1, 2018	January 31, 2019	$ 26.50	$ 489,375.50	$ 40,781.29
February 1, 2019	July 31, 2020	$ 27.00	$ 498,609.00	$ 41,550.75

8. Stockholders' Equity (in thousands except share and per share amounts)

2014 Public Offering

In April 2014, we consummated an underwritten public offering of 10,000,000 shares of our common stock (the "April 2014 Offering") at a price of $6.00 per share or $5.64 per share after deducting underwriting discounts and commissions. Upon the underwriters' exercise of the over-allotment option in connection with this offering, we issued an additional 279,461 shares of common stock resulting in total net proceeds to us of approximately $57.5 million after deducting underwriting discounts of $3.7 million and offering costs of $0.5 million. The Company intends to use the net proceeds of the April 2014 Offering to fund the continued development of its product candidates, primarily the completion of the REGULATE-PCI trial, and for general working capital.

In connection with the April 2014 Offering, the Company, each of its officers and directors and certain stockholders have agreed with the underwriters, subject to certain exceptions, not to dispose of or hedge any of their common stock or securities convertible into or exchangeable for shares of common stock for a 90-day period after the offering, except with the prior written consent of the underwriters.

Other 2014 Common and Preferred Stock Transactions

During the first quarter of 2014, we sold 4,000,000 shares of our common stock at a purchase price of $5.00 per share to certain accredited and institutional investors (the "2014 Private Placement"), raising an aggregate of $20.0 million before sales agency fees and offering costs of approximately $1.4 million. The net proceeds of approximately $18.6 million from this offering will be used for general corporate and working capital purposes, including the ongoing REGULATE-PCI clinical trial. In connection with this financing, the Company entered into a securities purchase agreement, pursuant to which it agreed to register the resale of the shares of common stock issued in the financing.

On March 21, 2014, we entered into an exchange agreement, ("Exchange Agreement"), with Biotechnology Value Fund, LP, Biotechnology Value Fund II, LP and Investment 10, LLC, ("the Exchanging Stockholders"), pursuant to which we effected an exchange, ("the Exchange"), of the 2,000,000 shares of our common stock purchased by the exchanging stockholders in our 2014 Private Placement for 10,000 shares of newly designated Series F Convertible Preferred Stock, ("Series F"), with a stated value of $1,000 per share, each share of which is convertible into 200 shares of our common stock (subject to adjustment in the event of stock splits, recapitalizations and other similar events affecting our common stock).

The preferred stock was issued without registration under the Securities Act of 1933, as amended, (the "Securities Act"), in reliance on the exemption from registration contained in Section 3(a)(9) of the Securities Act.

Series F Convertible Preferred Stock Terms

Pursuant to the terms of the Series F, the exchanging stockholders have the right to convert the Series F into 2,000,000 shares of our common stock, determined by dividing the stated value of $1,000 per share by the conversion price of $5.00 per share, subject to adjustment in the event of stock splits, recapitalizations and other similar events affecting our common stock; provided, however, that the preferred stock cannot be converted by the exchanging stockholders if, after giving effect thereto, the exchanging stockholders would beneficially own more than 9.99% of our common stock, calculated as provided in the certificate of designation establishing the preferred stock, subject to certain exceptions.

The holders of the preferred stock will not have the right to vote on any matter except to the extent required by Delaware law.

Series F convertible preferred shares are entitled to dividends in the same form as dividends actually paid on shares of common stock other than dividends in the form of common stock.

Upon the execution of a fundamental transaction which effects a merger or other change of control transaction of the Company, a holder will have the right to receive, upon any subsequent conversion of a share of Series F (in lieu of conversion shares) for each issuable conversion share, the same kind and amount of securities, cash or property as it would have been entitled to receive upon the occurrence of such fundamental transaction if it had been, immediately prior to such fundamental transaction, the holder of the shares of common stock into which such holder's shares of Series F is then convertible.

Accounting for the Series F Convertible Preferred Stock

Each share of the Series F is convertible into 200 shares of common stock at any time at the option of the holder, subject to adjustment, and the beneficial ownership limitation provision noted above. The Company has recorded the Series F in equity. The initial carrying value of the Series F was $24.8 million. Upon completion of the Exchange, the conversion option of the Series F was immediately exercisable; therefore, the $14.8 million discount related to the BCF was immediately accreted to Series F, resulting in an increase in the carrying value of the Series F by $14.8 million. For the six months ended June 30, 2014, the value of the BCF of $14.8 million was included in the Company's net loss applicable to common shareholders. See Note 11.

As the Series F are considered participating securities, the Series F participates in the earnings or losses of the Company. Consequently, net losses were adjusted for the deemed distributions relating to the BCF and losses attributable to preferred stockholders to calculate the net loss attributable to common stockholders for the six month period ended June 30, 2014.

IPO

We completed our IPO in August 2013. Inclusive of the underwriters' exercise of the over-allotment option in connection with the IPO in September 2013, we issued 11,671,500 shares of common stock, at a price of $4.00 per share, resulting in net proceeds to us of approximately $41.1 million after deducting underwriting discounts of $3.3 million and offering costs of $2.3 million.

Reverse Stock Split

In May 2013, we executed an amendment to our Fifth Amended and Restated Certificate of Incorporation instituting a 1–for-16.7 reverse split of common stock and an increase in the number of shares of common stock we are authorized to issue to 500,000,000. The par value of the common and the then outstanding convertible preferred stock were not adjusted as a result of the reverse split. All issued and outstanding common stock, options and warrants, and per share amounts contained in the financial statements have been retroactively adjusted to reflect the reverse split for all periods presented.

9. Stock Based Compensation

Equity Compensation Plans

The 2013 Equity Compensation Plan (the "2013 Plan") adopted by our Board of Directors in May 2013, became effective upon consummation of the IPO in August 2013. There are 4,408,369 common shares authorized for issuance under the 2013 Plan of which 404,499 were available as of June 30, 2014. Upon effectiveness of the 2013 Plan, stock options outstanding under the 2004 Equity Compensation Plan (the "2004 Plan") to acquire 1,406,910 shares of our common stock were assumed under the 2013 Plan, leaving stock options to acquire 34,342 shares of our common stock outstanding under the 2004 Plan. There will be no further awards made under the 2004 Plan.

The 2013 Plan includes an "evergreen provision" that allows for an annual increase in the number of shares of common stock available for issuance under the 2013 Plan. The annual increase will be added on the first day of each fiscal year starting January 1, 2014, inclusive, and will be equal to five percent of the total number of shares of Common Stock outstanding on December 31st of the preceding calendar year as determined by the board of directors (the "Board"). The Board may act prior to the first day of any calendar year, to provide that there shall be no increase in the share reserve for such calendar year or that the increase in the share reserve for such calendar year shall be a lesser number of shares of Common Stock than would otherwise occur. On January 1, 2014 another 1,065,530 shares became available for grant under this evergreen provision, increasing the number of shares authorized for issuance under the 2013 Plan from 3,342,839 shares to a total of 4,408,369 shares.

Stock Options

We use the Black-Scholes option pricing model to determine the fair value of our stock options. The determination of the fair value of stock-based payment awards on the date of grant using an option pricing model is affected by our stock price, as well as assumptions regarding a number of complex and subjective variables. These variables include our expected stock price volatility over the term of the awards, risk-free interest rate, actual employee exercise behaviors and expected dividends.

The following table shows the weighted average assumptions used to value stock options on the date of grant, as follows:

	Six Months Ended June 30, 2014	
	Employee	Non-Employees
Expected stock price volatility	54.77%	58.42%
Risk-free interest rate	2.52%	0.13%
Expected life of option (in years)	3.50	0.60
Estimated dividend yield	0.00%	0.00%
Weighted-average grant date fair value per share	$ 2.31	$ 1.41

There were no options granted during the six months ended June 30, 2013.

Expected stock price volatility was calculated based on the weighted-average of historical information of similar public entities. We will continue to use a weighted-average approach using other similar public entities' volatility information until our historical volatility is relevant to measure expected volatility for future option grants. The risk-free rate was based on the U.S. Treasury yield curve in effect at the time of grant commensurate with the expected life assumption. The average expected life was determined based on anticipated exercise strategy and cancellation behavior for employees and non-employee directors. For the six months ended June 30, 2014 a forfeiture rate of 1% and 0% was used for employees and nonemployee directors, respectively. We have not paid and do not anticipate paying cash dividends; therefore, the expected dividend rate was assumed to be 0%.

The following table summarizes our aggregate Equity Compensation Plan activity:

	Number of Options	Weighted Average Exercise Price	Weighted Average Contractual Term (in years)	Aggregate Intrinsic Value [1]
Outstanding – December 31, 2013	3,272,837			
Granted	1,178,611			
Exercised	(12,161)			
Forfeited	(65,591)			
Expired	(898)			
Outstanding – June 30, 2014	4,018,449	$ 5.48	7.92	$ 5,739,305
Exercisable – June 30, 2014	1,430,973	$ 6.82	5.29	$ (53,252)

(1) Intrinsic value is the excess of the fair value of the underlying common shares as of June 30, 2014 over the weighted-average exercise price. A negative intrinsic value indicates the weighted-average exercise price is greater than the fair value of the underlying common shares as of June 30, 2014.
(2) The number of stock options expected to vest takes into account an estimate of expected forfeitures.

The total intrinsic value of options exercised during the six months ended June 30, 2014 was $52,000.

Stock-Based Compensation Expense

Total stock-based compensation expense recognized based on the total grant date fair value of options vested and expected to vest was approximately $1,150,000 and $205,000 for the six months ended June 30, 2014 and 2013, respectively. Due to the valuation allowance against our net deferred tax asset, we have never recognized a tax benefit for stock-based compensation.

All stock options issued to nonemployees (excluding non-employee directors) have been recorded at fair value. Options issued to these nonemployees in exchange for services have resulted in expenses of $0 and $24,000, during the six months ended June 30, 2014 and 2013, respectively.

As of June 30, 2014, approximately $4.1 million of total unrecognized compensation cost related to unvested share options is expected to be recognized over a weighted-average period of 2.8 years.

10. Income Taxes

We estimate an annual effective tax rate of 0% for the year ending December 31, 2014, as the Company incurred losses for the six months ended June 30, 2014 and are forecasting additional losses through the end of 2014, resulting in an estimated net loss for both financial statement and tax purposes for the year ending December 31, 2014

Due to our history of losses since inception, there is not enough evidence at this time to support that we will generate future income of a sufficient amount and nature to utilize the benefits of its net deferred tax assets. Accordingly, the deferred tax assets have been reduced by a valuation allowance, since it has been determined that it is more likely than not that all of the deferred tax assets will not be realized. Therefore, no federal or state income taxes are expected and none have been recorded as of June 30, 2014. Income taxes have been accounted for using the liability method.

11. Net Loss per Share

The following table presents the computation of basic and diluted net loss per common share (in thousands, except share and per share data):

Basic net loss per share of common stock is computed by dividing the Company’s net loss attributable to its stockholders by the weighted-average number of shares of common stock outstanding during the period. Diluted net loss per share of common stock is computed by giving effect to all potentially dilutive securities, including stock options, warrants and convertible preferred stock. Basic and diluted net loss per share of common stock attributable to the Company’s stockholders was the same for all periods presented on the Consolidated Statements of Comprehensive Loss, as the inclusion of all potentially dilutive securities outstanding would have been anti dilutive. As such, the numerator and the denominator used in computing both basic and diluted net loss per share are the same for each period presented.

In March 2014, the Company issued the Series F with a BCF (See Note 8) and recorded a deemed dividend relating to the BCF of $14.8 million for 2014. The Series F participates in earnings or losses of the Company. Consequently, net losses were adjusted for the deemed distribution relating to the BCF and losses attributable to Series F stockholders to calculate the net loss attributable to common stockholders.

The following table presents the calculation of basic and diluted net loss per share of common stock attributable to the Company's common stockholders:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Net loss per share:				
Numerator:				
Net loss	$ (21,432)	$ (5,602)	$ (37,280)	$ (8,892)
Deemed dividend related to the beneficial conversion feature of Series F convertible preferred stock	—	—	(14,840)	—
Net loss attributable to common stockholders	(21,432)	(5,602)	(52,120)	(8,892)
Net loss attributable to preferred stockholders	1,269	—	2,032	—
Net loss attributable to common stockholders – basic and diluted	(20,163)	(5,602)	(50,088)	(8,892)
Denominator:				
Weighted average common shares outstanding, basic and diluted	31,777,266	231,161	27,659,526	226,221
Net loss per share attributable to common stockholders, basic and diluted	$ (0.63)	$ (24.24)	$ (1.81)	$ (39.31)

For all periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding due to our net loss position. Securities that may potentially dilute earnings per share in the future that have not been included in the calculation of diluted net loss per share because to do so would be anti-dilutive are as follows (in common equivalent shares):

	Three months ended June 30,		Six months ended June 30,	
	2014	2013	2014	2013
Convertible preferred stock	2,000,000	9,396,767	2,000,000	9,396,767
Common stock options	4,369,807	1,441,252	4,369,807	1,441,252
Warrants	9,356	16,332	9,356	16,332
Total	6,379,163	10,854,351	6,379,163	10,854,351

In August 2013, all convertible preferred stock converted into common stock in conjunction with the consummation of our IPO. During the six months ended June 30, 2014, 6,976 warrants were exercised at a weighted average exercise price of $0.17. As of June 30, 2014 and 2013, we had 9,356 and 16,332 warrants outstanding, respectively, that were exercisable into common shares at a weighted average price of $12.02 and $0.17 per share, respectively, at the option of the warrant holder.

12. Subsequent Events

On July 2, 2014, the Company announced that the DSMB, in agreement with the Company, was initiating a complete review of efficacy and safety data from the REGULATE-PCI trial. This review was initiated as a result of various SAEs that were reported by certain site investigators at several sites around the world. As a result, the Company voluntarily suspended patient enrollment in the REGULATE-PCI trial until the DSMB completes its analysis and communicates its recommendations. In addition, on July 9, 2014 the FDA informed the company that a clinical hold was placed on all patient enrollment and dosing of either study drug in the REGULATE-PCI trial. According to the FDA, this action was taken to formalize the involvement of the FDA in any decision to re-initiate enrollment and dosing in the trial in the future. During this period of data collection and analysis the Company and the principal investigators of the trial remain blinded. It is anticipated that the DSMB will complete their analysis by early September 2014.

On July 10, 2014, the first of two purported securities class action lawsuits was commenced in the United States District Court for the District of New Jersey, naming as defendants us and certain of our officers and directors. The lawsuits allege violations of the Securities Act of 1933 and the Securities Exchange Act of 1934 in connection with allegedly false and misleading statements made by us related to our Phase 3 trial of Revolixys in patients undergoing certain percutaneous coronary intervention procedures. Plaintiffs allege, among other things, that we failed to disclose facts related to the potential risk of several allergic reactions following the administration of Revolixys and therefore made false or misleading statements about Revolixys' safety. Plaintiffs seek damages and an award of reasonable costs and expenses, including attorney's fees. It is possible that additional suits will be filed, or allegations made by stockholders, with respect to these same or other matters and also naming us and/or our officers and directors as defendants. We believe that we have meritorious defenses and intend to defend these lawsuits vigorously.

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 in conjunction with the financial statements and notes thereto for the year ended December 31, 2013, 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, 2013. 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. These forward-looking statements are subject to risks and uncertainties, including those set forth under "Part I. Item 1. Business - Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2013, and elsewhere in this report, that could cause actual results to differ materially from historical results or anticipated results. Except as required by law, we undertake no obligation to update any forward-looking statements to reflect events or circumstances occurring after the date of this Quarterly Report on Form 10-Q.

Overview

We are a biopharmaceutical company focused on the discovery and development of novel, first-in-class, actively controllable antithrombotic drug systems for acute and sub-acute cardiovascular indications. We are pioneering the discovery and development of two-component drug systems consisting of a therapeutic aptamer and its specific active control agent. Our actively controllable product candidates have the potential to improve outcomes, enhance the patient experience and reduce overall treatment costs. Each of our product candidates, except the specific antidotes for oral FXa inhibitors, consists of a two-component system: an aptamer and its specific active control agent. The aptamer is administered first and achieves its therapeutic effect within minutes. When the therapeutic effect of the aptamer is no longer needed, the control agent is administered to rapidly and precisely reduce or eliminate it. The level of reduction is determined by the amount of control agent given compared to the aptamer dose. By contrast and for example, the therapeutic effect of existing antithrombotic drugs is not rapidly and precisely controllable and persists until the drug is metabolized by the patient, a process which varies from patient to patient and can take several hours or more.

Our lead product candidate, Revolixys™ Kit (formerly known as REG1), consists of pegnivacogin, a highly potent and selective anticoagulant, and anivamersen, its specific active control agent. We are developing Revolixys as an anticoagulant for use in patients with a wide variety of cardiovascular conditions undergoing percutaneous coronary intervention, or PCI, a hospital-based procedure used to mechanically open or widen obstructed coronary arteries. Interventional cardiologists performing PCIs must consider the risk of major bleeding events in determining the level of anticoagulation administered to patients to prevent ischemic events, including death, stroke, myocardial infarction, or MI, or the need for revascularization of the artery. As the anticoagulant effect of existing drugs persists long after administration, interventional cardiologists are forced to make a compromising medical decision because they lack the means to simultaneously reduce the risks of ischemic and major bleeding events. In 2005, we filed an investigational new drug application, or IND, for the use of Revolixys in this initial indication.

In March 2014, we announced that Revolixys received Fast Track designation from the U.S. Food and Drug Administration, or FDA, for anticoagulant therapy to be used in patients with coronary artery disease during PCI. On July 2, 2014, the Company announced that the Data Safety Monitoring Board, or DSMB, in agreement with the Company, was initiating a complete review of efficacy and safety data from the REGULATE-PCI trial. This review was initiated as a result of various serious adverse events, or SAEs, that were reported by certain site investigators at several sites around the world. As a result, the Company voluntarily suspended patient enrollment in the REGULATE-PCI trial until the DSMB completes its analysis and communicates its recommendations. In addition, on July 9, 2014 the United States Food and Drug Administration, or the FDA, informed the company that a clinical hold was placed on all patient enrollment and dosing of either study drug in the REGULATE-PCI trial. According to the FDA, this action was taken to formalize the involvement of the FDA in any decision to re-initiate enrollment and dosing in the trial in the future. During this period of data collection and analysis the Company and the principal investigators of the trial remain blinded. It is anticipated that the DSMB will complete their analysis by early September 2014.

We believe that Revolixys has the potential to become the standard of care for anticoagulation therapy for patients undergoing PCI and other cardiovascular procedures because it is designed to give the physician precise, on-demand control over anticoagulation levels. Revolixys is the first and only anticoagulant to demonstrate a reduction in both ischemic and major bleeding events in a clinical trial for PCI. In our clinical trials, Revolixys demonstrated a rapid and predictable anticoagulant effect that was precisely modulated or completely reversible in real time. In our randomized, partially blinded, dose-ranging Phase 2b trial involving 640 subjects, or the RADAR trial, when compared to standard of care heparin, Revolixys demonstrated both a rapid and predictable anticoagulant effect and ability to precisely modulate or eliminate that effect in real time. Revolixys also demonstrated the following important clinical and pharmacoeconomic benefits:

- an approximate 66.0% reduction in ischemic events;
- a reduction of up to 60.0% in major bleeding events;

- a substantial reduction in time from catheterization to catheter sheath removal from a median of 3.8 hours to a median of one hour;
- a substantial reduction in time of completion of the PCI procedure to catheter sheath removal from a median of three hours to a median of 24 minutes; and
- a substantial reduction in the time patients were required to remain still following catheter sheath removal from a median of 5.7 hours to a median of 2.8 hours.

Based on these clinical results and after discussion with the FDA and the European Medicines Agency, or EMEA, in September of 2013, we initiated a single, open-label, 13,200 subject Phase 3 trial of Revolixys™ Kit, or the REGULATE-PCI trial, in patients undergoing PCI procedures other than for the treatment of ST elevation myocardial infarctions. In March 2014, we announced that Revolixys received Fast Track designation from the FDA for anticoagulant therapy to be used in patients with coronary artery disease during PCI. On July 2, 2014, the Company announced that the DSMB, in agreement with the Company, was initiating a complete review of efficacy and safety data from the REGULATE-PCI trial. This review was initiated as a result of various SAEs that were reported by certain site investigators at several sites around the world. As a result, the Company voluntarily suspended patient enrollment in the REGULATE-PCI trial until the DSMB completes its analysis and communicates its recommendations. In addition, on July 9, 2014 FDA informed the company that a clinical hold was placed on all patient enrollment and dosing of either study drug in the REGULATE-PCI trial. According to the FDA, this action was taken to formalize the involvement of the FDA in any decision to re-initiate enrollment and dosing in the trial in the future. During this period of data collection and analysis the Company and the principal investigators of the trial remain blinded. It is anticipated that the DSMB will complete their analysis by early September 2014.

REGULATE-PCI, if successful, will serve as the basis for product registration applications worldwide. We believe that Revolixys has potential use in other PCI and interventional cardiovascular procedures, such as open heart surgery, or OHS, PCI as a treatment for ST segment elevation myocardial infarction as well as transcatheter aortic valve replacement or implantation, or TAVI.

We completed our initial public offering (“IPO”) in August 2013. Inclusive of the underwriters’ exercise of the over-allotment option in connection with the IPO in September 2013, we issued 11,671,500 shares of common stock at a price of $4.00 per share, resulting in net proceeds of approximately $41.1 million, after deducting underwriting discounts of $3.3 million and offering costs of $2.3 million. Pursuant to the IPO all shares of convertible preferred stock then outstanding automatically converted into an aggregate of 9,396,767 shares of common stock.

In early 2014, we sold 4,000,000 shares of our common stock at a purchase price of $5.00 per share to certain accredited and institutional investors (the “2014 Private Placement”) for net proceeds of approximately $ 18.6 million. In March 2014 we effected an exchange of the 2,000,000 shares of our common stock purchased by certain of the investors in the 2014 Private Placement for 10,000 shares of newly designated Series F Convertible Preferred Stock (the “Series F”), with a stated value of $1,000 per share, each share of which is convertible into 200 shares of our common stock (subject to adjustment in the event of stock splits, recapitalizations and other similar events affecting our common stock).

In April 2014, we consummated an underwritten public offering of 10,000,000 shares of our common stock (the “April 2014 Offering”) at a price of $6.00 per share or $5.64 per share after deducting underwriting discounts and commissions. Upon the underwriters’ exercise of the over-allotment option in connection with this offering, we issued an additional 279,461 shares of common stock resulting in total net proceeds to us of approximately $57.5 million after deducting underwriting discounts of $3.7 million and offering costs of $0.5 million. The Company intends to use the net proceeds of the April 2014 Offering to fund the continued development of its product candidates, primarily the completion of the REGULATE-PCI trial, and for general working capital.

We are not profitable and do not expect to be profitable in the foreseeable future. We have suffered negative cash flows from operating activities of $32.7 million during the six months ended June 30, 2014. We have devoted most of our financial resources to research and development, including our preclinical development activities and clinical trials. We have not completed development of any product candidate and we have therefore not generated any revenues from product sales. As a result, we expect to continue to incur net losses and negative cash flows for the foreseeable future. These net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders’ equity and working capital. Our recurring losses from operations raise substantial doubt about our ability to continue as a going concern, and as a result, our independent registered public accounting firm included an explanatory paragraph in its report on our financial statements as of and for the year ended December 31, 2013 with respect to this uncertainty. Due to the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve or maintain profitability.

Financial Operations Overview

Revenue

To date, we have not generated any product revenue. Our ability to generate product revenue, which we do not expect will occur for several years, if ever, will depend heavily on the successful development and eventual commercialization of our lead product candidate, Revolixys.

Research and Development Expenses

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

- employee salaries and related expenses, which include all compensation benefits for the personnel involved in our drug discovery and development activities, including stock based compensation;
- external research and development expenses incurred under agreements with third party AROs and CROs and investigative sites;
- clinical trial supplies when used or upon determination that they have no alternative future use and clinical trial supplies shipped to clinical sites for use in clinical studies;
- license fees for and milestone payments related to in-licensed products and technologies; and
- overhead costs related to facilities, depreciation, and supplies.

We expense research and development costs as incurred, with the exception of materials purchased and/or manufactured for use in clinical trials. We capitalize clinical trial supplies, which are comprised of materials that will be used in our clinical trials that also have an alternative future use in either ongoing or future clinical research or development projects. Capitalized clinical trial supplies that are determined to be unsuitable for future use are immediately expensed to research and development; otherwise, clinical trial supplies are expensed to research and development when shipped to clinical sites for use in clinical studies or when used in other research and development projects. Costs for clinical agreements, including ARO and CRO contracts, are recognized based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations, or information provided by vendors on their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in our financial statements as prepaid or accrued expenses.

Conducting a significant amount of research and development is central to our business model. Product candidates in late 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 late stage clinical trials. We expect our research and development expenses to increase in future periods for the foreseeable future as we seek to complete development of our lead product candidate, Revolixys, and to further develop our other product candidates.

We incurred aggregate research and development expenses of approximately $31.6 million and $6.0 million for the six months ended June 30, 2014 and 2013, respectively. We expect to incur increased research and development expenses primarily related to our REGULATE-PCI trial.

We track direct external development expenses and direct personnel expenses on each indication for our product candidates. Substantially all of our research and development expenses for Revolixys have related to its initial indication, although we expect certain of the data obtained will support development of additional Revolixys indications as well as the development of REG2. Indirect expenses, such as, overhead costs related to facilities, depreciation, and small supplies are not allocated to specific product candidates or indications. The following table is a summary of our research and development expenses for the three and six months ended June 30, 2014 and 2013 (in thousands):

	Three months ended June 30		Six months ended June 30	
	2014	2013	2014	2013
Revolixys™ Kit	$ 17,828	$ 3,620	$30,510	$4,736
REG3	10	121	13	246
REG2	—	94	—	206
Other	145	17	237	25
Total direct expenses	17,983	3,852	30,760	5,213
Indirect expenses	522	462	861	834
Total research and development expense	$ 18,505	$ 4,314	$31,621	$6,047

The successful development of our clinical and preclinical product candidates is highly uncertain. At this time, we can only reasonably estimate the nature, timing and costs of the efforts that will be necessary to complete the remainder of the development of any of our product candidates or the period, if any, in which material net cash inflows from those product candidates may commence. Our estimates are based on reasonable assumptions, past performance, experience and existing contracts. However, unforeseen changes may occur at any time due to the numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

- the number of sites included in the trials;
- the number of countries included in the trials;
- the ability to recruit subjects to participate in the trial;
- the per subject trial costs;
- the length of time required to enroll suitable subjects, achieve interim milestones and complete clinical trials; and
- the cost and timeliness of obtaining clinical trial supplies.

Development timelines, probability of success and development costs vary widely. As a result of the uncertainties discussed above, we anticipate that we will make determinations as to which product candidates and indications to pursue and how much funding to direct to each product candidate and indication on an ongoing basis. Accordingly, we cannot currently estimate with any degree of certainty the amount of time or money that we will be required to expend in the future on the research and development of our product candidates.

General and Administrative Expenses

General and administrative expenses consist principally of salaries and related benefit costs, including stock-based compensation for administrative personnel. Other general and administrative expenses include facility costs, and professional fees for legal, consulting, auditing and tax services. We anticipate that our general and administrative expenses will increase in future periods to support increases in our research and development activities and as a result of increased headcount, expanded infrastructure, and increased legal, compliance, accounting and investor and public relations expenses associated with being a public company.

Interest Income (Expense)

Interest income consists of interest earned on our cash and cash equivalents. We expect our interest income earned on cash and cash equivalents to increase as we invest the net proceeds from our 2014 Private Placement and the April 2014 Offering pending their use in our operations. Interest expense in 2014 consisted of fair value adjustments related to our warrant liability and interest charges related to the Comerica Loan. Interest expense in 2013 related to interest incurred on our MidCap loan, Comerica Loan and on our convertible notes.

Critical Accounting Policies and Significant Judgments and Estimates

Our discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue and expenses and the disclosure of contingent assets and liabilities in our financial statements. We evaluate our estimates and judgments, including those related to accrued expenses and share-based compensation, on an ongoing basis. 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 values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates.

For a description of our critical accounting policies and estimates, please refer to the “Critical Accounting Policies and Estimates” section of the “Management’s Discussion and Analysis of Financial Condition and Results of Operations” section in our

Annual Report on Form 10-K for the year ended December 31, 2013 filed with the Securities and Exchange Commission, or SEC, on March 12, 2014. We believe the following accounting policies to be most critical to the judgments and estimates used in preparation of our financial statements and such policies have been reviewed and discussed with our audit committee.

Accrued Expenses

As part of the process of preparing our financial statements, we are required to estimate accrued expenses. This process involves reviewing open contracts and purchase orders, communicating with applicable vendor personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual cost. The majority of our service providers invoice us monthly in arrears for services performed. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. Examples of estimated accrued expenses include:

- fees paid to CROs in connection with clinical trials;
- investigative site costs in connection with clinical trials;
- milestone payments; and
- unpaid salaries, wages and benefits.

We accrue our expenses related to clinical trials based on our estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that conduct and manage clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we will adjust the accrual accordingly. If we do not identify costs that we have begun to incur or if we underestimate or overestimate the level of services performed or the costs of these services, our actual expenses could differ from our estimates. We do not currently anticipate the future settlement of existing accruals to differ materially from our estimates.

Stock-based Compensation

In accordance with FASB ASC Topic 718, Stock Compensation, as modified or supplemented, we measure compensation cost for share-based payment awards granted to employees and non-employee directors at fair value using the Black-Scholes option-pricing model. We recognize compensation expense on a straight-line basis over the service period for awards expected to vest. Share-based compensation cost related to share-based payment awards granted to non-employees (excluding non-employee directors) is adjusted each reporting period for changes in the fair value of our common stock until the measurement date. The measurement date is generally considered to be the date when all services have been rendered or the date that options are fully vested.

We use the Black-Scholes-Merton option pricing model to determine the fair value of our stock options. The determination of the fair value of stock-based payment awards on the date of grant using an option pricing model is affected by our stock price, as well as assumptions regarding a number of complex and subjective variables. These variables include our expected stock price volatility over the term of the awards, risk-free interest rate, actual employee exercise behaviors and expected dividends.

The following table shows the weighted average assumptions used to value stock options on the date of grant, as follows:

	Six Months Ended June 30, 2014	
	Employee	Non-Employees
Expected stock price volatility	54.77%	58.42%
Risk-free interest rate	2.52%	0.13%
Expected life of option (in years)	3.5	0.6
Estimated dividend yield	0.00%	0.00%
Weighted-average grant date fair value per share	$ 2.31	$ 1.41

Expected stock price volatility was calculated based on the weighted-average of historical information of similar public entities. We will continue to use a weighted-average approach using other similar public entities' volatility information until our historical volatility is relevant to measure expected volatility for future option grants. The risk-free rate was based on the U.S. Treasury yield curve in effect at the time of grant commensurate with the expected life assumption. The average expected life was determined based on anticipated exercise strategy and cancellation behavior for employees and nonemployees, primarily non-employee directors. For the six month ended June 30, 2014 a forfeiture rate of 1% and 0% was used for employees and nonemployees, respectively. We have not paid and do not anticipate paying cash dividends; therefore, the expected dividend rate was assumed to be 0%. There were no stock option grants made during the six month period ended June 30, 2013.

Total stock-based compensation expense recognized based on the total grant date fair value of options vested and expected to vest was approximately $1,105,000 and $205,000 for the six months ended June 30, 2014 and 2013, respectively,. Due to the valuation allowance against our net deferred tax asset, we have never recognized a tax benefit for stock based compensation.

As of June 30, 2014, approximately $4.1 million of total unrecognized compensation cost related to unvested share options is expected to be recognized over a weighted-average period of 2.8 years.

Clinical Trial Supplies

We capitalize materials that will be used in our REGULATE-PCI clinical trials that also have an alternative future use in either ongoing or future clinical research and development projects. Clinical trial supplies may comprise material used to manufacture active pharmaceutical ingredients ("API") used to develop our product candidates, in-process or completed API, in-process or completed unlabeled finished drug product and labeled finished drug product. Clinical trial supplies are stated at cost, using the first-in, first-out method ("FIFO"), and are reported in the accompanying consolidated balance sheets in other current assets. Clinical trial supplies that are determined to be unsuitable for future use are immediately expensed; otherwise clinical trial supplies are expensed when shipped to clinical sites for use in clinical studies or when used in other research and development projects.

Accounting for Convertible Preferred Stock

On March 21, 2014, we entered into an exchange agreement (the "Exchange Agreement"), with Biotechnology Value Fund, LP, Biotechnology Value Fund II, LP and Investment 10, LLC (the "Exchanging Stockholders"), pursuant to which we effected an exchange (the "Exchange") of 2,000,000 shares of our common stock purchased by the exchanging stockholders in our 2014 Private Placement for 10,000 shares of newly designated Series F Convertible Preferred Stock ("Series F"), with a stated value of $1,000 per share, each share of which is convertible into 200 shares of our common stock (subject to adjustment in the event of stock splits, recapitalizations and other similar events affecting our common stock).

Pursuant to the terms of the Series F, the exchanging stockholders have the right to convert the Series F into 2,000,000 shares of our common stock, determined by dividing the stated value of $1,000 per share by the conversion price of $5.00 per share, subject to adjustment in the event of stock splits, recapitalizations and other similar events affecting our common stock; provided, however, that the Series F cannot be converted by the exchanging stockholders if, after giving effect thereto, the exchanging stockholders would beneficially own more than 9.99% of our common stock, calculated as provided in the certificate of designation establishing the preferred stock, subject to certain exceptions.

The holders of the preferred stock will not have the right to vote on any matter except to the extent required by Delaware law.

Series F are entitled to dividends in the same form as dividends actually paid on shares of common stock other than dividends in the form of common stock.

Upon the execution of a fundamental transaction which effects a merger or other change of control transaction of the Company, a holder will have the right to receive, upon any subsequent conversion of a share of Series F (in lieu of conversion shares) for each issuable conversion share, the same kind and amount of securities, cash or property as it would have been entitled to receive upon the occurrence of such fundamental transaction if it had been, immediately prior to such fundamental transaction, the holder of the shares of common stock into which such holder's shares of Series F is then convertible.

As the Series F are considered participating securities, the Series F participates in the earnings or losses of the Company. Consequently, net losses were adjusted for the deemed distributions relating to the beneficial conversion feature (the "BCF") and losses attributable to preferred stockholders to calculate the net loss attributable to common stockholders for the six months period ended June 30, 2014.

Results of Operations

Three Months Ended June 30, 2014 and 2013

The following table sets forth certain information concerning our results of operations for the periods shown (in thousands):

	Three Months Ended June 30,		Increase (Decrease)
	2014	2013	
Operating expenses:			
Research and development	$(18,505)	$(4,314)	$ 14,191
General and administrative	(2,838)	(1,133)	1,705
Total operating expenses	(21,343)	(5,447)	15,896
Other (expense) income:			
Interest income	47	68	(21)
Interest expense	(136)	(283)	147
Other Income	—	60	(60)
Total other (expense) income	(89)	(155)	(66)
Net loss	$(21,432)	$(5,602)	$ 15,830
Net loss attributable to preferred stockholders	1,269	—	(1,269)
Net loss attributable to common stockholders	$(20,163)	$(5,602)	$ 14,561

Research and Development Expenses

Research and development expenses increased by $14.2 million for the three months ended June 30, 2014 compared to the three months ended June 30, 2013 due to the inclusion of the costs of the REGULATE-PCI trial which commenced in September 2013.

General and Administrative Expenses

General and administrative expenses increased by $1.7 million for the three months ended June 30, 2014 compared to the three months ended June 30, 2013. The increase was primarily due to increased employee cash and equity compensation costs for existing employees and new hires, as well as, increases in accounting, legal, insurance and other administrative costs associated with becoming a public company.

Other Income (Expense)

Interest income decreased by $21,000 for the three months ended June 30, 2014, compared to the three months ended June 30, 2013 as a result of fair value adjustment related to our warrant liability.

Interest expense decreased by $147,000 for the three months ended June 30, 2014, compared to the three months ended June 30, 2013 primarily due to the termination of the MidCap loan which bore a higher interest rate as compared to the Comerica loan acquired in May 2013.

Other income decreased by $60,000 for the three months ended June 30, 2014, compared to the three months ended June 30, 2013 as a result of sale of patents from a deal with DRI related to our Series E financing. We transferred limited patent rights to Nova Medica in exchange for a negotiated fee with no future rights or obligations for those patents.

Six Months Ended June 30, 2014 and 2013

The following table sets forth certain information concerning our results of operations for the periods shown (in thousands):

	Six Months Ended June 30,		Increase (Decrease)
	2014	2013	
Operating expenses:			
Research and development	$(31,621)	$(6,047)	$ 25,574
General and administrative	(5,386)	(2,576)	2,810
Total operating expenses	(37,007)	(8,623)	28,384
Other (expense) income:			
Interest income	50	69	(19)
Interest expense	(323)	(398)	75
Other income	—	60	(60)
Total other (expense) income	(273)	(269)	4
Net loss	$(37,280)	$(8,892)	$ 28,388
Deemed dividend related to beneficial conversion feature of Series F convertible preferred stock	(14,840)	—	14,840
Net loss attributable to preferred stockholders	2,032	—	2,032
Net loss attributable to common stockholders	$(50,088)	$(8,892)	$ 41,196

Research and Development Expenses

Research and development expenses increased by $25.6 million for the six months ended June 30, 2014 compared to the six months ended June 30, 2013 due to the inclusion of the costs of the REGULATE-PCI trial which commenced in September 2013.

General and Administrative Expenses

General and administrative expenses increased by $2.8 million for the six months ended June 30, 2014 compared to the six months ended June 30, 2013. The increase was primarily due to increased employee cash and equity compensation costs for existing employees and new hires, as well as, increases in accounting, legal, insurance and other administrative costs associated with becoming a public company.

Other Income (Expense)

Interest income decreased by $19,000 for the six months ended June 30, 2014, compared to the six months ended June 30, 2013 as a result of the fair value adjustment related to our warrant liability.

Interest expense decreased by $75,000 for the six months ended June 30, 2014, compared to the six months ended June 30, 2013 primarily due to the termination of the MidCap loan which bore a higher interest rate as compared to the Comerica loan acquired in May 2013.

Other income decreased by $60,000 for the six months ended June 30, 2014, compared to the six months ended June 30, 2013 as a result of sale of patents from a deal with DRI related to our Series E financing. We transferred limited patent rights to NovaMedica in exchange for a negotiated fee with no future rights or obligations for those patents.

Series F Convertible Preferred Stock Accretion

Accretion of the Series F deemed dividend related to the Series F BCF was $ 14.8 million in 2014 compared to $0 in 2013. The rights and preferences of the Series F, as well as the BCF as a result of the issuance of the Series F, are described further in Note 8 to the notes to the financial statements.

Liquidity and Capital Resources

Sources of Liquidity

To date, we have not generated any product revenue. We have funded our operations to date through sales of our equity and debt securities, bank borrowings and government grants. As of June 30, 2014, we had $72.7 million in cash and cash equivalents.

During the six months ended June 30, 2014 we received net proceeds of $18.6 million from the sale of our common stock at a purchase price of $5.00 per share to certain accredited and institutional investors (the “2014 Private Placement”). In August 2013, we completed our IPO. Inclusive of the underwriters’ exercise of the over-allotment option in connection with the IPO, we issued

11,671,500 shares of common stock at a price of $4.00 per share, resulting in net proceeds of approximately $41.1 million. Prior to our IPO, we received net cash proceeds of $147.4 million from sales of preferred stock and convertible note proceeds including convertible notes that were converted to convertible preferred stock. Upon closing of the IPO, all shares of convertible preferred stock then outstanding automatically converted into an aggregate of 9,396,767 shares of common stock.

In April 2014, we consummated an underwritten public offering of 10,000,000 shares of our common stock at a price of $6.00 per share or $5.64 per share after deducting underwriting discounts and commissions. Upon the underwriters' exercise of the over-allotment option in connection with this offering, we issued an additional 279,461 shares of common stock resulting in total net proceeds to us of approximately $57.5 million after deducting underwriting discounts of $3.7 million and offering costs of $0.5 million. The Company intends to use the net proceeds of the April 2014 Offering to fund the continued development of its product candidates, primarily the completion of the REGULATE-PCI trial, and for general working capital.

In connection with the April 2014 Offering, the Company, each of its officers and directors and certain stockholders have agreed with the underwriters, subject to certain exceptions, not to dispose of or hedge any of their common stock or securities convertible into or exchangeable for shares of common stock for a 90-day period after the offering, except with the prior written consent of the underwriters.

Comerica Loan

In May 2013, we entered into a Loan and Security Agreement, or the Loan Agreement, with Comerica Bank, or Comerica. Pursuant to the terms of the Loan Agreement, we were initially eligible to borrow $4.5 million in an initial tranche, or Tranche One. Upon Comerica's receipt of evidence satisfactory to Comerica that (i) the 1,000 patient interim analysis in the REGULATE-PCI study is successful and performed by April 30, 2014 and (ii) upon our completion of the IPO and receipt of net proceeds of at least $50 million prior to September 30, 2013, we had the option to borrow an additional $4 million in the second tranche, or Tranche Two. Since the Tranche Two conditions were not satisfied, Tranche Two is solely at the discretion of Comerica.

The Comerica loan bears interest at Comerica's Prime Reference Rate (as defined in the Loan Agreement) subject to a floor of 30 day LIBOR plus 250 basis points plus 4.0%. The Comerica loan is interest-only until September 1, 2014. We must repay the principal amount in nine approximately equal consecutive monthly installments commencing on September 1, 2014. The loan matures on May 10, 2015.

In connection with the funding of Tranche One, we issued a warrant to Comerica, or the Comerica Warrant, to purchase 156,250 shares of our Series E Preferred Stock at a price of $0.72 per share, or the Warrant Price, subject to adjustment for stock splits, combinations, reclassifications or exchanges and certain dilutive issuances. After giving effect to our IPO and reverse stock-split, the Comerica Warrant was adjusted to a warrant to purchase 9,356 shares of our common stock at a price of $12.02 per share (the "Adjusted Warrant Price"). If Comerica, in its sole discretion, permits us to borrow the additional $4 million in Tranche Two, the Comerica Warrant will become exercisable for an additional number of shares of our common stock equal to 5,988 divided by the Adjusted Warrant Price.

The proceeds of Tranche One were used to repay in full amounts outstanding under our loan and security agreement with MidCap Financial SBIC, LP which has been terminated, and for general operating purposes.

Under the terms of the Loan Agreement, we granted Comerica a first priority security interest in substantially all of our assets other than our intellectual property. The Loan Agreement does not contain any ongoing financial covenants.

The Loan Agreement provides that upon the occurrence of and during a period of default as defined therein, interest on the loan will accrue at a penalty rate. Upon the occurrence and during the continuance of a default, Comerica may, at its election, make all obligations under the Loan Agreement immediately due and payable, cease advancing money or extending credit, exercise its right of setoff, foreclose on our assets, dispose of collateral at a public or private sale, and exercise any other remedies available to a secured creditor at law or in equity.

Cash Flows

Our net cash flow from operating, investing and financing activities for the periods below were as follows (in thousands):

	Six Months Ended June 30,	
	2014	2013
Net cash provided by (used in):		
Operating activities	$(32,728)	$(8,520)
Investing activities	(1,475)	(257)
Financing activities	76,235	8,512
Net increase/(decrease) in cash and cash equivalents	$ 42,032	$ (265)

Operating Activities

Net cash used in operating activities was $32.7 million for the six months ended June 30, 2014 and $8.5 million for the six months ended June 30, 2013. Net cash used in operating activities for the six months ended June 30, 2014 principally resulted from REGULATE-PCI trial expenses which commenced in September 2013 and to the increased costs of being a public company, in addition to an increase in accrued expenses. Net cash used in operating activities for the six months ended June 30, 2013 principally resulted from our net loss of $8.9 million which principally related to R&D expenditures and general and administrative costs.

Investing Activities

Net cash used in investing activities was $1.5 million for the six months ended June 30, 2014, of which $1.0 million was cash restricted for payment of an accrued milestone obligation. The remaining balance of approximately $476,000 in 2014, as well as, the $346,000 used in investing activities in 2013, principally resulted from the acquisition of intellectual property rights and equipment.

Financing Activities

Net cash provided by financing activities was $76.2 million for the six months ended June 30, 2014, while $8.5 million was provided by financing activities for the six months ended June 30, 2013. Net cash provided by financing activities for the six months ended June 30, 2014 resulted primarily from $76.2 million in net proceeds from the 2014 Private Placement and the April 2014 Offering. Net cash provided by financing activities for the six months ended June 30, 2013 principally resulted from the issuance of preferred shares net of issuance costs.

Funding Requirements

We have not completed development of any of our product candidates. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. We anticipate that our expenses will increase substantially as we:

- continue our REGULATE-PCI trial;
- continue the research and development activities for our other product candidates;
- seek to discover additional product candidates;
- seek regulatory approvals for our product candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure if we do not secure a strategic partner to commercialize products for which we may obtain regulatory approval;
- increase manufacturing capabilities in preparation for commercial launch of any such products; and
- add operational, financial and management information systems and personnel, including personnel to support our product development, planned commercialization efforts and our operation as a public company.

We believe that our existing cash and cash equivalents plus the proceeds from the 2014 Private Placement and our April 2014 Offering, together with our existing working capital, will be sufficient to fund the REGULATE-PCI trial and our operations through the first quarter of 2015. We need to raise additional financing in the near term to operate our business and fund our REGULATE-PCI trial to completion, which financing may not be available on favorable terms, or at all. Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the risk factors discussed in this report under the heading “Risk Factors” and in our Annual Report on Form 10-K. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect.

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

- the initiation, progress, timing, costs and results of preclinical studies and clinical trials for our product candidates and potential product candidates, including our REGULATE-PCI trial, and the continued development of our other product candidates;
- the number and characteristics of product candidates that we pursue;
- the terms and timing of any future collaboration, licensing or other arrangements that we may establish;
- the outcome, timing and cost of regulatory approvals;
- the cost of obtaining, maintaining, defending and enforcing intellectual property rights, including patent rights;
- the effect of competing technological and market developments;
- the cost and timing of completing commercial-scale outsourced manufacturing activities;
- market acceptance of any product candidates for which we may receive regulatory approval;
- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval; and
- the extent to which we acquire, license or invest in businesses, products or technologies.

Until we can generate a sufficient amount of revenue from our product candidates, if ever, we expect to finance future cash needs through public or private equity offerings, debt financings or corporate collaborations and licensing arrangements. Additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available, we may be required to delay our REGULATE-PCI trial, reduce the scope of or eliminate one or more of our research or development programs or our commercialization efforts. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience additional dilution, and debt financing, if available, may involve restrictive covenants. To the extent that we raise additional funds through collaborations and licensing arrangements, it may be necessary to relinquish some rights to our technologies or our product candidates or grant licenses on terms that may not be favorable to us. We may seek to access the public or private capital markets whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time.

We do not expect Revolixys™ Kit to be commercially available before 2017, if at all. The net proceeds of our IPO, 2014 Private Placement and April 2014 Offering will not be sufficient for us to complete the REGULATE-PCI trial and we will need to raise substantial additional capital to complete the development and commercialization of Revolixys. We also will need to raise substantial additional capital to complete the development and commercialization of Revolixys for additional indications and for our other product candidates. Since successful development of our product candidates is uncertain, we are unable to estimate the actual funds required to complete research and development and commercialize our products under development.

Off-Balance Sheet Arrangements

Since inception, we have not engaged in any off-balance sheet arrangements as defined in Item 303(a)(4) of Regulation S-K.

Recent Accounting Pronouncements

In June of 2014 the Financial Accounting Standards Board issued Accounting Standards Update ASU 2014-10, Development Stage Entities (Topic 915) “Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation” (“ASU 2014-10”). The amendments in ASU 2014-10 remove the definition of a development stage entity from the master glossary of the Accounting Standards Codification, thereby removing the financial reporting distinction between development stage entities and other reporting entities from U.S. GAAP. In addition, the amendments eliminate the requirements for development stage entities to (1) present inception-to-date information in the consolidated statements of comprehensive loss, cash flows, and changes in stockholders’ equity, (2) label the financial statements as those of a development stage entity, (3) disclose a description of the development stage activities in which the entity is engaged, and (4) disclose in the first year in which the entity is no longer a development stage entity that in prior years it had been in the development stage. The amendments in ASU 2014-10 will be effective prospectively for annual reporting periods beginning after December 15, 2014, and interim periods within those annual periods, however early adoption is permitted. We have elected to early adopt the provisions of ASU 2014-10 for the current period presented. Other than the changes in presentation noted above, the adoption of ASU 2014-10 did not have significant impact on our results of operations, financial condition or cash flows.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Our exposure to market risk is limited to our cash, cash equivalents and marketable securities, all of which have maturities of one year or less. The goals of our investment strategy are preservation of capital, fulfillment of liquidity needs and fiduciary control of cash and investments. We also seek to maximize income from our investments without assuming significant risk. To achieve our goals, we maintain a portfolio of cash equivalents and investments in a variety of securities that management believes to be of high credit quality. The securities in our investment portfolio are not leveraged, are classified as available for sale and are, due to their short-term nature, subject to minimal interest rate risk. We currently do not hedge interest rate exposure. Because of the short-term maturities of our investments, we do not believe that an increase in market rates would have a material negative impact on the value of our investment portfolio.

We do not have any material foreign currency exposure.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

As of June 30, 2014, our management, with the participation of our Chief Executive Officer and Principal Financial Officer, evaluated the effectiveness of our disclosure controls and procedures. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the Company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost benefit relationship of possible controls and procedures. Based on this evaluation, management concluded that our disclosure controls and procedures were not effective due to a material weakness in our internal control over financial reporting that was identified in connection with the preparation of our consolidated financial statements for the years ended December 31, 2011 and 2012 and is described in the following paragraph.

In connection with the preparation of our consolidated financial statements for the years ended December 31, 2012 and 2011, we identified past accounting errors, which resulted in the restatement of our previously issued financial statements. We and our independent registered public accounting firm identified a material weakness in internal control over financial reporting related to these items which required adjustment, specifically: (i) accounting for the purchase of supplies used in the production of our drug product, and (ii) accounting for purchase orders related to manufacturing services where work was contracted but not yet performed. A material weakness is defined as a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of a Company’s annual or interim financial statements will not be prevented or detected on a timely basis by the Company’s internal controls.

We have implemented and are continuing to implement procedures and controls designed to remediate the material weakness and underlying significant deficiencies. Amongst other actions, we have commenced implementation of enhanced review procedures; begun a comprehensive documentation of our internal controls and procedures; and implemented more formal procedures as to the evaluation of non-routine judgments and estimates. Although we believe these controls will be effective, we have not yet determined if we have successfully remediated the material weakness and those significant deficiencies.

Notwithstanding the identified material weakness in internal controls over financial reporting, management believes the consolidated financial statements included in this Quarterly Report on Form 10-Q fairly represent in all material respects our financial condition, results of operations and cash flows at and for the periods presented in accordance with GAAP.

Changes in Internal Control over Financial Reporting

Other than remediation efforts described above, there have been no changes in our internal control over financial reporting during the six months ended June 30, 2014 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings

On July 10, 2014, the first of two purported securities class action lawsuits was commenced in the United States District Court for the District of New Jersey, naming as defendants us and certain of our officers and directors. The lawsuits allege violations of the Securities Act of 1933 and the Securities Exchange Act of 1934 in connection with allegedly false and misleading statements made by us related to our Phase 3 trial of Revolixys in patients undergoing certain percutaneous coronary intervention procedures. Plaintiffs allege, among other things, that we failed to disclose facts related to the potential risk of several allergic reactions following the administration of Revolixys and therefore made false or misleading statements about Revolixys' safety. Plaintiffs seek damages and an award of reasonable costs and expenses, including attorney's fees. It is possible that additional suits will be filed, or allegations made by stockholders, with respect to these same or other matters and also naming us and/or our officers and directors as defendants. We believe that we have meritorious defenses and intend to defend these lawsuits vigorously.

In addition, from time to time and in the ordinary course of business, we are subject to various other claims, charges and litigation.

Item 1A. Risk Factors

The risk factors as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2013 and the following important factors could cause our actual business and financial results to differ materially from those contained in forward-looking statements made in this Quarterly Report on Form 10-Q or elsewhere by management from time to time. Except as set forth below, there have been no material changes to our risk factors as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2013.

Risks Relating to Our Financial Position and Need for Additional Capital

We will need to raise additional capital to complete the REGULATE-PCI trial and commercialize Revolixys. If we are unable to raise sufficient capital, we would be forced to delay, reduce or eliminate our product development programs.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is expensive. We expect our research and development expenses to increase in connection with our ongoing activities, particularly as we continue our REGULATE-PCI trial, undertake additional clinical trials of our other product candidates and continue to work on our other research programs. We believe that the net proceeds from the April 2014 Offering, together with our existing cash and cash equivalents will be sufficient for us to fund our projected operating requirements, including the REGULATE-PCI trial, through the first quarter of 2015. We will need to raise substantial additional capital to fund our operations and complete the development and commercialization of Revolixys, and to repay our debt with Comerica bank. If the U.S. Food and Drug Administration, or the FDA, or other regulators require that we perform additional studies beyond those we currently expect, or if there are any delays in completing our clinical trials or the development of any of our product candidates, our expenses could increase beyond what we currently anticipate and the timing of any potential product approval may be delayed. We have no commitments or arrangements for any additional financing to fund our research and development programs. We also will need to raise substantial additional capital in the future to complete the development and commercialization of Revolixys for additional indications and for our other product candidates. Because successful development of our product candidates is uncertain, we are unable to estimate the actual funds required to complete research and development and commercialize our products under development.

Until we can generate a sufficient amount of revenue from our product candidates, if ever, we expect to finance future cash needs through public or private equity offerings, debt financings or corporate collaborations and licensing arrangements. Additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate one or more of our research or development programs. To the extent that we raise additional funds by issuing equity securities, our stockholders will experience additional dilution, and debt financing, if available, may involve restrictive covenants. To the extent that we raise additional funds through collaborations and licensing arrangements, it may be necessary to relinquish some rights to our technologies or our product candidates or grant licenses on terms that may not be favorable to us. We may seek to access the public or private capital markets whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time.

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

- the progress, timing, costs and results of preclinical studies and clinical trials for our product candidates and potential product candidates, including our REGULATE-PCI trial and the continued development of our other product candidates;
- the number and characteristics of product candidates that we pursue;

- the terms and timing of any future collaboration, licensing or other arrangements that we may establish;
- the outcome, timing and cost of regulatory approvals;
- the cost of obtaining, maintaining, defending and enforcing intellectual property rights, including patent rights;
- the effect of competing technological and market developments;
- the cost and timing of completing commercial-scale outsourced manufacturing activities;
- market acceptance of any product candidates for which we may receive regulatory approval;
- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval; and
- the extent to which we acquire, license or invest in businesses, products or technologies.

We have a limited operating history and we expect a number of factors to cause our operating results to fluctuate on a quarterly and annual basis, which may make it difficult to predict our future performance.

We are a development stage biopharmaceutical company with a limited operating history. Our operations to date have been primarily limited to developing our technology and undertaking preclinical studies and clinical trials of Revolixys and our other product candidates. We have not yet obtained regulatory approvals for Revolixys or any of our other product candidates. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a longer operating history or commercialized products. Our financial condition and operating results have varied significantly in the past and will continue to fluctuate from quarter-to-quarter or year-to-year due to a variety of factors, many of which are beyond our control. Factors relating to our business that may contribute to these fluctuations include other factors described elsewhere or incorporated by reference in this report and also include:

- our ability to obtain additional funding to complete development and, if approved, the commercialization of Revolixys and to develop our other product candidates;
- delays in the commencement, enrollment and timing of clinical trials, including as a result of inability to manufacture or purchase sufficient drug supply to conduct a clinical trial;
- the success of our clinical trials through all phases of clinical development, including our REGULATE-PCI trial;
- any delays in regulatory review and approval of product candidates in clinical development;
- our ability to obtain and maintain regulatory approval for Revolixys or any of our other product candidates in the United States and foreign jurisdictions;
- potential side effects of our product candidates that could delay or prevent commercialization, limit the indications for any approved drug, require the establishment of risk evaluation and mitigation strategies, or REMS, or cause an approved drug to be taken off the market;
- our dependence on third-party manufacturers, or CMOs, to supply or manufacture our products;
- our dependence on clinical research organizations, or CROs, to conduct our clinical trials;
- our ability to establish or maintain collaborations, licensing or other arrangements;
- market acceptance of our product candidates;
- our ability to establish and maintain an effective sales and marketing infrastructure, either through the creation of a commercial infrastructure or through strategic collaborations;
- competition from existing products or new products that may emerge;
- the ability of patients or healthcare providers to obtain coverage of or sufficient reimbursement for our products;
- our ability to leverage our proprietary technology platform to discover and develop additional product candidates;
- our ability and our licensors' abilities to successfully obtain, maintain, defend and enforce intellectual property rights important to our business;
- our ability to attract and retain key personnel to manage our business effectively;
- our ability to build our finance infrastructure and improve our accounting systems and controls;
- potential product liability claims;
- potential liabilities associated with hazardous materials; and
- our ability to obtain and maintain adequate insurance policies.

Accordingly, the results of any quarterly or annual periods should not be relied upon as indications of future operating performance.

The audit opinion on our financial statements contains a going concern modification.

Based on our cash balances, recurring losses, net capital deficiency and debt outstanding as of December 31, 2013 and our projected spending in 2014, which raise substantial doubt about our ability to continue as a going concern, the audit opinion on our

audited financial statements as of and for the year ended December 31, 2013 contains a going concern modification. We believe that the net proceeds from the April 2014 Offering, together with our existing cash and cash equivalents will be sufficient for us to fund our projected operating requirements, including the REGULATE-PCI trial, through the first quarter of 2015. However, if we are unable to continue as a going concern, we might have to liquidate our assets and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our financial statements. Amounts due under our loan with Comerica Bank, or Comerica, may become immediately due and payable upon the occurrence of a material adverse change, as defined under the loan agreement. Under the terms of the Comerica loan agreement, we are subject to operational covenants, including limitations on our ability to incur liens or additional debt, pay dividends, redeem stock, make specified investments and engage in merger, consolidation or asset sale transactions, among other restrictions. In addition, the inclusion of a going concern statement by our auditors, our lack of cash resources and our potential inability to continue as a going concern may materially adversely affect our share price and our ability to raise new capital or to enter into critical contractual relations with third parties.

Risks Relating to the Development and Regulatory Approval of Our Product Candidates

Clinical failure can occur at any stage of clinical development. Because the results of earlier clinical trials are not necessarily predictive of future results, any product candidate we advance through clinical trials may not have favorable results in later clinical trials or receive regulatory approval.

Clinical failure can occur at any stage of clinical development. Currently, patient enrollment has been suspended in our REGULATE-PCI trial until the Data Safety Monitoring Board, or the DSMB, has finished its currently ongoing complete review of efficacy and safety data and communicated its recommendations and the FDA has lifted its clinical hold on enrollment and dosing. Clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical or preclinical trials. In addition, data obtained from trials are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate. Frequently, product candidates that have shown promising results in early clinical trials have subsequently suffered significant setbacks in later clinical trials. Our REGULATE-PCI trial is significantly larger than our RADAR trial, and the results of the RADAR trial may not predict the outcome of a trial so much larger in size. In addition, the design of a clinical trial can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. While members of our management team have experience in designing clinical trials, our company has limited experience in designing clinical trials and we may be unable to design and execute a clinical trial to support regulatory approval. Further, clinical trials of potential products often reveal that it is not practical or feasible to continue development efforts. For example, if the results of our REGULATE-PCI trial do not achieve the primary efficacy endpoints or demonstrate expected safety, the prospects for approval of Revolixys would be materially and adversely affected. If Revolixys or our other product candidates are found to be unsafe or lack efficacy, we will not be able to obtain regulatory approval for them and our business would be harmed.

In addition to the DSMB's current complete review of efficacy and safety data from the REGULATE-PCI trial, the trial includes three interim analyses of Revolixys by the DSMB. The first interim analysis was a general safety analysis after enrollment of 1,000 subjects which occurred in late March 2014, and following which, the trial steering committee recommended that we open the trial to "all comers" pursuant to the trial protocol and the DSMB chair advised the principal investigators for the trial that he did not object to expanding enrollment in the trial at that time. The second interim analysis will be another general safety analysis after 25% of the subjects are enrolled, which prior to the suspension in enrollment, was expected to occur during the third quarter of 2014. The final interim analysis will be an analysis of the general safety and efficacy of Revolixys after 50% of the subjects are enrolled, which prior to the suspension in enrollment, was expected to occur during the fall of 2014. We cannot currently predict the timing of the second or third interim analyses and will not be able to do so until the DSMB has finished its currently ongoing complete review of efficacy and safety data and communicated its recommendations and the FDA has lifted its clinical hold on enrollment and dosing. In addition, the DSMB, the FDA or similar foreign regulatory agencies may initiate other unplanned reviews of the safety and efficacy data, or other aspects of our REGULATE-PCI trial or other clinical trials. If, as a result of any of those interim analyses, the current complete review or any unplanned review, we or the DSMB determine that Revolixys is not safe or that it is futile to continue the trial because of a lack of efficacy, the trial will be terminated. If the results of any one of these analyses is unfavorable, our business would be harmed.

We cannot be certain that Revolixys or any of our other product candidates will receive regulatory approval, and without regulatory approval we will not be able to market our product candidates. Any delay in the regulatory review or approval of Revolixys or any of our other product candidates will materially or adversely harm our business.

We have invested a significant portion of our efforts and financial resources in the development of Revolixys, our most advanced product candidate. Our ability to generate revenue related to product sales, which we do not expect will occur for at least the next several years, if ever, will depend on the successful development and regulatory approval of our product candidates. We commenced

our REGULATE-PCI trial in September 2013. In late March 2014, the 1,000th patient was enrolled in REGULATE-PCI. At that time, the trial steering committee recommended that we open the trial to "all comers" pursuant to the trial protocol. In early April, the DSMB chair advised the principal investigators for the trial that he did not object to expanding enrollment in the trial at that time. On July 2, 2014, we announced that the DSMB, in agreement with us, was initiating a complete review of efficacy and safety data from the REGULATE-PCI trial. This review was initiated as a result of various SAEs that were reported by certain site investigators at several sites around the world. As a result, we voluntarily suspended patient enrollment in the REGULATE-PCI trial until the DSMB completes its analysis and communicates its recommendations. In addition, on July 9, 2014 the FDA informed us that a clinical hold was placed on all patient enrollment and dosing of either study drug in the REGULATE-PCI trial. According to the FDA, this action was taken to formalize the involvement of the FDA in any decision to re-initiate enrollment and dosing in the trial in the future. During this period of data collection and analysis we and the principal investigators of the trial remain blinded. It is anticipated that the DSMB will complete their analysis by early September 2014. In addition, the DSMB, the FDA or similar foreign regulatory agencies may initiate unplanned reviews of the safety and efficacy data, or other aspects of our REGULATE-PCI trial or other clinical trials, which may delay or prevent regulatory approval for Revolixys or any of our other product candidates. We may conduct our REGULATE-PCI trial only to learn that Revolixys is not a safe or effective treatment, in which case the REGULATE-PCI trial may not lead to regulatory approval for Revolixys. Similarly, our clinical development programs for our other product candidates may not lead to regulatory approval from the FDA and similar foreign regulatory agencies. This failure to obtain regulatory approvals would prevent our product candidates from being marketed and would have a material and adverse effect on our business.

All of our product candidates require regulatory review and approval prior to commercialization. Any delays in the regulatory review or approval of our product candidates would delay market launch, increase our cash requirements and result in additional operating losses.

The process of obtaining FDA and other required regulatory approvals, including foreign approvals, often takes many years and can vary substantially based upon the type, complexity and novelty of the products involved. Furthermore, this approval process is extremely complex, expensive and uncertain. We may be unable to submit any new drug application, or an NDA, in the United States or any marketing approval application in foreign jurisdictions for any of our products. If we submit an NDA including any amended NDA or supplemental NDA, to the FDA seeking marketing approval for any of our product candidates, the FDA must decide whether to accept or reject the submission for filing. We cannot be certain that any of these submissions will be accepted for filing and reviewed by the FDA, or that the marketing approval application submissions to any other regulatory authorities will be accepted for filing and review by those authorities. We cannot be certain that we will be able to respond to any regulatory requests during the review period in a timely manner, or at all, without delaying potential regulatory action. We also cannot be certain that any of our product candidates will receive favorable recommendations from any FDA advisory committee or foreign regulatory bodies or be approved for marketing by the FDA or foreign regulatory authorities. In addition, delays in approvals or rejections of marketing applications may be based upon many factors, including regulatory requests for additional analyses, reports, data and studies, regulatory questions regarding data and results, changes in regulatory policy during the period of product development and the emergence of new information regarding Revolixys or our other product candidates.

Data obtained from preclinical studies and clinical trials are subject to different interpretations, which could delay, limit or prevent regulatory review or approval of any of our product candidates. Furthermore, regulatory attitudes towards the data and results required to demonstrate safety and efficacy can change over time and can be affected by many factors, such as the emergence of new information, including on other products, policy changes and agency funding, staffing and leadership. We do not know whether future changes to the regulatory environment will be favorable or unfavorable to our business prospects.

In addition, the environment in which our regulatory submissions may be reviewed changes over time. For example, average review times at the FDA for NDAs have fluctuated over the last ten years, and we cannot predict the review time for any of our submissions with any regulatory authorities. Review times can be affected by a variety of factors, including budget and funding levels and statutory, regulatory and policy changes. Moreover, in light of widely publicized events concerning the safety risk of certain drug products, regulatory authorities, members of the U.S. Government Accountability Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the withdrawal of drug products, revisions to drug labeling that further limit use of the drug products and establishment of REMS measures that may, for instance, restrict distribution of drug products. The increased attention to drug safety issues may result in a more cautious approach by the FDA to clinical trials, including its current approach to the clinical hold on our REGULATE-PCI trial. Data from clinical trials may receive greater scrutiny with respect to safety, which may make the FDA or other regulatory authorities more likely to terminate clinical trials, including our REGULATE-PCI trial, before completion, or require longer or additional clinical trials that may result in substantial additional expense and a delay or failure in obtaining approval or may result in approval for a more limited indication than originally sought.

Delays in the commencement, enrollment and completion of our clinical trials could result in increased costs to us and delay or limit our ability to obtain regulatory approval for Revolixys and our other product candidates.

Delays in the commencement, enrollment and completion of clinical trials could increase our product development costs or limit the regulatory approval of our product candidates. We commenced our REGULATE-PCI trial in September 2013. In late March 2014, the 1,000th patient was enrolled in REGULATE-PCI. At that time, the trial steering committee recommended that we open the trial to "all comers" pursuant to the trial protocol. In early April, the DSMB chair advised the principal investigators for the trial that he did not object to expanding enrollment in the trial at that time; however, this clinical trial is currently on clinical hold until both the DSMB has completed its currently ongoing complete review of efficacy and safety data and communicated its recommendations and the FDA has lifted its clinical hold on enrollment and dosing and may not be completed on schedule, if at all. In addition, we do not know whether planned clinical trials of Revolixys in additional indications and of our other product candidates will begin on time or will be completed on schedule or at all. The commencement, enrollment and completion of our REGULATE-PCI trial or other clinical trials can be delayed for a variety of reasons, including:

- unfavorable results or recommendations from the DSMB's current complete review of efficacy and safety data from the REGULATE-PCI trial or the FDA's failure to lift its clinical hold on enrollment and dosing;
- any unplanned reviews of our REGULATE-PCI trial or other clinical trials by the DSMB, the FDA or similar foreign regulatory agencies;
- inability to reach agreements on acceptable terms with prospective CROs and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- inability to maintain necessary supplies of study drug and comparator to maintain predicted enrollment rates at clinical trial sites;
- regulatory objections to commencing a clinical trial;
- inability to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs, including some that may be for the same indication as our product candidates;
- withdrawal of clinical trial sites from our clinical trials as a result of changing standards of care or the ineligibility of a site to participate in our clinical trials;
- inability to obtain institutional review board approval to conduct a clinical trial;
- difficulty recruiting and enrolling subjects to participate in clinical trials for a variety of reasons, including meeting the enrollment criteria for our study and competition from other clinical trial programs for the same indication as our product candidates;
- inability to retain subjects in clinical trials due to the treatment protocol, personal issues, side effects from the therapy or lack of efficacy; and
- difficulty in importing and exporting clinical trial materials and study samples.

In addition, our REGULATE-PCI trial or any of our other clinical trials may be suspended or terminated by us, the FDA or other regulatory authorities due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- failure to pass inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities;
- failure of any CMOs that we use to comply with current Good Manufacturing Practices, or cGMP;
- unfavorable results or recommendations from the DSMB's current complete review of efficacy and safety data from the REGULATE-PCI trial or the FDA's failure to lift its clinical hold on enrollment and dosing;
- unfavorable results or recommendations in any planned or unplanned reviews of our REGULATE-PCI trial or other clinical trials by the DSMB, the FDA or similar foreign regulatory agencies;
- unforeseen safety issues or any determination that a clinical trial presents unacceptable health risks;
- changes in the regulatory requirement and guidance; or
- lack of adequate funding to continue the clinical trial due to unforeseen costs resulting from enrollment delays, requirements to conduct additional trials and studies, increased expenses associated with the services of our CROs and other third parties or other reasons.

If we are required to conduct additional clinical trials or other testing of Revolixys or our other product candidates beyond those currently contemplated, we may be delayed in obtaining, or may not be able to obtain, marketing approval for these product candidates.

We have never conducted a Phase 3 clinical trial or submitted an NDA before, and may be unable to do so for Revolixys and other product candidates we are developing.

We commenced our REGULATE-PCI trial in September 2013. In late March 2014, the 1,000th patient was enrolled in REGULATE-PCI. At that time, the trial steering committee recommended that we open the trial to "all comers" pursuant to the trial protocol. In early April, the DSMB chair advised the principal investigators for the trial that he did not object to expanding enrollment in the trial at that time. On July 2, 2014, we announced that the DSMB, in agreement with us, was initiating a complete review of efficacy and safety data from the REGULATE-PCI trial. This review was initiated as a result of various SAEs that were reported by certain site investigators at several sites around the world. As a result, we voluntarily suspended patient enrollment in the REGULATE-PCI trial until the DSMB completes its analysis and communicates its recommendations. In addition, on July 9, 2014 the FDA informed us that a clinical hold was placed on all patient enrollment and dosing of either study drug in the REGULATE-PCI trial. According to the FDA, this action was taken to formalize the involvement of the FDA in any decision to re-initiate enrollment and dosing in the trial in the future. During this period of data collection and analysis we and the principal investigators of the trial remain blinded. It is anticipated that the DSMB will complete their analysis by early September 2014. The conduct of Phase 3 clinical trials and the submission of a successful NDA is a complicated process. Although members of our management team have extensive industry experience, including in the development, clinical testing and commercialization of drug candidates, our company has never

conducted a Phase 3 clinical trial before, has limited experience in preparing, submitting and prosecuting regulatory filings, and has not submitted an NDA before. Consequently, we may be unable to successfully and efficiently execute and complete these planned clinical trials in a way that leads to NDA submission and approval of Revolixys and other product candidates we are developing. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of product candidates that we develop. Failure to commence or complete, or delays in, our planned clinical trials would prevent or delay commercialization of Revolixys and other product candidates we are developing.

We have never performed a clinical trial comparing the safety or efficacy of Revolixys to bivalirudin. Because our RADAR clinical trials used heparin as a comparator, the risk that our REGULATE-PCI trial does not achieve one or more of its primary endpoints may be increased.

We have never performed a clinical trial directly comparing the safety or efficacy of Revolixys to bivalirudin. Our randomized, partially blinded, dose-ranging Phase 2b trial involving 640 subjects, or the RADAR trial, used standard of care heparin as the comparator and, as a result, we have no clinical trial data directly comparing Revolixys and bivalirudin. The primary efficacy endpoint of our REGULATE-PCI trial is a 20% reduction in the occurrence of ischemic events using Revolixys compared to bivalirudin and the primary safety endpoint of the trial is non-inferiority of Revolixys compared to bivalirudin with respect to major bleeding events. Because we have no clinical trial data directly comparing Revolixys to bivalirudin, the prediction of Phase 3 success based on Phase 2 results is complicated and the risk that REGULATE-PCI does not achieve one or more of these endpoints may be increased.

Risks Relating to Our Intellectual Property

It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection.

Our commercial success will depend in part on obtaining and maintaining proprietary rights important to our business, as well as successfully defending and enforcing those proprietary rights if challenged. The procurement, defense and enforcement of intellectual property rights involve complex legal and factual questions. Changes in either the patent laws or in interpretations of patent laws in the United States and foreign jurisdictions may diminish the value of our intellectual property. Laws relating to patent rights continue to evolve in the United States and foreign jurisdictions, as does their interpretation by national patent offices and judicial systems, creating some uncertainty for patent applicants, patent owners and licensees.

Our ability to stop third parties from using our technology or making, using, selling, offering to sell or importing our products is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. If any patent we currently or in the future may own or license is deemed invalid or unenforceable, it could impact our commercial success. We cannot predict the breadth of claims that may be issued from any patent applications we currently or may in the future own or license from third parties.

The degree of future protection our proprietary rights may afford is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to make, use, sell, offer to sell or import products that are similar to our product candidates but that are not covered by the claims of our patents;
- we might not have been the first to make the inventions covered by our patent portfolio;
- we might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies in a manner that does not violate our trade secrets;
- our proprietary rights may not provide us with any competitive advantages;
- we may not develop additional technologies or products that are patentable or suitable to maintain as trade secrets; or
- the proprietary rights of others may have an adverse effect on our business.

As of June 30, 2014, we are the owner of record of at least five issued or allowed U.S. patents and at least nine issued or allowed non-U.S. patents, as well as the licensee of at least ten issued or allowed U.S. patents and at least twelve issued or allowed non-U.S. patents. We are actively pursuing at least an additional 13 U.S. patent applications, of which four are provisional and nine are non-provisional, at least three international patent applications and at least 48 non-U.S. patent applications in at least twelve jurisdictions as the owner of record, in addition to at least two U.S. patent applications and at least 12 non-U.S. patent applications under license.

We also may rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. Our ability to stop third parties from making, using, selling, offering to sell or importing our products or practicing our technology is dependent in part upon the extent to which we have rights in enforceable trade secrets that cover these activities. Trade secret rights can be lost through disclosure to third parties. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our trade secrets to third parties, resulting in loss of trade secret protection. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how, which would not constitute a violation of our trade secret rights. Enforcing a claim that a third party is engaged in the unlawful use of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, recognition of rights in trade secrets and a willingness to enforce trade secrets may differ in certain jurisdictions.

Risks Relating to Ownership of Our Common Stock

We and certain of our officers and directors have been named as defendants in two purported securities class action lawsuits. These, and potential similar or related lawsuits, could result in substantial damages, divert management's time and attention from our business, and have a material adverse effect on our results of operations. These lawsuits and any other lawsuits to which we are subject will be costly to defend or pursue and are uncertain in their outcome.

Securities class action and derivative litigation has often been brought against companies, including many biotechnology companies, which experience volatility in the market price of their securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies often experience significant stock price volatility in connection with their product development programs.

On July 10, 2014, the first of two purported securities class action lawsuits was commenced in the United States District Court for the District of New Jersey, naming as defendants us and certain of our officers and directors. The lawsuits allege violations of the Securities Act of 1933 and the Securities Exchange Act of 1934 in connection with allegedly false and misleading statements made by us related to our Phase 3 trial of Revolixys in patients undergoing certain percutaneous coronary intervention procedures. Plaintiffs allege, among other things, that we failed to disclose facts related to the potential risk of several allergic reactions following the administration of Revolixys and therefore made false or misleading statements about Revolixys' safety. Plaintiffs seek damages and an award of reasonable costs and expenses, including attorney's fees.

It is possible that additional suits will be filed, or allegations received from stockholders, with respect to these same or other matters and also naming us and/or our officers and directors as defendants. These lawsuits and any other related lawsuits are subject to inherent uncertainties, and the actual defense and disposition costs will depend upon many unknown factors. The outcome of these lawsuits is necessarily uncertain. We could be forced to expend significant resources in the defense of these suits and we may not prevail. In addition, we may incur substantial legal fees and costs in connection with these lawsuits. We currently are not able to estimate the possible cost to us from these matters, as these lawsuits are currently at an early stage, and we cannot be certain how long it may take to resolve these matters or the possible amount of any damages that we may be required to pay. We have not established any reserve for any potential liability relating to these lawsuits. It is possible that we could, in the future, incur judgments or enter into settlements of claims for monetary damages. A decision adverse to our interests on these actions could result in the payment of substantial damages, or possibly fines, and could have a material adverse effect on our cash flow, results of operations and financial position.

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 60.5% of our common stock as estimated as of June 30, 2014. 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.

Transfer restrictions have recently lapsed with respect to a significant portion of our total outstanding shares of common stock, which may now be sold into the market. This could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur in the future. These sales, or the perception in the market that the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock. In connection with our IPO, our 2014 Private Placement and our April 2014 Offering, certain of our stockholders entered into "lock-up" agreements restricting their ability to sell shares of common stock held by them. The last of these transfer restrictions expired in July 2014, and as a result these shares can now be sold in the public market, subject only to compliance with securities laws to the extent such shares are not registered under the Securities Act of 1933, as amended. In addition, certain holders of shares of our common stock have rights, subject to some conditions, to require us to file registration statements covering the resale or other disposition of up to 9,396,767 shares of our common stock or to require us to include those shares in registration statements that we may file for ourselves or other stockholders.

You may be diluted by exercises of outstanding options and warrants.

As of June 30, 2014, we had outstanding options to purchase an aggregate of 4,369,807 shares of our common stock at a weighted average exercise price of $5.48 per share and warrants to purchase an aggregate of 9,356 shares of our common stock at a weighted average exercise price of $12.02 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, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We expect that significant additional capital will be needed in the future to complete development and, if approved, commercialization of Revolixys and 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. If we sell common stock, convertible securities or other equity securities, your investment in our common stock will be diluted. These sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

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 newly 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 The NASDAQ Capital Market, 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. In that regard, we currently do not have an internal audit function, and we need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge.

However, for as long as we remain an "emerging growth company" as defined in the 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 cannot predict or estimate the amount of additional costs we may incur as a result of our recent transition to becoming a public company or the timing of such costs.

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

(a) Use of Proceeds from Initial Public Offering of Common Stock

During the third quarter of 2013, we completed our IPO issuing 11,671,500 shares of common stock, inclusive of the exercise of the underwriters' overallotment option, at a price of $4.00 per share, resulting in net proceeds to us of approximately $41.1 million, after deducting approximately $3.3 million of underwriting discounts and commissions and offering-related expenses reasonably estimated to be $2.3 million. The offer and sale of all of the shares in the offering were registered under the Securities Act pursuant to a registration statement on Form S-1, which was declared effective on August 21, 2013 (File No. 333-188209). Cowen and Company, LLC and BMO Capital Markets Corp. acted as book-running managers for the offering and as representatives of the underwriters.

No offering costs were paid directly or indirectly to any of our director or officers or persons owning ten percent or more of any class of our equity securities or to any other affiliates, other than payments in the ordinary course of business to officers for salaries and to non-employee directors as compensation for board or board committee service. There has been no material change in the planned use of proceeds from our IPO as described in the final prospectus dated August 22, 2013 filed with the Securities and Exchange Commission pursuant to Rule 424(b) under the Securities Act on August 22, 2013. As of June 30, 2014, we have used all $41.1 million of our net IPO proceeds, primarily towards funding the REGULATE-PCI trial.

Item 3. Defaults upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Not applicable.

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.

Table of Contents

SIGNATURES

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

REGADO BIOSCIENCES, INC.

DATED: August 11, 2014

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

DATED: August 11, 2014

By: /s/ R. Don Elsey
R. Don Elsey
Senior Vice President, Finance and Chief Financial Officer
(Principal Accounting and Financial Officer)

Table of Contents

EXHIBIT INDEX

Exhibit No.	Description
10.1	Employment Agreement, dated April 25, 2014, by and between the Company and R. Don Elsey (incorporated by reference to Exhibit 10.1 of the Current Report on Form 8-K filed by the registrant on May 1, 2014 (SEC File No. 001-35953)).
10.2	Lease Agreement, dated April 30, 2014, by and between the Company and 106 Allen Road LLC (incorporated by reference to Exhibit 1.1 of the Current Report on Form 8-K filed by the registrant on May 5, 2014 (SEC File No. 001-35953)).
10.3	Employment Agreement, dated May 19, 2014, by and between the Company and Nicholas J. Pelliccione, Ph.D. (incorporated by reference to Exhibit 10.1 of the Current Report on Form 8-K filed by the registrant on May 19, 2014 (SEC File No. 001-35953))
10.4	Regado Biosciences, Inc. 2013 Equity Compensation Plan, as amended (incorporated by reference to Exhibit 10.1 of the Current Report on Form 8-K filed by the registrant on June 11, 2014 (SEC File No. 001-35953)).
31.1*	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a) of 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 Rule 13a-14(a) and 15d-14(a) of 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 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 PRINCIPAL EXECUTIVE OFFICER

I, David J. Mazzo, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarter ended June 30, 2014 of Regado Biosciences, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: August 11, 2014

/s/ David J. Mazzo
David J. Mazzo
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER

I, R. Don Elsey, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarter ended June 30, 2014 of Regado Biosciences, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: August 11, 2014

/s/ R. Don Elsey
R. Don Elsey
Senior Vice President, Finance and Chief Financial Officer
(Principal Accounting and Financial Officer)

Exhibit 32.1

CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO RULE 13a-14(b)
OF THE SECURITIES EXCHANGE ACT OF 1934 AND 18 U.S.C. SECTION 1350

In connection with the Quarterly Report on Form 10-Q of Regado Biosciences, Inc. (the "Company") for the quarter ended June 30, 2014 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, David J. Mazzo, Chief Executive Officer of the Company, hereby certifies, to the knowledge of the undersigned, pursuant to 18 U.S.C. Section 1350, 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) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 11, 2014

/s/ David J. Mazzo
David J. Mazzo
Chief Executive Officer
(Principal Executive Officer)

This Certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed "filed" by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and shall not be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Report, irrespective of any general incorporation language contained in such filing.

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 32.2

CERTIFICATION OF THE PRINCIPAL FINANCIAL OFFICER
PURSUANT TO RULE 13a-14(b)
OF THE SECURITIES EXCHANGE ACT OF 1934 AND 18 U.S.C. SECTION 1350

In connection with the Quarterly Report on Form 10-Q of Regado Biosciences, Inc. (the "Company") for the quarter ended June 30, 2014 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, R. Don Elsey, Senior Vice President, Finance and Chief Financial Officer of the Company, hereby certifies, to the knowledge of the undersigned, pursuant to 18 U.S.C. Section 1350, 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) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 11, 2014

/s/ R. Don Elsey
R. Don Elsey
Senior Vice President, Finance and Chief Financial Officer
(Principal Accounting and Financial Officer)

This Certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed "filed" by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and shall not be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Report, irrespective of any general incorporation language contained in such filing.

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.