Anthera Pharmaceuticals Inc
Form 10-Q
August 14, 2014

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2014

OR

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

For the transition period from to

Commission file number: 001-34637

ANTHERA PHARMACEUTICALS, INC.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	20-1852016
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
25801 Industrial Boulevard, Suite B Hayward, California (Address of Principal Executive Offices)	94545 (Zip Code)

(510) 856-5600
(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 x No o

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 x No o

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 o	Accelerated filer o
Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company x

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

As of August 1, 2014, the number of outstanding shares of the registrant's common stock, par value $0.001 per share, was 22,714,465.

ANTHERA PHARMACEUTICALS, INC.

FORM 10-Q FOR THE QUARTER ENDED JUNE 30, 2014

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PART I — FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

ANTHERA PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share amounts)
(unaudited)

	June 30, 2014	December 31, 2013
ASSETS		
Current assets:		
Cash and cash equivalents	$ 20,897	$ 25,946
Prepaid expenses and other current assets	421	358
Total current assets	21,318	26,304
Property and equipment — net	633	812
Restricted cash	1,900	10,000
Other assets	182	301
TOTAL	$ 24,033	$ 37,417
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,923	$ 3,519
Accrued clinical expenses	932	472
Accrued liabilities	777	474
Accrued payroll and related costs	554	319
Short-term portion of notes payable, net of discount	2,777	2,777
Total current liabilities	7,963	7,561
Notes payable, net of discount	5,609	15,098
Total liabilities	13,572	22,659
Commitments and Contingencies (Note 5)		
Stockholders' equity:		
Common stock, $0.001 par value, 100,000,000 shares authorized; 22,644,006 and 19,415,901 shares issued and outstanding as of June 30, 2014 and December 31, 2013, respectively	23	19
Additional paid-in capital	312,817	301,946
Accumulated deficit	(302,379)	(287,207)
Total stockholders' equity	10,461	14,758
TOTAL	$ 24,033	$ 37,417

See accompanying notes to consolidated financial statements.

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ANTHERA PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except share and per share data)
(unaudited)

	Three months ended June 30,		Six months ended June 30,	
	2014	2013	2014	2013
OPERATING EXPENSES:				
Research and development	$ 5,279	$ 5,265	$ 11,044	$ 10,194
General and administrative	1,586	1,688	3,430	3,660
Total operating expenses	6,865	6,953	14,474	13,854
LOSS FROM OPERATIONS	(6,865)	(6,953)	(14,474)	(13,854)
OTHER INCOME (EXPENSE):				
Other income (expense)	(31)	(6)	(79)	19
Interest expense	(360)	(1,322)	(619)	(2,026)
Total other income (expense)	(391)	(1,328)	(698)	(2,007)
NET LOSS	$ (7,256)	$ (8,281)	$ (15,172)	$ (15,861)
Net loss per share—basic and diluted	$ (0.34)	$ (0.43)	$ (0.73)	$ (0.92)
Weighted-average number of shares used in per share calculation—basic and diluted	21,479,386	19,059,130	20,805,162	17,297,098

See accompanying notes to consolidated financial statements.

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ANTHERA PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(in thousands)
(unaudited)

	Three months ended June 30,		Six months ended June 30,	
	2014	2013	2014	2013
Net loss	$ (7,256)	$ (8,281)	$ (15,172)	$ (15,861)
Unrealized gain (loss) on short term investments	—	7	—	3
Comprehensive loss	$ (7,256)	$ (8,274)	$ (15,172)	$ (15,858)

See accompanying notes to consolidated financial statements.

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ANTHERA PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)
(unaudited)

	Six Months Ended June 30,	
	2014	2013
CASH FLOW FROM OPERATING ACTIVITIES:		
Net loss	$ (15,172)	$ (15,861)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	179	175
Realized (gain)/loss on short-term investments	—	12
Stock-based compensation expense	1,292	1,960
Amortization of discount on notes payable	39	939
Amortization of debt issuance costs	42	141
Changes in assets and liabilities:		
Prepaid expenses and other assets	(63)	(126)
Accounts payable	(519)	(3,465)
Accrued clinical expenses	460	(2,545)
Accrued liabilities	339	(1,180)
Accrued payroll and related costs	218	155
Net cash used in operating activities	(13,185)	(19,795)
INVESTING ACTIVITIES:		
Proceeds from sale of short-term investments	—	4,172
Decrease (increase) in restricted cash	8,100	(10,000)
Net cash provided by (used) in investing activities	8,100	(5,828)
FINANCING ACTIVITIES:		
Proceeds from issuance of convertible notes and notes payable, net of issuance costs	—	19,798
Principal payment against note payable	(9,528)	(21,008)
Proceeds from issuance of common stock, net of offering costs	9,560	44,693
Withholding taxes paid on vested restricted stock units	—	(30)
Proceeds from issuance of common stock pursuant to employee stock purchase plan and exercise of stock options, net	4	44
Net cash provided by financing activities	36	43,497
Effect of exchange rates on cash and cash equivalents	—	(1)
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(5,049)	17,873
CASH AND CASH EQUIVALENTS — Beginning of period	25,946	19,431
CASH AND CASH EQUIVALENTS — End of period	$ 20,897	$ 37,304
SUPPLEMENTAL CASH DISCLOSURES OF CASH FLOW INFORMATION:		
Interest Paid	$ 414	$ 1,818

See accompanying notes to consolidated financial statements.

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ANTHERA PHARMACEUTICALS, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

1. ORGANIZATION AND SIGNIFICANT ACCOUNTING POLICIES

Organization

Anthera Pharmaceuticals, Inc. (the "Company" or "Anthera") was incorporated on September 9, 2004 in the state of Delaware. Anthera is a biopharmaceutical company focused on developing and commercializing therapeutics to treat autoimmune diseases. The Company's primary product candidate, blisibimod, targets elevated levels of B-cell activating factor, or BAFF, which has been associated with a variety of B-cell mediated autoimmune diseases, including systemic lupus erythematosus, or lupus, IgA nephropathy, lupus nephritis, multiple myeloma, and others. The Company's second product candidate, liprotamase, is an enzyme product intended for the treatment of exocrine pancreatic insufficiency ("EPI"), often seen in patients with cystic fibrosis and other conditions.

The Company's planned principal operations are acquiring product and technology rights, raising capital and performing research and development activities. The Company is currently conducting research and development activities to treat autoimmune diseases. The Company's activities are subject to significant risks and uncertainties. Successful completion of the Company's development programs and, ultimately, the attainment of profitable operations are dependent on future events, including, among other things, its ability to access potential markets; secure financing; develop a customer base; attract, retain and motivate qualified personnel; and develop strategic alliances.

Since inception in 2004, the Company has funded its operations through equity offerings, private placements of convertible debt and debt financings. During the three and six month period ended June 30, 2014, the Company incurred a net loss of $7.3 million and $15.2 million, respectively. Cash used in operating activities was approximately $13.2 million for the six months ended June 30, 2014. The Company expects to continue to incur substantial losses and negative cash flows from operations over the next several years during its clinical development phase. As of the date of this report, the Company anticipates its existing cash, cash equivalents and access to additional capital through an equity purchase agreement and equity offering are sufficient to fund its near term liquidity needs for at least the next 12 months.

To fully execute its business plan, the Company will need to complete certain research and development activities and clinical studies. Further, the Company's product candidates will require regulatory approval prior to commercialization. These activities may span many years and require substantial expenditures to complete and may ultimately be unsuccessful. Any delays in completing these activities could adversely impact the Company. The Company will need substantial additional financing to conduct new trials in the development of its product candidates; such financing may not be available on terms favorable to the Company, if at all. The Company plans to meet its capital requirements primarily through issuances of equity securities, debt financing, potential partnerships and in the longer term, revenue from product sales. Failure to generate revenue or raise additional capital would adversely affect the Company's ability to achieve its intended business objectives.

Basis of Presentation

The accompanying unaudited consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States, or U.S. GAAP, for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not contain all of the information

and footnotes required by U.S. GAAP for complete financial statements. In the opinion of management, the accompanying unaudited consolidated financial statements reflect all adjustments, which include only normal recurring adjustments necessary to present fairly the Company's interim consolidated financial information. The results for the three and six months ended June 30, 2014 are not necessarily indicative of the results to be expected for the year ending December 31, 2014 or for any other period. The consolidated balance sheet as of December 31, 2013 has been derived from the audited financial statements as of that date but it does not include all of the information and notes required by U.S. GAAP. The accompanying unaudited consolidated financial statements and notes thereto should be read in conjunction with the audited financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2013, filed with the Securities and Exchange Commission ("SEC") on March 28, 2014.

Significant Accounting Policies

There have been no changes in the Company's significant accounting policies for the three and six months ended June 30, 2014 as compared to the significant accounting policies described in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2013.

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Use of Estimates

The preparation of these consolidated financial statements in conformity with U.S. GAAP requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, expenses and related disclosures. On an ongoing basis, management evaluates its estimates, including critical accounting policies or estimates related to clinical trial accruals, tax provision, warrant valuation and stock-based compensation. The Company bases its estimates on historical experience and on various other market specific and other relevant assumptions that it believes 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 significantly from these estimates.

Recent Accounting Pronouncements

On June 10, 2014, the Financial Accounting Standard Board ("FASB") issued guidance intended to reduce the overall cost and complexity associated with financial reporting for development stage entities, without reducing the availability of relevant information, Accounting Standards Update No. 2014-10 ("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 removes all incremental financial reporting requirements from U.S. GAAP for development stage entities. The amendments made by ASU 2014-10 are effective for public business entities for annual reporting periods beginning after December 15, 2014, and interim periods therein. Early application of each of the amendments is permitted for any annual reporting period or interim period for which the entity's financial statements have not yet been issued. The Company elected to early adopt the new provision of ASU 2014-10 commencing in the interim period ended June 30, 2014 and therefore, has eliminated the presentation of inception-to-date information in this Quarterly Report on Form 10-Q.

2. NET LOSS PER SHARE

Basic net loss attributable to common stockholders per share is computed by dividing loss available to common stockholders (the numerator) by the weighted-average number of common shares outstanding (the denominator) during the period. Shares issued during the period and shares reacquired during the period are weighted for the portion of the period that they were outstanding. The computation of diluted Earnings Per Share, or EPS, is similar to the computation of basic EPS except that the denominator is increased to include the number of additional common shares that would have been outstanding if the dilutive potential common shares had been issued. In addition, in computing the dilutive effect of convertible securities, the numerator is adjusted to add back any convertible preferred dividends and the after-tax amount of interest recognized in the period associated with any convertible debt. The numerator also is adjusted for any other changes in income or loss that would result from the assumed conversion of those potential common shares, such as profit-sharing expenses. Diluted EPS is identical to basic EPS since common equivalent shares are excluded from the calculation, as their effect is anti-dilutive.

The following table summarizes the Company's calculation of net loss per common share (in thousands except share and per share amounts):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Net loss per share				
Numerator				
Net loss	$ (7,256)	$ (8,281)	$ (15,172)	$ (15,861)
Denominator				
	21,479,386	19,059,130	20,805,162	17,297,098

Denominator for basic and diluted net loss per share				
Basic and diluted net loss per share	$ (0.34)	$ (0.43)	$ (0.73)	$ (0.92)

As the Company incurred net losses for all of the periods presented, the following outstanding potentially dilutive securities were excluded from the computation of diluted net loss per share, as the effect of including them would have been antidilutive.

	Three and Six Months Ended June 30,	
	2014	2013
Options to purchase common stock	2,155,659	1,973,696
Warrants to purchase common stock	675,006	675,006
Restricted stock units	2,999	43,047
Total	2,833,664	2,691,749

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3. CASH EQUIVALENTS

At June 30, 2014 and December 31, 2013, the amortized cost and estimated fair value of investments are set forth in the following tables (in thousands):

	June 30, 2014		
	Amortized Cost	Gross Unrealized Losses	Estimated Fair Value
Cash	$ 550	$ —	$ 550
Money market funds	20,347	—	20,347
Total	$ 20,897	$ —	$ 20,897

	December 31, 2013		
	Amortized Cost	Gross Unrealized Losses	Estimated Fair Value
Cash	$ 1,006	$ —	$ 1,006
Money market funds	24,940	—	24,940
Total	$ 25,946	$ —	$ 25,946

4. FAIR VALUE OF FINANCIAL INSTRUMENTS

Pursuant to the accounting guidance for fair value measurement and its subsequent updates, fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (i.e., the “exit price”) in an orderly transaction between market participants at the measurement date. The accounting guidance establishes a hierarchy for inputs used in measuring fair value that minimizes the use of unobservable inputs by requiring the use of observable market data when available. Observable inputs are inputs that market participants would use in pricing the asset or liability based on active market data. Unobservable inputs are inputs that reflect the assumptions market participants would use in pricing the asset or liability based on the best information available in the circumstances.

The fair value hierarchy is broken down into the three input levels summarized below:

- Level 1 — Valuations are based on quoted prices in active markets for identical assets or liabilities and readily accessible by us at the reporting date. Examples of assets and liabilities utilizing Level 1 inputs are certain money market funds, U.S. Treasuries and trading securities with quoted prices on active markets.

- Level 2 — Valuations based on inputs other than the quoted prices in active markets that are observable either directly or indirectly in active markets. Examples of assets and liabilities utilizing Level 2 inputs are U.S. government agency bonds, corporate bonds, commercial paper, certificates of deposit and over-the-counter derivatives.

- Level 3 — Valuations based on unobservable inputs in which there is little or no market data, which require us to develop our own assumptions.

The following tables present the Company’s fair value hierarchy for all its financial assets (including those in cash and cash equivalents), in thousands, by major security type measured at fair value on a recurring basis:

	June 30, 2014			
	Estimated	Level 1	Level 2	Level 3

	Fair Value			
Money market funds	$ 20,347	$ 20,347	$ —	$ —

	December 31, 2013			
	Estimated Fair Value	Level 1	Level 2	Level 3
Money market funds	$ 24,940	$ 24,940	$ —	$ —

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At June 30, 2014 and December 31, 2013, the fair value of the principal amount of the Company's outstanding notes payable are classified within the hierarchy as follows (in thousands):

	June 30, 2014			
	Estimated Fair Value	Level 1	Level 2	Level 3
Notes Payable ($8,566, net of $180 note discount)	$ 8,386	$ —	$ —	$ 8,386

	December 31, 2013			
	Estimated Fair Value	Level 1	Level 2	Level 3
Notes Payable ($18,095, net of $220 note discount)	$ 17,875	$ —	$ —	$ 17,875

The fair value of notes payable is estimated based on current interest rates available to the Company for debt instruments in similar terms, degrees of risk and remaining maturities. The carrying value of these obligations, as of each period presented, approximate their respective fair values. For disclosure purposes, the fair value of the principal amount of the Company's outstanding debt obligations is considered to be a Level 3 measurement.

There were no transfers between Level 1, Level 2 or Level 3 for the periods ended June 30, 2014 and 2013.

5. COMMITMENTS AND CONTINGENCIES

Leases

The Company leases its main operating facility in Hayward, California. The lease is for approximately 14,000 square feet and expires in September 2017. The Company recognizes rental expense on the facility on a straight line basis over the term of the lease. Differences between the straight-line net expenses on rent payments is classified as deferred rent liability and included in the accrued liabilities on the balance sheet.

Other Commitments

In December 2007, the Company and Amgen, Inc. ("Amgen") entered into a worldwide, exclusive license agreement (the "Amgen Agreement") to develop and commercialize blisibimod in any indication, including for the treatment of systemic lupus erythematosus ("lupus"). Under the terms of the Amgen Agreement, the Company paid a nonrefundable, upfront license fee of $6.0 million. As there was no future alternative use for the technology, the Company expensed the license fee in research and development expenses during 2007.

Under the terms of the Amgen Agreement, the Company is obligated to make additional milestone payments to Amgen of up to $33.0 million upon the achievement of certain development and regulatory milestones. The Company is also obligated to pay tiered royalties on future net sales of products, ranging from the high single digits to the low double digits. The Company's royalty obligations as to a particular licensed product will be payable, on a country-by-country and licensed product-by-licensed product basis, for the longer of (a) the date of expiration of the last to expire valid claim within the licensed patents that covers the manufacture, use or sale, offer to sell or import of such licensed product by the Company or a sublicense in such country or (b) 10 years after the first commercial sale of the applicable licensed product in the applicable country. As of June 30, 2014, there were no outstanding obligations due to Amgen.

6. NOTES PAYABLE

In March 2011, the Company entered into a Loan and Security Agreement ("Loan Agreement") with Hercules Technology Growth Capital, Inc. and Hercules Technology II, L.P. (together, "Hercules"). In conjunction with the Hercules loan, the Company issued a seven-year warrant to purchase 40,178 shares of the Company's common stock at an exercise price of $48.00 per share. The warrant was immediately exercisable and expires in March 2018. The Company estimated the fair value of this warrant using the Black-Scholes option valuation model with the following assumptions: expected term of seven years, a risk-free interest rate of 2.87%, expected volatility of 63% and 0% expected dividend yield, resulting in a $1.3 million discount from the par value of the loan, which was amortized as additional interest expense over the term of the loan using the effective interest rate method. Additionally, the Company was obligated to pay an end of the term charge of $937,500, which was also being expensed over the term of the loan. The Company repaid indebtedness under the Loan Agreement in full on April 3, 2013 in conjunction with the Company's debt refinance (see below). The unamortized note discount and end of term charge was fully expensed to interest expense in April 2013 as a result of the payoff. As of June 30, 2014, the warrant remained outstanding and exercisable.

On April 3, 2013, the Company entered a Credit and Security Agreement (the "Midcap Credit Agreement") with MidCap Financial SBIC, LP ("Midcap"), pursuant to which Midcap made a $10.0 million loan (the "Midcap Loan") to the Company. Proceeds from the Midcap Loan were used to repay the entire outstanding principal and end of term charge due to Hercules. The MidCap Credit Agreement matures on October 3, 2016 and the loan bears interest at an annual rate equal to 9.75%. Additionally, the Company is also obligated to pay an end of term charge of $400,000, which is being expensed over the term of the Midcap Credit Agreement using the effective interest rate method. Interest and principal are payable in cash on a monthly basis beginning May 1, 2013. At June 30, 2014, the outstanding principal owed under the Midcap Credit Agreement was $6.7 million.

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The loan is secured by a pledge of substantially all assets of the Company, excluding intellectual property as well as the Cash Security Account (see further discussion below). In conjunction with the Midcap Loan, the Company issued a warrant to purchase 73,529 shares of its common stock, at an exercise price of $5.44 per share. The warrant was immediately exercisable and expires on October 3, 2016. The Company estimated the fair value of this warrant using the Black-Scholes option valuation model with the following assumptions: expected term of 3.5 years, a risk-free interest rate of 0.39%, expected volatility of 124% and 0% expected dividend yield. The Company applied the relative fair value method to allocate the $10.0 million proceeds received under the MidCap Credit Agreement between the loan and warrant. The initial carrying amount assigned to the loan was $9.7 million and was recorded as Notes payable—net of discount on the Company's balance sheet. The fair value allocated to the warrant of $280,000 was recorded as an increase to additional paid-in capital in the Company's balance sheet. The resulting $280,000 discount from the $10.0 million par value of the loan is amortized as an additional interest expense over the term of the loan using the effective interest rate method. At June 30, 2014, this warrant remained outstanding and exercisable.

On April 3, 2013, the Company entered into a Loan and Security Agreement (the "Square 1 Loan Agreement") with Square 1 Bank, pursuant to which Square 1 Bank made a $10.0 million loan to the Company. The proceeds of such loan are used exclusively to fund a cash security account (the "Cash Security Account") at Square 1 Bank. The term loan under the Square 1 Loan Agreement matures on April 3, 2017 and bears interest at an annual rate equal to 1.00%. Interest is payable in cash on a monthly basis starting May 1, 2013 and the principal is payable in a lump sum upon maturity of the term loan. However, the Company may prepay the principal in whole or in part from time to time without penalty or premium. For the six months ended June 30, 2014, the Company repaid $8.1 million in principal to Square 1 Bank. At June 30, 2014, the outstanding principal owed under the Square 1 Loan Agreement was $1.9 million.

The Square 1 Loan Agreement contains customary representations and warranties and certain affirmative and negative covenants including, among other things, maintenance of a balance in the Cash Security Account of not less than the lesser of (a) $10.0 million and (b) the aggregate amount all debt, principal, interest and other amounts owed to Square 1 Bank in the Cash Security Account, and restrictions on mergers. The loan under the Square 1 Term Loan Agreement is not guaranteed by any of the Company's existing subsidiaries, nor have any existing subsidiaries of the Company pledged any of their assets to secure the loan.

In connection with the Midcap and Square 1 Agreements, the Company incurred note issuance costs of approximately $298,000, which are recorded as long-term assets on the Company's balance sheet. The note issuance costs are being amortized to interest expense over the term of the Loan Agreements using the effective interest rate method.

7. STOCKHOLDERS' EQUITY

Common Stock

Prior to the Company's initial public offering ("IPO"), the Company funded its operations through private equity offerings and placements of convertible debt, raising net proceeds of approximately $47.6 million. In connection with the completion of the IPO in February 2010, all of the Company's shares of preferred stock outstanding at the time of the offering were converted into common stock and no liquidation preference remained.

In July and September 2009, the Company sold (i) convertible promissory notes, ("2009 Notes") and (ii) warrants, ("2009 Warrants"), to purchase shares of the Company's equity securities to certain of its investors for an aggregate purchase price of $10.0 million. The 2009 Notes and accrued interest were converted into shares of the Company's common stock at a discount of 25% in March 2010 upon the closing of the Company's IPO. The 2009 Warrants carry an exercise price of $56.00 per share. Each of the 2009 Warrants is exercisable in whole or in part at any time until the latest date of September 9, 2014. Each of the warrants contains a net issuance feature, which allows the warrant holder

to pay the exercise price of the warrant by forfeiting a portion of the exercised warrant shares with a value equal to the aggregate exercise. The Company accounted for the warrants in accordance with Accounting Standards Codification 815, Derivatives and Hedging ("ASC 815") and measured the fair value of the 2009 Warrants using the Black-Scholes option pricing model on issuance date and adjusted the fair value at the end of each reporting period until conversion of the 2009 Notes into shares of common stock at the completion of the Company's IPO. As of June 30, 2014, warrants to purchase 44,639 shares of common stock remained outstanding and exercisable.

In February 2010, the Company's Registration Statement on Form S-1 was declared effective for its IPO, pursuant to which the Company sold 750,000 shares of its common stock at a public offering price of $56.00 per share. The Company received net proceeds of approximately $37.1 million from this transaction. Concurrent with the closing of the IPO, the Company received an aggregate of $17.1 million from the issuance of 324,847 shares of its common stock to certain of its investors pursuant to a common stock purchase agreement.

In April 2010, the Company sold 75,561 shares of common stock pursuant to the exercise of the underwriters' over-allotment option in connection with the Company's IPO and received net proceeds of approximately $4.0 million.

In September 2010, the Company completed a private placement transaction with certain accredited investors pursuant to which the Company sold an aggregate of 1,312,492 units at a purchase price of $24.00 per unit, with each unit consisting of one share of common stock and a warrant to purchase an additional 0.40 shares of common stock. Each warrant is exercisable in whole or in part at any time until September 24, 2015 at a per share exercise price of $26.40, subject to certain adjustments as specified in the warrant. The Company received net proceeds of approximately $22.8 million. The exercise price of the warrants became fixed on July 24, 2012 upon the closing of an equity offering by the Company pursuant to which the Company sold common stock at $8.00 per share, which triggered an adjustment to the exercise price of the warrants to a floor price of $23.20 per share as specified in the warrants.

In June 2011, the Company utilized its shelf registration statement to sell 958,333 shares of its common stock at $60.00 per share. The Company received net proceeds of approximately $53.9 million.

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In January 2012, the Company filed a universal shelf registration statement with the SEC on Form S-3 (which File No. 333-179043), which was declared effective on January 24, 2012, for the proposed offering from time to time of up to $100.0 million in shares of its securities, including common stock, preferred stock, debt securities and/or warrants. In July 2012, the Company issued 4,743,750 shares of its common stock at $8.00 per share pursuant to the shelf registration, raising net proceeds of approximately $35.6 million. In January 2013, the Company issued 7,575,757 shares of common stock at $5.28 per share under the shelf registration statement at an initial closing of a public offering, followed by 1,136,362 shares at a second closing in February 2013, raising net proceeds of approximately $42.7 million. In April 2013, the Company increased the amount of securities that may be issued under the registration statement by $3.2 million through the filing of a post-effective amendment pursuant to Rule 462(b) of the Securities Act. On April 5, 2013, the Company entered into an equity purchase agreement (the "Purchase Agreement") with Lincoln Park Capital Fund, LLC ("LPC"), pursuant to which the Company has the right to sell to LPC up to an aggregate of $18.5 million of the Company's common stock. Upon executing the agreement, LPC made an initial purchase of $2.0 million of common stock. Subsequent to the initial purchase, the Company has sold approximately $1.6 million of common stock to LPC as of June 30, 2014, which results in approximately $14.9 million of the Company's common stock remaining available to be sold under the Purchase Agreement. In April 2013, the Company registered approximately $19.0 million for sale under the LPC Purchase Agreement, leaving a balance of approximately $0.2 million under this shelf registration statement for future issuance as of June 30, 2014.

On April 5, 2013, the Company filed a universal shelf registration statement with the SEC on Form S-3 (File No. 333-187780) for the proposed offering from time to time of up to $100.0 million of its securities, including common stock, preferred stock, debt securities and/or warrants. On November 15, 2013, the Company entered into a Sales Agreement (the "Agreement") with Cowen and Company, LLC ("Cowen") to create an at-the-market equity program ("ATM") under which the Company from time to time may offer and sell shares of its common stock, par value $0.001 per share, having an aggregate offering price of up to $25.0 million through Cowen, as agent. The Company registered $25.0 million under the registration statement for the ATM. As of June 30, 2014, the Company had sold $9.4 million of common stock pursuant to the ATM and $15.6 million remained available for future issuance under this ATM. In addition, $75 million remained available for future issuance under the S-3 shelf registration statement.

8. SHARE-BASED COMPENSATION PLANS

Option Plans

On March 25, 2013, the Company's board of directors adopted the 2013 Stock Option and Incentive Plan (the "2013 Plan"), which was also approved by the Company's stockholders at its annual general meeting on May 16, 2013. The Company initially reserved 1,750,000 shares of its common stock for the issuance of awards under the 2013 Plan, plus all shares remaining available for grant under the Company's 2010 Stock Option and Incentive Plan (the "2010 Plan"), plus any additional shares returned under the 2010 Plan or 2013 Plan as a result of the cancellation, forfeiture or other termination (other than by exercise or forfeiture to satisfy tax withholding) of awards issued pursuant to the 2010 Plan or 2013 Plan, subject in all cases to adjustment including reorganization, recapitalization, reclassification, stock dividend, stock split, reverse stock split or other similar change in the Company's capital stock. In June 2014, the Company's stockholders approved an increase of 500,000 shares of common stock for future issuance under the 2013 Plan. Of the shares of common stock reserved for issuance under the 2013 Plan, no more than 750,000 shares will be issued to any individual participant as incentive options, non-qualified options or stock appreciation rights during any calendar year. The 2013 Plan permits the granting of incentive and non-statutory stock options, restricted and unrestricted stock awards, restricted stock units, stock appreciation rights, performance share awards, cash-based awards and dividend equivalent rights to eligible employees, directors and consultants. The option exercise price of an option granted under the 2013 Plan may not be less than 100% of the fair market value of a share of the Company's common stock on the date the stock option is granted. Options granted under the 2013 Plan have a maximum term of 10 years and generally vest over four years. In addition, in the case of certain large stockholders, the minimum

exercise price of incentive options must equal 110% of fair market value on the date of grant and the maximum term is limited to five years. Subject to overall 2013 Plan limitations, the maximum aggregate number of shares of common stock that may be issued in the form of incentive options shall not exceed 6,250,000 shares of common stock.

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The 2013 Plan does not allow the option holders to exercise their options prior to vesting.

The terms of awards granted during the three and six months ended June 30, 2014 and the methods for determining the grant date fair value of the awards were consistent with those described in the financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2013.

The following table summarizes stock option activity under the Company's share-based compensation plans for the six months ended June 30, 2014 (in thousands except share and per share amounts):

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life in Years	Aggregate Intrinsic Value
Balance at December 31, 2013	1,997,075	$ 5.21	9.11	$ 48
Granted	235,493	$ 3.32		
Exercised	(2,000)	$ 2.08		
Cancelled and expired	(52,297)	$ 6.90		
Forfeited	(22,612)	$ 4.82		
Balance at June 30, 2014	2,155,659	$ 4.97	8.82	$ 101
Vested at June 30, 2014	672,052	$ 5.79	8.36	$ 66

The intrinsic value of stock options represents the difference between the exercise price of stock options and the market price of the Company's stock as of June 30, 2014 for all the options that are in the money.

As of June 30, 2014, the number of vested and expected to vest stock options was 2,125,453 and there were 982,473 shares available for future issuance under the 2013 Plan.

2010 Employee Stock Purchase Plan

Effective July 2010, under the terms of the 2010 Employee Stock Purchase Plan (the "ESPP"), eligible employees of the Company may authorize the Company to deduct amounts from their compensation, which amounts are used to enable the employees to purchase shares of the Company's common stock. The Company initially reserved 12,500 shares of common stock for issuance thereunder plus on January 1, 2011 and each January 1 thereafter, the number of shares of stock reserved and available for issuance under the ESPP shall be cumulatively increased by the lesser of (i) one percent (1%) of the number of shares of common stock issued and outstanding on the immediately preceding December 31 or (ii) 31,250 shares of common stock. On January 1, 2014, in accordance with the ESPP's annual increase provisions, the authorized shares in the ESPP increased by 31,250.

The purchase price per share is 85% of the fair market value of the common stock as of the first date or the ending date of the applicable semi-annual purchase period, whichever is less (the "Look-Back Provision"). The 15% discount and Look-Back Provision make the ESPP compensatory. No shares were issued pursuant to the ESPP during the six months ended June 30, 2014 and 2013.

Restricted Stock Units

The Company grants restricted stock unit awards ("RSUs") under its 2013 Plan and 2010 Plan, as determined by the Company's compensation committee. The RSUs granted represent a right to receive shares of common stock at a future date determined in accordance with the participant's award agreement. An exercise price and monetary payment

are not required for receipt of RSUs or the shares issued in settlement of the award. Instead, consideration is furnished in the form of the participant's services to the Company.

Recipients of RSUs granted from the 2013 Plan are not permitted to net share settle in excess of the minimum statutory withholding amount for taxes and therefore, in accordance with guidance issued by the FASB, RSUs granted from the 2013 Plan are classified as equity and the fair value of the awards are recognized on a straight-line basis over the vesting term of the awards.

Recipients of RSUs granted from the 2010 Plan are permitted to net share settle in excess of the minimum statutory withholding amount for taxes and therefore, in accordance with guidance issued by the FASB, RSUs granted from the 2010 Plan are classified as liability with the subsequent change in fair value being recorded as expense. The unsettled RSUs are re-measured at each reporting date and will continue to be re-measured until they are fully vested in approximately 1.40 years. Any changes in valuation are recorded as compensation expense for the period. As of June 30, 2014, the liability related to the unsettled awards was not significant.

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The following table summarizes activity related to the Company's restricted stock units and awards:

	Shares	Weighted-Average Grant Date Fair Value	Weighted-Average Remaining Contractual Life in Years
Outstanding at December 31, 2013	42,042	$11.06	0.33
RSUs granted	45,226	$3.30	
RSUs released	(84,269)	$3.25	
Outstanding at June 30, 2014	2,999	$2.51	7.51

Compensation expense for stock options and stock purchase rights granted is based on the grant date fair value and is recognized over the vesting period of the applicable option on a straight-line basis. The estimated grant date fair values of employee stock options and stock purchase rights were calculated using the Black-Scholes option pricing model. Option pricing models require the input of subjective assumptions and these assumptions can vary over time. The assumptions used to calculate the estimated grant date fair values of employee stock options and stock purchase rights were as follows:

Stock Option Plans

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Expected Volatility	90%	85%	95%	85%
Dividend Yield	0%	0%	0%	0%
Risk-Free Interest Rate	0.50%	0.62%	1.32%	0.62%
Expected Term (years)	1.97	4.0	4.03	4.0
Weighted-average fair value per share	$ 1.49	$ 2.97	$ 2.09	$ 2.97

ESPP

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Expected Volatility	—	126%	—	126%
Dividend Yield	—	0%	—	0%
Risk-Free Interest Rate	—	0.11%	—	0.11%
Expected Term (years)	—	0.5	—	0.5

Total stock-based compensation expense for equity awards recognized was as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Research and development	$ 187	$ 95	$ 541	$ 996
General and administrative	269	168	751	964
Total stock-based compensation	$ 456	$ 263	$ 1,292	$ 1,960

As of June 30, 2014, there was $4.6 million of unrecognized compensation expense related to options. The unrecognized compensation expense is expected to be recognized over a weighted-average remaining period of 2.75 years.

9. SUBSEQUENT EVENT

On July 11, 2014, the Company entered into a license agreement (the "License Agreement") with Eli Lilly and Company ("Eli Lilly"), pursuant to which the Company obtained an exclusive worldwide license to certain technology and compounds relating to the Phase 3 novel investigational Pancreatic Enzyme Replacement Therapy ("PERT"), Sollpura ™ (liprotamase), intended for the treatment of patients with Exocrine Pancreatic Insufficiency, or EPI, often seen in patients with cystic fibrosis and other conditions.

Under the terms of the License Agreement, the Company obtained (i) exclusive rights to develop, make, have made, use, import, offer for sale and sell licensed compounds and pharmaceutical formulations thereof, including liprotamase and (ii) certain rights to grant sublicenses. The licensed patent rights include a specific set of previously filed U.S. and foreign patents and patent applications, as well as any patent applications filed after the execution date by Eli Lilly that relate to licensed know-how.

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The Company assumes sole control of and responsibility for all aspects of developing, obtaining regulatory approval for, and commercializing the licensed products worldwide. Anthera, either on its own or through its sublicensees, is obligated to use commercially reasonable efforts to undertake all development work necessary to obtain regulatory approval for at least one licensed product in the United States and at least one licensed product in each of the Additional Countries, as defined in the License Agreement. In addition, Anthera, either on its own or through its sublicensees, is obligated to use commercially reasonable efforts to promote, market and sell licensed products for which regulatory approval has been obtained, in the countries of such approval.

Under the terms of the License Agreement, the Company is obligated to make milestone payments of up to $43 million upon the achievement of certain regulatory and commercial sales milestones. In addition, after sales of the licensed products have exceeded an aggregate of $100 million in the United States, the Company is obligated to pay tiered royalties on future net sales of products, ranging from the high single digits to the low mid-double digits, that are developed and approved as defined in the License Agreement. The Company's royalty obligations as to a particular licensed product will be payable, on a licensed product-by-licensed product basis, for the longer of (a) the date of expiration of the last to expire valid claim within the licensed patents that covers the manufacture, use or sale, offer to sell, or import of such licensed product by the Company or a sublicense in such country, or (b) 12 years after the first commercial sale of the applicable licensed product in the applicable country.

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ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This Quarterly Report on Form 10-Q 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 (the "Exchange Act"), which are subject to the "safe harbor" created by those sections. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. All statements other than statements of historical factors are "forward-looking statements" for purposes of these provisions. In some cases you can identify forward-looking statements by terms such as "may," "will," "should," "could," "would," "expec "plan," "anticipate," "believe," "estimate," "project," "predict," "potential" and similar expressions intended to identify forward-looking statements. Such forward-looking statements are subject to risks, uncertainties and other important factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified below and those discussed in the section titled "Risk Factors" in this report. Furthermore, such forward-looking statements speak only as of the date of this report. Except as required by law, we undertake no obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements.

Overview

Anthera Pharmaceuticals, Inc. is a biopharmaceutical company that incorporated as a Delaware corporation in September 2004. Our focus is on the development and commercialization of products to treat serious diseases associated with inflammation and autoimmune diseases. Our primary Phase 3 product candidate, blisibimod, targets B-cell activating factor, or BAFF, which has been shown to be elevated in a variety of B-cell mediated autoimmune diseases, including systemic lupus erythematosus, (lupus), Immunoglobin A nephropathy (IgA nephropathy), lupus nephritis, vasculitis and others. Elevated BAFF is also reported in hematological diseases such as multiple myeloma and idiopathic thrombocytopenia purpura. Our second product candidate, Sollpura TM (liprotamase), was acquired by the Company in July 2014 from Eli Lilly and Company ("Eli Lilly"). Liprotamase is a Phase 3 novel investigational Pancreatic Enzyme Replacement Therapy ("PERT") intended for the treatment of patients with Exocrine Pancreatic Insufficiency, or EPI, often seen in patients with cystic fibrosis and other conditions.

Since inception, we have funded our operations through equity offerings, private placements of convertible debt and debt financings. We will need substantial additional financing to continue to develop our product candidates, obtain regulatory approvals and to fund operating expenses, which we will seek to raise through public or private equity or debt financings, collaborative or other arrangements with third parties or through other sources of financing. We cannot assure you that such funds will be available on terms favorable to us, if at all. We may never successfully complete development of any of our product candidates, obtain adequate patent protection for our technology, obtain necessary government regulatory approval for our product candidates or achieve commercial viability for any approved product candidates. In addition, we may not be profitable even if we succeed in commercializing our product candidates.

Our BAFF Antagonism Portfolio

BAFF, also known as B lymphocyte stimulator or BLyS, is a tumor necrosis family member and is critical to the development, maintenance and survival of multiple B-cell lineages as well as plasma cells. B-cells and plasma cells are a vital part of the human immune system, producing natural antibody responses to invading pathogens such as viruses. Abnormal elevations in BAFF, B-cells and plasma cells have been associated with several autoimmune diseases. BAFF is primarily expressed by macrophages, monocytes and dendritic cells and interacts with three different receptors on B-cells and plasma cells including BAFF receptor, or BAFF-R, B-cell maturation antigen, or

BCMA, and transmembrane activator and cyclophilin ligand interactor, or TACI. The potential role of BAFF inhibition and associated reductions in B-cell and plasma cell numbers in lupus and rheumatoid arthritis has been validated in multiple clinical studies with blisibimod and other BAFF antagonists. Based on data from our Phase 2b clinical study, we have advanced the clinical development of our BAFF inhibitor, blisibimod, to exploit its potential clinical utility in a number of autoimmune diseases. Blisibimod, a peptibody directed against BAFF, was developed as an alternative to antibodies and is produced in Escherichia coli bacterial culture, as opposed to antibodies that are typically produced in mammalian cell culture. A peptibody is a novel fusion protein that is distinct from an antibody with several potential advantages, including ease of manufacture, potency and relatively small molecular weight. Blisibimod inhibits both soluble and membrane-bound BAFF. We have worldwide rights to blisibimod for all potential indications.

In 2012, we completed the PEARL-SC Phase 2b clinical study, which evaluated the efficacy and safety of multiple doses of subcutaneous blisibimod versus placebo in patients with active and seropositive lupus. Lupus patients suffer from a chronic autoimmune disease, where an inappropriate or abnormal immune response often leads to severe skin rash, fatigue, joint pain, ulceration, major kidney complications, including proteinuria, and cardiovascular disease. Inhibition of BAFF is believed to reduce survival of B-cells and plasma cells and autoantibodies, leading to a reduction in severity of disease and resolution of lupus symptoms.

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The development program for blisibimod is focused on evaluating the efficacy and safety of blisibimod in patients with lupus, IgA nephropathy and multiple myeloma for which we believe current treatments are either inadequate or non-existent. Our current plan includes continuing the ongoing CHABLIS-SC1 registration clinical study in patients with active lupus and the BRIGHT-SC phase 2/3 clinical study in patients with IgA nephropathy, and evaluating the potential of blisibimod in hematological diseases through clinical and nonclinical investigations. We have successfully manufactured blisibimod at launch-scale quantities. The blisibimod product is designed for at-home, self-administration and is presented as a pre-filled syringe for subcutaneous administration. We are actively pursuing various partnerships with major pharmaceutical and biotech companies to develop and commercialize blisibimod for both lupus and IgA nephropathy in territories outside the United States.

Our Pancreatic Enzyme Replacement Therapy Portfolio

Pancreatic enzyme replacement therapy is currently the mainstay of treatment for nutrient malabsorption in patients with digestive enzyme deficiencies known as EPI. EPI occurs when diseases such as cystic fibrosis, or CF, and chronic pancreatitis impede or destroy the exocrine function of the pancreas. Orally delivered porcine PERTs have been available for many years for the treatment of EPI. Sollpura is a novel non-porcine PERT that contains three biotechnology-derived digestive enzymes: a cross-linked crystallized lipase, a crystallized protease and an amorphous amylase. Liprotamase was studied from 2002 to 2009 in seven clinical studies, two of which were short-term efficacy trials.

Unmet medical needs for the treatment of EPI remain. For example, as the porcine-derived proteins contained in the PERTs pass through the low pH environment of the stomach, enzyme activity rapidly diminishes and, as a consequence, large doses of porcine enzymes are often required. Since protease and lipase can become irreversibly inactivated in an acid environment, most products are provided as enteric-coated microbeads. Patient-to-patient variability in acidification of the intestine makes dissolution variable. Poor stability and variability in terms of potency and pharmaceutical properties have also been identified as important factors contributing to a poor response of some patients to PERTs.

Sollpura is more stable in the low pH environment of the stomach and unlike porcine-derived PERTs, does not have an enteric polymer coating, nor does it contain porcine proteins or purines that could cause allergic reactions.

Completed clinical trials by Eli Lilly demonstrated that dietary fat and nitrogen (protein) absorption are significantly increased in patients with cystic fibrosis and EPI who received Sollpura. In 2013, Eli Lilly gained agreement from the U.S. Food and Drug Administration (“U.S. FDA”) on the design of a pivotal trial that would provide adequate evaluation of efficacy and safety.

Product Development Programs

Blisibimod

Our Systemic Lupus Erythematosus (Lupus) Development Program

In the third quarter of 2012 at an End of Phase 2 meeting with the U.S. FDA, we presented the results of the PEARL-SC clinical study and our plans for Phase 3 registration studies in patients with active lupus. As a result of this meeting we initiated patient enrollment in the initial Phase 3 CHABLIS-SC1 study in March 2013.

CHABLIS-SC1 is a multicenter, randomized, double-blind, placebo-controlled study designed to evaluate the efficacy, safety, tolerability and immunogenicity of blisibimod in patients with seropositive, clinically-active lupus (SELENA-SLEDAI > 10) who require corticosteroid therapy in addition to standard-of-care for treatment of their

disease. The study plans to randomize up to 400 patients to receive either 200mg of blisibimod or placebo for 52 weeks. As agreed with the U.S. FDA, the primary endpoint of the CHABLIS-SC1 will be clinical improvement in the SRI-8 response at 52 weeks. Key secondary outcomes from the study, including reduction of flare and steroid use, are intended to further differentiate blisibimod from currently available therapies. CHABLIS-SC1 is recruiting across 11 countries in Eastern Europe, Latin America and Southeast Asia. Enrollment rate for the CHABLIS-SC1 study has exceeded our initial expectations. As of June 30, 2014, we have enrolled more than 50% of the 400 subjects planned for the CHABLIS-SC1 study. Based on current enrollment rate we expect to fully enroll the CHABLIS-SC1 study by the first half of 2015. To date, enrolled patient demographics and disease characteristics for the CHABLIS-SC1 study are consistent with our goal to enroll patients with higher levels of lupus activity and positive biomarkers despite the stable use of corticosteroids. These characteristics were predictive of improved outcomes in our previous Phase 2 clinical study.

An interim analysis of CHABLIS-SC1 is planned to be conducted by an independent unblinded statistician after a minimum of 100 subjects have completed 24 weeks of treatment to confirm the clinical and commercial assumptions of the design of this study. This futility analysis is not intended to provide any rules for stopping for overwhelming efficacy, change in study sample size, or alteration of the study design. In July of 2014, an independent Data Safety Monitoring Board (“DSMB”) recommended continuing the CHABLIS-SC1 clinical study following the second scheduled interim data and safety review. Regardless of the outcome of the interim analysis, all patients randomized into the CHABLIS-SC1 study will be allowed to complete the full 52 weeks of blinded treatment to provide additional safety and efficacy data for future regulatory filings for other potential indications for blisibimod. In addition to serving as a registration study for a potential lupus indication, observations in this study will be included in marketing applications for blisibimod in IgA nephropathy and other indications.

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In the first quarter of 2014, we submitted the final protocol to the U.S. FDA for our second lupus registration study, CHABLIS-SC2. The study design of the CHABLIS-SC2 study is very similar to that of the CHABLIS-SC1study. It is also planned to be a multicenter, randomized, double-blind, placebo-controlled study and intends to enroll up to 400 patients with clinical diagnosis of lupus with or without renal disease including patients with glomerulonephritis and patients who may have a previous diagnosis of lupus nephritis. Consistent with the CHABLIS-SC1 clinical study, the primary endpoint of this second study will be SRI-8 response. These two pivotal studies are anticipated to form the basis of submission for blisibimod as a treatment for lupus patients with active lupus despite the use of steroids.

Our Immunoglobulin A Nephropathy Development Program

The BRIGHT-SC study is a Phase 2/3 multicenter, randomized, double-blind, placebo-controlled study to evaluate the efficacy, safety, tolerability and immunogenicity of blisibimod in IgA nephropathy. Initially we intend to enroll up to 48 patients with biopsy-proven IgA nephropathy who have proteinuria greater than one gram per 24 hours (1g/24hr) and are receiving standard of care medication including angiotensin converting enzyme inhibitors and angiotensin receptor blockers. We initiated our BRIGHT-SC1 study in the second quarter of 2013. Patients enrolled in the BRIGHT-SC study receive 300mg weekly blisibimod or placebo subcutaneously during the first 8 weeks of therapy, the induction phase, followed by 24 weeks of 200mg weekly blisibimod or placebo, the maintenance phase. When the first 48 patients have completed eight weeks of treatment we plan to conduct an interim analysis to determine the effect of blisibimod on proteinuria and other relevant renal biomarkers such as IgA and IgG levels. As a result of discussion with the U.S. FDA on the potential to use proteinuria as the endpoint for Subpart E approval for blisibimod, the Company amended the BRIGHT-SC study endpoints during the fourth quarter of 2013. The amendment serves to potentially transform BRIGHT-SC into one of two registration studies for blisibimod and adjust its endpoints to patients achieving less than one gram of proteinuria per 24 hours at 24 weeks. The BRIGHT-SC clinical study is currently recruiting patients in seven countries in Southeast Asia. We plan to conduct an interim analysis to determine the effect of blisibimod on proteinuria after eight weeks of treatment in the second half of 2014.

We believe blisibimod and the BRIGHT-SC clinical study evaluates the only therapeutic approach intended to specifically target the underlying biological problem of IgA nephropathy – immunoglobulin complex formation. Unlike potential anti-inflammatory treatments for IgA nephropathy, Blisibimod's specific targeting of B cells and plasma cells may safely reduce IgA and IgG production and inflammation and potentially halt further damage to the kidney, which is key to improving clinical outcomes.

To date, baseline characteristics of patients enrolled in the BRIGHT-SC study are consistent with our objectives to enroll patients with a biopsy diagnosis of IgA Nephropathy, high levels of proteinuria, and kidney function indicative of progressive kidney disease.

In April 2014, we met with the Japan Pharmaceuticals and Medical Devices Agency ("PMDA") to discuss our registration program with blisibimod in IgA nephropathy. In this meeting we gained the PMDA's agreement on the acceptability of proteinuria as the primary efficacy endpoint to support marketing approval in Japan and have amended the BRIGHT-SC study to meet the specific data requirements of the PMDA.

Our Multiple Myeloma Development Program

In the first quarter of 2014, building on data generated by Amgen, Inc., from whom we licensed blisibimod, we initiated a preclinical study to evaluate the effect of blisibimod on multiple myeloma. The goal of the preclinical study is to examine the potential use of blisibimod for the treatment of multiple myeloma in combination with current therapies including the new class of proteasome inhibitors. Data from the preclinical study is expected to guide a Phase 2 study to evaluate the effects of blisibimod on survival, progression and biomarkers in patients with relapsed or refractory multiple myeloma treated with at least one prior regimen.

Sollpura

Our PERT Development Program

We acquired the rights to Sollpura from Eli Lilly in July 2014. Based on data generated by Eli Lilly , we intend to develop Sollpura in oral capsule and sachet form in a Phase 3 pivotal trial as agreed with the U.S. FDA in the United States and Europe in 2015 to evaluate the effect of Sollpura in comparison with other PERTs to support U.S. marketing approval . The therapeutic aim of the Sollpura program is to replace the enzyme deficiency associated with EPI with purified, non-porcine, biotechnology-derived digestive enzymes. Completed clinical trials demonstrate that nutrient absorption is significantly increased in patients with cystic fibrosis and EPI who received Sollpura.

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Revenue

To date, we have not generated any revenue. We do not expect to generate revenue unless or until we obtain regulatory approval of and commercialize our product candidates or in-license additional products that generate revenue. We intend to seek to generate revenue from a combination of product sales, up-front fees and milestone payments in connection with collaborative or strategic relationships and royalties resulting from the licensing of the commercial rights to our intellectual property. We expect that any revenue we generate will fluctuate from quarter to quarter as a result of the nature, timing and amount of milestone payments we may receive upon the sale of our products, to the extent any are successfully commercialized, as well as any revenue we may receive from our collaborative or strategic relationships.

Research and Development Expenses

Since our inception, we have focused our activities on our product candidate development programs. We expense research and development costs as they are incurred. Research and development expenses consist of operational personnel costs, including salaries, benefits and stock-based compensation, clinical studies performed by contract research organizations, or CROs, materials and supplies, licenses and fees and overhead allocations consisting of various supporting functions and facilities-related costs. Research and development activities are also separated into three main categories: licensing, clinical development and pharmaceutical development. Licensing costs consist primarily of fees paid pursuant to license agreements. Historically, our clinical development costs have included costs for preclinical and clinical studies. We expect to incur substantial clinical development costs for the continued development of our product candidates. Pharmaceutical development costs consist of expenses incurred relating to clinical studies and product formulation and manufacturing.

We expense both internal and external research and development costs as incurred. We are developing our product candidates in parallel, and we typically use our employee and infrastructure resources across several projects. Thus, some of our research and development costs are not attributable to an individually named project, but rather are allocated across our clinical stage programs. These unallocated costs include salaries, stock-based compensation charges and related “fringe benefit” costs for our employees (such as workers compensation and health insurance premiums), consulting fees and travel.

The following table shows our total research and development expenses for the three and six months ended June 30, 2014 and June 30, 2013 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Allocated costs:				
Varespladib	$ —	$ (193)	$ (375) (1)	$ 249
Blisibimod	4,374	4,559	9,338	7,327
Unallocated costs	905	899	2,081	2,618
Total development	$ 5,279	$ 5,265	$ 11,044	$ 10,194

(1) Includes a one-time refund of $0.4 million from a vendor for our VISTA-16 clinical study, which was terminated in March 2012.

We expect our research and development expenses to continue to be significant as we continue our development activities. We intend to fund our development expenses with existing cash and proceeds from potential future debt and equity offerings.

We expect that a large percentage of our research and development expenses in the future will be incurred in support of our current and future clinical development programs. These expenditures are subject to numerous uncertainties in timing and cost to completion. As we obtain results from clinical studies, we may elect to discontinue or delay clinical studies for certain product candidates or programs in order to focus our resources on more promising product candidates or programs. Completion of clinical studies may take several years or more, but the length of time generally varies according to the type, complexity, novelty and intended use of a product candidate. The cost of clinical studies may vary significantly over the life of a program as a result of differences arising during clinical development, including:

- Ÿ the number of sites included in the studies;
- Ÿ the length of time required to enroll suitable patient subjects;
- Ÿ the number of patients that participate in the studies;
- Ÿ the number of doses that patients receive;

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- Ÿ the drop-out or discontinuation rates of patients; and
- Ÿ the duration of patient follow-up.

Our expenses related to clinical studies are based on estimates of the services received and efforts expended pursuant to contracts with many research institutions, CROs and other service providers that conduct and manage clinical studies on our behalf. The financial terms of these agreements are subject to negotiation and vary from contract to contract and may result in uneven payment flows. Generally, these agreements set forth the scope of work to be performed at a fixed fee or unit price. Payments under the contracts are mainly driven by time and materials incurred by these service providers. Expenses related to clinical studies generally are accrued based on time and materials incurred by the service providers and in accordance with the contract. If timelines or contracts are modified based upon changes to the clinical study design or scope of work to be performed, we modify our estimates of accrued expenses accordingly on a prospective basis.

None of our product candidates has received U.S. FDA or foreign regulatory marketing approval. In order to grant marketing approval, the U.S. FDA or foreign regulatory agencies must conclude that clinical data establishes the safety and efficacy of a product candidate and that the manufacturing facilities, processes and controls are adequate. Despite our efforts, our product candidates may not offer therapeutic or other improvement over existing, comparable drugs, be proven safe and effective in clinical studies, or meet applicable regulatory standards.

As a result of the uncertainties discussed above, we are unable to determine the duration and completion costs of our clinical development activities or when and to what extent we will receive cash inflows from the commercialization and sale of an approved product candidate, if ever.

General and Administrative Expenses

General and administrative expenses consist primarily of compensation for our chief executive officer and employees in administration, finance and business development functions. Other significant costs include professional fees for legal services, including legal services associated with obtaining and maintaining patents. We will continue to incur significant general and administrative expenses as a public company, including costs for insurance, costs related to the hiring of additional personnel, payment to outside consultants, lawyers and accountants and complying with the corporate governance, internal controls and similar requirements applicable to public companies.

Critical Accounting Policies and Estimates

Our management’s discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses. On an ongoing basis, we evaluate these estimates and judgments, including those described below. We base our estimates on our historical experience and on various other assumptions that we believe to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results and experiences may differ materially from these estimates.

While our significant accounting policies are more fully described in the notes to the financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2013, we believe that the following accounting policies are the most critical to aid you in fully understanding and evaluating our reported financial results and affect the more significant judgments and estimates that we use in the preparation of our financial statements.

Warrants

Warrants are recorded either as equity instruments or derivative liabilities at their estimated fair value at the date of issuance. In the case of warrants recorded as liabilities, subsequent changes in estimated fair value are recorded in other income (expense) in the Company's statement of operations in each subsequent period. The warrants are measured at estimated fair value using the Black Scholes valuation model, which is based, in part, upon inputs for which there is little or no observable market data, requiring the Company to develop its own assumptions. Inherent in this model are assumptions related to expected stock price volatility, expected life, risk-free interest rate and dividend yield. We estimate the volatility of our common stock at the date of issuance, and at each subsequent reporting period, based on historical volatility that matches the expected remaining life of the warrants. The risk-free interest rate is based on the U.S. Treasury zero-coupon yield curve on the measurement date for a maturity similar to the expected remaining life of the warrants. The expected life of the warrants is assumed to be equivalent to their remaining contractual term. The dividend rate is based on our historical rate, which we anticipate to remain at zero. The assumptions used in calculating the estimated fair value of the warrants represent our best estimates. However, these estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and different assumptions are used, the warrant liability and the change in estimated fair value could be materially different.

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Accrued Clinical Expenses

We make estimates of our accrued clinical expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. This process involves reviewing open contracts and purchase orders, communicating with our applicable 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 at least monthly in arrears for services performed. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. Examples of estimated accrued clinical expenses include:

- fees paid to CROs in connection with clinical studies;
- fees paid to investigative sites in connection with clinical studies;
- fees paid to contract manufacturers in connection with the production of clinical study materials; and
- fees paid to vendors in connection with preclinical development activities.

We base our accruals related to clinical studies on our estimates of the services received and efforts expended pursuant to contracts with many research institutions and CROs that conduct and manage clinical studies 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. Generally, these agreements set forth the scope of work to be performed at a fixed fee or unit price. Payments under the contracts are mainly driven by the time and materials incurred by these service providers. In accruing service fees, we estimate the time and materials incurred by these service providers in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual 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 estimate.

Results of Operations

Comparison of the Three Months ended June 30, 2014 and 2013

Research and Development Expenses ($ in thousands)

	Three Months Ended June 30,			
	2014	2013	$ Change	% Change
Research and development expenses	$ 5,279	$ 5,265	$ 14	—%

Research and development expenses remained flat during the three months ended June 30, 2014 as compared to the same period in 2013. The expense trend between these two comparable periods is reasonable given our consistent focus on our Phase 3 CHABLIS-SC1 and Phase 2/3 BRIGHT-SC studies.

General and Administrative Expenses ($ in thousands)

	Three Months Ended June 30,			
	2014	2013	$ Change	% Change
General and administrative expense	$ 1,586	$ 1,688	$ (102)	(6)%

General and administrative expenses decreased during the three months ended June 30, 2014 from the same period in 2013 primarily due to a decrease in consulting and professional services, reflecting the Company's ongoing cost reduction efforts.

Other Income (Expense) ($ in thousands)

	Three Months Ended June 30,			
	2014	2013	$ Change	% Change
Other income (expense)	$ (31)	$ (6)	$ (25)	417 %
Interest expense	(360)	(1,322)	962	(73)%
Total other income (expense)	$ (391)	$ (1,328)	$ 937	(71)%

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Total other expense, net decreased during the three months ended June 30, 2014 from the same period in 2013 primarily due to the refinancing of our debt from Hercules Technology II, L.P. and Hercules Technology Growth Capital, Inc. (together, “Hercules) to Midcap Financial SBIC, LP (“Midcap”) and Square 1 Bank in April 2013 which trigged full recognition of an end of term charge as well as unamortized debt issuance cost, in addition to a significantly reduced blended interest rate.

Comparison of the six months ended June 30, 2014 and 2013

Research and Development Expenses

The following table summarizes our research and development expenses for the six months ended June 30, 2014 and 2013 (in thousands, except percentages):

	Six Months Ended June 30,			
	2014	2013	$ Change	% Change
Research and development expenses	$ 11,044	$ 10,194	$ 850	8%

Research and development expenses increased during the six months ended June 30, 2014 from the same period in 2013 primarily due to higher laboratory and drug resupply costs due to more frequent dosing of study subjects in the Company’s current clinical trials as compared to the PEARL-SC open label extension study in the previous year.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the six months ended June 30, 2014 and 2013 (in thousands, except percentages):

	Six Months Ended June 30,			
	2014	2013	$ Change	% Change
General and administrative expense	$ 3,430	$ 3,660	$ (230)	(6)%

General and administrative expenses decreased during the six months ended June 30, 2014 from the same period in 2013 primarily due to a decrease in consulting and professional services, reflecting the Company's ongoing cost reduction efforts.

Other Income (Expense)

The following table summarizes our other income (expense) for the six months ended June 30, 2014 and 2013 (in thousands, except percentages):

	Six Months Ended June 30,			
	2014	2013	$ Change	% Change
Other income (expense)	$ (79)	$ 19	$ (98)	(516) %
Interest expense	(619)	(2,026)	1,407	(70) %

Total other income (expense)	$ (698)	$ (2,007)	$ 1,309	(65) %

Total other expense, net decreased during the three months ended June 30, 2014 from the same period in 2013 primarily due to the refinancing of our debt from Hercules Technology II, L.P. and Hercules Technology Growth Capital, Inc. (together, “Hercules”) to Midcap Financial SBIC, LP (“Midcap”) and Square 1 Bank in April 2013 which trigged full recognition of an end of term charge as well as unamortized debt issuance cost, in addition to a significantly reduced blended interest rate.

Liquidity and Capital Resources

To date, we have funded our operations primarily through private placements of preferred stock and common stock, convertible debt, debt financings and our initial public offering (“IPO”), raising aggregate net proceeds of approximately $335.1 million. As of June 30, 2014, we had cash and cash equivalents of approximately $20.9 million.

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Our principal liquidity requirements are primarily to meet our working capital needs, support ongoing business activities, research and development, and to meet our capital expenditure needs.

In January 2012, we filed a universal shelf registration statement with the U.S. Securities and Exchange Commission, or SEC, on Form S-3 (File No. 333-179043) for the proposed offering from time to time of up to $100.0 million of our securities, including common stock, preferred stock, debt securities and/or warrants. In July 2012, we issued 4,743,750 shares at $8.00 per share pursuant to the shelf registration, raising net proceeds of approximately $35.6 million. In January 2013, we issued 7,575,757 shares at $5.28 per share pursuant to the shelf registration statement in an initial closing of a public offering, followed by 1,136,362 shares in a second closing in February 2013, raising net proceeds of approximately $42.7 million. In April 2013, we increased the amount of securities that may be issued under the registration statement by $3.2 million through the filing of a post-effective amendment pursuant to Rule 462(b) of the Securities Act. On April 5, 2013, we entered into an equity purchase agreement (the "Purchase Agreement") with Lincoln Park Capital Fund, LLC ("LPC"), pursuant to which we have the right to sell to LPC up to an aggregate of $18.5 million in shares of our common stock. Upon executing the agreement, LPC made an initial purchase of $2.0 million of common stock. Subsequent to the initial purchase, we have sold approximately $1.6 million of common stock to LPC. As of June 30, 2014, approximately $14.9 million of common stock remained available to be sold under the Purchase Agreement. In April 2013, we registered approximately $19.0 million for sale under the LPC Purchase Agreement, leaving a balance of approximately $0.2 million under this shelf registration statement for future issuance as of June 30, 2014.

In April 2013, we filed a universal shelf registration statement with the SEC on Form S-3 (File No. 333-187780) for the proposed offering from time to time of up to $100.0 million of our securities, including common stock, preferred stock, debt securities and/or warrants. On November 15, 2013, we registered $25.0 million under the registration statement for an at-the-market equity program ("ATM"). As of June 30, 2014, we sold $9.4 million of common stock pursuant to the ATM and $15.6 million remained available for future sale under this ATM. As of June 30, 2014, $75 million remained available for future issuance under this shelf registration statement.

Cash Flows

Comparison of Six Months Ended June 30, 2014 and 2013

Our cash flow from operations during the six months ended June 30, 2014 and 2013 consists of the following (in thousands):

	Six Months Ended June 30,	
	2014	2013
Net cash used in operating activities	$ (13,185)	$ (19,795)
Net cash provided by (used in) investing activities	8,100	(5,828)
Net cash provided by financing activities	36	43,497
Effect of exchange rate on cash	—	(1)
Total	$ (5,049)	$ 17,873

During the six months ended June 30, 2014 and 2013, our operating activities used cash of $13.2 million and $19.8 million, respectively, primarily resulting from our net losses and changes in our working capital accounts adjusted for non-cash items including stock based compensation. The decrease in cash used in operating activities during the six months ended June 30, 2014 as compared to 2013 was primarily due to reduced spending on clinical development activities as we continued to focus our development efforts on blisibimod.

During the six months ended June 30, 2014, cash provided by investing activities was $8.1 million, which is due to a reduction in our restricted cash. During the six months ended June 30, 2013, cash used by investing activities was $5.8 million and consisted primarily of $4.2 million in proceeds from the maturities of short-term investments, offset by an increase of $10 million in restricted cash for the collateral of the Square 1 Bank debt.

During the six months ended June 30, 2014, financing activities provided cash of $36,000 and was driven by net proceeds of $9.6 million received from the sale of our common stock through the ATM with Cowen and Company, LLC (“Cowen”) and equity purchase agreement with LPC, offset by $9.5 million principal repayment against the Company’s notes payable owed to Square 1 Bank and Midcap. During the six months ended June 30, 2013, financing activities provided cash of $43.5 million which was primarily derived from proceeds received from our public offering of common stock in the first quarter of 2013 from which we raised net proceeds of $42.7 million; proceeds of $2.0 million from the issuance of shares to LPC pursuant to an equity purchase agreement executed in April 2013; and net proceeds of $19.8 million from refinancing the Hercules loan with new debt arrangements with MidCap and Square 1 Bank. Total raise was offset by principal repayment and end of term charge of $18.5 million made to Hercules as a result of paying off the Hercules notes payable.

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Contractual Obligations and Commitments

We have lease obligations consisting of an operating lease for our operating facility that expires September 2017.

In April 2013, we entered into borrowing agreements with Midcap and Square 1 Bank for an aggregate of $20.0 million. We used the proceeds from the new loans to repay the outstanding balance owed to Hercules. As of June 30, 2014, outstanding principal owed to Midcap and Square 1 Bank was $8.6 million.

Funding Requirements

We expect to incur substantial expenses and generate significant operating losses as we continue to advance our product candidates into preclinical studies and clinical studies and as we:

- continue clinical development of our product candidates;
- hire additional clinical, scientific and management personnel; and
- implement new operational, financial and management information systems.

Our future capital uses and requirements depend on numerous forward-looking factors. These factors include the following:

- the progress of preclinical development and clinical studies of our product candidates;
- the time and costs involved in obtaining regulatory approvals;
- delays that may be caused by evolving requirements of regulatory agencies;
- the costs involved in filing and prosecuting patent applications and enforcing or defending patent claims;
- our ability to establish, enforce and maintain selected strategic alliances; and
- the acquisition of technologies, product candidates and other business opportunities that require financial commitments.

As of the date of this report, we believe our existing cash, cash equivalents and short-term investments will enable us to meet our obligations and sustain our operations through at least the next 12 months. However, we may require significant additional funds earlier than we currently expect to conduct additional or extended clinical studies and seek regulatory approval of our product candidates. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical studies.

Additional funding may not be available to us on acceptable terms, or at all. In addition, the terms of any financing may adversely affect the holdings or the rights of our stockholders. For example, if we raise additional funds by issuing equity securities or by selling debt securities, if convertible, further dilution to our existing stockholders may result. To the extent our capital resources are insufficient to meet our future capital requirements, we will need to finance our future cash needs through public or private equity offerings, collaboration agreements, debt financings or licensing arrangements.

If adequate funds are not available, we may be required to terminate, significantly modify or delay our development programs, reduce our planned commercialization efforts, or obtain funds through collaborators that may require us to relinquish rights to our technologies or product candidates that we might otherwise seek to develop or commercialize independently. We may elect to raise additional funds even before we need them if the conditions for raising capital are favorable.

Off-Balance Sheet Arrangements

We do not currently have, nor have we ever had, any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. In addition, we do not engage in trading activities involving non-exchange traded contracts.

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ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. We are exposed to market risk related to fluctuations in interest rates, market prices and foreign currency exchange rates. However, since a majority of our investments are in highly liquid money market funds, we do not believe we are subject to any material market risk exposure. As of June 30, 2014, we did not have any material derivative financial instruments. The fair value of our cash and cash equivalents was $20.9 million as of June 30, 2014.

Our investment policy is to limit credit exposure through diversification and investment in highly rated securities. We actively review, along with our investment advisors, current investment ratings, company specific events and general economic conditions in managing our investments and in determining whether there is a significant decline in fair value that is other-than-temporary. We also monitor and evaluate the accounting for our investment portfolio on a quarterly basis for additional other-than-temporary impairment charges.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and principal accounting officer, evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of June 30, 2014. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities and Exchange Act of 1934, 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 Securities Exchange Act of 1934 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 Securities Exchange Act of 1934 is accumulated and communicated to that company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Based on this evaluation, our chief executive officer and principal accounting officer concluded that our disclosure controls and procedures were not effective as of June 30, 2014 at the reasonable assurance level due to a material weakness that we identified as of December 31, 2013 that has not been fully remediated. The material weakness we identified relates to the lack of a process to timely and appropriately account for warrants that provided the holders with anti-dilution price protection. The material weakness resulted in restatement of our consolidated financial statements for the years ended December 31, 2010, 2011 and 2012, respectively, and each of the quarterly periods from March 31, 2012 through September 30, 2012. Notwithstanding the existence of the material weakness, management has concluded that the consolidated financial statements included in this report present fairly, in all material respects, our consolidated financial position, results of operations and cash flows for the periods presented in conformity with U.S. GAAP.

Management's Remediation Activities

With the oversight of senior management and our audit committee, we have begun to take steps intended to address the underlying causes of the material weakness, primarily through the establishment of a formal review process of non-routine and complex transactions, reassessment of the accounting treatment for all historical warrants, and the implementation and validation of improved accounting and financial reporting procedures.

We began the implementation of the remediation activities in the second quarter of 2014. As of June 30, 2014, we have not yet been able to remediate this material weakness but intend to fully remediate the weakness by the end of the current fiscal year. As we continue to evaluate and work to improve our internal control over financial reporting,

we may determine to take additional measures to address the material weakness.

Changes in Internal Control over Financial Reporting

Other than the actions taken as described above under “Management's Remediation Activities,” there has been no change in the Company’s internal control over financial reporting that occurred during the second quarter 2014 that has materially affected, or is reasonably likely to affect materially, the Company’s internal control over financial reporting.

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PART II — OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are not subject to any material pending legal proceedings. From time to time, we may be involved in routine legal proceedings, as well as demands, claims and threatened litigation, which arise in the normal course of our business.

ITEM 1A. RISK FACTORS

You should carefully consider the risks described below, together with the other information contained in this Quarterly Report on Form 10-Q, including the financial statements and the related notes that appear in this report. We believe the risks described below are the risks that are material to us as of the date of this report. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock could decline, and you may lose all or part of your investment.

Risks Related to Our Financial Condition and Capital Requirements

We have incurred significant losses since our inception and anticipate that we will incur continued significant losses for the foreseeable future.

Since our inception in 2004, we have focused primarily on developing three of our product candidates, blisibimod, varespladib and varespladib sodium. The two latter product candidates were terminated in March 2012. In July 2014, we entered into a license agreement with Eli Lilly, pursuant to which we obtained an exclusive worldwide license to certain technology and compounds relating to a Phase 3, novel investigational PERT, liprotamase, intended for the treatment of EPI. We have financed our operations exclusively through equity offerings, private placements of convertible debt, and debt financings and we have incurred losses in each year since our inception in September 2004. Substantially all of our losses resulted from costs incurred in connection with our product development programs and from general and administrative costs associated with our operations.

We expect to incur additional losses over the next several years, and these losses may increase if we cannot generate revenues. Our historical losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital. In addition, if we obtain regulatory approval for our product candidates, we may incur significant sales, marketing, in-licensing and outsourced manufacturing expenses as well as continued product development expenses. As a result, we expect to continue to incur significant and increasing losses for the foreseeable future.

Our existing and future debt obligations could impair our liquidity and financial condition, and in the event we are unable to meet our debt obligations, the lenders could foreclose on our assets.

In connection with a credit facility agreement entered into on April 3, 2013, Midcap advanced a loan to us, in the aggregate principal amount of $10 million. Our debt obligations could:

- impair our liquidity and make it more difficult for us to satisfy our other obligations;
- require us to dedicate cash flow to payments on our debt obligations, which would reduce the availability of our cash flow to fund working capital, capital expenditures and other corporate requirements;
-

impose restrictions on our ability to incur other indebtedness and grant liens on our assets, other than permitted indebtedness and permitted liens, and could impede us from obtaining additional financing in the future for working capital, capital expenditures, acquisitions and general corporate purposes;

- impose restrictions on us with respect to the use of our available cash, including in connection with future acquisitions;

- adversely affect our ability to enter into strategic transactions and similar agreements, or require us to obtain the consent of our lenders;

- make us more vulnerable in the event of a downturn in our business prospects and could limit our flexibility to plan for, or react to, changes in our licensing markets; and

- place us at a competitive disadvantage when compared to our competitors who are not similarly restricted.

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We have pledged substantially all of our assets to secure our obligations under the Midcap loan. In the event that we were to fail in the future to make any required payment under the Midcap loan, or fail to comply with the covenants contained in the credit facility agreement and other related agreements, we would be in default regarding that indebtedness. A debt default would enable the lender to foreclose on the assets securing such debt and could significantly diminish the market value and marketability of our common stock and could result in the acceleration of the payment obligations under all or a portion of our consolidated indebtedness.

We have never generated any revenue and may never be profitable.

Our ability to generate revenue and achieve profitability depends on our ability, alone or with collaborators, to successfully complete the development of our product candidates, conduct preclinical tests in animals and clinical studies in human beings, obtain the necessary regulatory approvals for our product candidates and commercialize any approved products. We have not generated any revenue from our development-stage product candidates, and we do not know when, or if, we will generate any revenue. The commercial success of our development-stage product candidates will depend on a number of factors, including, but not limited to, our ability to:

- obtain favorable results for and advance the development of blisibimod, our product candidate for the treatment of B-cell mediated autoimmune diseases, including successfully launching and completing clinical studies in patients with systemic lupus erythematosus, or lupus, IgA nephropathy, or other indications related to the development of blisibimod;

- obtain favorable results for and advance the development of liprotamase, our product candidate for the treatment of patients with low digestive enzyme levels, or EPI, and potentially other diseases;

- obtain regulatory approval for blisibimod and liprotamase;

- if regulatory approvals are obtained, begin the commercial manufacturing of our product candidates with third-party manufacturers;

- launch commercial sales and effectively market our product candidates, either independently or in strategic collaborations with third parties; and

- achieve broad market acceptance of our product candidates in the medical community and with third-party payors.

Our product candidates are subject to the risks of failure inherent in the development of therapeutics based on new technologies. Currently, we have one product candidate in clinical development, which is blisibimod. Our second product candidate, liprotamase, which we acquired the rights to from Eli Lilly in July 2014, is planned for a Phase 3 pivotal trial in the United States and Europe in 2015. Our product candidates could fail in clinical studies if we are unable to demonstrate that it is effective or if it causes unacceptable adverse effects in the patients we treat. Failure of our product candidates in clinical studies would have a material adverse effect on our ability to generate revenue or become profitable. If we are not successful in achieving regulatory approval for our product candidates or are significantly delayed in doing so, our business will be materially harmed.

Our drug discovery efforts may not produce any other viable or marketable product candidates.

Even if our product candidates are approved for commercial sale, the approved product candidates may not gain market acceptance or achieve commercial success. Physicians, patients, payors or the medical community in general may be unwilling to accept, utilize or recommend our product. We would anticipate incurring significant costs associated with commercializing any approved product. Even if we are able to generate product sales, which we

cannot guarantee, we may not achieve profitability soon thereafter, if ever. If we are unable to generate product revenues, we will not become profitable and may be unable to continue operations without additional funding.

We will need substantial additional capital in the future to fund our operations. If additional capital is not available, we will have to delay, reduce or cease operations.

We will need to raise substantial additional capital to fund our operations and to develop our product candidates. Our future capital requirements could be substantial and will depend on many factors including:

- the scope, size, rate of progress, results and costs of our clinical studies and other development activities for our product candidates;

- manufacturing campaign for blisibimod and liprotamase clinical matters, including formulation development and product enhancement;

- non-clinical activities that we may pursue parallel to our clinical studies;

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- the cost, timing and outcomes of regulatory proceedings;
- payments received under any strategic collaborations;
- the filing, prosecution and enforcement of patent claims;
- the costs associated with commercializing our product candidates if they receive regulatory approval, including the cost and timing of developing sales and marketing capabilities, or entering into strategic collaboration with others relating to the commercialization of our product candidates; and
- revenues received from approved products, if any, in the future

As of the date of this report, we anticipate that our existing cash, cash equivalents and short-term investments, will enable us to meet our obligations and sustain our operations through at least the next 12 months. Changing circumstances may cause us to consume capital significantly faster than we currently anticipate. Additional financing may not be available when we need it or may not be available on terms that are favorable to us. If adequate funds are not available to us on a timely basis, or at all, we may be required to:

- terminate, reduce or delay clinical studies or other development activities for our product candidates; or
- terminate, reduce or delay our (i) establishment of sales and marketing capabilities, (ii) pursuit of strategic collaborations with others relating to the sales, marketing and commercialization of our product candidates or (iii) other activities that may be necessary to commercialize our product candidates, if approved for sale.

The timing of the milestone and royalty payments we are required to make to our licensors is uncertain and could adversely affect our cash flows and results of operations.

In December 2007, we entered into a license agreement with Amgen Inc., or Amgen, pursuant to which we obtained an exclusive worldwide license to certain technology and compounds relating to blisibimod. Pursuant to our license agreement with Amgen, we are required to make various milestone payments upon our achievement of certain development, regulatory and commercial objectives for any blisibimod formulation. We are required to pay up to $10.0 million upon achievement of certain pre-approval clinical development milestones and up to $23.0 million upon achievement of certain post-approval milestones. We are also required to make tiered quarterly royalty payments on net sales, which increase as a percentage from the high single digits to the low double digits as net sales increase.

In July 2014, we entered into a license agreement with Eli Lilly, pursuant to which we obtained an exclusive worldwide license to certain technology and compounds relating to liprotamase. Pursuant to our license agreement with Eli Lilly, we are required to make various milestone payments upon our achievement of certain regulatory and commercial objectives for any liprotamase formulation. We are also required to make tiered royalty payments on net sales, which percentage increases from the high single digits to the mid-double digits as net sales increase.

The timing of our achievement of these events and corresponding milestone payments becoming due to our licensors is subject to factors relating to the clinical and regulatory development and commercialization of our product candidates, as applicable, many of which are beyond our control. We may become obligated to make a milestone payment during a period in which we do not have the cash on hand to make such payment, which could require us to delay our clinical studies, curtail our operations, scale back our commercialization and marketing efforts, seek funds to meet these obligations at terms unfavorable to us or default on our license agreements, which could result in license termination.

Our limited operating history makes it difficult to evaluate our business and prospects.

We were incorporated in September 2004. Our operations to date have been limited to organizing and staffing our company, acquiring product and technology rights, conducting product development activities for our primary product candidate, blisibimod, varespladib and varespladib sodium (the two latter product candidates were terminated in March 2012), and performing research and development. We have not yet demonstrated an ability to obtain regulatory approval for or commercialize a product candidate. Consequently, any predictions about our future performance may not be as accurate as they could be if we had a history of successfully developing and commercializing pharmaceutical products.

Risks Associated with Development and Commercialization of Our Product Candidates

We depend substantially on the success of our product candidates which are still under clinical development. We cannot assure you that our product candidates will receive regulatory approval or be successfully commercialized.

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To date, we have not obtained marketing approval for, or marketed, distributed or sold any products. The success of our business depends primarily upon our ability to develop and commercialize our product candidates successfully.

Our product candidates are prone to the risks of failure inherent in drug development. Before obtaining regulatory approvals for the commercial sale of any product candidate for a target indication, we must demonstrate with substantial evidence gathered in preclinical and well-controlled clinical studies, and, with respect to approval in the United States, to the satisfaction of the U.S. FDA and, with respect to approval in other countries, similar regulatory authorities in those countries, that the product candidates are safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate. Despite our efforts, our product candidates may not:

- offer therapeutic or other improvement over existing, comparable therapeutics;
- be proven safe and effective in clinical studies;
- meet applicable regulatory standards;
- be capable of being produced in sufficient quantities at acceptable costs;
- be successfully commercialized; or
- obtain favorable reimbursement.

We are not permitted to market our product candidates in the United States until the U.S. FDA approves our biologics license applications, or BLAs, or in any foreign countries until we receive the requisite approval from such countries. We have not submitted any BLA or received marketing approval for our product candidates.

Preclinical testing and clinical studies are long, expensive and uncertain processes. We may spend several years completing our testing for any particular product candidate, and failure can occur at any stage. Negative or inconclusive results or adverse medical events during a clinical study could also cause the U.S. FDA or us to terminate a clinical study or require that we repeat it or conduct additional clinical studies. Additionally, data obtained from a clinical study are susceptible to varying interpretations and the U.S. FDA or other regulatory authorities may interpret the results of our clinical studies less favorably than we do. The U.S. FDA and equivalent foreign regulatory agencies have substantial discretion in the approval process and may decide that our data are insufficient to support a marketing application and require additional preclinical, clinical or other studies.

From time to time during the regulatory approval process of our product candidates, we engage in discussions with the U.S. FDA and other non-US regulatory authorities regarding the regulatory requirements for our development programs. We may receive informal verbal and or written guidance from these authority agencies which may help form the basis of our clinical trial designs. The U.S. FDA and other non-US regulatory agencies may change their position on such informal guidance prior to the approval of our product candidates. As a result, we are unable to determine whether the outcome of informal deliberations will become final. If we are unable to effectively and efficiently resolve and comply with inquires and requests from the U.S. FDA and other non-US regulatory authorities, the approval of our product candidates may be delayed and their value maybe be reduced.

Any termination or suspension of, or delays in the commencement or completion of, clinical testing of our product candidates could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospect.

Delays in the commencement or completion of clinical testing could significantly affect our product development costs. We do not know whether planned clinical studies will begin on time or be completed on schedule, if at all. The commencement and completion of clinical studies can be delayed for a number of reasons, including delays related to:

- obtaining regulatory approval to commence a clinical study or complying with conditions imposed by a regulatory authority regarding the scope or design of a clinical study;
- reaching agreement on acceptable terms with prospective clinical research organizations, or CROs, and study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and study sites;
- manufacturing, including manufacturing sufficient quantities of product candidates or other materials for use in clinical studies;
- obtaining institutional review board, or IRB, approval or the approval of other reviewing entities to conduct a clinical study at prospective sites;

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- recruiting and enrolling patients to participate in clinical studies for a variety of reasons, including size of patient population, nature of clinical study protocol, the availability of approved effective treatments for the relevant disease and competition from other clinical study programs for similar indications;

- severe or unexpected drug-related adverse effects experienced by patients in a clinical study; and

- retaining patients who have initiated a clinical study, but may withdraw due to treatment protocol, adverse effects from the therapy, lack of efficacy from the treatment, personal issues or who are lost to further follow-up.

Clinical studies may also be delayed, suspended or terminated as a result of ambiguous or negative interim results, or results that are inconsistent with earlier results. In addition, a clinical study may be suspended or terminated by us, the U.S. FDA, the IRB or other reviewing entity overseeing the clinical study at issue, any of our clinical study sites with respect to that site, or other regulatory authorities due to a number of factors, including:

- failure to conduct the clinical study in accordance with regulatory requirements or our clinical protocols;

- inspection of the clinical study operations or study sites by the U.S. FDA or other regulatory authorities resulting in the imposition of a clinical hold;

- unforeseen safety issues or any determination that a clinical study presents unacceptable health risks; and

- lack of adequate funding to continue the clinical study, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional clinical studies and increased expenses associated with the services of our CROs and other third parties.

Product development costs to us will increase if we have delays in testing or approval of our product candidates or if we need to perform more or larger clinical studies than planned. We typically rely on third-party clinical investigators at medical institutions and health care facilities to conduct our clinical studies and, as a result, we may face additional delays outside our control.

Additionally, changes in regulatory requirements and policies may occur and we may need to amend clinical development plans or clinical study protocols to reflect these changes. Amendments may require us to resubmit our clinical study protocols to IRBs for re-examination, which may impact the costs, timing or successful completion of a clinical study. If we experience delays in completion of, or if we, the U.S. FDA or other regulatory authorities, the IRB or other reviewing entities, or any of our clinical study sites suspend or terminate any of our clinical studies, the commercial prospects for our product candidates may be harmed and our ability to generate product revenues will be delayed. In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical studies may also ultimately lead to the denial of regulatory approval of our product candidates. Also, if one or more clinical studies are delayed, our competitors may be able to bring products to market before we do, and the commercial viability of our product candidates could be significantly reduced.

Because the results of preclinical testing or earlier clinical studies are not necessarily predictive of future results, any product candidate we advance into clinical studies may not have favorable results in later clinical studies or receive regulatory approval.

Success in preclinical testing and early clinical studies does not ensure that later clinical studies will generate adequate data to demonstrate the efficacy and safety of an investigational drug or biologic. A number of companies in the pharmaceutical and biotechnology industries, including those with greater resources and experience, have suffered significant setbacks in Phase 3 clinical studies, even after seeing promising results in earlier clinical studies. Despite

the results reported in earlier clinical studies for our product candidates, we do not know whether any Phase 3 or other clinical studies we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market our product candidates. If later stage clinical studies do not produce favorable results, our ability to achieve regulatory approval for any of our product candidates may be adversely impacted. Even if we believe that our product candidates have performed satisfactorily in preclinical testing and clinical studies, we may nonetheless fail to obtain U.S. FDA approval for our product candidates.

If we breach the license agreements for our product candidates, we could lose the ability to continue the development and commercialization of our product candidates.

We are party to an agreement with Amgen containing exclusive worldwide licenses of the compositions of matter and methods of use for blisibimod, as well as non-exclusive worldwide licenses of compositions of matter and methods of use relating to peptibodies generally. We are also party to an agreement with Eli Lilly containing an exclusive worldwide license of the compositions of matters and methods of use for liprotamase. These agreements require us to make timely milestone and royalty payments, provide regular information, maintain the confidentiality of and indemnify our licensors under the terms of the agreements.

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If we fail to meet these obligations, our licensors may terminate our licenses and may be able to re-obtain licensed technologies and aspects of any intellectual properties controlled by us that relate to the licensed technologies that originated from our licensors. Our licensors could effectively take control of the development and commercialization of the licensed product candidates after an uncured, material breach of our license agreements by us or if we voluntarily terminate the agreements. While we would expect to exercise all rights and remedies available to us, including seeking to cure any breach by us, and otherwise seek to preserve our rights under the patents and patent applications licensed to us, we may not be able to do so in a timely manner, at an acceptable cost or at all. Any uncured, material breach under the license agreements could result in our loss of exclusive rights and may lead to a complete termination of our product development and any commercialization efforts for our product candidates.

Our industry is subject to intense competition. If we are unable to compete effectively, our product candidates may be rendered non-competitive or obsolete.

The pharmaceutical industry is highly competitive and subject to rapid and significant technological change. Our potential competitors include large pharmaceutical and more established biotechnology companies, specialty pharmaceutical and generic drug companies, academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. All of these competitors currently engage in, have engaged in or may engage in the future in the development, manufacturing, marketing and commercialization of pharmaceuticals and biotechnologies, some of which may compete with our present or future product candidates. It is possible that any of these competitors could develop technologies or products that would render our product candidates obsolete or non-competitive, which could adversely affect our revenue potential. Key competitive factors affecting the commercial success of our product candidates are likely to be efficacy, safety profile, reliability, convenience of dosing, price and reimbursement.

The market for inflammatory disease therapeutics is especially large and competitive. For lupus, GlaxoSmithKline plc's BAFF antagonist monoclonal antibody, Benlysta®, was approved by the U.S. FDA for treatment of lupus. Further, we are aware of companies with other products in development that are being tested for potential treatment of lupus: Bristol-Myers Squibb Company and Merck Serono S.A., whose dual BAFF/APRIL antagonist fusion protein, Atacicept, recently completed a Phase 2/3 clinical study for lupus; Immunomedics, Inc. and UCB S.A., who reported favorable results for their CD-22 antagonist humanized antibody, epratuzumab, in a Phase 2b clinical study in lupus, is now conducting two Phase 3 clinical studies; and Eli Lilly's anti-BAFF monoclonal antibody, Tabalumab (LY2127399), is currently being evaluated in two Phase 3 studies in patients with lupus.

The market for pancreatic enzyme replacement therapy is also highly competitive. There are currently several marketed products for EPI caused by cystic fibrosis, including Creon marketed by AbbVie, Inc., Pancreaze by Janssen Pharmaceuticals, Inc., Pertzye by Cornestone Therapeutics, Inc., and Ultresa and Zenpep by Aptalis Pharma US. Inc. We are also aware of companies with other products in development that are being tested for potential treatment of EPI caused by cystic fibrosis: Johnson and Johnson Research and Development LLC recently completed a Phase 3 study to assess the effectiveness and safety of oral pancrelipase MT in the treatment of adult and pediatric/adolescent cystic fibrosis patients with clinical symptoms of EPI; and Nordmark Arzneimittel GmbH & Co. KG's compound, Burlulipase, is being tested in a Phase 3 study in patients with EPI.

Many of our potential competitors have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of drug candidates, and in obtaining U.S. FDA and other regulatory approvals of products and the commercialization of those products. Accordingly, our competitors may be more successful than we may be in obtaining U.S. FDA approval for drugs and achieving widespread market acceptance. Our competitors' drugs may be more effective, have fewer adverse effects, be less expensive to develop and manufacture or be more effectively marketed and sold than any product candidates we may commercialize and

may render our product candidates obsolete or non-competitive before we can recover the expenses of developing and commercializing our product candidates. We anticipate that we will face intense and increasing competition as new drugs enter the market and advanced technologies become available. These entities may also establish collaborative or licensing relationships with our competitors. Finally, the development of new treatment methods for the diseases we are targeting could render our drugs non-competitive or obsolete. All of these factors could adversely affect our business.

Our product candidates may cause undesirable adverse effects or have other properties that could delay or prevent their regulatory approval or limit the commercial profile of any approved label.

Undesirable adverse effects caused by our product candidates could cause us, IRBs or other reviewing entities, clinical study sites, or regulatory authorities to interrupt, delay or halt clinical studies and could result in the denial of regulatory approval by the U.S. FDA or other regulatory authorities. Phase 2 clinical studies conducted by us with blisibimod have generated differences in adverse effects and serious adverse events. The most common adverse effects seen with our product candidates versus placebo include injection site erythema and nasopharyngitis. The most common serious adverse events seen with blisibimod include Herpes zoster, pneumonia, urinary tract infections and deep vein thrombosis, cellulitis, intervertebral disc protrusion, spontaneous abortion, and kidney stones. During the placebo-controlled Phase 2 PEARL study, blisibimod was safe and well-tolerated at all dose levels with no meaningful imbalances in serious adverse events or infections between blisibimod and placebo. Discontinuation due to adverse event was lower amongst blisibimod-treated subjects (5.7%) compared to placebo (7.9%). Amongst the commonly-reported adverse events, imbalance was observed only with injection site reactions (200mg QW blisibimod = 15%, matched placebo = 7%), but these were not serious or severe and did not result in discontinuation of treatment. Studies conducted by our licensor on liprotamase have generated the following common adverse effects: general gastrointestinal disorder, such as abdominal pain, flatulence, loose stools and diarrhea.

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Our second product candidate, liprotamase, which we licensed from Eli Lilly in July 2014, received a complete response letter ("CRL") from the U.S. FDA while it was under development by Eli Lilly in April 2011. Eli Lilly addressed most of the material items highlighted by the U.S. FDA and worked directly with the U.S. FDA on a registration path for liprotamase which, if successful, could result in regulatory approval of liprotamase. There are still open items from the CRL that we will need to address with the U.S. FDA. While we plan to make reasonable efforts to accommodate and address the U.S. FDA's inquires and request, we are unable to determine the final outcome of the CRL. Any delay in addressing the CRL to the satisfaction of the U.S. FDA may result in postponement of our Phase 3 clinical trial of liprotamase in patients with EPI.

If serious adverse events that are considered related to our product candidates are observed in any Phase 3 clinical studies, our ability to obtain regulatory approval for our product candidates may be adversely impacted. Further, if our product candidates receive marketing approval and we or others later discover, after approval and use in an increasing number of patients, that our products could have adverse effect profiles that limit their usefulness or require their withdrawal (whether or not the therapies showed the adverse effect profile in Phase 1 through Phase 3 clinical studies), a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of the products;
- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications;
- we may be required to change the way the products are administered, conduct additional clinical studies or change the labeling of the products;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidates and could substantially increase the costs of commercialization.

Even if we succeed in completing clinical studies for orphan drug diseases, we are not guaranteed exclusive marketing rights.

Orphan drug designation is granted to drugs intended to treat a rare disease or condition, which in the United States is defined as having a prevalence of less than 200,000 individuals in the United States and in the European Union, or EU, is defined as no more than five in 10,000 people in the EU, which is the equivalent of 250,000 people or fewer. Orphan drug designation must be requested before submitting a marketing application. Our product candidates are potentially qualified for orphan drug designations in IgA nephropathy and PERT often seen in patients with cystic fibrosis. We intend to apply for orphan drug designations for blisibimod and for liprotamase. Because of the small number of patients in an orphan drug disease indication, there are certain inherent risks associated with the conduct of clinical studies involving these types of patients, including challenges in patient recruitment and retention of patients over the course of clinical studies. After an orphan drug becomes approved, its exclusive marketing rights can be lost under certain conditions, such as if the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug.

After the completion of our clinical studies, we cannot predict whether or when we will obtain regulatory approval to commercialize our product candidates and we cannot, therefore, predict the timing of any future revenue from the product candidates.

Even if we project positive clinical results and file for regulatory approval, we cannot commercialize any product candidate until the appropriate regulatory authorities have reviewed and approved the applications for such product candidate. We cannot assure you that the regulatory agencies will complete their review processes in a timely manner or that we will obtain regulatory approval for any product candidates we develop. Satisfaction of regulatory requirements typically takes many years, is dependent upon the type, complexity and novelty of the product and requires the expenditure of substantial resources. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action or changes in U.S. FDA policy during the period of product development, clinical studies and U.S. FDA regulatory review.

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Even if our product candidates receive regulatory approval, they may still face future development and regulatory difficulties.

Even if U.S. regulatory approval is obtained, the U.S. FDA may still impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. For example, the label ultimately approved for blisibimod or liprotamase, if any, may include restrictions on use. Further, the U.S. FDA has indicated that long-term safety data on blisibimod may need to be obtained as a post-market requirement. Our product candidates will also be subject to ongoing U.S. FDA requirements governing the labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, recordkeeping and reporting of safety and other post-market information. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the U.S. FDA and other regulatory authorities for compliance with current good manufacturing procedures, or cGMP, regulations. If we or a regulatory agency discovers previously unknown problems with our product candidates, such as adverse events of unanticipated severity or frequency, or problems with the facility where the products are manufactured, a regulatory agency may impose restrictions on the products, the manufacturing facility or us, including requiring recall or withdrawal of the products from the market or suspension of manufacturing. If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

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

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

New legal and regulatory requirements could make it more difficult for us to obtain approvals for our product candidates and could limit or make more burdensome our ability to commercialize any approved products.

New federal legislation or regulatory requirements could affect the requirements for obtaining regulatory approvals of our product candidates or otherwise limit our ability to commercialize any approved products or subject our products to more rigorous post-approval requirements. For example, the U.S. FDA Amendments Act of 2007, or FDAAA, granted the U.S. FDA new authority to impose post-approval clinical study requirements, require safety-related changes to product labeling and require the adoption of risk management plans, referred to in the legislation as risk evaluation and mitigation strategies, or REMS. The REMS may include requirements for special labeling or medication guides for patients, special communication plans to health care professionals, and restrictions on distribution and use. Pursuant to the FDAAA, if the U.S. FDA makes the requisite findings, it might require that a new product be used only by physicians with specified specialized training, only in specified designated health care settings, or only in conjunction with special patient testing and monitoring. The legislation also included the following: requirements for providing the public information on ongoing clinical studies through a clinical study

registry and for disclosing clinical study results to the public through such registry; renewed requirements for conducting clinical studies to generate information on the use of products in pediatric patients; and substantial new penalties, for example, for false or misleading consumer advertisements. Other proposals have been made to impose additional requirements on drug approvals, further expand post-approval requirements, and restrict sales and promotional activities. The new legislation, and the additional proposals if enacted, may make it more difficult or burdensome for us to obtain approval of our product candidates, any approvals we receive may be more restrictive or be subject to onerous post-approval requirements, our ability to successfully commercialize approved products may be hindered and our business may be harmed as a result.

If our product candidates for which we receive regulatory approval do not achieve broad market acceptance, the revenue that we generate from their sales, if any, will be limited.

The commercial success of our product candidates for which we obtain marketing approval from the U.S. FDA or other regulatory authorities will depend upon the acceptance of these products by the medical community, including physicians, patients and health care payors. The degree of market acceptance of our approved products will depend on a number of factors, including:

- demonstration of clinical safety and efficacy compared to other products;
- the relative convenience, ease of administration and acceptance by physicians and payors of our product candidates;

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- the prevalence and severity of any adverse effects;
- limitations or warnings contained in a product's U.S. FDA-approved labeling;
- availability of alternative treatments;
- pricing and cost-effectiveness;
- the effectiveness of our or any future collaborators' sales and marketing strategies;
- our ability to obtain and maintain sufficient third-party coverage or reimbursement from government health care programs, including Medicare and Medicaid; and
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage.

If our product candidates are approved but do not achieve an adequate level of acceptance by physicians, health care payors and patients, we may not generate sufficient revenue from these products, and we may not become or remain profitable. In addition, our efforts to educate the medical community and third- party payors on the benefits of our product candidates may require significant resources and may never be successful.

Our future success depends on our ability to retain our chief executive officer and other key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on Mr. Paul F. Truex, our President and Chief Executive Officer, Dr. Colin Hislop, our Senior Vice President and Chief Medical Officer, Dr. Debra Odink, our Senior Vice President and Chief Technology Officer and the other principal members of our executive team. The loss of the services of any of these persons might impede the achievement of our research, development and commercialization objectives. Recruiting and retaining qualified scientific personnel and possibly sales and marketing personnel will also be critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific personnel from universities and research institutions. Failure to succeed in clinical studies may make it more challenging to recruit and retain qualified scientific personnel. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

Recently enacted and future legislation or regulatory reform of the health care system in the United States and foreign jurisdictions may affect our ability to sell our products profitably.

Our ability to commercialize our future products successfully, alone or with collaborators, will depend in part on the extent to which reimbursement for the products will be available from government and health administration authorities, private health insurers and other third-party payors. The continuing efforts of the U.S. and foreign governments, insurance companies, managed care organizations and other payors of health care services to contain or reduce health care costs may adversely affect our ability to set prices for our products which we believe are fair, and our ability to generate revenues and achieve and maintain profitability.

Specifically, in both the United States and some foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the health care system in ways that could affect our ability to sell our products profitably. In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as

amended by the Health Care and Education Reconciliation Act, or collectively, the Health Care Reform Law, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

We will not know the full effects of the Health Care Reform Law until applicable federal and state agencies issue regulations or guidance under the new law. Although it is too early to determine the effect of the Health Care Reform Law, the new law appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and also may increase our regulatory burdens and operating costs. We expect further federal and state proposals and health care reforms to continue to be proposed by legislators, which could limit the prices that can be charged for any product we develop and may limit our commercial opportunity.

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Also in the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, also called the Medicare Modernization Act, or MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for drugs. In addition, this legislation authorized Medicare Part D prescription drug plans to use formularies where they can limit the number of drugs that will be covered in any therapeutic class. As a result of this legislation and the expansion of federal coverage of drug products, we expect that there will be additional pressure to contain and reduce costs. These cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for any approved products and could seriously harm our business. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors.

The continuing efforts of government and other third-party payors to contain or reduce the costs of health care through various means may limit our commercial opportunity. It will be time-consuming and expensive for us to go through the process of seeking reimbursement from Medicare and private payors. Our products may not be considered cost-effective, and government and third- party private health insurance coverage and reimbursement may not be available to patients for any of our future products or sufficient to allow us to sell our products on a competitive and profitable basis. Our results of operations could be adversely affected by the MMA, the Health Care Reform Law and additional prescription drug coverage legislation, by the possible effect of this legislation on amounts that private insurers will pay and by other health care reforms that may be enacted or adopted in the future. In addition, increasing emphasis on managed care in the United States will continue to put pressure on the pricing of pharmaceutical products. Cost control initiatives could decrease the price that we or any potential collaborators could receive for any of our future products and could adversely affect our profitability.

In some foreign countries, including major markets in the EU and Japan, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take six to 12 months or longer after the receipt of regulatory marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical study that compares the cost-effectiveness of our product candidates to other available therapies. Such pharmacoeconomic studies can be costly and the results uncertain. Our business could be harmed if reimbursement of our products is unavailable or limited in scope or amount or if pricing is set at unsatisfactory levels.

We face potential product liability exposure, and, if successful claims are brought against us, we may incur substantial liability.

The use of product candidates in clinical studies and the sale of any products for which we obtain marketing approval expose us to the risk of product liability claims. Product liability claims might be brought against us by consumers, health care providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. If we cannot successfully defend ourselves against product liability claims, we could incur substantial liabilities. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- Ÿ impairment of our business reputation;
- Ÿ withdrawal of clinical study participants;
- Ÿ costs of related litigation;
- Ÿ distraction of management’s attention from our primary business;

- substantial monetary awards to patients or other claimants;
- the inability to commercialize product candidates; and
- decreased demand for product candidates, if approved for commercial sale.

Our product liability insurance coverage for our clinical studies may not be sufficient to reimburse us for all expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If and when we obtain marketing approval for any product candidate, we intend to expand our insurance coverage to include the sale of commercial products; however, we may be unable to obtain this product liability insurance on commercially reasonable terms. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

If we use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.

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Our research and development activities involve the controlled use of potentially hazardous substances, including toxic chemical and biological materials. We could be held liable for any contamination, injury or other damages resulting from these hazardous substances. In addition, our operations produce hazardous waste products. While third parties are responsible for disposal of our hazardous waste, we could be liable under environmental laws for any required cleanup of sites at which our waste is disposed. Federal, state, foreign and local laws and regulations govern the use, manufacture, storage, handling and disposal of these hazardous materials. If we fail to comply with these laws and regulations at any time, or if they change, we may be subject to criminal sanctions and substantial civil liabilities, which may harm our business. Even if we continue to comply with all applicable laws and regulations regarding hazardous materials, we cannot eliminate the risk of accidental contamination or discharge and our resultant liability for any injuries or other damages caused by these accidents.

We rely on third parties to conduct, supervise and monitor our clinical studies, and those third parties may perform in an unsatisfactory manner, such as by failing to meet established deadlines for the completion of these clinical studies, or may harm our business if they suffer a catastrophic event.

We rely on third parties such as CROs, medical institutions and clinical investigators to enroll qualified patients and conduct, supervise and monitor our clinical studies. Our reliance on these third parties for clinical development activities reduces our control over these activities. Our reliance on these third parties, however, does not relieve us of our regulatory responsibilities, including ensuring that our clinical studies are conducted in accordance with good clinical practices, or GCP, and the investigational plan and protocols contained in the relevant regulatory application, such as the investigational new drug application, or IND. In addition, the CROs with whom we contract may not complete activities on schedule, or may not conduct our preclinical studies or clinical studies in accordance with regulatory requirements or our clinical study design. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, our efforts to obtain regulatory approvals for, and to commercialize, our product candidates may be delayed or prevented. In addition, if a catastrophe such as an earthquake, fire, flood or power loss should affect one of the third parties on which we rely, our business prospects could be harmed. For example, if a central laboratory holding all of our clinical study samples were to suffer a catastrophic loss of their facility, we would lose all of our samples and would have to repeat our studies.

Any failure by our third-party manufacturers on which we rely to produce our preclinical and clinical drug supplies and on which we intend to rely to produce commercial supplies of any approved product candidates may delay or impair our ability to commercialize our product candidates.

We have relied upon a small number of third-party manufacturers and active pharmaceutical ingredient formulators for the manufacture of our material for preclinical and clinical testing purposes and intend to continue to do so in the future. We also expect to rely upon third parties to produce materials required for the commercial production of our product candidates if we succeed in obtaining necessary regulatory approvals. If we are unable to arrange for third-party manufacturing sources, or to do so on commercially reasonable terms, we may not be able to complete development of our product candidates or market them.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured product candidates ourselves, including reliance on the third party for regulatory compliance and quality assurance, the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control (including a failure to synthesize and manufacture our product candidates in accordance with our product specifications) and the possibility of termination or nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or damaging to us. In addition, the U.S. FDA and other regulatory authorities require that our product candidates be manufactured according to cGMP and similar foreign standards. Any failure by our third-party manufacturers to comply with cGMP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities in a timely manner, could lead to a delay in, or failure to obtain,

regulatory approval. In addition, such failure could be the basis for action by the U.S. FDA to withdraw approvals previously granted to us and for other regulatory action, including recall or seizure, total or partial suspension of production or injunction.

We rely on our manufacturers to purchase from third-party suppliers the materials necessary to produce drug product for our clinical studies. There are a small number of suppliers, and in some instances, a single supplier for certain capital equipment and raw materials that we use to manufacture drug product. Such suppliers may not sell these raw materials to our manufacturers at the times we need them or on commercially reasonable terms. We do not have any control over the process or timing of the acquisition of these raw materials by our manufacturers. Moreover, we currently do not have any agreements for the commercial production of these raw materials. Although we generally do not begin a clinical study unless we believe we have a sufficient supply of a product candidate to complete the clinical study, any significant delay in the supply of a product candidate or the raw material components thereof for an ongoing clinical study due to the need to replace a third-party manufacturer could considerably delay completion of our clinical studies, product testing and potential regulatory approval. If our manufacturers or we are unable to purchase these raw materials after regulatory approval has been obtained, the commercial launch would be delayed or there would be a shortage in supply of such product candidate, which would impair our ability to generate revenues from the sale of such product candidate.

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Because of the complex nature of our compounds, our manufacturers may not be able to manufacture our compounds at a cost or in quantities or in a timely manner necessary to make commercially successful products. If we successfully commercialize a product candidate, we may be required to establish large-scale commercial manufacturing capabilities. In addition, as our drug development pipeline increases and matures, we will have a greater need for clinical study and commercial manufacturing capacity. We have no experience manufacturing pharmaceutical products on a commercial scale and some of these suppliers will need to increase their scale of production to meet our projected needs for commercial manufacturing, which may not occur on a timely basis.

Some of our manufacturing suppliers are located overseas, and the transportation of drug supplies to or from these facilities to their intended destinations is subject to certain risks of loss and damage beyond our control. Additionally, the importation of drug supplies into the U.S. from foreign countries is subject to customs regulations that may require us to incur additional regulatory costs.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate any revenue.

We do not currently have an organization for the sales, marketing and distribution of pharmaceutical products and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. In order to market any products that may be approved by the U.S. FDA, we must build our sales, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate product revenue and may not become profitable. We will be competing with many companies that currently have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

Guidelines and recommendations published by various organizations may adversely affect the use of any products for which we may receive regulatory approval.

Government agencies issue regulations and guidelines directly applicable to us and to our product candidates. In addition, professional societies, practice management groups, private health or science foundations and organizations involved in various diseases from time to time publish guidelines or recommendations to the medical and patient communities. These various sorts of recommendations may relate to such matters as product usage and use of related or competing therapies. Changes to these recommendations or other guidelines advocating alternative therapies could result in decreased use of any products for which we may receive regulatory approval, which may adversely affect our results of operations.

Risks Related to Our Intellectual Property

If our or our licensors' patent positions do not adequately protect our product candidates or any future products, others could compete with us more directly or prevent us from commercializing our products, which would harm our business.

We hold license rights to numerous U.S. European Patents ("EP"), and non-EP foreign patents and patent applications relating to blisibimod and liprotamase. Our blisibimod portfolio is made up of exclusively and non-exclusively licensed patents and patent applications from Amgen, Inc. Our liprotomase portfolio is made up of exclusively licensed patents and patent applications from Eli Lilly.

We also own several U.S. and non-U.S. patents and patent applications relating to our terminated varespladib sodium/varespladib programs. These patents and patent applications include both patents and patent applications originally filed by Anthera and patents assigned to Anthera by Eli Lilly or Shionogi & Co., Ltd. Our varespladib sodium/varespladib portfolio previously included a larger set of patents and patent applications relating to sPLA 2 inhibiting compounds and exclusively licensed from Eli Lilly and Shionogi & Co., Ltd. In August 2012, we provided notice of termination to our collaborators to terminate the license agreement. The license agreement was effectively terminated in November 2012. Due to termination of the varespladib programs, we do not expect to incur further payments to our collaborators under the license agreement.

Our commercial success will depend in part on our and our licensors' ability to obtain additional patents and protect our existing patent positions, particularly those patents for which we have secured exclusive rights, as well as our ability to maintain adequate protection of other intellectual property for our technologies, product candidates and any future products in the United States and other countries. If we or our licensors do not adequately protect our intellectual property, competitors may be able to use our technologies and erode or negate any competitive advantage we may have, which could materially harm our business, negatively affect our position in the marketplace, limit our ability to commercialize our product candidates and delay or render impossible our achievement of profitability. The laws of some foreign countries do not protect our proprietary rights to the same extent as the laws of the United States, and we may encounter significant problems in protecting our proprietary rights in these countries.

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The patent positions of biotechnology and pharmaceutical companies, including our patent position, involve complex legal and factual questions, and, therefore, validity and enforceability cannot be predicted with certainty. Patents may be challenged, deemed unenforceable, invalidated or circumvented. We and our licensors will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies, product candidates and any future products are covered by valid and enforceable patents or are effectively maintained as trade secrets.

The degree of future protection for our proprietary rights is uncertain, and we cannot ensure that:

- we or our licensors were the first to make the inventions covered by each of our pending patent applications;
- we or our licensors were the first to file patent applications for these inventions;
- others will not independently develop similar or alternative technologies or duplicate any of our technologies;
- any of our or our licensors' pending patent applications will result in issued patents;
- any of our or our licensors' patents will be valid or enforceable;
- any patents issued to us or our licensors and collaborators will provide a basis for commercially viable products, will provide us with any competitive advantages or will not be challenged by third parties;
- we will develop additional proprietary technologies or product candidates that are patentable; or
- the patents of others will not have an adverse effect on our business.

We are aware of two families of third party United States patents and pending foreign applications that contain broad claims related to BLyS or BAFF binding polypeptides. Based on our analyses, if these patents were asserted against us, we do not believe that blisibimod would be found to infringe any valid claim of these patents. If we were to challenge the validity of any issued United States patent in court, we would need to overcome the presumption of validity that attaches to every United States patent by presenting clear and convincing evidence as to the invalidity of the patent's claims. There is no assurance that a court would find in our favor on questions of infringement or validity, and we could incur substantial costs in litigation if we are required to defend against patent suits brought by third parties or if we initiate these suits. If third party patents are determined to be valid and construed to cover blisibimod, the development and commercialization of this program could be affected, subjecting us to potential liability for damages and in addition may require us to obtain a license to continue marketing the affected product. Such a license may not be available on commercially acceptable terms, if at all.

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

We rely on trade secrets to protect our proprietary know-how and technological advances, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights. Failure to obtain or maintain trade secret protection could enable competitors to use our proprietary information to develop products that compete with our products or cause additional, material adverse

effects upon our competitive business position.

We license patent rights from third-party owners. If we, or such owners, do not properly maintain or enforce the patents underlying such licenses, our competitive position and business prospects will be harmed.

We are party to a license agreement with Amgen that provides exclusive and worldwide rights to develop and commercialize the novel BAFF inhibitor blisibimod, as well as non-exclusive rights to certain technology relating to peptibody compositions and formulations. We are also a party to a license agreement with Eli Lilly and Company that provides exclusive and worldwide rights to develop and commercialize liprotamase, as well as non-exclusive rights to certain technology relating to liprotamase's compositions and formulations.

We depend in part on our licensors to protect the proprietary rights covering blisibimod and liprotamase. Our licensors are responsible for maintaining certain issued patents and prosecuting certain patent applications. We have limited, if any, control over the amount or timing of resources that our licensors devote on our behalf or the priority they place on maintaining these patent rights and prosecuting these patent applications to our advantage. Our licensors may also be notified of alleged infringement and be sued for infringement of third-party patents or other proprietary rights. We may have limited, if any, control or involvement over the defense of these claims, and our licensors could be subject to injunctions and temporary or permanent exclusionary orders in the United States or other countries. Our licensors are not obligated to defend or assist in our defense against third-party claims of infringement. We have limited, if any, control over the amount or timing of resources, if any, that our licensors devote on our behalf or the priority they place on defense of such third-party claims of infringement.

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Our success will depend in part on the ability of us or our licensors to obtain, maintain and enforce patent protection for their intellectual property, in particular, those patents to which we have secured exclusive rights. We or our licensors may not successfully prosecute the patent applications which we have licensed. Even if patents issue in respect of these patent applications, we or our licensors may fail to maintain these patents, may determine not to pursue litigation against other companies that are infringing these patents or may pursue such litigation less aggressively than we would. Without protection for the intellectual property we license, other companies might be able to offer substantially identical products for sale, which could adversely affect our competitive business position and harm our business prospects.

If we do not obtain protection under the Hatch-Waxman Act and similar foreign legislation to extend our licensed patent terms and to obtain market exclusivity for our product candidates, our business will be materially harmed.

The United States Drug Price Competition and Patent Term Restoration Act of 1984, more commonly known as the "Hatch-Waxman Act," provides for an extension of patent term for drug compounds for a period of up to five years to compensate for time spent in the regulatory approval process. Assuming we gain a five-year patent term extension for blisibimod and that we continue to have rights under our license agreement with respect to blisibimod, we would have exclusive rights to blisibimod's U.S. new chemical entity patent until 2027 or 2028. In Europe, similar legislative enactments allow patent terms in the European Union to be extended for up to five years through the grant of a Supplementary Protection Certificate. Assuming we gain such a five-year extension for blisibimod and that we continue to have rights under our license agreement with respect to blisibimod, we would have exclusive rights to blisibimod's European new chemical entity patents until 2027. Further, since blisibimod has not been previously approved, blisibimod could be eligible for 12 years of data exclusivity from the U.S. FDA. During the data exclusivity period, competitors are barred from relying on the innovator biologic's safety and efficacy data to gain approval. Similarly, the European Union provides that companies who receive regulatory approval for a new small molecule compound or biologic will have a 10-year period of data exclusivity for that compound or biologic (with the possibility of a further one-year extension) in most EU countries, beginning on the date of such European regulatory approval, regardless of when the European new chemical entity patent covering such compound expires. A generic version of the approved drug may not be marketed or sold during such market exclusivity period. However, there is no assurance that we will receive the extensions of our patents or other exclusive rights available under the Hatch-Waxman Act or similar foreign legislation. If we fail to receive such Hatch-Waxman extensions or marketing exclusivity rights or if we receive extensions that are materially shorter than expected, our ability to prevent competitors from manufacturing, marketing and selling generic versions of our products will be materially harmed.

Our current patent positions and license portfolio may not include all patent rights needed for the full development and commercialization of our product candidates. We cannot be sure that patent rights we may need in the future will be available for license to us on commercially reasonable terms, or at all.

We typically develop product candidates using compounds for which we have in-licensed and original composition of matter patents and patents that claim the activities and methods for such compounds' production and use to the extent known at that time. As we learn more about the mechanisms of action and new methods of manufacture and use of product candidates, we may file additional patent applications for these new inventions or we may need to ask our licensors to file them. We may also need to license additional patent rights or other rights on compounds, treatment methods or manufacturing processes because we learn that we need such rights during the continuing development of our product candidates.

Although our in-licensed and original patents may prevent others from making, using or selling similar products, they do not ensure that we will not infringe the patent rights of third parties. We may not be aware of all patents or patent applications that may impact our ability to make, use or sell our product candidates. For example, because we sometimes identify the mechanism of action or molecular target of a given product candidate after identifying its

composition of matter and therapeutic use, we may not be aware until the mechanism or target is further elucidated that a third party has an issued or pending patent claiming biological activities or targets that may cover our product candidates. U.S. patent applications filed after November 29, 2000 are confidential in the U.S. Patent and Trademark Office for the first 18 months after such applications' earliest priority date, and patent offices in non-U.S. countries often publish patent applications for the first time six months or more after filing. Furthermore, we may not be aware of published or granted conflicting patent rights. Any conflicts resulting from patent applications and patents of others could significantly reduce the coverage of our patents and limit our ability to obtain meaningful patent protection. If others obtain patents with conflicting claims, we may need to obtain licenses to these patents or to develop or obtain alternative technology.

We may not be able to obtain any licenses or other rights to patents, technology or know-how from third parties necessary to conduct our business as described in this report and such licenses, if available at all, may not be available on commercially reasonable terms. Any failure to obtain such licenses could delay or prevent us from developing or commercializing our product candidates or proposed product candidates, which would harm our business. Litigation or patent interference proceedings may be necessarily brought against third parties, as discussed below, to enforce any of our patents or other proprietary rights or to determine the scope and validity or enforceability of the proprietary rights of such third parties.

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Litigation regarding patents, patent applications and other proprietary rights may be expensive and time consuming. If we are involved in such litigation, it could cause delays in bringing product candidates to market and harm our ability to operate.

Our commercial success will depend in part on our ability to manufacture, use, sell and offer to sell our product candidates and proposed product candidates without infringing patents or other proprietary rights of third parties. Although we are not currently aware of any litigation or other proceedings or third-party claims of intellectual property infringement related to our product candidates, the pharmaceutical industry is characterized by extensive litigation regarding patents and other intellectual property rights. Other parties may obtain patents in the future and allege that the use of our technologies infringes these patent claims or that we are employing their proprietary technology without authorization. Likewise, third parties may challenge or infringe upon our or our licensors' existing or future patents.

Proceedings involving our patents or patent applications or those of others could result in adverse decisions regarding the patentability of our inventions relating to our product candidates or the enforceability, validity or scope of protection offered by our patents relating to our product candidates.

Even if we are successful in these proceedings, we may incur substantial costs and divert management time and attention in pursuing these proceedings. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, defend an infringement action or challenge the validity of the patents in court. Patent litigation is costly and time-consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we do not obtain a license, develop or obtain non-infringing technology, fail to defend an infringement action successfully or have our patents declared invalid, we may incur substantial monetary damages; encounter significant delays in bringing our product candidates to market; or be precluded from participating in the manufacture, use or sale of our product candidates or methods of treatment requiring licenses.

Risks Related to the Securities Markets and Investment in Our Common Stock

Market volatility may affect our stock price and the value of your investment.

The market price for our common stock has been and is likely to continue to be volatile. In addition, the market price of our common stock may fluctuate significantly in response to a number of factors, most of which we cannot predict or control, including:

- plans for, progress in and results from clinical studies for our product candidates;
- announcements of new products, services or technologies, commercial relationships, acquisitions or other events by us or our competitors;
- developments concerning proprietary rights, including those pertaining to patents patent applications held by our licensors;
- failure of any of our product candidates, if approved, to achieve commercial success;
- fluctuations in stock market prices and trading volumes of securities of similar companies;
- general market conditions and overall fluctuations in U.S. equity markets;
- variations in our operating results, or the operating results of our competitors;

- changes in our financial guidance or securities analysts' estimates of our financial performance;
- changes in accounting principles;
- sales of large blocks of our common stock, including sales by our executive officers, directors and significant stockholders;
- additions or departures of any of our key personnel;
- announcements related to litigation;
- changing legal or regulatory developments in the United States and other countries; and

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- Ÿ discussion of us or our stock price by the financial press and in online investor communities.

Although our common stock is listed for trading on The NASDAQ Global Market, our securities have been relatively thinly traded. Investor trading patterns could serve to exacerbate the volatility of the price of the stock. Accordingly, it may be difficult to sell shares of common stock quickly without significantly depressing the value of the stock. Unless we are successful in developing continued investor interest in our stock, sales of our stock could result in major fluctuations in the price of the stock. In addition, the stock market in general, and The NASDAQ Global Market in particular, have experienced substantial price and volume volatility that is often seemingly unrelated to the operating performance of particular companies. These broad market fluctuations may cause the trading price of our common stock to decline. In the past, securities class action litigation has often been brought against a company after a period of volatility in the market price of its common stock. We may become involved in this type of litigation in the future. Any securities litigation claims brought against us could result in substantial expenses and the diversion of our management's attention from our business.

Because a small number of our existing stockholders own a material amount of our voting stock, your ability to influence corporate matters will be limited.

Our executive officers, directors and greater than 5% stockholders, in the aggregate, own approximately 21.48% of our outstanding common stock. As a result, such persons, acting together, will have the ability to influence our management and affairs and substantially all matters submitted to our stockholders for approval, including the election and removal of directors and approval of any significant transaction. These persons will also have the ability to influence our management and business affairs. This concentration of ownership may have the effect of delaying, deferring or preventing a change in control, impeding a merger, consolidation, takeover or other business combination involving us, or discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of our business, even if such a transaction would benefit other stockholders.

Future sales of our common stock may cause our stock price to decline.

As of June 30, 2014, there were 22,644,006 shares of our common stock outstanding. In addition, as of June 30, 2014, we had outstanding options, restricted stock units and warrants to purchase shares of our common stock of 2,833,264 that, if exercised or released, will result in these additional shares becoming available for sale. A large portion of these shares and outstanding equity awards are held by a small number of persons and investment funds. Sales by these stockholders or option holders of a substantial number of shares could significantly reduce the market price of our common stock. Moreover, certain holders of shares of common stock will have rights, subject to some conditions, to require us to file registration statements covering the shares they currently hold, or to include these shares in registration statements that we may file for ourselves or other stockholders.

We have registered or will register all common stock that we may issue under our 2013 Stock Option and Incentive Plan (the "2013 Plan"), our Amended and Restated 2010 Stock Option and Incentive Plan (the "2010 Plan") and our Employee Stock Purchase Plan (the "ESPP"). As of June 30, 2014, an aggregate of 110,123 shares of our common stock had been reserved for future issuance under the 2013 Plan, plus any shares cancelled under our 2005 Equity Incentive Plan and 2010 Plan, and an aggregate of 110,123 shares had been reserved for future issuance under our ESPP. These shares can be freely sold in the public market upon issuance. If a large number of these shares are sold in the public market, the sales could reduce the trading price of our common stock.

In addition, we may sell shares of stock pursuant to an equity purchase agreement with LPC, pursuant to which we have the right to sell to LPC up to an aggregate of $18.5 million of our common stock, of which approximately $14.9 million remained available to be sold as of June 30, 2014. We may also sell shares of stock pursuant to an ATM with Cowen under which we may from time to time offer and sell up to $25.0 million shares of our common stock, $15.6

million of which remained available to be sold as of June 30, 2014. Finally, we maintain effective shelf registration statements on Form S-3 with the SEC for the issuance and sale from time to time of up to approximately $75.2 million of our equity and debt securities.

We will need to raise additional capital to fund our operations, which may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights.

We will need to seek additional capital through a combination of private and public equity offerings, debt financings and collaboration, strategic and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest may be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring debt, making capital expenditures or declaring dividends. If we raise additional funds through collaboration, strategic alliance and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates or grant licenses on terms that are not favorable to us.

We have identified a material weakness in our internal control over financial reporting that resulted in the restatement of our consolidated financial statements included in our Annual Report on Form 10-K filed on March 28, 2014. This material weakness could continue to adversely affect our ability to report our results of operations and financial condition accurately and in a timely manner.

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Our management is responsible for establishing and maintaining adequate internal control over financial reporting designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with U.S. GAAP. Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2013 and identified a material weakness related to our prior interpretation of Accounting Standard Codification 815 and our initial classification and subsequent accounting of warrants as either liabilities or equity instruments. As a result of this material weakness, our management concluded that our internal control over financial reporting was not effective as of December 31, 2013. This material weakness resulted in a material misstatement of our liabilities, non-cash expense relating to the changes in fair value of common stock warrants and accumulated deficit accounts and related financial disclosures and the restatement of our accompanying consolidated financial statements as disclosed in our annual report on Form 10-K for the year ended December 31, 2013. We began the implementation of the remediation activities in the second quarter of 2014. As of June 30, 2014, we have not yet been able to remediate this material weakness. As we continue to evaluate and work to improve our internal control over financial reporting, we may determine to take additional measures to address the material weakness.

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim consolidated financial statements will not be prevented or detected on a timely basis. The effectiveness of any controls or procedures is subject to certain limitations, and as a result, internal control over financial reporting may not prevent or detect misstatements. A control can provide only reasonable, not absolute, assurance that the objectives of the control system will be attained. Although we have begun the implementation of the remediation activities in the second quarter of 2014, we have not yet been able to fully remediate this material weakness as of the date of this filing. We can give no assurance that additional material weaknesses or restatements of financial results will not arise in the future due to a failure to implement and maintain adequate internal control over financial reporting or circumvention of these controls. Additionally, even our improved controls and procedures may not be adequate to prevent or identify errors or irregularities or ensure that our financial statements are prepared in accordance with U.S. GAAP. If we cannot maintain and execute adequate internal control over financial reporting or implement required new or improved controls that provide reasonable assurance of the reliability of the financial reporting and preparation of our financial statements for external use, we could suffer harm to our reputation, fail to meet our public reporting requirements on a timely basis, cause investors to lose confidence in our reported financial information or be unable to properly report on our business and the results of our operations, and the trading price of our common stock could be materially adversely affected.

Operating as a public company increases our expenses and administrative burden.

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, our administrative staff will be required to perform additional tasks. For example, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, as well as rules subsequently implemented by the SEC and The NASDAQ Global Market, impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. We must also bear all of the internal and external costs of preparing and distributing periodic public reports in compliance with our obligations under the securities laws.

In particular, the Sarbanes-Oxley Act requires, among other things, that we maintain effective internal control over financial reporting and disclosure controls and procedures. We must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. Our compliance with Section 404 will require that we incur substantial accounting expense and expend significant management time on compliance-related issues. Moreover, if we are not able to comply with the requirements of Section 404 in a timely

manner, our stock price could decline, and we could face sanctions, delisting or investigations by The NASDAQ Global Market, or other material adverse effects on our business, reputation, results of operations, financial condition or liquidity.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

We have never declared or paid any cash dividend on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the value of their stock.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

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Provisions in our amended and restated certificate of incorporation and amended and restated bylaws may delay or prevent an acquisition of us or a change in our management. These provisions include:

- a classified and staggered board of directors whose members can only be dismissed for cause;
- the prohibition on actions by written consent of our stockholders;
- the limitation on who may call a special meeting of stockholders;
- the establishment of advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted upon at stockholder meetings;
- the ability of our board of directors to issue preferred stock without stockholder approval, which would increase the number of outstanding shares and could thwart a takeover attempt; and
- the requirement of at least 75% of the outstanding common stock to amend any of the foregoing provisions.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which limits the ability of stockholders owning in excess of 15% of our outstanding voting stock to merge or combine with us. Although we believe these provisions collectively provide for an opportunity to obtain greater value for stockholders by requiring potential acquirers to negotiate with our board of directors, they would apply even if an offer rejected by our board were considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management.

Our ability to use our net operating loss carryforwards may be subject to limitation and may result in increased future tax liability to us.

Generally, a change of more than 50% in the ownership of a corporation’s stock, by value, over a three-year period constitutes an ownership change for U.S. federal income tax purposes. An ownership change may limit a company’s ability to use its net operating loss carryforwards attributable to the period prior to such change. We incurred an ownership change within the meaning of Section 382 ownership of the Internal Revenue Code during 2012 and as such, our net operating loss carryforward are limited. In addition, the pre-change R&D tax credits have also been limited for federal tax purposes. If we earn net taxable income, our ability to use our pre-change net operating loss carryforwards to offset U.S. federal taxable income will be subject to limitations, which will result in increased future tax liability to us.

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ITEM 6. EXHIBITS

The following exhibits are filed as part of this report:

Number	Description
3.1	Fifth Amended and Restated Certificate of Incorporation (filed as Exhibit 3.6 to the registrant's Registration Statement on Form S-1/A (File No. 333-161930) filed with the SEC February 3, 2010 and incorporated herein by reference).
3.2	Certificate of Amendment to the Fifth Amended and Restated Certificate of Incorporation (filed as Annex A to the registrant's Definitive Proxy Statement on Schedule 14A, filed with the SEC October 20, 2012 and incorporated herein by reference).
3.3	Certificate of Amendment to the Fifth Amended and Restated Certificate of Incorporation filed July 12, 2013 and effective July 15, 2013(Filed as Exhibit 3.1 to the registrant Current Report on Form 8-K, filed with the SEC on July 16, 2013 and incorporated herein by reference.)
3.4	Amended and Restated Bylaws (filed as Exhibit 3.7 to the registrant's Registration Statement on Form S-1/A (File No. 333-161930) filed with the SEC February 3, 2010 and incorporated herein by reference).
10.1+	License Agreement between the Company and Eli Lilly and Company, dated as of July 11, 2014.
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.
32.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as adopted pursuant Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	XBRL Instance Document.
101.SCH*	XBRL Taxonomy Extension Schema Document.
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document.

* In accordance with Rule 406T of Regulation S-T, the XBRL related information in Exhibit 101 to this Quarterly Report on Form 10-Q is furnished and shall not be deemed to be "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liability of the section, and shall not be part of any registration statement or other document filed under the Securities Act or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

\+ Certain portions of this Exhibit have been omitted pursuant to a request for confidential treatment.

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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.

ANTHERA PHARMACEUTICALS, INC.

August 14, 2014	By:	/s/ Paul F. Truex Paul F. Truex President and Chief Executive Officer
August 14, 2014	By:	/s/ May Liu May Liu Senior Vice President, Finance and Administration (Principal Accounting Officer)