

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2013

OR

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

For the transition period from _____ to _____

Commission file number: 001-34637

ANTHERA PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware

(State or Other Jurisdiction of Incorporation or Organization)

20-1852016

(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 No

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

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

Large accelerated filer

Accelerated filer

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

Smaller reporting company

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

As of November 8, 2013, the number of outstanding shares of the registrant's common stock, par value \$0.001 per share, was 19,304,116

ANTHERA PHARMACEUTICALS, INC.

FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2013

INDEX

	<u>Page</u>
Part I — Financial Information	3
<u>Item 1. Financial Statements (unaudited)</u>	3
<u>Consolidated Balance Sheets as of September 30, 2013 and December 31, 2012</u>	3
<u>Consolidated Statements of Operations for the Three and Nine Months Ended September 30, 2013 and 2012</u> <u>and for the period from September 9, 2004 (Date of Inception) to September 30, 2013</u>	4
<u>Consolidated Statements of Comprehensive Loss for the Three and Nine Months Ended September 30, 2013 and 2012</u> <u>and for the period from September 9, 2004 (Date of Inception) to September 30, 2013</u>	5
<u>Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2013 and 2012 and cumulative</u> <u>period from September 9, 2004 (Date of Inception) to September 30, 2013</u>	6
<u>Notes to Consolidated Financial Statements</u>	7
<u>Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	17
<u>Item 3. Controls and Procedures</u>	26
Part II — Other Information	27
<u>Item 1. Legal Proceedings</u>	27
<u>Item 1A. Risk Factors</u>	27
<u>Item 6. Exhibits</u>	44
<u>Signatures</u>	45
EX-3.1	
EX-3.2	
EX-3.3	
EX-31.1	
EX-31.2	
EX-32.1	
EX-32.2	
EX-101	

PART I — FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	<u>September 30, 2013</u>	<u>December 31, 2012</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 31,561	\$ 19,431
Short-term investments	479	5,322
Prepaid expenses and other current assets	1,145	426
Total current assets	33,185	25,179
Property and equipment — net	901	1,150
Debt issuance costs	249	116
Restricted cash	10,000	—
TOTAL	<u>\$ 44,335</u>	<u>\$ 26,445</u>
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	\$ 1,617	\$ 5,206
Accrued clinical expenses	629	3,374
Accrued liabilities	236	497
Accrued payroll and related costs	328	344
Short term portion of notes payable, net of discount	2,778	9,329
Total current liabilities	5,588	18,750
Notes payable, net of discount	15,792	11,221
Total liabilities	21,380	29,971
Commitments and Contingencies (Note 5)		
Stockholders' equity (deficit)		
Common stock, \$0.001 par value, 100,000,000 shares authorized; 19,304,116 and 9,893,924 shares issued and outstanding as of September 30, 2013 and December 31, 2012, respectively	19	10
Additional paid-in capital	304,996	256,859
Accumulated other comprehensive loss	(18)	(17)
Deficit accumulated during the development stage	(282,042)	(260,378)
Total stockholders' equity (deficit)	22,955	(3,526)
TOTAL	<u>\$ 44,335</u>	<u>\$ 26,445</u>

See accompanying notes to consolidated financial statements.

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

	Three months ended		Nine months ended		Cumulative Period from September 9, 2004 (Date of Inception) to September 30, 2013
	September 30,		September 30,		
	2013	2012	2013	2012	
OPERATING EXPENSES:					
Research and development	\$ 4,051	\$ 9,527	\$ 14,245	\$ 42,130	\$ 229,526
General and administrative	1,470	1,594	5,130	5,715	35,920
Total operating expenses	<u>5,521</u>	<u>11,121</u>	<u>19,375</u>	<u>47,845</u>	<u>265,446</u>
LOSS FROM OPERATIONS	<u>(5,521)</u>	<u>(11,121)</u>	<u>(19,375)</u>	<u>(47,845)</u>	<u>(265,446)</u>
OTHER INCOME (EXPENSE):					
Other income (expense)	14	(46)	33	(84)	1,533
Interest expense	(296)	(806)	(2,322)	(2,557)	(10,024)
Mark-to-market adjustment of warrant liability	—	—	—	—	(3,796)
Beneficial conversion features	—	—	—	—	(4,309)
Total other income (expense)	<u>(282)</u>	<u>(852)</u>	<u>(2,289)</u>	<u>(2,641)</u>	<u>(16,596)</u>
NET LOSS	<u>\$ (5,803)</u>	<u>\$ (11,973)</u>	<u>\$ (21,664)</u>	<u>\$ (50,486)</u>	<u>\$ (282,042)</u>
Net loss per share—basic and diluted	<u>\$ (0.30)</u>	<u>\$ (1.38)</u>	<u>\$ (1.21)</u>	<u>\$ (7.97)</u>	
Weighted-average number of shares used in per share calculation—basic and diluted	<u>19,196,140</u>	<u>8,703,790</u>	<u>17,937,069</u>	<u>6,330,705</u>	

See accompanying notes to consolidated financial statements.

ANTHERA PHARMACEUTICALS, INC.
(A Development Stage Company)
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(in thousands)
(unaudited)

	Three months ended		Nine months ended		Cumulative
	September 30,		September 30,		Period
	2013	2012	2013	2012	from
					September 9,
					2004
					(Date of
					Inception)
					to
					September 30,
					2013
Net loss	(5,803)	(11,973)	(21,664)	(50,486)	(282,042)
Unrealized gain (loss) on short term investments, net	(4)	49	(1)	(12)	(18)
Comprehensive loss	<u>\$ (5,807)</u>	<u>\$ (11,924)</u>	<u>\$ (21,665)</u>	<u>\$ (50,498)</u>	<u>\$ (282,060)</u>

See accompanying notes to consolidated financial statements.

ANTHERA PHARMACEUTICALS, INC.
(A Development Stage Company)
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)
(unaudited)

	Nine Months Ended September 30,		September 9, 2004 (Date of Inception) to September 30, 2013
	2013	2012	
CASH FLOW FROM OPERATING ACTIVITIES:			
Net loss	\$ (21,664)	\$ (50,486)	\$ (282,042)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	264	243	765
Amortization of premium/(discount) on short-term investments	—	—	56
Realized (gain)/loss on short-term investments and foreign currency exchange rates fluctuation	12	46	(106)
Stock-based compensation expense	2,452	1,052	7,172
Issuance of preferred and common stock for license fee, interest and service	—	—	6,122
Beneficial conversion feature	—	—	4,309
Amortization of discount and deferred interest on convertible notes and notes payable	959	556	3,013
Amortization of debt issuance costs	166	93	706
Mark-to-market adjustment on warrant liability	—	—	3,796
Changes in assets and liabilities:			
Prepaid expenses and other assets	(719)	69	(1,146)
Accounts payable	(3,661)	(13,309)	1,736
Accrued clinical expenses	(2,745)	3,179	631
Accrued liabilities	(1,231)	(74)	(996)
Accrued payroll and related costs	(16)	478	301
Net cash used in operating activities	<u>(26,183)</u>	<u>(58,153)</u>	<u>(255,683)</u>
INVESTING ACTIVITIES:			
Property and equipment purchases	(15)	(207)	(1,675)
Purchase of short-term investments	—	(5,355)	(55,155)
Proceeds from maturities of short-term investments	4,831	5,624	54,771
Increase in restricted cash	(10,000)	—	(10,000)
Net cash (used in)/provided by investing activities	<u>(5,184)</u>	<u>62</u>	<u>(12,059)</u>
FINANCING ACTIVITIES:			
Proceeds from issuance of convertible notes and notes payable, net of issuance costs	19,798	—	70,750
Principal payment against note payable	(21,722)	(2,201)	(26,190)
Net proceeds from issuance of preferred stock	—	—	32,210
Proceeds from issuance of common stock, net of offering costs	45,410	35,575	222,266
Withholding taxes paid on vested restricted stock units	(32)	(35)	(948)
Proceeds from issuance of common stock pursuant to exercise of warrant	—	—	220
Proceeds from issuance of common stock pursuant to employee stock purchase plan and exercise of stock options, net	44	168	1,027
Net cash provided by financing activities	<u>43,498</u>	<u>33,507</u>	<u>299,335</u>
Effect of exchange rates on cash and cash equivalents	(1)	(55)	(32)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	12,130	(24,639)	31,561
CASH AND CASH EQUIVALENTS — Beginning of period	19,431	65,624	—
CASH AND CASH EQUIVALENTS — End of period	<u>\$ 31,561</u>	<u>\$ 40,985</u>	<u>\$ 31,561</u>
NONCASH INVESTING AND FINANCING ACTIVITIES:			
Conversion of convertible promissory notes and accrued interest into common stock, Series A-2 convertible preferred stock and Series B-2 convertible preferred stock, including unamortized debt discount	\$ —	\$ —	\$ 27,386
Beneficial conversion features	\$ —	\$ —	\$ 4,309
Reclassification of issuance costs charged to equity	\$ —	\$ —	\$ 3,565

See accompanying notes to consolidated financial statements.

ANTHERA PHARMACEUTICALS, INC.
(A Development Stage Company)

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 serious diseases associated with inflammation and 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, vasculitis, rheumatoid arthritis, idiopathic thrombocytopenia purpura, and others.

The Company’s activities since inception have consisted principally of acquiring product and technology rights, raising capital, and performing research and development. Accordingly, the Company is considered to be in the development stage as of September 30, 2013, as defined by guidance issued by the Financial Accounting Standards Board (“FASB”). 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. Through September 30, 2013, the Company has funded its operations through equity offerings, private placements of convertible debt and debt financings, raising net proceeds of approximately \$325.2 million.

From September 9, 2004 (Date of Inception) through September 30, 2013, the Company had an accumulated deficit of \$282.0 million. During the three and nine month periods ended September 30, 2013, the Company incurred a net loss of \$5.8 million and \$21.7 million, respectively. Cash used in operating activities was approximately \$26.2 million for the nine months ended September 30, 2013. 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, short-term investments, and access to additional capital through an equity purchase agreement 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 candidate 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 candidate; 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 nine months ended September 30, 2013 are not necessarily indicative of the results to be expected for the year ending December 31, 2013 or for any other period. The consolidated balance sheet as of December 31, 2012 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, 2012, filed with the Securities and Exchange Commission (“SEC”) on March 26, 2013.

On July 15, 2013, the Company effectuated a 1-for-8 reverse split of its outstanding common stock. The par value of the Company’s common stock remains unchanged at \$0.001 per share. All references to shares of common stock outstanding and per share data for all periods presented in the accompanying consolidated financial statements and notes thereto have been adjusted to reflect such reverse split.

Significant Accounting Policies

There have been no changes in our significant accounting policies for the three and nine months ended September 30, 2013 as compared to the significant accounting policies described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2012.

Restricted Cash

At September 30, 2013, the Company had restricted cash of \$10.0 million to fund a cash security account related to its Square 1 Bank Loan Agreement (see Note 6 for further details). The Company did not have any restricted cash at December 31, 2012.

Use of Estimates

The preparation of these 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, our tax provision 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.

2. NET LOSS PER SHARE

Basic net loss attributable to common stockholders per share is computed by dividing loss attributed 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 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 September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Net loss per share				
Numerator				
Net loss	\$ (5,803)	\$ (11,973)	\$ (21,664)	\$ (50,486)
Denominator				
Weighted-average common shares outstanding	19,196,140	8,703,807	17,937,069	6,330,888
Less: Weighted-average shares subject to repurchase	—	(17)	—	(183)
Denominator for basic and diluted net loss per share	19,196,140	8,703,790	17,937,069	6,330,705
Basic and diluted net loss per share	\$ (0.30)	\$ (1.38)	\$ (1.21)	\$ (7.97)

The following table shows weighted-average historical dilutive common share equivalents outstanding, which are not included in the above calculation as the effect of their inclusion is anti-dilutive during each period.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Options to purchase common stock	20,185	43,454	23,566	65,365
Common stock subject to repurchase	—	17	—	183
Warrants to purchase common stock	—	—	—	38,405
Restricted stock units	42,990	31,029	43,017	35,526
Total	63,175	74,500	66,583	139,479

3. CASH, CASH EQUIVALENTS AND SHORT TERM INVESTMENTS

At September 30, 2013 and December 31, 2012, the amortized cost and estimated fair value of investments is set forth in the following tables (in thousands):

	September 30, 2013		
	Amortized Cost	Gross Unrealized Losses	Estimated Fair Value
Cash	\$ 119	\$ —	\$ 119
Money market funds	31,442	—	31,442
Certificates of deposit	496	(17)	479
Total	32,057	(17)	32,040
Less amounts classified as cash and cash equivalents	(31,561)	—	(31,561)
Total short term investments	\$ 496	\$ (17)	\$ 479

	December 31, 2012		
	Amortized Cost	Gross Unrealized Loss	Estimated Fair Value
Cash	\$ 3,811	\$ —	\$ 3,811
Money market funds	15,620	—	15,620
Certificates of deposit	5,325	(3)	5,322
Total	24,756	(3)	24,753
Less amounts classified as cash and cash equivalents	(19,431)	—	(19,431)
Total short term investments	<u>\$ 5,325</u>	<u>\$ (3)</u>	<u>\$ 5,322</u>

4. FAIR VALUE OF 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 are 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:

	September 30, 2013			
	Estimated Fair Value	Level 1	Level 2	Level 3
Money market funds	\$ 31,442	\$ 31,442	\$ —	\$ —
Certificates of deposit	479	—	479	—
Total	<u>\$ 31,921</u>	<u>\$ 31,442</u>	<u>\$ 479</u>	<u>\$ —</u>

	December 31, 2012			
	Estimated Fair Value	Level 1	Level 2	Level 3
Money market funds	\$ 15,620	\$ 15,620	\$ —	\$ —
Certificates of deposit	5,322	—	5,322	—
Total	<u>\$ 20,942</u>	<u>\$ 15,620</u>	<u>\$ 5,322</u>	<u>\$ —</u>

There were no transfers between level 1 and level 2 for the period ended September 30, 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 on September 1, 2014. 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 expense and rent payments is classified as deferred rent liability and included in accrued liabilities on the balance sheets. In November 2013, the Company renewed its facility lease for an additional three years beginning October 2014 and ending September 2017. See Note 10 of our consolidated financial statements for more information.

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 non-refundable, upfront license fee of \$6.0 million. As there is 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, which are developed and approved as defined by this collaboration. 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 September 30, 2013, 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 Technology Growth Capital, Inc. and Hercules Technology II, L.P. (together, “Hercules”). The Company repaid indebtedness under the Loan Agreement in full on April 3, 2013 in conjunction with the Company’s debt refinancing (see below). The Company was also obligated to pay an end of the term charge of \$937,500, which was being expensed over the term of the Loan Agreement. The unamortized end of term charge of \$312,000 was fully expensed to interest expense in April 2013 as a result of the payoff. Pursuant to the Loan Agreement, 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 March 2018. At September 30, 2013, 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%. Interest and principal are payable in cash on a monthly basis beginning May 1, 2013. 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 is 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. At September 30, 2013, this warrant remained outstanding and exercisable.

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.

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 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. 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

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 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 \$29.1 million.

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 \$54.0 million.

In January 2012, the Company filed a shelf registration statement with the SEC under which the Company may issue up to \$100.0 million in shares of common stock, preferred stock, debt securities and/or warrants. In July 2012, the Company utilized its shelf registration statement to sell 4,125,000 and 618,750 shares of its common stock pursuant to the underwriters' option to purchase additional shares, at a price of \$8.00 per share, resulting in net proceeds of approximately \$35.6 million. In January 2013, the Company issued 7,575,757 shares of its common stock 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 \$43.0 million. As of September 30, 2013, the Company has approximately \$13.3 million available for future offering under the January 2012 shelf registration.

In April 2013, the Company filed a shelf registration statement with the Securities and Exchange Commission ("SEC") under which the Company may issue up to \$100.0 million in shares of common stock, preferred stock, debt securities and/or warrants. No shares have been issued under the April 2013 shelf registration.

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 \$18.5 million in shares of the Company's common stock. The Company has the right, from time to time, at its sole discretion and subject to certain conditions, to direct LPC to purchase up to 62,500 shares of common stock from the Company for a total amount not exceeding \$500,000. In addition, the Company may direct LPC to purchase additional amounts as accelerated purchases if on the date of a regular purchase the closing sale price of the common stock is not below \$5.20 per share.

Upon executing the agreement, LPC made an initial purchase of \$2.0 million in shares of common stock from the Company at a purchase price of \$5.18 per share. In the three and nine months ended September 30, 2013, the Company raised approximately \$0.7 million in net proceeds from the sale of its common stock under the Purchase Agreement. As of September 30, 2013, the Company can sell an additional \$15.8 million in shares of its common stock to LPC under the Purchase Agreement.

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 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) 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. 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 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.

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 nine months ended September 30, 2013 and the methods for determining 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, 2012.

The following table summarizes stock option activity under the Company's share-based compensation plans for the nine months ended September 30, 2013 (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, 2012	300,468	\$ 24.15	2.29	\$ 0
Granted	2,020,250	\$ 4.87	—	—
Exercised	—	\$ —	—	—
Cancelled and expired	(382,708)	\$ 17.54		
Balance at September 30, 2013	1,938,010	\$ 5.36	9.34	\$ 85
Vested at September 30, 2013	171,215	\$ 10.12	6.36	\$ 85
Vested and expected to vest at September 30, 2013	1,938,010	\$ 5.36	9.34	\$ 85

The intrinsic value of stock options represents the difference between the exercise price of stock options and the market price of our stock on that day for all the options that are in the money.

As of September 30, 2013, there were 770,361 shares available for future issuance under the 2013 Plan.

2010 Employee Stock Purchase Plan

Effective July 2010, under the terms of 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 Plan 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, 2013, 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. Purchases are generally made on the last trading day of each June and December. There were 13,904 shares issued under the ESPP during the nine months ended September 30, 2013. As of September 30, 2013, 78,930 shares were available for future purchase under the ESPP.

Restricted Stock Units

The Company grants restricted stock unit awards (“RSUs”) under its equity 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. Substantially all of the RSUs vest over four years.

The following table summarizes activity related to the Company’s restricted stock unit awards:

	Shares	Weighted-Average Grant Date Fair Value	Weighted-Average Remaining Contractual Life in Years
Outstanding at December 31, 2012	28,106	\$ 43.04	0.71
RSUs granted	53,584	\$ 5.12	
RSUs released	(36,836)	\$ 24.30	
RSU forfeitures and cancellations	(1,874)	\$ 42.88	
Outstanding at September 30, 2013	<u>42,980</u>	<u>\$ 11.83</u>	0.57

RSUs are converted into common stock upon vesting. Upon the vesting of RSUs, the Company offers the use of the net share settlement approach and withholds a portion of the shares issued to the employee by the corresponding whole number share value, if required. The number and the value of the shares netted for employee taxes are summarized in the table below (in thousands, except share amounts):

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	2013	2012	2013	2012
Shares withheld	28	121	6,241	2,046
Fair value of shares withheld	\$ 0	\$ 1	\$ 34	\$ 35

9. STOCK-BASED COMPENSATION

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. There were 19,250 and 2,020,250 stock options granted in the three and nine months period ended September 30, 2013, respectively. 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

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>		<u>Period from September 9, 2004 (Date of Inception) to September 30, 2013</u>
	2013	2012	2013	2012	2013
Expected Volatility	85%	66%	85%	66%	82%
Dividend Yield	0%	0%	0%	0%	0%
Risk-Free Interest Rate	0.62%	1.30%	0.62%	1.30%	1.10%
Expected Term (years)	4.00	6.25	3.97	6.25	4.45

ESPP

	Three Months Ended September 30,		Nine Months Ended September 30,		Period from September 9, 2004 (Date of Inception) to September 30, 2013
	2013	2012	2013	2012	
	Expected Volatility	54%	242%	116%	
Dividend Yield	0%	0%	0%	0%	0%
Risk-Free Interest Rate	0.09%	0.14%	0.11%	0.19%	0.13%
Expected Term (years)	0.50	0.50	0.50	0.50	0.47

Compensation cost for stock options 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 per share weighted-average fair values of stock options granted were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,		Period from September 9, 2004 (Date of Inception) to September 30, 2013
	2013	2012	2013	2012	
	Estimated per share weighted-average fair value	\$ 2.71	\$ 0	\$ 2.96	

RSUs

The Company's equity plan allows individuals who had received RSUs to net share settle in excess of the minimum statutory withholding amount for taxes. In accordance with guidance issued by the FASB, this modification resulted in the RSUs being classified as a liability, and the subsequent change in fair value to be recorded as expense. The unsettled RSUs are remeasured at each reporting date and will continue to be remeasured until they are fully vested in approximately 0.68 year. Any changes in valuation are recorded as compensation expense for the period. As of September 30, 2013, the liability related to the unsettled awards is not material.

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

	Three Months Ended September 30,		Nine Months Ended September 30,		Period from September 9, 2004 (Date of Inception) to September 30, 2013
	2013	2012	2013	2012	
	Research and development	\$ 172	\$ 185	\$ 1,168	
General and administrative	320	202	1,283	627	3,947
Total stock-based compensation	\$ 492	\$ 387	\$ 2,451	\$ 1,052	\$ 7,172

Stock based compensation expense in the nine month period ended September 30, 2013 includes a one-time charge of approximately \$1.5 million associated with the voluntary surrender of stock options by the Company's employees. As of September 30, 2013, there was \$6.1 million of unrecognized compensation expense related to stock options. The unrecognized compensation expense will be amortized on a straight-line basis over a weighted-average remaining period of 3.37 years.

10. SUBSEQUENT EVENTS

In November 2013, pursuant to the terms of the facility lease agreement, the Company renewed its facility lease for an additional three years beginning October 2014 and ending September 2017. Total future minimum lease payment over the renewed term of the lease is \$495,000.

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 facts 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," "expect," "plan," "anticipate," "believe," "estimate," "project," "predict," and "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

We are a biopharmaceutical company focused on developing and commercializing products to treat serious diseases associated with inflammation and autoimmune diseases. Our Phase 3 ready 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 system lupus erythematosus (SLE), or lupus, IgA nephropathy, lupus nephritis, vasculitis, idiopathic thrombocytopenia purpura, and others.

We were incorporated and commenced operations in September 2004. Since our inception, we have generated significant losses. As of September 30, 2013, we had an accumulated deficit of approximately \$282.0 million. In January 2012, Anthera Pharmaceuticals, Limited, a wholly-owned subsidiary, was incorporated in Ireland. The establishment of this subsidiary was part of our ongoing growth activities and strategic plan. As of the date of this filing, we have never generated any revenue and have generated only interest income from cash and cash equivalents and short-term investments. We expect to incur substantial losses for at least the next several years as we pursue the development and commercialization of our product candidates.

Blisibimod is a peptibody antagonist of the BAFF cytokine, also known as B-cell activating factor, which is initially being developed as a treatment for patients with severe systemic lupus. BAFF is critical to the development, maintenance and survival of B-cells and Plasma cells. It 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 BAFF-R receptor is expressed primarily on peripheral B-cells.

Based on data from our Phase 2 clinical study results, we intend to advance the clinical development of our BAFF inhibitor, blisibimod, to exploit its broad 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 versus antibodies that are 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 and relatively small molecular weight. We have worldwide rights to blisibimod in all potential indications.

In June and July 2012, we announced results from our Phase 2b PEARL-SC clinical study in patients with SLE. In September 2012, we completed the End of Phase 2 discussions with the U.S. Food and Drug Administration, or FDA and announced our intention to advance blisibimod into Phase 3 clinical trials for patients with SLE. The Phase 3 studies (CHABLIS-SC1 and CHABLIS-SC2) are planned to be multicenter, placebo-controlled, randomized, double-blind studies designed to evaluate the efficacy, safety, tolerability and immunogenicity of blisibimod in patients with clinically active SLE (SELENA-SLEDAI > 10) who require corticosteroid therapy in addition to standard-of-care for treatment of their disease. Each study will randomize up to 400 patients to receive either 200mg of blisibimod or placebo for 52 weeks. As agreed with the FDA, the primary endpoint of the Phase 3 studies will be clinical improvement in the SRI-8 response at 52 weeks.

In March 2013, we announced the initiation of the Phase 3 CHABLIS-SC1 study. The enrollment target for the first 100 patients in the Phase 3 CHABLIS-SC1 study is expected before the end of 2013. We intend to complete an interim analysis of efficacy in the first 100 patients randomized into the CHABLIS-SC1 clinical study. This is estimated to occur in mid-2014 when these 100 enrolled subjects have completed 24 weeks of treatment. This interim analysis is intended to validate commercial and statistical assumptions incorporated in the CHABLIS-SC1 clinical study. Enrollment of the remaining total sample size of 300 patients would be contingent on a positive outcome from this interim analysis. 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 any future regulatory filings. In addition to serving as a registration study for the SLE indication, we believe available safety data from CHABLIS-SC1 will be included in the potential IgA Nephropathy registration application for blisibimod.

Following recent input from the FDA, we plan to submit a second study, CHABLIS-SC2, to the US FDA before the end of 2013. This study is planned to enroll patients with clinical diagnosis of renal disease including glomerulonephritis and stable lupus nephritis. It is anticipated that the two CHABLIS studies will form the basis of approval for blisibimod to treat a severely diseased lupus patient population.

Patients with SLE who completed the PEARL-SC study were able to participate in an Open-Label Extension (OLE) study in which they were treated with active drug (blisibimod). Interim data from the combined PEARL-SC and OLE studies were presented at the 2013 Annual Scientific Meeting of the American College of Rheumatology and Association of Rheumatology Health Professionals (ACR/ARHP). These emerging data corroborate the effects of 24-week therapy with blisibimod observed in the PEARL-SC study. Specifically, the improvements in proteinuria observed in the subgroup of patients with abnormal proteinuria at enrollment, as well as anti-double-stranded DNA autoantibodies and complement C3 and C4 observed over 24 weeks of dosing in the PEARL-SC study were found to be durable over 52-weeks of therapy through the OLE study. Importantly, significant decreases in immunoglobulins IgG and IgM were also observed in patients treated with blisibimod compared with placebo. Blisibimod was safe and well-tolerated at all dose levels through the PEARL-SC and OLE studies, with no associated increase in the risk of severe infection. These data support the ongoing exploration of blisibimod's efficacy and safety in the Phase 3 study in patients with SLE (CHABLIS-SC1) as well as the Phase 2 study in patients with IgA nephropathy (BRIGHT-SC).

We initiated our BRIGHT-SC Phase 2 proof-of-concept study for the treatment of IgA nephropathy (IgAN) in the second quarter of 2013. BRIGHT-SC is our first clinical study for the treatment of renal disease and we believe it will serve as one of our initial Phase 3 clinical studies for registration of blisibimod in IgAN. Initially we intend to enroll up to 48 patients with biopsy-proven IgAN who have proteinuria greater than one gram per 24 hours (1g/24hr) and are receiving standard of care. Patients will receive 300mg weekly blisibimod or placebo for 8 weeks, 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.

In May 2013, we met with the FDA to discuss the blisibimod development program for IgA nephropathy. As a result of feedback from the FDA on the potential use of a change in proteinuria as the endpoint for Subpart E approval for blisibimod, we amended the BRIGHT-SC study endpoints accordingly. Upon implementation of this new amendment it is our intention to use the BRIGHT-SC study as one of two studies necessary to support the marketing approval of blisibimod for the treatment of IgA nephropathy under the accelerated approval pathway (FDA Subpart E). In addition, the FDA indicated a requirement for us to provide data from a post-marketing study which would include measurements of clinical endpoints, such as changes in kidney function, progression to dialysis and death in patients previously enrolled in the two registration studies.

In June 2013, we met with the Japanese Pharmaceutical and Medical Devices Agency, or PMDA to discuss the development of blisibimod for the treatment of IgA nephropathy in Japan. At this initial meeting the PMDA agreed to consider a change in proteinuria as the basis for an initial approval of blisibimod for the treatment of IgA nephropathy. Additional discussions with the PMDA regarding development of blisibimod in Japan are planned for early 2014.

Prior to the end of 2013, we plan to submit an IND, to the FDA for the investigation of blisibimod in IgA nephropathy incorporating feedback from both the initial meetings with the FDA and PMDA. As part of this submission we will provide a second clinical study protocol, BRILLIANT-SC, intended to evaluate the use of blisibimod as a treatment for proteinuria in patients with IgA nephropathy.

As of September 30, 2013, we have funded our operations through equity offerings, private placements of convertible debt and debt financings, raising net proceeds of approximately \$325.2 million. 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. In addition to the normal risks associated with development-stage companies, we may never successfully complete development of our product candidate, obtain adequate patent protection for our technology, obtain necessary government regulatory approval for our product candidate or achieve commercial viability for any approved product candidates. In addition, we may not be profitable even if we succeed in commercializing our product candidate.

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 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 administrative 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 blisibimod. 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 candidate 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 nine months ended September 30, 2013 and September 30, 2012 and for the period from September 9, 2004 (Date of Inception) through September 30, 2013 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,		For the Period
	2013	2012	2013	2012	September 9, 2004 (Date of Inception) to September 30, 2013
Allocated costs:					
Varespladib	\$ 68	\$ 2,084	\$ 317	\$ 18,408	\$ 114,014(1)(2)
Blisibimod	3,046	6,377	10,373	19,648	78,793(3)
Varespladib sodium	1	—	1	51	6,681
Unallocated costs	936	1,066	3,554	4,023	30,038
Total development	\$ 4,051	\$ 9,527	\$ 14,245	\$ 42,130	\$ 229,526

(1) Includes milestone payments of \$3.5 million pursuant to amendments to the license agreements with each of Eli Lilly and Shionogi & Co. Ltd.

(2) Includes license fees of \$4.0 million pursuant to a license agreement with each of Eli Lilly and Shionogi & Co. Ltd., which were paid in cash and shares of preferred stock in 2006.

(3) Includes a one-time license initiation fee of \$6.0 million pursuant to a license agreement with Amgen.

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:

- ☒ the number of sites included in the studies;
- ☒ the length of time required to enroll suitable patient subjects;
- ☒ the number of patients that participate in the studies;
- ☒ the number of doses that patients receive;
- ☒ the drop-out or discontinuation rates of patients; and
- ☒ 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 multiple research institutions and clinical research organizations 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 depend on factors such as the successful enrollment of patients or the completion of clinical study milestones. Expenses related to clinical studies generally are accrued based on contracted amounts and the achievement of milestones such as number of patients enrolled. 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 have received FDA, or foreign regulatory marketing approval. In order to grant marketing approval, the 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 employees in administration, finance and business development. 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, 2012, 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.

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 multiple 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. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical study milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual accordingly. If we do not identify costs that we have begun to incur or if we underestimate or overestimate the level of services performed or the costs of these services, our actual expenses could differ from our estimates.

Results of Operations

Comparison of the three months ended September 30, 2013 and 2012

Research and Development Expenses

The following table summarizes our research and development expenses for the three months ended September 30, 2013 and 2012 (in thousands, except percentages):

	Three Months Ended September 30,		\$ Change	% Change
	2013	2012		
Research and development expenses	\$ 4,051	\$ 9,527	\$ (5,476)	(57)%

Research and development expenses decreased during the three months ended September 30, 2013 from the same period in 2012 primarily due to decreased direct and indirect clinical study costs and manufacturing expense as we focus on the development of blisibimod for systemic lupus erythematosus and IgA nephropathy.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the three months ended September 30, 2013 and 2012 (in thousands, except percentages):

	Three Months Ended September 30,		\$ Change	% Change
	2013	2012		
General and administrative expense	\$ 1,470	\$ 1,594	\$ (124)	(8)%

General and administrative expenses decreased during the three months ended September 30, 2013 from the same period in 2012 primarily due to reduced spending on professional services and reflects our ongoing cost reduction efforts.

The following table summarizes our other income (expense) for the three months ended September 30, 2013 and 2012 (in thousands, except percentages):

	Three Months Ended September 30,		\$ Change	% Change
	2013	2012		
Other income (expense)	\$ 14	\$ (46)	\$ 60	130%
Interest expense	(296)	(806)	510	(63)%
Total other income (expense)	\$ (282)	\$ (852)	\$ 570	(67)%

Other income (expense) increased during the three months ended September 30, 2013 from the same period in 2012 primarily due to interest earned on our cash, cash equivalent and short-term investments. Other expense for the three months ended September 2012 was primarily due to foreign currency exchange fluctuations in connection with payments made to our oversea vendors. The decrease in interest expense during the three months ended September 30, 2013 as compared to the same period in 2012 is primarily due to the refinancing of our debt from Hercules to Midcap and Square 1 Bank in April 2013, which resulted in significantly reduced interest rate.

Comparison of the nine months ended September 30, 2013 and 2012

Research and Development Expenses

The following table summarizes our research and development expenses for the nine months ended September 30, 2013 and 2012 (in thousands, except percentages):

	Nine Months Ended September 30,		\$ Change	% Change
	2013	2012		
Research and development expenses	\$ 14,245	\$ 42,130	\$ (27,885)	(66)%

During the nine months ended September 30, 2013, our research and development costs consisted primarily of start-up clinical expenses for the Phase 3 CHABLIS-SC1, and Phase 2 BRIGHT-SC studies and the ongoing costs to support the PEARL-SC OLE study. Research and development expenses decreased during the nine months ended September 30, 2013 from the same period in 2012 as we completed the PEARL SC study and we terminated our Phase 3 clinical study with varespladib for cardiovascular disease in March 2012. This resulted in decreased CRO, central laboratory, and investigator expense of approximately \$23.3 million. Furthermore, manufacturing activities for the Phase 2 PEARL study of blisibimod was substantially completed by December 2011 and all patients completed dosing by June 2012, which contributed to the decrease in manufacturing expenses by approximately \$2.6 million in the nine month period ended September 30, 2013 in comparison to the same period in the prior year.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the nine months ended September 30, 2013 and 2012 (in thousands, except percentages):

	Nine Months Ended September 30,		\$ Change	% Change
	2013	2012		
General and administrative expense	\$ 5,130	\$ 5,715	\$ (585)	(10)%

General and administrative expenses decreased during the nine months ended September 30, 2013 from the same period in 2012 primarily due to reduced spending on professional services and reflect our ongoing cost reduction efforts.

Other Income (Expense)

The following table summarizes our other income (expense) for the nine months ended September 30, 2013 and 2012 (in thousands, except percentages):

	Nine Months Ended September 30,		\$ Change	% Change
	2013	2012		
Other income (expense)	\$ 33	\$ (84)	\$ 117	139%
Interest expense	(2,322)	(2,557)	\$ 235	(9)%
Total other income (expense)	\$ (2,289)	\$ (2,641)	\$ 352	(13)%

Other income (expense) increased during the three months ended September 30, 2013 from the same period in 2012 primarily due to interest earned on our cash, cash equivalent and short-term investments. Other expense for the three months ended September 2012 was primarily due to foreign currency exchange fluctuations in connection with payments made to our oversea vendors. The decrease in interest expense during nine months ended September 30, 2013 as compared to the same period in 2012 is primarily due to the refinancing of our debt from Hercules to Midcap and Square 1 Bank in April 2013, which resulted in significantly reduced 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 IPO raising net proceeds of approximately \$325.2 million.

Cash, cash equivalents and short-term investments consist of the following (in thousands):

	<u>September 30, 2013</u>	<u>December 31, 2012</u>
Cash and cash equivalents	\$ 31,561	\$ 19,431
Short-term investments	479	5,322
Total	<u>\$ 32,040</u>	<u>\$ 24,753</u>

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

In January 2012, we filed a universal shelf registration statement with the 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 1,136,363 shares in a second closing in February 2013, raising net proceeds of approximately \$43.0 million. As of September 30, 2013, there is approximately \$13.3 million available for future offering under the January 2012 shelf registration.

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 \$18.5 million in shares of the Company's common stock. We have the right, from time to time, at our sole discretion and subject to certain conditions, to direct LPC to purchase up to 62,500 shares of common stock from us for a total amount not exceeding \$500,000. In addition, we may direct LPC to purchase additional amounts as accelerated purchases if on the date of a regular purchase the closing sale price of the common stock is not below \$5.20 per share.

Upon executing the agreement, LPC made an initial purchase of \$2.0 million in shares of common stock from us at a purchase price of \$5.18 per share. In the three and nine months ended September 30, 2013, we raised approximately \$0.7 million in net proceeds from the sale of its common stock under the Purchase Agreement. As of September 30, 2013, we can sell an additional \$15.8 million in shares of its common stock to LPC under the Purchase Agreement.

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. No shares have been issued pursuant to the shelf registration statement as of the date of this report.

Our cash flow from continuing operations during the nine months ended September 30, 2013 and 2012 consist of the following (in millions):

	Nine Months Ended	
	September 30,	
	<u>2013</u>	<u>2012</u>
Net cash (used in) operating activities	\$ (26,183)	\$ (58,153)
Net cash (used in) provided by investing activities	(5,184)	62
Net cash provided by financing activities	43,498	33,507
Effect of exchange rate changes on cash	(1)	(55)
Total	<u>\$ 12,130</u>	<u>\$ (24,639)</u>

[Table of Contents](#)

During the nine months ended September 30, 2013 and 2012, our operating activities used cash of \$26.2 million and \$58.2 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 nine months ended September 2013 as compared to 2012 was primarily due to reduced spending on clinical development activities as we shifted our development resource to our blisibimod program after the termination of the varespladib program.

During the nine months ended September 30, 2013, cash used in investing activities was \$5.2 million, as compared to cash provided by investing activities of \$0.06 million during the same period in 2012. Our investing activities consisted primarily of purchases and maturities of short term investments.

During the nine months ended September 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 \$43.0 million; proceeds of \$2.7 million from the issuance of shares to LPC pursuant to a stock purchase agreement executed in April 2013, and net proceeds of \$19.9 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 full repayment of indebtedness to Hercules.

Contractual Obligations and Commitments

We have lease obligations consisting of an operating lease for our operating facility that expires September 2014, for office space, and an office equipment lease that expired in June 2013. In November 2013, the Company renewed its facility lease for an additional three years beginning October 2014 and ending September 2017. See Note 10 of our consolidated financial statements for more information.

On March 25, 2011, we entered into a Loan Agreement with Hercules. The loan was fully repaid in April 2013 in conjunction with our debt refinance (see below).

In April 2013, we entered into borrowing agreements with Midcap Financial and Square 1 Bank for an aggregate of \$20.0 million. We used the proceeds from the new loans to pay off the outstanding principal balance owed to Hercules.

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 unrestricted 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 candidate. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidate, 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.

ITEM 3. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintains a set of disclosure controls and procedures designed to ensure that information required to be disclosed by us in reports that it files or submits under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized, and reported within the time periods specified in Securities and Exchange Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that it files or submits under the Securities Exchange Act of 1934 is accumulated and communicated to the our management, including our principal executive and principal financial officers, as appropriate, to allow timely decisions regarding required disclosure. An evaluation was carried out under the supervision and with the participation of the our management, including the Chief Executive Officer, or CEO and Principal Accounting Officer and Senior Vice President, Finance & Administration, of the effectiveness of our disclosure controls and procedures. Based on that evaluation, the CEO and the Principal Accounting Officer and Senior Vice President, Finance & Administration have concluded that as of September 30, 2013, the our disclosure controls and procedures were effective to ensure that information required to be disclosed was accumulated and communicated to management as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting that occurred during the third quarter 2013 that has materially affected, or is reasonably likely to affect materially, our internal control over financial reporting.

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.

We are a development stage company with only eight years of operating history. We have focused primarily on developing our three product candidates, blisibimod, varespladib and varespladib sodium. The two latter product candidates were terminated in March 2012. 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. As of September 30, 2013, we had an accumulated deficit of approximately \$282.0 million. 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 candidate, 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.

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 candidate and commercialize any approved products. We have not generated any revenue from our development-stage product candidate, and we do not know when, or if, we will generate any revenue. The commercial success of our development-stage product candidate will depend on a number of factors, including, but not limited to, our ability to:

- obtain favorable results for and advance the development of our product candidate blisibimod 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 regulatory approval for blisibimod;
- if regulatory approvals are obtained, begin the commercial manufacturing of our product candidate with third-party manufacturers;
- launch commercial sales and effectively market our product candidate, either independently or in strategic collaborations with third parties; and
- achieve broad market acceptance of our product candidate in the medical community and with third-party payors.

Our product candidate is 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. Blisibimod 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 candidate 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 candidate 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 candidate is approved for commercial sale, the approved product candidate 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 candidate. 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 candidate;
- manufacturing campaign for blisibimod clinical matters, including formulation development and product enhancement;
 - non-clinical activities that we may pursue parallel to our clinical studies;
 - 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 candidate 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 candidate; 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 candidate; 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 candidate or (iii) other activities that may be necessary to commercialize our product candidate, if approved for sale.

The timing of the milestone and royalty payments we are required to make to Amgen Inc. 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. The timing of our achievement of these events and corresponding milestone payments becoming due to Amgen is subject to factors relating to the clinical and regulatory development and commercialization of blisibimod, 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 candidates, 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 Candidate

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

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

Our lead product candidate blisibimod has completed several Phase 1 and Phase 2 clinical studies. In July 2010, we received clearance from the FDA to begin recruitment of lupus patients into the PEARL-SC Phase 2b clinical study. In November 2010, we placed a voluntary hold on the PEARL-SC study due to problems found with vials. Patient enrollment in the study was temporarily suspended and dosing was discontinued in patients who were enrolled in the study while we conducted an analysis of the problem. We resolved the issues found with the vials in December 2010. After analysis, simulation and consultation with industry experts, we determined that shipping on dry ice was the root cause of the issue. Shipping logistics were modified and we reinitiated enrollment in PEARL-SC and dosing in January 2011. We have received no reports of patient-related side effects or problems with drug administration that could be attributed to the vial problem. On October 24, 2011 we filed an amendment with the FDA for the PEARL-SC clinical study to modify the primary efficacy SLE response index and to include an option for an interim efficacy analysis. The trial was completed and results were announced during 2012.

Our product candidate is 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 FDA and, with respect to approval in other countries, similar regulatory authorities in those countries, that the product candidate is safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate. Despite our efforts, our product candidate 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 blisibimod our product candidate in the United States until we receive approval of a biologics license application, or BLA, from the FDA, or in any foreign countries until we receive the requisite approval from such countries. We have not submitted a BLA or received marketing approval for our product candidate.

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 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 FDA or other regulatory authorities may interpret the results of our clinical studies less favorably than we do. The 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.

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

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 a product candidate 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 a prospective site;
- ☒ 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 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 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 and our collaborators 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 delaying factors outside our control.

Additionally, changes in regulatory requirements and policies may occur and we may need to amend clinical study protocols to reflect these changes. Amendments may require us to resubmit our clinical study protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical study. If we experience delays in completion of, or if we, the 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 a product candidate. 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 any of 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 FDA approval for our product candidate.

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. This agreement requires us to make timely milestone and royalty payments, provide regular information, maintain the confidentiality of and indemnify Amgen under the terms of the agreements.

If we fail to meet these obligations, Amgen may terminate our license and may be able to re-obtain licensed technology and aspects of any intellectual property controlled by us that relate to the licensed technology that originated from Amgen. Amgen could effectively take control of the development and commercialization of blisibimod after an uncured, material breach of our license agreement by us or if we voluntarily terminate the agreement. 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 could result in our loss of exclusive rights and may lead to a complete termination of our product development and any commercialization efforts for blisibimod.

Our industry is subject to intense competition. If we are unable to compete effectively, our product candidate 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. Specifically, Human Genome Sciences, Inc.'s and GlaxoSmithKline plc's BAFF antagonist monoclonal antibody, Benlysta, is marketed 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, is in a Phase 3 clinical study for lupus; and Immunomedics, Inc. and UCB S.A., who recently reported favorable results for their CD-22 antagonist humanized antibody, epratuzumab, which completed a Phase 2b clinical study in lupus and has begun two Phase 3 studies, and Eli Lilly's anti-BLYS monoclonal antibody, LY2127399, which has begun two Phase 3 studies.

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 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 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 candidate 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 candidate. 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 FDA or other regulatory authorities. Phase 2 clinical studies conducted by us with our product candidates have generated differences in adverse effects and serious adverse events. The most common adverse effects seen with any of our product candidates versus placebo include diarrhea, headache, nausea and increases in alanine aminotransferase, which is an enzyme that indicates liver cell injury. The most common serious adverse events seen with any of our product candidates include death, VOC and congestive heart failure. While none of these serious adverse events were considered related to the administration of our product candidates by the clinical investigators, 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 any of our product candidates receives 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 product;
- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications;
- we may be required to change the way the product is administered, conduct additional clinical studies or change the labeling of the product;
- 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 candidate and could substantially increase the costs of commercialization.

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 these 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 candidate 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 FDA policy during the period of product development, clinical studies and FDA regulatory review.

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

Even if U.S. regulatory approval is obtained, the 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, if any, may include restrictions on use. Further, the FDA has indicated that long-term safety data on blisibimod may need to be obtained as a post-market requirement. Our product candidate will also be subject to ongoing 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 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 a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. If we, our product candidate or the manufacturing facilities for our product candidate 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 FDA Amendments Act of 2007, or FDAAA, granted the 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 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 any of our product candidates for which we receive regulatory approval does not achieve broad market acceptance, the revenue that we generate from its sales, if any, will be limited.

The commercial success of our product candidates for which we obtain marketing approval from the 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 any 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 blisibimod in the treatment of lupus;
- ☒ the prevalence and severity of any adverse effects;
- ☒ limitations or warnings contained in a product'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 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.

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 European Union 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:

- impairment of our business reputation;
- withdrawal of clinical study participants;
- costs of related litigation;
- 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.

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 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 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.

In December 2011, we completed the technology transfer from Amgen and manufacturing scale up to 3,000 liters at our contract manufacturing organization, or CRO (Fujifilm Diosynth Bioservices or “Fujifilm”). Two (2) batches of blisibimod produced under FDA good manufacturing procedures, or GMP, at the 3,000 liter scale passed all physical quality specifications and comparability assessments. We submitted plans to the FDA on March 4, 2011 and September 9, 2011 establishing criteria to demonstrate comparability of blisibimod manufactured by Fujifilm to that manufactured by Amgen. Data confirming comparability to Phase 1 material (Amgen) was filed with the FDA on August 8, 2011 and September 8, 2011. In September 2012, we received comments from the FDA on the submissions listed above. The FDA agreed that the material manufactured by Fujifilm was comparable to that previous manufactured by Amgen.

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 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.

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, the satisfaction of which on a timely basis may not be met.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell a product candidate, 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 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 four 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.

As of the date of this report, we hold license rights to numerous U.S. EP, and non-EP foreign patents and patent applications for blisibimod. Our blisibimod portfolio includes exclusively and non-exclusively licensed patents and patent applications from Amgen, Inc.

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 sPLA2 inhibiting compounds and exclusively licensed from Eli Lilly 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 candidate 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 candidate 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.

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 candidate 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 depend in part on our licensors to protect the proprietary rights covering blisibimod. 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.

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 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 a product candidate.

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 a product candidate. 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 candidate. 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 a product candidate or a proposed product candidate, which would harm our business. Litigation or other proceedings such as patent interferences, oppositions, reexaminations, or post-grant reviews 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.

Litigation and other proceedings regarding patents, patent applications and other proprietary rights may be expensive and time consuming. If we are involved in such litigation or other proceedings, 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. In addition, our patents or patent applications or those of others could be subject to other proceedings such as patent interferences, oppositions, reexaminations, or post-grant reviews.

Litigation and other 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 such 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

If we fail to maintain compliance with the listing requirements of The NASDAQ Global Market, we may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted.

Our common stock is currently listed on The NASDAQ Global Market, or NASDAQ. NASDAQ has minimum requirements that a company must meet in order to remain listed on NASDAQ. These requirements include maintaining a minimum closing bid price of \$1.00 per share.

On December 20, 2012, we received a letter from The NASDAQ Global Stock Market informing us that for the last 30 consecutive business days the bid price of our common stock has closed below the minimum \$1.00 per share requirement for continued inclusion under Listing Rule 5450(a)(1). The letter stated that NASDAQ will provide the Company a grace period of 180 calendar days, or until June 18, 2013, to regain compliance. To regain compliance, any time before June 18, 2013, the bid price of our common stock must close at \$1.00 per share or more for a minimum of 10 consecutive business days.

On July 15, 2013, we effectuated a 1-for-8 reverse stock split of our common stock. As a result of the reverse split, every eight shares of the Company's authorized and outstanding common stock were converted into one authorized and outstanding share of common stock. On July 30, 2013, we were notified that we had regained compliance with the minimum closing bid requirement for continued inclusion under Listing Rule 5450(a)(1).

This reverse stock split may not prevent our common stock from dropping back down below The NASDAQ Global Market minimum closing bid price requirement in the future. It is also possible that we would otherwise fail to satisfy another NASDAQ Global Market requirement for continued listing of our common stock.

If our common stock were to be delisted, the liquidity of our common stock would be adversely affected and the market price of our common stock could decrease. In addition, if delisted we would no longer be subject to NASDAQ rules, including rules requiring us to have a certain number of independent directors and to meet other corporate governance standards. Our failure to be listed on NASDAQ or another established securities market would have a material adverse effect on the value of your investment in us.

If our common stock is not listed on NASDAQ or another national exchange, the trading price of our common stock is below \$5.00 per share and we have net tangible assets of \$6,000,000 or less, the open-market trading of our common stock will be subject to the "penny stock" rules promulgated under the Securities Exchange Act of 1934, as amended. If our shares become subject to the "penny stock" rules, broker-dealers may find it difficult to effectuate customer transactions and trading activity in our securities may be adversely affected. Under these rules, broker-dealers who recommend such securities to persons other than institutional accredited investors must:

- make a special written suitability determination for the purchaser;
- receive the purchaser's written agreement to the transaction prior to sale;
- provide the purchaser with risk disclosure documents which identify certain risks associated with investing in "penny stocks" and which describe the market for these "penny stocks" as well as a purchaser's legal remedies; and
- obtain a signed and dated acknowledgment from the purchaser demonstrating that the purchaser has actually received the required risk disclosure document before a transaction in a "penny stock" can be completed.

As a result of these requirements, the market price of our securities may be adversely impacted, and current stockholders may find it more difficult to sell our securities.

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 blisibimod and our other 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 Amgen concerning blisibimod;
- ☒ 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
- ☒ 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 28% 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 September 30, 2013, there were 19,304,116 shares of our common stock outstanding. In addition, as of September 30, 2013, we had a total of 1,980,990 shares of outstanding options, and restricted stock units, 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.

In addition, at September 30, 2013, we had reserved the following shares for future issuance:

Common stock warrants outstanding	675,006
Common stock options available for future grant under stock option plans	770,361
Common stock shares available for future purchase under the ESPP	78,930
Total	<u>1,524,297</u>

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.

We filed a universal shelf registration statement with the SEC on Form S-3 (File No. 333-179043) on January 17, 2012, which was declared effective on January 24, 2012, 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 at an initial closing of a public offering, followed by 1,136,362 at a second closing in February 2013, raising net proceeds of approximately \$43.0 million. As of September 30, 2013, there is approximately \$13.3 million available for future offering under the January 2012 shelf registration.

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 \$18.5 million in shares of our common stock. We have the right, from time to time, at our sole discretion and subject to certain conditions, to direct LPC to purchase up to 62,500 shares of common stock from us for a total amount not exceeding \$500,000. In addition, we may direct LPC to purchase additional amounts as accelerated purchases if on the date of a regular purchase the closing sale price of the common stock is not below \$5.20 per share.

Upon executing the agreement, LPC made an initial purchase of \$2.0 million in shares of common stock from us at a purchase price of \$5.18 per share. In the three and nine months ended September 30, 2013, we raised approximately \$0.7 million in net proceeds from the sale of its common stock under the Purchase Agreement. As of September 30, 2013, we can sell an additional \$15.8 million in shares of our common stock to LPC under the Purchase Agreement.

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. No shares have been issued pursuant to the shelf registration statement as of the date of this report.

We may 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 may 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.

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 verify 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.

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 research & development 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.

ITEM 6. EXHIBITS

The exhibits listed in the accompanying Exhibit Index are filed or incorporated by reference as part of this report.

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.

November 14, 2013

By: /s/ Paul F. Truex
Paul F. Truex
President and Chief Executive Officer

November 14, 2013

By: /s/ May Liu
May Liu
Principal Accounting Officer and Senior Vice President,
Finance & Administration

EXHIBIT INDEX

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 August 20, 2012 and incorporated herein by reference).
3.3	Certificate of Amendment to the Fifth Amended and Restated Certificate of Incorporation (filed as Exhibit 3.1 to the registrant's current report on Form 8-K filed with the SEC on July 16, 2013 and incorporated herein by reference).
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.

* The information in this exhibit is furnished and deemed not filed with the Securities and Exchange Commission for purposes of section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and is not to be incorporated by reference into any filing of Anthera Pharmaceuticals, Inc. under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

** 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.

**Certification of President and Chief Executive Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, Paul F. Truex, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Anthera Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 14, 2013

/s/ Paul F. Truex

Paul F. Truex

President and Chief Executive Officer

**Certification of Chief Financial Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, May Liu, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Anthera Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 14 , 2013

/s/ May Liu

May Liu

Principal Accounting Officer and Senior Vice President, Finance &
Administration

**Certification Pursuant to
Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350**

I, Paul F. Truex, certify, pursuant to the requirement set forth in 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, that the Quarterly Report of Anthera Pharmaceuticals, Inc. on Form 10-Q for the quarter ending June 30, 2013 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Quarterly Report on Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of Anthera Pharmaceuticals, Inc.

By: /s/ Paul F. Truex
Name: Paul F. Truex
Title: President and Chief Executive Officer

Date: November 14, 2013
