Table of Contents

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, 2011

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	**20-1852016**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
25801 Industrial Boulevard, Suite B **Hayward, California**	**94545**
(Address of Principal Executive Offices)	(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 October 31, 2011, the number of outstanding shares of the registrant's common stock, par value $0.001 per share, was 40,907,945.

ANTHERA PHARMACEUTICALS, INC.

FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2011

INDEX

PART I — FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

ANTHERA PHARMACEUTICALS, INC.
(A Development Stage Company)

CONDENSED BALANCE SHEETS
(in thousands, except share amounts)
(unaudited)

	September 30, 2011	December 31, 2010
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 89,526	$ 40,030
Short-term investments	3,735	23,351
Prepaid expenses and other current assets	728	1,865
Total current assets	93,989	65,246
Property and equipment — net	1,316	17
Debt issuance costs	275	—
TOTAL	$ 95,580	$ 65,263
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 17,476	$ 3,791
Accrued clinical studies	5,131	3,137
Accrued liabilities	401	468
Accrued payroll and related costs	781	609
Total current liabilities	23,789	8,005
Notes payable— net of discount	24,128	—
Total liabilities	47,917	8,005
Commitments and Contingencies (Note 6)		
Stockholders' equity		
Preferred stock, $0.001 par value, 5,000,000 shares authorized, 0 shares issued and outstanding as of September 30, 2011 and December 31, 2010	—	—
Common stock, $0.001 par value, 95,000,000 shares authorized; 40,899,668 and 32,853,032 shares issued and outstanding as of September 30, 2011 and December 31, 2010, respectively	41	33
Additional paid-in capital	219,491	162,919
Accumulated comprehensive loss	(46)	(50)
Deficit accumulated during the development stage	(171,823)	(105,644)
Total stockholders' equity	47,663	57,258
TOTAL	$ 95,580	$ 65,263

See accompanying notes to condensed financial statements.

ANTHERA PHARMACEUTICALS, INC.
(A Development Stage Company)

CONDENSED STATEMENTS OF OPERATIONS
(in thousands, except share and per share data)
(unaudited)

	Three months ended September 30,		Nine months ended September 30,		Cumulative Period from September 9, 2004 (Date of Inception) to September 30,
	2011	2010	2011	2010	2011
OPERATING EXPENSES:					
Research and development	$ 21,546	$ 6,885	$ 58,449	$ 18,565	$ 139,230
General and administrative	1,824	1,510	6,260	4,244	22,478
Total operating expenses	23,370	8,395	64,709	22,809	161,708
LOSS FROM OPERATIONS	(23,370)	(8,395)	(64,709)	(22,809)	(161,708)
OTHER INCOME (EXPENSE):					
Other income (expense)	(153)	61	421	76	1,426
Interest expense	(920)	—	(1,891)	(845)	(3,436)
Mark-to-market adjustment of warrant liability	—	—	—	(3,796)	(3,796)
Beneficial conversion features	—	—	—	—	(4,309)
Total other income (expense)	(1,073)	61	(1,470)	(4,565)	(10,115)
NET LOSS	$ (24,443)	$ (8,334)	$ (66,179)	$ (27,374)	$ (171,823)
Net loss per share—basic and diluted	$ (0.60)	$ (0.36)	$ (1.83)	$ (1.40)	
Weighted-average number of shares used in per share calculation—basic and diluted	40,833,495	22,964,279	36,238,662	19,567,058	

See accompanying notes to condensed financial statements.

ANTHERA PHARMACEUTICALS, INC.
(A Development Stage Company)

CONDENSED STATEMENTS OF CASH FLOWS
(in thousands)
(unaudited)

	Nine Months Ended September 30,		September 9, 2004 (Date of Inception) to September 30,
	2011	2010	2011
CASH FLOW FROM OPERATING ACTIVITIES:			
Net loss	$ (66,179)	$ (27,374)	(171,823)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	12	13	102
Amortization of premium/(discount) on short-term investments	84	—	56
Realized (gain)/loss on short-term investments	(8)	(5)	(164)
Stock-based compensation expense	1,877	353	3,214
Issuance of preferred and common stock for license fee, interest and service	—	3,673	6,122
Beneficial conversion feature	—	—	4,309
Amortization of discount on convertible notes and notes payable	424	541	1,102
Amortization of debt issuance costs	76	228	382
Mark-to-market adjustment on warrant liability	—	3,796	3,796
Changes in assets and liabilities:			
Prepaid expenses and other assets	1,132	(1,793)	(732)
Accounts payable	13,618	1,413	17,667
Accrued clinical studies	1,995	403	5,132
Accrued liabilities	(280)	(248)	181
Accrued payroll and related costs	145	421	754
Net cash used in operating activities	(47,104)	(18,579)	(129,902)
INVESTING ACTIVITIES:			
Property and equipment purchases	(1,318)	(21)	(1,425)
Purchase of short-term investments	(4,735)	(22,459)	(44,484)
Proceeds from sale of short-term investments	24,307	747	40,839
Net cash provided by (used in) investing activities	18,254	(21,733)	(5,070)
FINANCING ACTIVITIES:			
Proceeds from issuance of convertible notes and notes payable, net of issuance costs	24,700	(210)	50,952
Net proceeds from issuance of preferred stock	—	—	32,210
Proceeds from issuance of common stock, net of offering costs	54,012	87,839	141,281
Witholding taxes paid on vested restricted stock units	(879)	—	(879)
Proceeds from issuance of common stock pursuant to exercise of warrant	220	—	220
Proceeds from issuance of common stock pursuant to employee stock purchase plan and exercise of stock options, net	293	89	714
Net cash provided by financing activities	78,346	87,718	224,498
NET INCREASE IN CASH AND CASH EQUIVALENTS	49,496	47,406	89,526
CASH AND CASH EQUIVALENTS — Beginning of period	40,030	3,803	—
CASH AND CASH EQUIVALENTS — End of period	$ 89,526	$ 51,209	89,526
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	$ —	$ 14,069	$ 27,386
Beneficial conversion features	$ —	$ —	$ 4,309
Reclassification of issuance costs charged to equity	$ —	$ 3,508	$ 3,565

See accompanying notes to condensed financial statements.

ANTHERA PHARMACEUTICALS, INC.
(A Development Stage Company)

NOTES TO THE CONDENSED 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, including cardiovascular and autoimmune diseases. Two of the Company's primary product candidates, varespladib and A-001, are inhibitors of the family of human enzymes known as secretory phospholipase A_2, or $sPLA_2$. The Company's other primary product candidate, blisibimod (A-623), targets elevated levels of B-cell activating factor, or BAFF. 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, 2011. 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; develop strategic alliances; and generate revenues. Although management believes that the Company will be able to successfully fund its operations, there can be no assurance that the Company will be able to do so or that the Company will ever operate profitably.

From September 9, 2004 (Date of Inception) through September 30, 2011, the Company had accumulated a deficit of approximately $171.8 million. During the three and nine months ended September 30, 2011, the Company incurred a net loss of $24.4 million and $66.2 million respectively. Cash used in operating activities was approximately $47.1 million for the nine months ended September 30, 2011. The Company expects to continue to incur substantial losses and negative cash flows over the next several years during its clinical development phase. To fully execute its business plan, the Company will need to complete certain research and development activities and clinical studies. Further, the Company's product candidates will require regulatory approval prior to commercialization. These activities may span many years and require substantial expenditures to complete and may ultimately be unsuccessful. Any delays in completing these activities could adversely impact the Company. The Company plans to meet its capital requirements primarily through issuances of equity securities, debt financing, securing strategic alliances, 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 condensed financial statements have been prepared in conformity with accounting principles generally accepted in the United States ("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 for complete financial statements. In the opinion of management, the accompanying unaudited condensed 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 nine months ended September 30, 2011 are not necessarily indicative of the results to be expected for the year ending December 31, 2011 or for any other period. The condensed balance sheet as of December 31, 2010 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 condensed 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, 2010, filed with the Securities and Exchange Commission ("SEC") on March 7, 2011.

Significant Accounting Policies

There have been no changes in our significant accounting policies for the three and nine month period ended September 30, 2011, as compared to the significant accounting policies described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2010.

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.

Recent Accounting Pronouncements

In June 2011, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2011-05, *Presentation of Comprehensive Income* ("ASU 2011-05"), which will enhance comparability between entities that report under U.S. GAAP and those that report under International Financial Reporting Standards ("IFRS"). ASU 2011-05 requires companies to present the components of net income and other comprehensive income either as one continuous statement or as two consecutive statements. It eliminates the option to present components of other comprehensive income as part of the statement of equity. ASU 2011-05 is effective for the Company's interim and annual periods beginning after December 15, 2011 and must be applied retrospectively. Early adoption is permitted. The Company does not anticipate that the adoption of ASU 2011-05 will have a material effect on its financial position or results of operations.

2. NET LOSS PER SHARE

Basic net loss attributable to common stockholders per share is computed by dividing income (loss) available to common stockholders by the weighted-average number of common shares outstanding 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 net loss per share is similar to the computation of basic net loss per share 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. For the periods presented, diluted net loss per share is identical to basic net loss per share 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,	
	2011	2010	2011	2010
Net loss per share				
Numerator				
Net loss	$ (24,443)	$ (8,334)	$ (66,179)	$ (27,374)
Denominator				
Weighted-average common shares outstanding	40,843,960	23,009,288	36,254,292	19,619,670
Less: Weighted-average shares subject to repurchase	(10,465)	(45,009)	(15,630)	(52,612)
Denominator for basic and diluted net loss per share	40,833,495	22,964,279	36,238,662	19,567,058
Basic and diluted net loss per share	$ (0.60)	$ (0.36)	$ (1.83)	$ (1.40)

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Options to purchase common stock	824,186	965,977	835,250	749,613
Common stock subject to repurchase	10,465	45,009	15,630	52,612
Warrants to purchase common stock	4,851,029(1)	676,701(2)	4,771,562(1)	464,828(2)
Restricted Stock Units	162,750	273,652	250,459	93,220
Total	5,848,430	1,961,339	5,872,901	1,360,273

(1) Consists of warrants to purchase 357,136 shares of common stock which carry a contractual term of five years and terminate upon the earlier of i) five years from the date of issuance, which will be July 17, 2014 or September 9, 2014, and ii) upon certain corporate transactions; warrants to purchase 4,172,464 and 4,190,721 shares of common stock, for the three and nine months ended September 30, 2011, respectively, which carry a contractual term of five years expiring September 24, 2015; and warrants to purchase 321,429 and 223,705 shares of common stock, for the three and nine months ended September 30, 2011, respectively, which carry a contractual term of seven years expiring March 25, 2018. Each of the warrants contains a customary net issuance feature, which allows the warrant holder to pay the exercise price of the warrant by forfeiting a portion of the executed warrant shares with a value equal to the aggregate exercise price.

(2) Consists of warrants to purchase 357,136 shares of common stock which carry a contractual term of five years and terminate upon the earlier of i) five years from the date of issuance, which will be July 17, 2014 or September 9, 2014, and ii) upon certain corporate transactions; and warrants to purchase 319,565 and 107,692 shares of common stock, for the three and nine months ended September 30, 2010, respectively, which carry a contractual term of five years expiring September 24, 2015. Each of the warrants contains a customary net issuance feature, which allows the warrant holder to pay the exercise price of the warrant by forfeiting a portion of the executed warrant shares with a value equal to the aggregate exercise price.

3. CASH EQUIVALENTS AND INVESTMENTS

At September 30, 2011 and December 31, 2010, the amortized cost and estimated fair value of investments is set forth in the following tables (in thousands):

	September 30, 2011		
	Amortized Cost	Gross Unrealized Losses	Estimated Fair Value
Cash	$ 6,240	$ —	$ 6,240
Money market funds	83,286	—	83,286
Certificates of deposit	3,739	(4)	3,735
Total	93,265	(4)	93,261
Less amounts classified as cash and cash equivalents	(89,526)	—	(89,526)
Total	$ 3,739	$ (4)	$ 3,735

	December 31, 2010		
	Amortized Cost	Gross Unrealized Losses	Estimated Fair Value
Cash	$ 15,499	$ —	$ 15,499
Money market funds	19,467	—	19,467
Certificates of deposit	14,478	(7)	14,471
Corporate bonds	4,011	—	4,011
Investments in foreign sovereign debt	10,017	(84)	9,933
Total	63,472	(91)	63,381
Less amounts classified as cash and cash equivalents	(40,045)	15	(40,030)
Total	$ 23,427	$ (76)	$ 23,351

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 is little or no market data, which require us to develop our own assumptions. Examples of assets and liabilities utilizing Level 3 inputs are cost method investments, auction rate securities (ARS) and the Primary Fund.

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 as of September 30, 2011 and December 31, 2010:

	September 30, 2011			
	Estimated Fair Value	Level 1	Level 2	Level 3
Money market funds	$ 83,286	$ 83,286	$ —	$ —
Certificates of deposit	3,735	—	3,735	—
Total	$ 87,021	$ 83,286	$ 3,735	$ —

	December 31, 2010			
	Estimated Fair Value	Level 1	Level 2	Level 3
Money market funds	$ 19,467	$ 19,467	$ —	$ —
Certificates of deposit	14,471	—	14,471	—
Corporate bonds	4,011	—	4,011	—
Investments in foreign sovereign debt	9,933	—	9,933	—
Total	$ 47,882	$ 19,467	$ 28,415	$ —

5. PROPERTY AND EQUIPMENT

Property and equipment are comprised of the following (in thousands):

	September 30, 2011	December 31, 2010
Computers and software	$ 77	$ 77
Office equipment and furniture	17	17
Leasehold improvements	11	11
Lab equipment	22	—
Construction in progress	1,289	—
Total property and equipment	1,416	105
Less accumulated depreciation	(100)	(88)
Property and equipment, net	$ 1,316	$ 17

6. COMMITMENTS AND CONTINGENCIES

The Company leases its main operating facility in Hayward, California. The Company began occupying this operating facility in the fourth quarter of 2008 and amended its lease for the facility in April 2011. The new lease commences on August 1, 2011 and includes approximately $245,000 in tenant improvement reimbursements from the landlord. Pursuant to the amendment, the lease increased the Company's square footage from 7,800 square feet to 14,034 square feet. The new lease expires on September 30, 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 on rent payments is classified as deferred rent liability on the balance sheet.

In July 2006, the Company with Shionogi & Co., Ltd. and Eli Lilly and Company (collectively "Eli Lilly") entered into a license agreement (the "Eli Lilly Agreement") to develop and commercialize certain $sPLA_2$ inhibitors for any indications, including for the treatment of inflammatory diseases. The Eli Lilly Agreement granted the Company commercialization rights to Shionogi & Co., Ltd.'s and Eli Lilly's $sPLA_2$ inhibitors, including varespladib and A-001. Under the terms of the Eli Lilly Agreement, the Company's license is worldwide, with the exception of Japan where Shionogi & Co., Ltd. has retained rights. Pursuant to this license agreement, the Company paid Shionogi & Co., Ltd. and Eli Lilly a one-time license initiation fee of $250,000 in the aggregate. Additionally, in consideration for the licensed technology, the Company issued an aggregate of 257,744 shares of Series A-2 convertible preferred stock at $5.14 per share and an aggregate of 127,297 shares of Series B-1 convertible preferred stock at $7.28 per share with a total aggregate value of $2.3 million to Shionogi & Co., Ltd. and Eli Lilly. As there is no future alternative use for the technology, the Company recorded the initiation and license fees in research and development expenses during 2006. In March 2010, the Company

paid $1.75 million each to Eli Lilly and Shionogi & Co., Ltd. in the form of the Company's common stock upon the commencement of the Company's Phase 3 VISTA-16 study of varespladib.

Under the terms of the Eli Lilly Agreement, the Company is obligated to make additional milestone payments to Eli Lilly of up to $97.5 million upon the achievement of certain development and regulatory milestones. The Company is also obligated to pay tiered royalties, which increase as a percentage from the mid-single digits to the low double digits as net sales increase, on future net sales of products that are developed and approved as defined by this collaboration. The Company's obligation to pay royalties with respect to each licensed product in each country will expire upon the later of (a) 10 years following the date of the first commercial sale of such licensed product in such country and (b) the first date on which generic version(s) of the applicable licensed product achieve a total market share, in the aggregate, of 25% or more of the total unit sales of wholesalers to pharmacies of licensed product and all generic versions combined in the applicable country. As of September 30. 2011, there were no outstanding obligations due to Eli Lilly.

On December 18, 2007, the Company with Amgen, Inc. ("Amgen") entered into a worldwide, exclusive license agreement (the "Amgen Agreement") to develop and commercialize blisibimod (A-623) in any indication, including for the treatment of systemic lupus erythematosus ("lupus"). Under the terms of the Amgen Agreement, the Company paid a nonrefundable, upfront license fee of $6.0 million. As there 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, 2011, there were no outstanding obligations due to Amgen.

7. COMPREHENSIVE LOSS

Comprehensive loss is comprised of net loss and certain changes in equity that are excluded from net loss. Components of comprehensive loss include unrealized gains on available-for-sale securities, and unrealized gains related to foreign currency transactions. The components of comprehensive loss are as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Net loss	$ (24,443)	(8,334)	$ (66,179)	(27,374)
Unrealized gain (loss) on available-for-sale securities	(13)	(15)	(12)	(46)
Foreign currency translation adjustments	—	208	17	208
Comprehensive loss	$ (24,456)	$ (8,141)	$ (66,174)	$ (27,212)

8. NOTES PAYABLE

Term Loan Agreement

Hercules Technology Growth Capital

In March 2011, the Company entered into a Loan and Security Agreement ("Loan Agreement") with Hercules Technology Growth Capital, Inc. and Hercules Technology II, L.P. (together, "Hercules"). Under the terms of the Loan Agreement, the Company borrowed $25.0 million at an interest rate of the higher of (i) 10.55% or (ii) 7.30% plus the prime rate as reported in the Wall Street Journal, and issued to Hercules a secured term promissory note evidencing the loan. The loan is secured by the Company's assets, excluding intellectual property. The Company will make interest only payments for the initial 12 months, which will be extended an additional three months if (a) positive biomarker analysis results are obtained from VISTA-16 Phase 3 FDA Clinical Trial on or before July 31, 2011, and (b) full enrollment of the PEARL-SC Phase 2b FDA Clinical Trial is obtained on or before March 31, 2012. The Company obtained positive biomarker analysis results on April 18, 2011. The Company reached full enrollment of the PEARL-SC Phase 2b FDA Clinical Trial on October 24, 2011. Thereafter, the loan will be repaid in 30 equal monthly installments of approximately $952,000, at the initial interest rate. The Company will also be obligated to pay an end of the term charge of $937,500, which will be expensed over the term of the Loan Agreement using the effective interest rate.

The Loan Agreement limits both the seniority and amount of future debt the Company may incur. The Company may be required to prepay the loan in the event of a change in control. In conjunction with the loan, the Company issued a seven-year warrant to purchase 321,429 shares of the Company's common stock at an exercise price of $6.00 per share. The warrant is immediately exercisable and expires March 2018. The Company estimated the fair value of this warrant using the Black-Scholes option valuation model with the following assumptions: expected term of seven years, a risk-free interest rate of 2.87%, expected volatility of 63% and 0% expected dividend yield.

The Company applied the relative fair value method, described in ASC 470-20-30-1, to allocate the $25.0 million proceeds received under the Loan Agreement between the loan and warrant. The initial carrying amount assigned to the loan was $23.7 million and was recorded as Notes payable — net of discount on the Company's balance sheet. The fair value allocated to the warrant of $1.3 million was recorded as an increase to additional paid-in capital in the Company's balance sheet. The resulting $1.3 million discount from the $25.0 million par value of the loan is being amortized as an additional interest expense over the term of the loan using the effective interest rate method. At September 30, 2011, this warrant remained outstanding and exercisable.

In connection with the Loan Agreement, the Company incurred note issuance costs of approximately $370,200, 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 Agreement using the effective interest rate method.

9. STOCKHOLDERS' EQUITY

On June 8, 2011, the Company utilized its shelf registration statement to sell 7,666,667 shares of its common stock at $7.50 per share. The Company received net proceeds of approximately $54.0 million, which is used for general corporate purposes.

10. SHARE-BASED COMPENSATION PLANS

Option Plans

At September 30, 2011, the Company had the following plans that give rise to share-based compensation: (i) two stock option plans, the 2005 Equity and Incentive Plan (the "2005 Plan") and the 2010 Stock Option and Incentive Plan (the "2010 Plan"), and (ii) the 2010 Employee Stock Purchase Plan (the "ESPP Plan"). The terms of awards granted during the nine months ended September 30, 2011 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, 2010.

On January 1, 2011, in accordance with the 2010 Plan annual increase provisions, the authorized shares in the 2010 Plan increased by 1,315,214.

The following table summarizes stock option activity under the Company's share-based compensation plans for the nine months ended September 30, 2011 (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, 2010	1,275,991	$ 1.26	7.07	$ 4,701
Granted	1,413,000	$ 5.77		
Exercised	(255,334)	$ 1.08		
Cancelled	(134,886)	$ 6.53		
Balance at September 30, 2011	2,298,771	$ 3.75	8.12	$ 3,574
Vested at September 30, 2011	982,538	$ 1.48	6.54	$ 3,409
Vested and expected to vest at September 30, 2011	2,298,771	$ 3.75	8.12	$ 3,574

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 in-the-money options.

As of September 30, 2011, there were 215,434 shares available for future issuance under the 2010 Plan.

Restricted Stock Units

The Company grants restricted stock unit awards ("RSU's") under its 2010 Plan, as determined by the Company's compensation committee. The restricted stock units 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 restricted stock units 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 restricted stock units vest over four years.

In June 2011, the Company amended the 2010 Plan to allow individuals who had received RSU's to net share settle in excess of the minimum statutory withholding amount for taxes. In accordance with ASC 718-10-25, this modification resulted in the RSU's being classified as a liability, and the subsequent change in fair value to be recorded as expense. The unsettled RSU's are remeasured at each reporting date and any changes in valuation are recorded as compensation expense for the period. The Company recognized approximately $0.3 million in expense related to the remeasurement of the awards in June 2011. As of September 30, 2011, the liability related to the unsettled awards was not significant.

The following table summarizes activity related to our restricted stock units and awards:

	Shares	Weighted-Average Grant Date Fair Value
Outstanding at December 31, 2010	302,500	$ 5.13
RSU's granted	10,000	$ 4.88
RSU's released	(140,000)	$ 5.20
RSU forfeitures and cancellations	(10,125)	$ 4.48
Outstanding at September 30, 2011	162,375	$ 5.09

RSUs are converted into common stock upon vesting. Upon the vesting of restricted stock units, we offer the use of the net share settlement approach and withhold 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):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Shares withheld	1,200	—	128,075	—
Fair value of shares withheld	$ 9	—	$ 881	—

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 100,000 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) 250,000 shares of common stock. On January 1, 2011, in accordance with the ESPP's annual increase provisions, the authorized shares in the ESPP increased by 250,000.

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 13,187 shares issued under the ESPP during the nine months ended September 30, 2011. As of September 30, 2011, 311,897 shares were available for future purchase under the ESPP.

11. STOCK-BASED COMPENSATION

Employee Stock-Based Compensation

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

Stock Option Plans

	Three Months Ended September 30,		Nine Months Ended September 30,		Period from September 9, 2004 (Date of Inception) to September 30,
	2011	2010	2011	2010	2011
Expected Volatility	64%	63%	63%	69%	73%
Dividend Yield	0%	0%	0%	0%	0%
Risk-Free Interest Rate	1.20%	1.59%	2.25%	1.91%	3.25%
Expected Term (years)	6.25	6.25	6.25	6.25	6.25

ESPP

	Three Months Ended September 30,		Nine Months Ended September 30,		Period from September 9, 2004 (Date of Inception) to September 30,
	2011	2010	2011	2010	2011
Expected Volatility	68%	67%	61%	67%	64%
Dividend Yield	0%	0%	0%	0%	0%
Risk-Free Interest Rate	0.05%	0.16%	0.13%	0.16%	0.12%
Expected Term (years)	0.50	0.33	0.50	0.33	0.50

The estimated per share weighted-average fair values of stock options granted to employees were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,		Period from September 9, 2004 (Date of Inception) to September 30,
	2011	2010	2011	2010	2011
Estimated per share weighted-average fair value	$ 2.82	$ 2.47	$ 3.47	$ 3.10	$ 1.68

Stock-Based Compensation Summary

Total stock-based compensation expense for equity awards granted to employees and non-employees 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, 2011
	2011	2010	2011	2010	
Research and development	$ 233	$ 82	$ 723	$ 114	$ 1,165
General and administrative	291	157	1,154	230	2,049
Total stock-based compensation	$ 524	$ 239	$ 1,877	$ 344	$ 3,214

As of September 30, 2011, there was $4.3 million of unrecognized compensation expense related to options. The unrecognized compensation expense will be amortized on a straight-line basis over a weighted-average remaining period of 3.09 years.

12. RELATED PARTY TRANSACTIONS

The Company engaged an outside service provider whose chief executive officer is a founder of the Company and spouse of an officer of the Company, for clinical management services. In consideration for the services rendered, the Company paid the following fees (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,		Period from September 9, 2004 (Date of Inception) to September 30,
	2011	2010	2011	2010	2011
Project management fees	$ 978	$ 330	$ 2,477	$ 490	$ 3,142

As of September 30, 2011, the Company had approximately $1.0 million payable to this organization for services performed during the period compared to approximately $0.5 million payable as of December 31, 2010. There were no changes to the scope of services performed by this entity in the quarter ended September 30, 2011 as compared to the quarter ended June 30, 2011. Further, we anticipate this relationship to continue for the foreseeable future.

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

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), which are subject to the "safe harbor" created by those sections. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. All statements other than statements of historical factors are "forward-looking statements" for purposes of theses 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, including cardiovascular and autoimmune diseases. We currently have one Phase 3 clinical program, varespladib, and two Phase 2 clinical programs, blisibimod (A-623) and A-001. Two of our product candidates, varespladib and A-001, are designed to inhibit a novel enzyme target known as secretory phospholipase A_2, or $sPLA_2$. Elevated levels of $sPLA_2$ have been implicated in a variety of acute inflammatory conditions, including acute coronary syndrome and acute chest syndrome associated with sickle cell disease, as well as in chronic diseases, including stable coronary artery disease. In addition, our Phase 2 product candidate, blisibimod (A-623), 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, lupus nephritis, rheumatoid arthritis, multiple sclerosis, Sjögren's Syndrome, Graves' Disease and others.

We were incorporated and commenced operations in September 2004. Since our inception, we have generated significant losses. As of September 30, 2011, we had an accumulated deficit of approximately $171.8 million. 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 and increasing losses for at least the next several years as we pursue the development and commercialization of our product candidates.

To date, we have funded our operations through equity offerings, private placements of convertible debt and debt financings, raising net proceeds of approximately $225.4 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 any of our product candidates, obtain adequate patent protection for our technology, obtain necessary government regulatory approval for our product candidates or achieve commercial viability for any approved product candidates. In addition, we may not be profitable even if we succeed in commercializing any of our product candidates.

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 our Phase 3 clinical study named VISTA- 16 for varespladib and for our Phase 2b clinical study named PEARL-SC for blisibimod (A-623), as well as for the development of our other product candidates. Pharmaceutical development costs consist of expenses incurred relating to clinical studies and product formulation and manufacturing.

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

The following table shows our total research and development expenses for the three and nine months ended September 30, 2011 and 2010, and for the period from September 9, 2004 (Date of Inception) through September 30, 2011 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,		For the Period September 9, 2004 (Date of Inception) to September 30,
	2011	2010	2011	2010	2011
Allocated costs:					
A-001	$ (67)	$ 13	$ 100	$ 126	$ 6,608
Varespladib	11,072	3,923	32,374	11,885(1)	79,465(1)(2)
Blisibimod (A-623)	8,758	1,486	20,839	3,644	32,809(3)
Unallocated costs	1,783	1,463	5,136	2,910	20,348
Total research and development	$ 21,546	$ 6,885	$ 58,449	$ 18,565	$ 139,230

(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 increase significantly as we continue to develop our product candidates. We began enrollment of patients in the VISTA-16 study of varespladib for the treatment of patients experiencing acute coronary syndrome in June 2010. We also initiated the PEARL-SC study of blisibimod (A-623) in July 2010. We intend to fund our clinical studies 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 U.S. Food and Drug Administration, or 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 our product candidates 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 development projects 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 executive and operational functions, including clinical, chemical manufacturing, regulatory, 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, 2010, 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 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.

Stock-Based Compensation

Compensation costs related to all equity instruments, excluding RSU's, are recognized at the grant date fair value of the awards. RSU's are accounted for as a liability award, and as such the fair value of the awards are remeasured at each reporting date. Additionally, we are required to include an estimate of the number of awards that will be forfeited in calculating compensation costs, which are recognized over the requisite service period of the awards on a straight-line basis. We account for stock-based compensation using the Black-Scholes option pricing model to estimate the fair value of each option grant on the date of grant. Black-Scholes option pricing model requires the input of highly subjective assumptions, including the expected stock price volatility, expected term, and forfeiture rate. Any changes in these highly subjective assumptions could significantly impact stock-based compensation expense.

Results of Operations

Comparison of the Three and Nine Months Ended September 30, 2011 and 2010

Research and development expenses. Research and development expenses consist of personnel costs for employees in clinical, chemical manufacturing and regulatory functions, clinical studies performed by CROs, pharmaceutical development costs including product formulation and manufacturing, preclinical costs, license fees and overhead allocations consisting of various administrative and facilities-related costs. Research and development expenses for the three and nine month periods ended September 30, 2011 and September 2010 were as follows (in millions).

	Three Months ended September 30,			Nine Months ended September 30,		
	2011	2010	Change	2011	2010	Change
Research and development expense	$ 21.5	$ 6.9	212%	$ 58.4	$ 18.6	214%

Research and development expenses for the three months ended September 30, 2011 increased due primarily to increased clinical trial costs associated with our Phase 3 clinical study of varespladib and Phase 2 clinical study of blisibimod (A-623) of approximately $10.1 million. The trial costs increased as a result of accelerating enrollment and additional clinical sites for the VISTA-16 and PEARL-SC clinical studies. Manufacturing development activities also increased by approximately $3.6 million over the prior period in 2010. We increased headcount to support our clinical development activities.

Research and development expenses for the nine months ended September 30, 2011 increased due primarily to increased clinical trial costs associated with our Phase 3 clinical study of varespladib and Phase 2 clinical study of blisibimod (A-623) of approximately $29.8 million. The trial costs increased as a result of accelerating enrollment and additional clinical sites for the VISTA-16 and PEARL-SC clinical studies. Manufacturing development activities also increased by approximately $9.1 million over the prior period in 2010. We increased headcount to support our clinical development activities.

General and administrative expenses. General and administrative expenses consist of personnel costs for employees in executive, business development and operational functions, professional service fees including corporate legal fees, accountant fees and overhead allocations consisting of various administrative and facilities-related costs. General and administrative expenses for the three and nine month periods ended September 30, 2011 and September 2010 were as follows (in millions).

	Three Months ended September 30,			Nine Months ended September 30,		
	2011	2010	Change	2011	2010	Change
General and administrative expense	$ 1.8	$ 1.5	20%	$ 6.3	$ 4.2	48%

General and administrative expenses for the three and nine month periods ended September 30, 2011 increased due primarily to increased headcount and related salaries and benefits to support our expanding business activities, and increased professional services incurred in connection with our financial audit and other costs associated with operating as a public company.

Other income/expense. Other income/expense consists of interest earned on our cash, cash equivalents and short-term investments and realized gains relating to investments. Other income/expense was approximately $0.2 million of expense and $0.4 million of income for the three and nine months ended September 30, 2011 as compared to $0.06 million of income and $0.08 million of income for the prior period. The increase is primarily due to higher cash and investment balances in the current year due to proceeds received from the issuance of note payable and equity offering as compared to the prior year. Further included in the nine months ended September 30, 2011 were realized foreign currency gains of approximately $0.5 million on our short-term investments.

Interest expense. Interest expense was $0.9 million and $1.9 million for the three and nine months ended September 30, 2011, compared with $0 and $0.8 million for the three and nine months September 30, 2010. Interest expense for the three and nine months ended September 30, 2011 consists primarily of interest expense, amortization of note discount and note issuance costs, and an end of term charge associated with our notes issued under a Loan and Security Agreement with Hercules in March 2011. Interest expense for the three and nine months ended September 30, 2010 consists of primarily non-cash charge related to the amortization of discounts associated with our convertible promissory notes issued in July and September of 2009, which were converted into shares of our common stock upon the closing of our initial public offering ("IPO") in March 2010.

Liquidity and Capital Resources

To date, we have funded our operations primarily through private placements of preferred and common stock, convertible and nonconvertible debt and our IPO. As of September 30, 2011, we had received net proceeds of approximately $173.5 million from the sale of equity securities, approximately $26.2 million from the issuance of convertible promissory notes, and approximately $24.7 million from the issuance of notes payable.

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

	September 30, 2011	December 31, 2010
Cash and cash equivalents	$ 89,526	$ 40,030
Short-term investments	3,735	23,351
Total	$ 93,261	$ 63,381

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

In March 2011, we filed a shelf registration statement with the Securities and Exchange Commission ("SEC") under which we may issue up to $75.0 million in shares of common stock, preferred stock, debt securities and/or warrants. As of September 30, 2011, $57.5 million (or 7,666,667 shares of common stock) have been issued under the shelf registration statement.

Cash Flows

Cash flows from operating activities

For the nine months ended September 30, 2011 and 2010, we incurred a net loss of approximately $66.2 million and $27.4 million, respectively.

Net cash used in operating activities was approximately $47.1 million for the nine months ended September 30, 2011. The net loss is higher than cash used in operating activities by $19.1 million. The primary drivers for the difference are adjustments for non-cash charges of $2.0 million in clinical trial accruals which is based upon our estimated clinical trial performance to date, changes in other

operating assets and liabilities of $14.6 million, and adjustments for non-cash charges including stock-based compensation, amortization of discount on notes payable and debt issuance costs totaling $2.5 million.

Net cash used in operating activities was approximately $18.6 million for the nine months ended September 30, 2010. The net loss is higher than cash used in operating activities by $8.8 million. The primary drivers for the difference are adjustments for non-cash charges such as stock-based compensation of approximately $0.4 million, amortization of note discount and debt issuance cost of approximately $0.8 million, issuance of $3.5 million worth of common stock in lieu of cash milestone payments due to Eli Lilly and Shionogi & Co., Ltd., the conversion of approximately $0.3 million of accrued interest into shares of common stock upon conversion of certain convertible promissory notes, mark-to-market adjustments relating to warrant and derivative liability of $3.8 million, offset by a decrease in operating assets and liabilities of approximately $0.2 million.

Cash flows from investing activities

Net cash provided by investing activities was approximately $18.3 million for the nine months ended September 30, 2011, and was driven by the maturities of short-term investments of $24.3 million during the period, offset by purchases of short-term investments of $4.7 million and property and equipment of $1.3 million.

Net cash used by investing activities was $21.7 million for the nine months ended September 30, 2010 and was primarily driven by the purchase of short-term investments during the period.

Cash flows from financing activities

Net cash provided by financing activities was approximately $78.3 million for the nine months ended September 30, 2011 and consisted primarily of net proceeds of approximately $24.7 million received from the issuance of notes payable with Hercules in March 2011, and approximately $54.0 million in net proceeds received from the equity offering in June 2011.

Net cash provided by financing activities was approximately $87.7 million for the nine months ended September 30, 2010 and consisted of proceeds of approximately $61.2 million received from the issuance of common stock at our IPO, the exercise of the overallotment option by our underwriters in connection with our IPO, the release of funds held in an escrow account concurrent with the closing of our IPO, and proceeds of $29.6 million received from the issuance of common stock and warrants in connection with the private placement offering, offset by approximately $2.9 million of issuance cost paid during the period.

Contractual Obligations and Commitments

The Company has lease obligations consisting of an operating lease in connection with a sublease for our operating facility that commenced in October 2008 and expires September 2014, for approximately 7,800 square feet, through July 2011, and 14,034 square feet, subsequent to July 2011, of office space, and office equipment leases that commenced in October 2007 and will expire in June 2013.

On March 25, 2011, the Company entered into a Loan and Security Agreement ("Loan Agreement") with Hercules Technology Growth Capital, Inc. and Hercules Technology II, L.P. (together, "Hercules"). Under the terms of the Loan Agreement, the Company borrowed $25.0 million at an interest rate of the higher of (i) 10.55% or (ii) 7.30% plus the prime rate as reported in the Wall Street Journal, and issued to Hercules a secured term promissory note evidencing the loan. The loan is secured by the Company's assets, excluding intellectual property. The Company will make interest only payments for the initial 12 months, which will be extended an additional three months if (a) positive biomarker analysis results are obtained from VISTA-16 Phase 3 FDA Clinical Trial on or before July 31, 2011, and (b) full enrollment of the PEARL-SC Phase 2b FDA Clinical Trial is obtained on or before March 31, 2012. The Company obtained positive biomarker analysis results from VISTA-16 Phase 3 FDA Clinical Trial on April 18, 2011. The Company reached full enrollment of the PEARL-SC Phase 2b FDA Clinical Trial on October 24, 2011. Thereafter, the loan will be repaid in 30 equal monthly installments of approximately $952,000, at the initial interest rate. The Company will also be obligated to pay an end of the term charge of $937,500, which will be expensed over the term of the Loan Agreement using the effective interest rate.

The following table summarizes our estimated scheduled future minimum contractual obligations and commitments as of September 30, 2011 (in thousands) :

Payments Due by Period	Note Payable	Facility Lease	Equipment Lease	Total
Less than 1 yr	$ 7,044	223	3	7,270
1-3 Years	22,840	471	2	23,313
3-5 Years	1,005	—	—	1,005
Total	$ 30,889	$ 694	$ 5	$ 31,588

The above amounts exclude potential payments to be made under our license agreements to our licensors that are based on the progress of our product candidates in development, as these payments are not determinable, and potential milestone payments on the development of blisibimod (A-623). Please refer to Note 6 to our financial statements for additional details of these potential payments.

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 varespladib;
- continue clinical development of blisibimod (A-623);
- 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.

To date, we have not generated any revenue. We do not expect to generate commercial product revenue unless or until we obtain regulatory approval of, and commercialize, our product candidates. We expect our continuing operating losses to result in increases in cash used in operations over the next several years. Our future capital requirements will depend on a number of factors including the progress and results of our clinical studies, the costs, timing and outcome of regulatory review of our product candidates, our revenue, if any, from successful development and commercialization of our product candidates, the costs of commercialization activities, the scope, progress, results and costs of preclinical development, laboratory testing and clinical studies for other product candidates, the emergence of competing therapies and other market developments, the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property rights, the extent to which we acquire or invest in other product candidates and technologies, and our ability to establish collaborations and obtain milestone, royalty or other payments from any collaborators.

We expect our existing resources as of the date of this report, to be sufficient to fund our planned operations, including our continued product candidate development, for at least the next 12 months. However, we may require significant additional funds earlier than we currently expect to conduct additional or extended clinical studies and seek regulatory approval of our product candidates. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical studies.

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

If adequate funds are not available, we may be required to terminate, significantly modify or delay our development programs, reduce our planned commercialization efforts, or obtain funds through collaborators that may require us to relinquish rights to our

technologies or product candidates that we might otherwise seek to develop or commercialize independently. We may elect to raise additional funds even before we need them if the conditions for raising capital are favorable.

Off-Balance Sheet Arrangements

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

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. We are exposed to market risk related to fluctuations in interest rates, market prices, and foreign currency exchange rates. However, since a majority of our investments are in short-term certificates of deposit, FDIC-insured corporate bonds and money market funds, we do not believe we are subject to any material market risk exposure. As of September 30, 2011, we did not have any material derivative financial instruments. The fair value of our marketable securities, including those included in cash equivalents and short-term investments, was $93.2 million as of September 30, 2011.

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

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive and financial officers, evaluated the effectiveness of our disclosures controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of September 30, 2011. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate, to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2011, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting during the quarter ended September 30, 2011 identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

ITEM 1. 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.

We believe there is no litigation pending that could, individually or in the aggregate, have a material adverse effect on our results of operations or financial condition.

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 seven years of operating history. We have focused primarily on developing our three product candidates, varespladib, blisibimod (A-623) and A-001. 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, 2011, we had an accumulated deficit of approximately $171.8 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. We expect our development expenses, as well as our clinical product manufacturing expenses, to increase in connection with our pivotal Phase 3 clinical study named VISTA-16 for varespladib, our Phase 2b clinical study named PEARL-SC for blisibimod (A-623) and other clinical studies related to the development of blisibimod (A-623). In addition, we will incur additional costs of operating as a public company and, if we obtain regulatory approval for any of our product candidates, we may incur significant sales, marketing, in-licensing and outsourced manufacturing expenses as well as continued product development expenses. As a result, we expect to continue to incur significant and increasing losses for the foreseeable future.

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

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

- obtain favorable results for and advance the development of our lead product candidate, varespladib, for the treatment of acute coronary syndrome, including successfully completing the VISTA-16 study;
- obtain favorable results for and advance the development of our product candidate blisibimod (A-623) for the treatment of B-cell mediated autoimmune diseases, including successfully launching and completing PEARL-SC or other clinical studies in patients with systemic lupus erythematosus, or lupus, or other indications related to the development of blisibimod (A-623);
- obtain favorable results for and advance the development of our product candidate A-001 for the prevention of acute chest syndrome associated with sickle cell disease, including completing a multi-center Phase 2 clinical study;
- successfully execute our planned preclinical studies in animals and clinical studies in human beings for our other product candidates;
- obtain regulatory approval for varespladib, blisibimod (A-623), A-001 and our other product candidates;
- if regulatory approvals are obtained, begin the commercial manufacturing of our product candidates with our third-party manufacturers;
- launch commercial sales and effectively market our product candidates, either independently or in strategic collaborations with third parties; and

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

All of our product candidates are subject to the risks of failure inherent in the development of therapeutics based on new technologies. Currently, we have three product candidates in clinical development: varespladib, blisibimod (A-623) and A-001. These product candidates could fail in clinical studies if we are unable to demonstrate that they are effective or if they cause unacceptable adverse effects in the patients we treat. Failure of our product candidates in clinical studies would have a material adverse effect on our ability to generate revenue or become profitable. If we are not successful in achieving regulatory approval for our product candidates or are significantly delayed in doing so, our business will be materially harmed.

Additionally, all of our other product candidates are in preclinical development. Our drug discovery efforts may not produce any other viable or marketable product candidates.

Even if our product candidates are approved for commercial sale, the approved product 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 any of our products. We would anticipate incurring significant costs associated with commercializing any approved product. Even if we are able to generate product sales, which we cannot guarantee, we may not achieve profitability soon thereafter, if ever. If we are unable to generate product revenues, we will not become profitable and may be unable to continue operations without additional funding.

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

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

- the rate of progress of our Phase 3 clinical study named VISTA-16 study for varespladib and our Phase 2b clinical study named PEARL-SC or other studies for blisibimod (A-623);
- the scope, size, rate of progress, results and costs of our preclinical studies, clinical studies and other development activities for one or more of our other product candidates;
- manufacturing campaign for blisibimod (A-623) clinical matters, including formulation development and product enhancement;
- non-clinical activities that we may pursue parallel to clinical trials for each clinical compound;
- the cost, timing and outcomes of regulatory proceedings;
- payments received under any strategic collaborations;
- the filing, prosecution and enforcement of patent claims;
- the costs associated with commercializing our product candidates if they receive regulatory approval, including the cost and timing of developing sales and marketing capabilities, or entering into strategic collaboration with others relating to the commercialization of our product candidates; and
- revenues received from approved products, if any, in the future.

As of the date of this report, we anticipate that our existing cash, cash equivalents and short-term investments, will enable us to maintain our currently planned 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 preclinical studies, clinical studies or other development activities for one or more of our product candidates; or

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

The timing of the milestone and royalty payments we are required to make to each of Eli Lilly and Company, Shionogi & Co., Ltd. and Amgen Inc. is uncertain and could adversely affect our cash flows and results of operations.

In July 2006, we entered into a license agreement with Eli Lilly and Company, or Eli Lilly, and Shionogi & Co., Ltd. to develop and commercialize certain secretory phospholipase A_2, or $sPLA_2$, inhibitors for the treatment of cardiovascular disease and other diseases. Pursuant to our license agreement with them, we have an obligation to pay to each of Eli Lilly and Shionogi & Co., Ltd. significant milestone and royalty payments based upon how we develop and commercialize certain $sPLA_2$ inhibitors, including varespladib and A-001, and our achievement of certain significant corporate, clinical and financial events. For varespladib, we are required to pay up to $32.0 million upon achievement of certain approval and post-approval sales milestones. For A-001, we are required to pay up to $3.0 million upon achievement of certain clinical development milestones and up to $25.0 million upon achievement of certain approval and post-approval sales milestones. For other product formulations that we are not currently developing, we would be required to pay up to $2.0 million upon achievement of certain clinical development milestones and up to $35.5 million upon achievement of certain approval and post-approval sales milestones.

In addition, 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 (A-623). 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 (A-623) 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 Eli Lilly, Shionogi & Co., Ltd. and Amgen is subject to factors relating to the clinical and regulatory development and commercialization of certain $sPLA_2$ inhibitors or blisibimod (A-623), 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, varespladib, blisibimod (A-623) and A-001, and performing research and development. We have not yet demonstrated an ability to obtain regulatory approval for or commercialize a product candidate. Consequently, any predictions about our future performance may not be as accurate as they could be if we had a history of successfully developing and commercializing pharmaceutical products.

Risks Associated with Development and Commercialization of Our Product Candidates

We depend substantially on the success of our three primary product candidates, varespladib, blisibimod (A-623) and A-001, which are still under clinical development. We cannot assure you that these product candidates or any of our other product candidates 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 three primary product candidates successfully. Our lead product candidate is varespladib, which has completed its Phase 2 clinical studies and for which we have received (i) an agreement from the U.S. Food and Drug Administration, or FDA, on a Special Protocol Assessment, or SPA, for the VISTA-16 Phase 3 study protocol, and (ii) scientific advice from the European Medicines Agency on our European development strategy for varespladib. We initiated the VISTA-16 study for varespladib in June 2010.

Our next product candidate is blisibimod (A-623), which has completed several Phase 1 clinical studies and began enrollment in 2010 for our Phase 2b clinical study. 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 a proposed amendment to 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.

Our third product candidate A-001 is an intravenously administered inhibitor of $sPLA_2$. We have completed a Phase 2 clinical study for the prevention of acute chest syndrome associated with sickle cell disease. A pre-specified interim review of our Phase 2 clinical study results by a Data Safety Monitoring Board, or DSMB, indicated A-001, at a certain dose, reduced $sPLA_2$ activity by more than 80% from baseline within 48 hours. Furthermore, the incidence of acute chest syndrome appeared to be related to the level of $sPLA_2$ activity. A Phase 2 clinical study protocol is on file with the FDA and has been submitted to an institutional regulatory body ("IRB") for approval.

Our product candidates are prone to the risks of failure inherent in drug development. Before obtaining regulatory approvals for the commercial sale of any product candidate for a target indication, we must demonstrate with substantial evidence gathered in preclinical and well-controlled clinical studies, and, with respect to approval in the United States, to the satisfaction of the 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 candidates may not:

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

We are not permitted to market our varespladib and A-001 product candidates in the United States until we receive approval of a new drug application, or NDA, or with respect to our blisibimod (A-623) product candidate, 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 an NDA or BLA or received marketing approval for any of our product candidates.

Preclinical testing and clinical studies are long, expensive and uncertain processes. We may spend several years completing our testing for any particular product candidate, and failure can occur at any stage. Negative or inconclusive results or adverse medical events during a clinical study could also cause the 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 candidates 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. For example, while an independent statistician has completed an analysis of various biomarkers of cardiovascular risk and determined that treatment with once-daily varespladib met the pre-specified criteria for the VISTA-16 study to proceed, an independent DSMB reviewing the clinical data from the VISTA-16 study may recommend the clinical study discontinue based on safety and tolerability. 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. For example, we may need to increase our sample size for our VISTA-16 study for varespladib if the overall major adverse cardiovascular event, or MACE, rate is lower than expected. 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.

The results of biomarker assays in earlier clinical studies in varespladib are not necessarily predictive of future results, and therefore the results of biomarker assays in the VISTA-16 study may not be similar to those observed previously.

Success in our Phase 2 clinical studies in lowering low-density lipoprotein cholesterol, or LDL-C, C-reactive protein, or CRP, $sPLA_2$ and interleukin-6, or IL-6, during treatment with varespladib does not ensure that later clinical studies, such as our VISTA-16 study, will demonstrate similar reductions in these biomarkers. Each of these biomarkers has been associated with an increased risk for secondary MACE following an acute coronary syndrome. Our inability to demonstrate similar biomarker effects in our VISTA-16 study may reduce our ability to achieve our primary endpoint to reduce MACE and to achieve regulatory approval of varespladib.

Recently, an independent statistician completed an analysis of various biomarkers of cardiovascular risk and determined that treatment with once-daily varespladib met the pre-specified criteria for the study to proceed. The analysis required patients on varespladib to demonstrate pre-defined treatment effects versus placebo at relevant time points on a collection of biomarkers including: secretory phospholipase A_2 ($sPLA_2$), low density lipoprotein cholesterol (LDL-C), C-reactive protein (CRP), interleukin-6 (IL-6), and a composite responder endpoint defined as patients achieving LDL-C less than 70 mg/dL and CRP below 1.0 mg/L. Despite these interim results on biomarkers from VISTA-16, those results do not necessarily equate with reductions in MACE.

Because the results of preclinical testing or earlier clinical studies are not necessarily predictive of future results, varespladib, blisibimod (A-623), A-001 or any other 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, including varespladib, blisibimod (A-623) and A-001, 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 candidates.

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

We are party to an agreement with Eli Lilly and Shionogi & Co., Ltd. containing exclusive, worldwide licenses, except for Japan, of the composition of matter, methods of making and methods of use for certain $sPLA_2$ inhibitors. We are also party to an agreement with Amgen containing exclusive, worldwide licenses of the composition of matter and methods of use for blisibimod (A-623). These agreements require us to make timely milestone and royalty payments, provide regular information, maintain the confidentiality of and indemnify Eli Lilly, Shionogi & Co., Ltd. and Amgen under the terms of the agreements.

If we fail to meet these obligations, our licensors may terminate our exclusive licenses 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 the licensors. Our licensors could effectively take control of the development and commercialization of varespladib, blisibimod (A-623) and A-001 after an uncured, material breach of our license agreements by us or if we voluntarily terminate the agreements. While we would expect to exercise all rights and remedies available to us, including seeking to cure any breach by us, and otherwise seek to preserve our rights under the patents 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 licenses could result in our loss of exclusive rights and may lead to a complete termination of our product development and any commercialization efforts for varespladib, blisibimod (A-623) or A-001.

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

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

The market for inflammatory disease therapeutics is especially large and competitive. All of the $sPLA_2$ inhibitor compounds we are currently developing, if approved, will face intense competition, either as monotherapies or in combination therapies. We are aware of other companies with products in development that are being tested for anti-inflammatory benefits in patients with acute coronary syndrome, such as Via Pharmaceuticals, Inc. and its 5-lipoxygenase, or 5-LO, inhibitor, which has been evaluated in Phase 2 clinical studies; and GlaxoSmithKline plc and its product candidate, darapladib, which is a lipoprotein associated phospholipase A2, or Lp-PLA2, inhibitor currently being evaluated in Phase 3 clinical studies. Although there are no $sPLA_2$ inhibitor compounds

currently approved by the FDA for the treatment of acute chest syndrome associated with sickle cell disease, Droxia, or hydroxyurea, is approved for the prevention of vaso-occlusive crisis, or VOC, in sickle cell disease and thus could reduce the pool of patients with VOC at risk for acute chest syndrome. For lupus, Human Genome Sciences, Inc.'s and GlaxoSmithKline plc's BAFF antagonist monoclonal antibody, Benlysta, was recently approved by the FDA for treatment of lupus. Further, we are aware of companies with other products in development that are being tested for potential treatment of lupus, ZymoGenetics, Inc. 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 a Phase 3 study, 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, 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 any of our product candidates. We anticipate that we will face intense and increasing competition as new drugs enter the market and advanced technologies become available. These entities may also establish collaborative or licensing relationships with our competitors. Finally, the development of new treatment methods for the diseases we are targeting could render our drugs non-competitive or obsolete. All of these factors could adversely affect our business.

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

Undesirable adverse effects caused by our product candidates could cause us, IRBs or other reviewing entities, clinical study sites, or regulatory authorities to interrupt, delay or halt clinical studies and could result in the denial of regulatory approval by the 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 commercializing our product candidates.

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 of our product candidates until the appropriate regulatory authorities have reviewed and approved the applications for such product candidates. 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.

Our agreement with the FDA on a SPA for our VISTA-16 study of varespladib for the potential treatment of acute coronary syndrome does not guarantee any particular outcome from regulatory review of the study or the product candidate.

The FDA's SPA process creates a written agreement between the sponsoring company and the FDA regarding clinical study design and other clinical study issues that can be used to support approval of a product candidate. The SPA is intended to provide assurance that if the agreed upon clinical study protocols are followed and the clinical study endpoints are achieved, the data may serve as the primary basis for an efficacy claim in support of an NDA. However, the SPA agreement is not a guarantee of an approval of a product or any permissible claims about the product. In particular, the SPA is not binding on the FDA if public health concerns unrecognized at the time of the SPA agreement is entered into become evident, other new scientific concerns regarding product safety or efficacy arise or if the sponsor company fails to comply with the agreed upon clinical study protocols. Although we have an agreement with the FDA on an SPA for our VISTA-16 clinical study of varespladib for the potential short-term (16-week) treatment of acute coronary syndrome, we do not know how the FDA will interpret the commitments under our agreed upon SPA, how it will interpret the data and results or whether it will approve our varespladib product candidate for the short-term (16-week) treatment of acute coronary syndrome. Regardless of our SPA agreement, we cannot guarantee any particular outcome from regulatory review of our VISTA-16 study.

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

Even if U.S. regulatory approval is obtained, the 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 varespladib, if any, may include restrictions on use. Further, the FDA has indicated that long-term safety data on varespladib may need to be obtained as a post-market requirement. Our product candidates 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 practices, 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 candidates or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

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

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

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

New federal legislation or regulatory requirements could affect the requirements for obtaining regulatory approvals of our product candidates or otherwise limit our ability to commercialize any approved products or subject our products to more rigorous post-approval requirements. For example, the 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 varespladib in the treatment of acute coronary syndrome, blisibimod (A-623) in the treatment of lupus and A-001 in the prevention of acute chest syndrome associated with sickle cell disease;
- the prevalence and severity of any adverse effects;
- limitations or warnings contained in a product's FDA-approved labeling;
- availability of alternative treatments, including, in the case of varespladib, a number of competitive products being studied for anti-inflammatory benefits in patients with acute coronary syndrome or expected to be commercially launched in the near future;
- 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 the products 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 our 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 our product candidates; and
- decreased demand for our 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 of our product candidates, 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 of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates. In addition, such failure could be the basis for action by the FDA to withdraw approvals for product candidates previously granted to us and for other regulatory action, including recall or seizure, total or partial suspension of production or injunction.

Anthera implemented the transfer of manufacture of blisibimod (A-623) drug substance to a new facility (Fujifilm Diosynth Bioservices [Fujifilm]). We have submitted plans to the FDA on March 4, 2011 and September 9, 2011 establishing criteria to demonstrate comparability of blisibimod (A-623) 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. To date we have had no comments on any of these submissions. Should the FDA not agree with our comparability assessment or if we are unable to agree on the specifications for future blisibimod (A-623) manufacturing, further clinical development of blisibimod (A-623) beyond the PEARL-SC clinical study would be substantially delayed and we would incur substantial additional expense.

We rely on our manufacturers to purchase from third-party suppliers the materials necessary to produce our product candidates for our clinical studies. There are a small number of suppliers for certain capital equipment and raw materials that we use to manufacture our drugs. 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 of our product candidates. If our manufacturers or we are unable to purchase these raw materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply of such product candidates, which would impair our ability to generate revenues from the sale of our product candidates.

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 any of our drugs, 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 our product candidates, we may be unable to generate any revenue.

We do not currently have an organization for the sales, marketing and distribution of pharmaceutical products and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. In order to market any products that may be approved by the 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. For example, organizations like the American Heart Association have made recommendations about therapies in the cardiovascular therapeutics market. Changes to these recommendations or other guidelines advocating alternative therapies could result in decreased use of any products for which we may receive regulatory approval, which may adversely affect our results of operations.

Risks Related to Our Intellectual Property

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

As of the date of this report, we either own or hold license rights to numerous US, EP, and non-EP foreign patents relating to A-001/varespladib, other sPLA2 inhibiting compounds, and blisibimod (A-623). Our A-001/varespladib portfolio includes patents and patent applications originally filed by Anthera and exclusively licensed or assigned cases from Eli Lilly and Shionogi & Co., Ltd. Our blisibimod (A-623) portfolio includes exclusively and non-exclusively licensed patents and patent applications from Amgen Inc.

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

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

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

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

We 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 have obtained exclusive, worldwide licenses, except for Japan, of the composition of matter, methods of making and methods of use for certain $sPLA_2$ compounds from Eli Lilly and Shionogi & Co., Ltd. In addition, we are party to a license agreement with Amgen that provides exclusive and worldwide rights to develop and commercialize blisibimod (A-623), a novel BAFF inhibitor, as well as non-exclusive rights to certain technology relating to peptibody compositions and formulations. We may enter into additional licenses to third-party intellectual property in the future.

We depend in part on our licensors to protect the proprietary rights covering our in-licensed $sPLA_2$ compounds and blisibimod (A-623), respectively. 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 each of our current product candidates in clinical development, and that we continue to have rights under our license agreements with respect to these product candidates, we would have exclusive rights to varespladib's U.S. "new chemical entity" patent (the primary patent covering the compound as a new composition of matter) until 2019 and to blisibimod's (A-623's) U.S. new chemical entity patent until 2027. 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 each of our current product candidates in clinical development, and that we continue to have rights under our license agreements with respect to these product candidates, we would have exclusive rights to varespladib's European new chemical entity patents until 2020 and to blisibimod's (A-623's) European new chemical entity patents until 2027. In addition, since varespladib has not been previously approved in the United States, varespladib could be eligible for up to five years of New Chemical Entity, or NCE, exclusivity from the FDA. NCE exclusivity would prevent the FDA from approving any generic competitor following NDA approval independent of the patent status of varespladib. Further, since blisibimod (A-623) has not been previously approved, blisibimod (A-623) 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 our 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 these product candidates, we may file additional patent applications for these new inventions or we may need to ask our licensors to file them. We may also need to license additional patent rights or other rights on compounds, treatment methods or manufacturing processes because we learn that we need such rights during the continuing development of our product candidates.

Although our in-licensed and original patents may prevent others from making, using or selling similar products, they do not ensure that we will not infringe the patent rights of third parties. We may not be aware of all patents or patent applications that may impact our ability to make, use or sell any of our product candidates or proposed product candidates. For example, because we sometimes identify the mechanism of action or molecular target of a given product candidate after identifying its composition of matter and therapeutic use, we may not be aware until the mechanism or target is further elucidated that a third party has an issued or pending patent claiming biological activities or targets that may cover our product 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 our drug candidates or proposed product candidates, which would harm our business. Litigation or patent interference proceedings may be necessarily brought against third parties, as discussed below, to enforce any of our patents or other proprietary rights or to determine the scope and validity or enforceability of the proprietary rights of such third parties.

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

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

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

Even if we are successful in these proceedings, we may incur substantial costs and divert management time and attention in pursuing these proceedings. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, defend an infringement action or challenge the validity of the patents in court. Patent litigation is costly and time-consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we do not obtain a license, develop or obtain non-infringing technology, fail to defend an infringement action successfully or have our patents declared invalid, we may

incur substantial monetary damages; encounter significant delays in bringing our product candidates to market; or be precluded from participating in the manufacture, use or sale of our product candidates or methods of treatment requiring licenses.

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

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

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

- plans for, progress in and results from clinical studies for varespladib, blisibimod (A-623), A-001 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 held by Eli Lilly and Shionogi & Co., Ltd. concerning our $sPLA_2$ inhibitors and Amgen concerning blisibimod (A-623);
- 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 majority 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 40% of our outstanding common stock. As a result, such persons, acting together, will have the ability to control 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 control 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, 2011, there were 40,907,945 shares of our common stock outstanding. In addition, as of September 30, 2011, we had outstanding options to purchase shares of our common stock and restricted stock units of 2,461,146 that, if exercised or released, will result in these additional shares becoming available for sale. A large portion of these shares and outstanding equity awards are held by a small number of persons and investment funds. Sales by these stockholders or option holders of a substantial number of shares could significantly reduce the market price of our common stock. Moreover, certain holders of shares of common stock will have rights, subject to some conditions, to require us to file registration statements covering the shares they currently hold, or to include these shares in registration statements that we may file for ourselves or other stockholders.

We have registered all common stock that we may issue under our Amended and Restated 2010 Stock Option and Incentive Plan (the "2010 Plan") and our Employee Stock Purchase Plan (the "ESPP"). As of September 30, 2011, an aggregate of 1,778,261 shares of our common stock has been reserved for future issuance under the 2010 Plan, plus any shares reserved and unissued under our 2005 Equity Incentive Plan, and an aggregate of 350,000 shares has been reserved for future issuance under our ESPP. These shares can be freely sold in the public market upon issuance. If a large number of these shares are sold in the public market, the sales could reduce the trading price of our common stock.

In addition, we have filed a universal shelf registration statement with the SEC on Form S-3 (File No. 333-172637) on March 7, 2011, which was declared effective on March 11, 2011, for the proposed offering from time to time of up to $75.0 million of our securities, including common stock, preferred stock, debt securities and/or warrants. In June 2011, we issued 7,666,667 shares of common stock for $57.5 million in gross proceeds. We may issue securities in the future pursuant to the shelf registration statement based on market conditions or other circumstances.

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. Commencing in 2011, we must perform system and process evaluation and testing of our internal control over financial reporting to allow management and our independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. Our compliance with Section 404 will require that we incur substantial accounting expense and expend significant management time on compliance-related issues. Moreover, if we are not able to comply with the requirements of Section 404 in a timely manner, our stock price could decline, and we could face sanctions, delisting or investigations by The NASDAQ Global Market, or other material adverse effects on our business, reputation, results of operations, financial condition or liquidity.

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

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

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

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 acquirors 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 have not performed a detailed analysis to determine whether an ownership change under Section 382 of the Internal Revenue Code has occurred after each of our previous private placements of preferred stock and convertible debt, or our previous issuances of common stock, which if sufficient, taking into account prior or future shifts in our ownership over a three-year period, could cause us to undergo an ownership change. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards to offset U.S. federal taxable income may become subject to limitations, which could potentially result in increased future tax liability to us.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. (REMOVED AND RESERVED)

ITEM 5. OTHER INFORMATION

None.

Table of Contents

ITEM 6. EXHIBITS

The following exhibits are filed as part of this report:

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 on February 3, 2010, and incorporated herein by reference).
3.2	Amended and Restated Bylaws (filed as Exhibit 3.7 to the registrant's Registration Statement on Form S-1/A (File No. 333-161930) filed with the SEC on February 3, 2010, and incorporated herein by reference).
10.1	Second Amended and Restated Change in Control Agreement, dated August 5, 2011 by and between the Company and Dr. Colin Hislop (filed as Exhibit 10.1 to the registrant's current Report on Form 8-K filed with the SEC on August 9, 2011, and incorporated herein by reference).
10.2	Second Amended and Restated Change in Control Agreement, dated August 5, 2011 by and between the Company and Dr. Debra Odink (filed as Exhibit 10.2 to the registrant's current Report on Form 8-K filed with the SEC on August 9, 2011, and incorporated herein by reference).
10.3	Second Amended and Restated Change in Control Agreement, dated August 5, 2011 by and between the Company and Ms. Georgina Kilfoil (filed as Exhibit 10.3 to the registrant's current Report on Form 8-K filed with the SEC on August 9, 2011, 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.SHC+	XBRL Taxonomy Extension Schema Document.
101.CAL+	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF+	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB+	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE+	XBRL Taxonomy Extension Presentation Linkbase Document.

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

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 8, 2011 By: /s/ Paul F. Truex
Paul F. Truex
President and Chief Executive Officer

November 8, 2011 By: /s/ Christopher P. Lowe
Christopher P. Lowe
Chief Financial Officer

Exhibit 31.1

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)) 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) 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

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

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

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

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

Date: November 8, 2011

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

Exhibit 31.2

Certification of Chief Financial Officer and Vice President of Administration
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Christopher P. Lowe, 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)) 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) 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

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

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

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

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

Date: November 8, 2011

/s/ Christopher P. Lowe
Christopher P. Lowe
Chief Financial Officer

Exhibit 32.1

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 September 30, 2011 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 8, 2011

Exhibit 32.2

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

I, Christopher P. Lowe, 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 September 30, 2011 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/ Christopher P. Lowe
Name: Christopher P. Lowe
Title: Chief Financial Officer

Date: November 8, 2011