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ANTHERA PHARMACEUTICALS INC

FORM 10-Q
(Quarterly Report)

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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, 2016

OR

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

For the transition period from to

Commission file number: 001-34637

ANTHERA PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in Its Charter)

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

(510) 856-5600
(Registrant's Telephone Number, Including Area Code)

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

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

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

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

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

As of October 31, 2016, the number of outstanding shares of the registrant's common stock, par value $0.001 per share, was 41,955,126.

ANTHERA PHARMACEUTICALS, INC.

FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2016

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PART I — FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

ANTHERA PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except per share data)
(unaudited)

	September 30, 2016	December 31, 2015 (1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 32,570	$ 46,951
Accounts receivable	—	326
Prepaid expenses and other current assets	943	585
Total current assets	33,513	47,862
Property and equipment — net	973	263
TOTAL	$ 34,486	$ 48,125
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,391	$ 5,259
Accrued clinical expenses	4,561	1,377
Accrued liabilities	517	98
Accrued payroll and related costs	1,722	1,596
Warrant liability	3,509	—
Deferred revenue – current	—	138
Total current liabilities	13,700	8,468
Total liabilities	13,700	8,468
Commitments and contingencies (Note 7)		
Series X contingently redeemable convertible preferred stock, $0.001 par value, 5,000,000 shares authorized; 17,000 and 0 shares issued and outstanding as of September 30, 2016 and December 31, 2015, respectively (2)	9,553	—
Stockholders' equity:		
Right granted to investors to purchase future shares of Series X-1 convertible preferred stock	3,689	—
Common stock, $0.001 par value, 100,000,000 shares authorized; 41,955,126 and 40,004,037 shares issued and outstanding as of September 30, 2016 and December 31, 2015, respectively	42	40
Additional paid-in capital	402,071	391,648
Accumulated deficit	(394,569)	(352,031)
Total stockholders' equity	11,233	39,657
TOTAL	$ 34,486	$ 48,125

The accompanying notes are an integral part of these Condensed Consolidated Financial Statements .

(1) Derived from audited Financial Statements.
(2) The Company has designated (i) 17,000 of the 5,000,000 authorized shares of preferred stock as Series X Preferred Stock and (ii) 28,330 of the 5,000,000 authorized shares of preferred stock as Series X-1 Preferred Stock.

ANTHERA PHARMACEUTICALS, INC.

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

	Three months ended September 30,		Nine months ended September 30,	
	2016	2015	2016	2015
Revenues:				
License fee revenue	$ —	$ 548	$ 139	$ 743
Collaborative revenue	—	185	6	524
Total revenues	—	733	145	1,267
Operating Expenses:				
Research and development	$ 14,096	$ 10,359	$ 35,686	$ 24,893
General and administrative	2,504	2,091	7,318	5,694
Research award	—	(367)	(261)	(1,467)
Total operating expenses	16,600	12,083	42,743	29,120
Loss From Operations	(16,600)	(11,350)	(42,598)	(27,853)
Other Income (Expense):				
Other income (expense)	(47)	24	(109)	(28)
Change in fair value of warrant liability	169	—	169	—
Net Loss	$ (16,478)	$ (11,326)	$ (42,538)	$ (27,881)
Deemed dividends attributable to preferred stock	(8,807)	—	(8,807)	—
Net Loss Applicable to Common Stockholders	$ (25,285)	$ (11,326)	$ (51,345)	$ (27,881)
Net loss per share—basic and diluted	$ (0.61)	$ (0.29)	$ (1.25)	$ (0.81)
Weighted-average number of shares used in per share calculation—basic and diluted	41,682,669	39,241,738	40,924,480	34,260,866

The accompanying notes are an integral part of these Condensed Consolidated Financial Statements .

ANTHERA PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENT OF CONTINGENTLY REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY
(in thousands, except per share data)
(unaudited)

	Series X Contingently Redeemable Convertible Preferred Stock		Series X-1 Convertible Preferred Stock		Common Stock				
	Shares	Amount	Shares	Amount	Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
Balance at December 31, 2015	-	$ -	-	$ -	40,004,037	$ 40	$ 391,648	$ (352,031)	$ 39,657
Issuance of common stock pursuant to exercise of stock options and employee stock purchase plan	-	-	-	-	135,275	-	304	-	304
Share-based compensation related to equity awards	-	-	-	-	-	-	4,084	-	4,084
Issuance of common stock pursuant to an at-the-market equity program, net of issuance cost of $265	-	-	-	-	1,300,985	2	4,456	-	4,458
Issuance of common stock pursuant to an equity purchase agreement, net of issuance cost of $87	-	-	-	-	514,829	-	1,579	-	1,579
Issuance of Series X contingently redeemable, convertible preferred stock, net of issuance costs of $80	17,000	16,920	-	-	-	-	-	-	-
Investors' right to acquire future shares of Series X-1 convertible preferred stock	-	(3,689)	-	3,689	-	-	-	-	3,689
Beneficial conversion feature on Series X contingently redeemable convertible preferred stock	-	(8,807)	-	-	-	-	8,807	-	-
Deemed dividend attributable to beneficial conversion feature on Series X contingently redeemable convertible preferred stock	-	8,807	-	-	-	-	(8,807)	-	-
Issuance of warrants related to Series X contingently redeemable convertible preferred stock	-	(3,678)	-	-	-	-	-	-	-
Net loss	-	-	-	-		-		(42,538)	(42,538)
Balance at September 30, 2016	17,000	$ 9,553	-	$ 3,689	41,955,126	$ 42	$ 402,071	$ (394,569)	$ 11,233

ANTHERA PHARMACEUTICALS, INC.

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

	Nine Months Ended September 30,	
	2016	2015
CASH FLOW FROM OPERATING ACTIVITIES:		
Net loss	$ (42,538)	$ (27,881)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	241	213
Stock-based compensation expense	3,943	2,495
Change in fair value of warrant liability	(169)	—
Changes in assets and liabilities:		
Accounts receivable	326	(983)
Prepaid expenses and other assets	(358)	9
Accounts payable	(1,868)	4,789
Accrued clinical expenses	3,184	468
Accrued liabilities	419	113
Accrued payroll and related costs	267	66
Deferred revenue	(138)	(743)
Net cash used in operating activities	(36,691)	(21,454)
INVESTING ACTIVITIES:		
Property and equipment purchases	(952)	(80)
Net cash used in investing activities	(952)	(80)
FINANCING ACTIVITIES:		
Proceeds from issuance of Series X contingently redeemable convertible preferred stock, warrants and option to purchase Series X-1 convertible future stock, net of offering cost	16,920	—
Proceeds from issuance of common stock, net of offering cost	6,037	65,378
Proceeds from issuance of common stock to collaborative partner	—	9,000
Proceeds from issuance of common stock pursuant to exercise of stock options	305	279
Net cash provided by financing activities	23,262	74,657
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(14,381)	53,123
CASH AND CASH EQUIVALENTS — Beginning of period	46,951	2,639
CASH AND CASH EQUIVALENTS — End of period	$ 32,570	$ 55,762
SUPPLEMENTAL CASH DISCLOSURES OF CASH FLOW INFORMATION		
Non-cash financing activities:		
Fair value of warrants issued in connection with Series X contingently redeemable convertible preferred stock	$ 3,678	$ —
Issuance of common stock as a commitment fee pursuant to an equity purchase agreement	$ 87	$ 60

The accompanying notes are an integral part of these Condensed Consolidated Financial Statements .

ANTHERA PHARMACEUTICALS, INC.
NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

1. ORGANIZATION AND SIGNIFICANT ACCOUNTING POLICIES

Organization

Anthera Pharmaceuticals, Inc. (the "Company" or "Anthera") is a biopharmaceutical company focused on advancing the development and commercialization of innovative medicines that benefit patients with unmet medical needs. The Company currently has two compounds in development, liprotamase, also known as Sollpura™, and blisibimod. The Company licensed liprotamase from Eli Lilly & Co ("Eli Lilly") in July 2014. Liprotamase is a novel non-porcine investigational Pancreatic Enzyme Replacement Therapy ("PERT") intended for the treatment of patients with Exocrine Pancreatic Insufficiency ("EPI"), often seen in patients with cystic fibrosis and other conditions. The Company licensed blisibimod from Amgen, Inc. ("Amgen") in December 2007. Blisibimod targets B-cell activating factor ("BAFF") which has been shown to be elevated in a variety of B-cell mediated autoimmune diseases, including systemic lupus erythematosus ("SLE"), or lupus, Immunoglobulin A nephropathy, or IgA nephropathy, lupus nephritis, and others.

Liquidity and Need for Additional Capital

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

Since inception in 2004, the Company has funded its operations through equity offerings, private placements of convertible debt, debt financing, equity investment and cost reimbursement from a former collaborative partner, Zenyaku Kogyo Co., Ltd ("Zenyaku"), and a research award from Cystic Fibrosis Foundation Therapeutics Incorporated ("CFFT"). On April 21, 2016, the Company entered into an At Market Issuance Sales Agreement ("ATM Agreement") with H.C. Wainwright & Co., LLC ("H.C. Wainwright") to create an at-the-market equity program under which the Company from time to time may offer and sell shares of its common stock, par value $0.001 per share, having an aggregate offering price of up to $25.0 million through H.C. Wainwright, as agent. On April 27, 2016, the Company amended an existing equity purchase agreement with Lincoln Park Capital Fund, LLC ("LPC"), pursuant to which the Company has the right, but not the obligation, to sell to LPC up to an aggregate of $15.0 million in shares of common stock by March 2017.

In September 2016, the Company entered into a subscription agreement with certain institutional investors pursuant to which it sold 17,000 units for a purchase price of $1,000 per unit in a registered direct offering. Each unit consists of one share of Series X contingently redeemable convertible preferred stock and a warrant to purchase shares of common stock. Assuming an exercise price equal to $3.54 per share, which is a 20% premium over the closing price of our common stock on September 6, 2016, each unit would include a warrant to purchase up to 70.62 shares of common stock. The offering resulted in gross proceeds of $17.0 million. The subscription agreement provides that the investors have the right, but not the obligation, to make additional investments as follows: within 20 trading days following the Company's initial public announcement of top-line data from the Company's ongoing SOLUTION study (Phase 3 study evaluating the efficacy and safety of Liprotamase in subjects with cystic fibrosis-related exocrine pancreatic insufficiency), the investors may purchase up to 28,330 shares of Series X-1 convertible preferred stock at a purchase price of $1,000 per share for an aggregate purchase price of $28.3 million ("Additional Investment").

As of the date of this report, the Company anticipates its existing cash, and access to additional cash through the ATM Agreement with H.C. Wainwright and an equity purchase agreement with LPC will be sufficient to fund its near term liquidity needs for at least the next 12 months.

To fully execute its business plan, the Company will need to complete certain research and development activities and clinical studies. Further, the Company's product candidates will require regulatory approval prior to commercialization. These activities may span many years and require substantial capital to complete and may ultimately be unsuccessful. Any delays in completing these activities could adversely impact the Company. The Company will need substantial additional financing to continue development of its product candidates, obtain regulatory approvals, and prepare for commercial readiness if the clinical trials are successful; such financing may not be available on terms favorable to the Company, if at all. If adequate funds are not available, the Company may be required to delay, reduce the scope of, or eliminate one or more of its clinical trials. The Company plans to meet its capital requirements primarily through future partnerships, issuances of equity securities, debt financing, 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 Consolidated Financial Statements have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC") for Quarterly Reports on Form 10-Q and do not contain all of the information and footnotes required by U.S. generally accepted accounting principles ("U.S. GAAP") for complete financial statements. The accompanying unaudited Condensed Consolidated financial statements and notes thereto should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2015, filed with the SEC on March 14, 2016. In the opinion of management, the accompanying unaudited Condensed Consolidated financial statements reflect all adjustments, which include only normal recurring adjustments necessary to present fairly the Company's interim consolidated financial information. The results for the three and nine months ended September 30, 2016 are not necessarily indicative of the results to be expected for the year ending December 31, 2016 or for any other period. The consolidated balance sheet as of December 31, 2015 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 Company has evaluated events and transactions subsequent to the balance sheet date and has disclosed all events or transactions that occurred subsequent to the balance sheet date but prior to filing this Quarterly Report on Form 10-Q that would require recognition or disclosure in the unaudited Condensed Consolidated Financial Statements.

Use of Estimates

The preparation of these condensed consolidated financial statements in conformity with U.S. GAAP requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, expenses and related disclosures. On an ongoing basis, management evaluates its estimates, including critical accounting policies or estimates related to clinical trial accruals, tax provision, stock-based compensation, warrant liabilities, and the computation of beneficial conversion features. 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.

Financial Instruments with Characteristics of Both Equity and Liabilities

The Company has issued certain financial instruments, including warrants to purchase common stock and rights to purchase shares of Series X-1 convertible preferred stock, which have the characteristics of both liability and equity. Financial instruments such as warrants that are evaluated to be classified as liabilities are fair valued upon issuance and are remeasured at fair value at subsequent reporting periods with the resulting change in fair value recorded in other income/(expense). The fair value of warrants is estimated using the Monte Carlo simulation model and requires the input of subjective assumptions including expected stock price volatility, expected life and the Company's assumptions about future announcements of topline clinical data from the Company's clinical studies and their impact to the exercise price of the warrants.

Recent Accounting Pronouncements

In September 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update No. 2014-15, Presentation of Financial Statements - Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as Going Concern ("ASU 2014-15"). ASU 2014-15 defines when and how companies are required to disclose going concern uncertainties, which must be evaluated each interim and annual period. Specifically, the ASU requires management to determine whether substantial doubt exists regarding the entity's going concern presumption. Substantial doubt about an entity's ability to continue as a going concern exists when relevant conditions and events, considered in the aggregate, indicate that it is probable that the entity will be unable to meet its obligations as they become within one year after the financial statements are issued (or available to be issued). If substantial doubt exists, certain disclosures are required; the extent of those disclosures depends on an evaluation of management's plans (if any) to mitigate the going concern uncertainty. The guidance is effective for fiscal years ending after December 15, 2016 and for interim periods thereafter. The Company does not expect the adoption of this guidance to materially affect its consolidated financial statements.

In November 2015, the FASB issued guidance on the classification of deferred taxes, Accounting Standards Update No. 2015-17 ("ASU 2015-17"), Balance Sheet Classification of Deferred Taxes. ASU 2015-17 eliminates the guidance in Topic 740, Income Taxes, that required an entity to separate deferred tax liabilities and assets between current and noncurrent amounts in a classified balance sheet. The amendments require that all deferred tax liabilities and assets of the same tax jurisdiction or a tax filing group, as well as any related valuation allowance, be offset and presented as a single amount in a classified balance sheet. The amendments are effective for public business entities for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2016. Early adoption is permitted as of the beginning of any interim period or annual reporting period. The Company does not expect the adoption of this guidance to materially affect its consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02 Leases (Topic 842). ASU 2016-02 impacts any entity that enters into a lease with some specified scope exceptions. The guidance updates and supersedes Topic 840, Leases. For public entities, ASU 2016-02 is effective for fiscal years, and interim periods with those years, beginning after December 15, 2018, and early adoption is permitted. The Company does not expect the adoption of this standard to materially affect its consolidated financial statements.

In March 2016, the FASB issued ASU No. 2016-09, Compensation—Stock Compensation (Topic 718). This standard makes several modifications to Topic 718 related to the accounting for forfeitures, employer tax withholding on share-based compensation and the financial statement presentation of excess tax benefits or deficiencies. ASU 2016-09 also clarifies the statement of cash flows presentation for certain components of share-based awards. The standard is effective for interim and annual reporting periods beginning after December 15, 2016, although early adoption is permitted. The adoption of ASU 2016-09 is not expected to have a significant impact on the Company's consolidated financial position or results of operations.

2. COLLABORATIVE AGREEMENT

In December 2014, the Company entered into an exclusive license agreement with Zenyaku ("Zenyaku Agreement") for the development and commercialization of blisibimod in Japan and potentially other countries throughout Asia, while the Company retained full development and commercialization rights of blisibimod for all other global territories including North America and the European Union. In September 2015, Zenyaku provided the Company a notice of its intent to terminate the Zenyaku Agreement, effective January 7, 2016 ("Termination Notice"). As a result of the Termination Notice, the Company changed the amortization period of its deferred revenue and has fully amortized its deferred revenue as of January 7, 2016.

3. RESEARCH AWARD

In March 2015, the Company received a research award of up to $3 million from the CFFT for the Company's development of liprotamase. The Company retains the right to develop and commercialize liprotamase and will owe royalties to CFFT on net sales of any drug candidate approved and commercialized under the collaboration. The funding is to be disbursed by CFFT to the Company upon the Company's achievement of milestones specified in the award agreement. At its discretion, the Company may choose to fund a particular stage of the liprotamase development plan without CFFT funds. Any CFFT funds not expended on the development program of liprotamase must be returned to CFFT and, upon such return, the amounts of such returned funds will not be included as part of the research award for the purpose of calculating royalties or other amounts owed by the Company to CFFT. To the extent CFFT provides or makes available any information, expertise, know-how or other intellectual property related to cystic fibrosis or the treatment, prevention or cure there-of ("CFFT Know-How") to the Company, CFFT grants to the Company a non-exclusive, transferrable, sublicensable, worldwide rights and license under all of CFFT's rights in such CFFT Know-How to assist the Company to research, develop, commercialize, make or have made, use, sell, have sold, offer for sale, import, export and otherwise exploit the product.

In consideration for CFFT's research award and any licenses of intellectual property granted by CFFT, the Company agrees to pay royalties to CFFT as follows: i) a one-time royalty in an amount equal to five times the actual award, payable in three installments between the first and second anniversaries of the first commercial sale of a product; ii) a one-time royalty in an amount equal to the actual award after net product sales reaches $100 million; and iii) in the event of a license, sale or other transfer of the product or a change of control transaction prior to the commercial sale of the product, a milestone payment equal to three times the actual award.

For the nine months ended September 30, 2016 and 2015, the Company recognized $0.3 million and $1.5 million, respectively, from CFFT in connection with achieving certain milestones specified in the award agreement and included it as an offset to operating expense. There was no milestone recognized for the three months ended September 30, 2016 and $0.4 million recognized for the three months ended September 30, 2015. As of September 30, 2016, there was $0.1 million remaining under the research award.

4. NET LOSS PER SHARE

Basic net loss attributable to common stockholders per share is computed by dividing income available to common stockholders (the numerator) by the weighted-average number of common shares outstanding (the denominator) during the period. Shares issued during the period and shares reacquired during the period are weighted for the portion of the period that they were outstanding. The computation of diluted Earnings Per Share, or EPS, is similar to the computation of basic EPS except that the denominator is increased to include the number of additional common shares that would have been outstanding if the dilutive potential common shares had been issued.

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,	
	2016	2015	2016	2015
Net loss per share				
Numerator				
Net loss	$ (16,478)	$ (11,326)	$ (42,538)	$ (27,881)
Deemed dividend attributable to preferred stock	(8,807)	—	(8,807)	—
Net loss applicable to common stockholders	$ (25,285)	$ (11,326)	$ (51,345)	$ (27,881)
Denominator				
Weighted average common shares outstanding	41,682,669	39,241,738	40,924,480	34,260,866
Basic and diluted net loss per share	$ (0.61)	$ (0.29)	$ (1.25)	$ (0.81)

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

	As of September 30,	
	2016	2015
Options to purchase common stock	5,982,673	4,282,356
Warrants to purchase common stock	40,178	40,178
Restricted Stock Units	—	937
Total	6,022,851	4,323,471

In addition to the above outstanding equity instruments, the Company also excluded the conversion of its Preferred Stock and warrants as follows (see Note 8 for terms of Preferred Stock):

	As of September 30, 2016	
Potential conversion of Series X contingently redeemable convertible preferred stock	5,762,712 (1)	5,396,825 (2)
Potential conversion of Series X-1 convertible preferred stock	5,487,651 (3)	11,991,534 (4)
Potential warrants for common stock issuable upon exercise of warrants	1,200,565 (5)	1,124,339 (6)

(1) The number of potential shares is based on gross proceeds of $17 million from the issuance of Series X contingently redeemable convertible preferred stock divided by the stated conversion price of $2.95 applicable through the date of the initial public announcement of topline and/or efficacy data from the Chablis-SC1 study or the announcement of the suspension, abandonment or other termination of the Chablis SC-1 study.

(2) The number of potential shares is based on gross proceeds of $17 million from the issuance of Series X contingently redeemable convertible preferred stock divided by an assumed conversion price of $3.15, which is based on the Company's five-day volume-weighted average price, or VWAP, of the Company's common stock price over the five full trading days ending September 30, 2016. The holder of the Series X contingently redeemable convertible preferred stock is able to convert at the lower of the $2.95 or the five-day VWAP, of the Company's common stock price over the five full trading days following the earlier of the initial public announcement of topline and/or efficacy data from the Chablis-SC1 study or the announcement of the suspension, abandonment or other termination of the Chablis SC-1 study.

(3) In connection with the issuance of Series X contingently redeemable convertible preferred stock, the Company granted a right to the Series X preferred stock investors to purchase Series X-1 convertible preferred stock in a future period. The number of potential shares is calculated assuming the right is fully exercised. The resulting gross proceeds of $28.33 million from the potential issuance of Series X-1 convertible preferred stock are divided by an assumed conversion price of $5.16, representing 175% of the Series X contingently redeemable convertible preferred stock's assumed conversion price of $2.95 noted in (1) above.

(4) In connection with the issuance of Series X contingently redeemable convertible preferred stock, the Company granted a right to the Series X preferred stock investors to purchase Series X-1 convertible preferred stock in a future period. The number of potential shares is calculated assuming the right is fully exercised. The resulting gross proceeds of $28.33 million from the issuance of Series X-1 preferred stock are divided by an assumed conversion price of $2.36, representing 75% of Series X contingently redeemable convertible preferred stock's assumed conversion price of $3.15 noted in (2) above.

(5) The number of potential warrant shares is based on $4.25 million divided by the exercise price of $3.54 representing a 20% premium over the Series X contingently redeemable convertible preferred stock's assumed conversion price of $2.95 as noted in (1) above.

(6) The number of potential warrant shares is based on $4.25 million divided by the exercise price of $3.78 representing a 20% premium over the Series X contingently redeemable convertible preferred stock's assumed conversion price of $3.15 as noted in (2) above.

5. FAIR VALUE OF FINANCIAL INSTRUMENTS

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

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

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

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

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

The following tables present the Company's fair value hierarchy for all its financial assets (including those in cash and cash equivalents), in thousands, by major security type measured at fair value on a recurring basis as of September 30, 2016 and December 31, 2015 (in thousands):

	September 30, 2016			
	Estimated Fair Value	Level 1	Level 2	Level 3
Asset s:				
Money market funds	$ 30,410	$ 30,410	$ —	$ —
Liabilities :				
Warrant liability	$ 3,509	$ —	$ —	$ 3,509

	December 31, 2015			
	Estimated Fair Value	Level 1	Level 2	Level 3
Money market funds	$ 45,156	$ 45,156	$ —	$ —

The Company used quoted market prices to determine the fair value of cash equivalents, which consist of money market funds and therefore these are classified in Level 1 of the fair value hierarchy.

Warrants with an exercise price that is not yet determinable are accounted for as liabilities, with changes in the fair values included in net loss for the respective periods. Because some of the inputs to the valuation model are either not observable or are not derived principally from or corroborated by observable market data by correlation or other means, the warrant liability is classified as Level 3 in the fair value hierarchy.

The following table summarizes the changes in the Company's Level 3 warrant liability (in thousands):

	September 30, 2016
Beginning balance	$ —
Issuance of warrants	3,678
Change in fair value	(169)
Ending balance	$ 3,509

There were no transfers between Level 1, Level 2 or Level 3 for the nine months ended September 30, 2016 and year-ended December 31, 2015.

6 . WARRANT LIABILITY

In connection with the subscription agreement for the sale of convertible preferred stock entered in September 2016, the Company issued common stock warrants to certain institutional investors. Each warrant has an exercise price equal to 120% of the conversion price of the Series X convertible preferred stock (Note 8). The warrants are exercisable after March 13, 2017 and expire on September 13, 2019. The initial fair value of the liability associated with these warrants was $3.7 million, and the fair value decreased to $3.5 million as of September 30, 2016. All future changes in the fair value of the warrants will be recognized in the Company's consolidated statements of operations until the earlier of (a) the exercise price becomes fixed; b) the warrants are exercised; or c) the warrants expire. The warrants are not traded in an active securities market, and as such the estimated fair value was determined by using the Monte Carlo simulation model with the following assumptions:

	September 14, 2016	September 30, 2016
Common stock price	$ 3.20	$ 3.15
Initial Series X contingently redeemable convertible preferred stock conversion price	$ 2.95	$ 2.95
Expected volatility	120%	120%
Dividend yield	0%	0%
Risk-free interest rate	0.90%	0.87%
Expected term (years)	3	2.96

Expected volatility is based on both historical and implied volatility. Historical volatility was computed using daily pricing observations for recent periods that correspond to the expected term of the warrants while implied volatility was computed using publicly traded options of the Company as well as the Company's peer companies. The Company believes this method produces an estimate that is representative of its expectations of future volatility over the expected term of these warrants. The Company currently has no reason to believe future volatility over the expected remaining life of these warrants is likely to differ materially from historical volatility. The expected life is based on the remaining contractual term of the warrants. The risk-free interest rate is the U.S. Treasury bond rate as of the valuation date. The fair value of these warrants also incorporates the Company's assumptions about future performance.

7. COMMITMENTS AND CONTINGENCIES

Leases

The Company leases its main operating facility in Hayward, California. The lease is for approximately 14,000 square feet and the lease agreement will expire in September 2017.

Other Commitments

In December 2007, the Company and Amgen entered into a worldwide, exclusive license agreement (the "Amgen Agreement") to develop and commercialize blisibimod in any indication, including for the treatment of systemic lupus erythematosus ("lupus"). Under the terms of the Amgen Agreement, the Company paid a nonrefundable, upfront license fee of $6.0 million. As there was no future alternative use for the technology, the Company expensed the license fee in research and development expenses during 2007. Under the terms of the Amgen Agreement, the Company is obligated to make additional milestone payments to Amgen of up to $33.0 million upon the achievement of certain development and regulatory milestones. The Company is also obligated to pay tiered royalties on future net sales of products, ranging from the high single digits to the low double digits, which are developed and approved as set forth in the Amgen Agreement. 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.

In connection with the collaborative arrangement with Zenyaku pursuant to the Zenyaku Agreement, the Company amended the Amgen Agreement in November 2014 to (i) adjust certain royalty and milestone payment obligations payable to Amgen in light of the collaboration between Anthera and Zenyaku and (ii) provide that the sublicense granted by Anthera to Zenyaku shall survive the termination of the Amgen Agreement. Under this amendment, Anthera also agreed to grant Amgen that number of shares of its common stock equal to $1.0 million divided by the volume weighted average price of the Company's common stock for 20 trading days prior to issuance. The Company issued 420,751 shares of common stock to Amgen at $2.3767 per share on January 28, 2015, pursuant to a subscription agreement with Amgen, with the consideration paid by Amgen in the form of a waiver of a fee otherwise payable to Amgen under the Amgen Agreement.

On July 11, 2014, the Company and Eli Lilly and Company ("Eli Lilly") entered into a worldwide, exclusive license agreement (the "Lilly Agreement"), to develop and commercialize liprotamase, a Phase 3 novel investigational Pancreatic Enzyme Replacement Therapy ("PERT"), for the treatment of patients with Exocrine Pancreatic Insufficiency, or EPI, often seen in patients with cystic fibrosis and other conditions. Under the terms of the Lilly Agreement, the Company was not required to make any up-front payment but is obligated to make milestone payments of up to up to $33.5 million for capsule products and $9.5 million for reformulated products upon the achievement of certain regulatory and commercial sales milestones, none of which have been achieved as of September 30, 2016. In addition, after sales of the licensed products exceed an aggregate of $100.0 million in the United States, the Company is obligated to pay tiered royalties on future net sales of products, ranging from the single digits to the mid-teens, that are developed and approved as defined in the Lilly Agreement. The Company's royalty obligations as to a particular licensed product will be payable, on a licensed product-by-licensed product basis, for the longer of (a) the date of expiration of the last to expire valid claim within the licensed patents that covers the manufacture, use or sale, offer to sell, or import of such licensed product by the Company or a sublicense in such country, or (b) 12 years after the first commercial sale of the applicable licensed product in the applicable country.

See Note 3 – "Research Award" for discussion of commitments and contingencies associated with the research award received from the CFFT.

8. STOCKHOLDERS' EQUITY

Preferred Stock

The Company has authorized 5,000,000 shares of $0.001 par value preferred stock. The Company's Board of Directors is authorized to designate the terms and conditions of any preferred stock issued by the Company without further action by the common stockholders. The Company designated 17,000 shares of its authorized and unissued preferred stock as Series X convertible preferred stock and filed an Amended and Restated Certificate of Designation of Preferences, Rights and Limitations of Series X Convertible Preferred Stock with the Delaware Secretary of State. There were 17,000 Series X contingently redeemable convertible preferred shares issued and outstanding as of September 30, 2016.

In September, 2016, the Company entered into a subscription agreement with certain institutional investors pursuant to which it sold 17,000 ("Initial Tranche") units for a purchase price of $1,000 per unit in a registered direct offering. Each unit consists of one share of Series X contingently redeemable convertible preferred stock and a warrant to purchase shares of common stock. Assuming an exercise price equal to $3.54 per share, which is a 20% premium over the closing price of our common stock on September 6, 2016, each unit would include a warrant to purchase up to 70.62 shares of common stock. The registered direct offering resulted in gross proceeds of $17.0 million. The conversion price for the Series X contingently redeemable convertible preferred stock is equal to the lower of: (a) $2.95 or (b) the five-day VWAP of the Company's common stock over the five full trading days following the earlier of (1) the date of the Company's initial public announcement of topline and/or efficacy data from the ongoing Chablis-SC1 study or (2) if applicable, the date of the Company's initial public announcement of the suspension (including through the imposition of a clinical hold), abandonment or other termination of the Chablis-SC1 study, provided, however, that notwithstanding the above, the conversion price shall not be less than $0.60. The Series X contingently redeemable convertible preferred stockholders do not have any voting rights nor the right to elect any members to the board of directors. The Series X contingently redeemable convertible preferred stock has a contingent redemption clause. T he Company is not required to issue any shares of common stock upon conversion of any shares of Series X contingently redeemable convertible preferred stock to the extent that (i) the aggregate issuance of common stock will be greater than 8,385,828 shares or 19.99% of the total outstanding shares of the Company (the "Threshold Amount") and (ii) the conversion has not been approved by the Company's stockholders in accordance with the stockholder approval requirements of Nasdaq Marketplace Rule 5635(d) (a "Blocked Conversion"). In the event that a Blocked Conversion occurs after April 30, 2017, the holders of shares of Series X Stock who are not able to convert their Series X convertible preferred stock in full because of the Blocked Conversion shall have the right to require the Company to redeem any or all of the Series X contingently redeemable convertible preferred stock that is ineligible for conversion at a redemption price equal to the product of: (x) the number of their shares underlying the to-be-redeemed Series X contingently redeemable convertible preferred stock, multiplied by (y) the two-day volume weighted average price of the Company's common stock prior to the date of delivery of such notice of redemption. As of September 30, 2016, no units had been converted into shares of common stock and no warrants had been exercised.

The subscription agreement also provides that the investors have the right, but not the obligation, to make additional investments as follows: within 20 trading days following the Company's initial public announcement of top-line data from the Company's ongoing SOLUTION study (Phase 3 study evaluating the efficacy and safety of Liprotamase in subjects with cystic fibrosis-related exocrine pancreatic insufficiency), the investors may purchase up to 28,330 ("Second Tranche") shares of convertible Series X-1 convertible preferred stock at a purchase price of $1,000 per share for an aggregate purchase price of $28.3 million ("Additional Investment"). The terms of the Series X-1 convertible preferred stock are identical to the Series X convertible preferred stock, except as follows: t he conversion price for the Series X-1 convertible preferred stock will be equal to the lower of: (a) 75% of the five-day VWAP of the Company's common stock over the five full trading days following the Company's initial public announcement of topline clinical efficacy and safety data from the ongoing "SOLUTION" clinical study (Phase 3 study evaluating the efficacy and safety of Liprotamase in subjects with cystic fibrosis-related exocrine pancreatic insufficiency), or (b) 175% of the then-applicable conversion price for the Series X contingently redeemable convertible preferred stock, provided that the conversion price will in no event be lower than $2.95. The Series X-1 convertible preferred stock is not redeemable other than in the event of a deemed liquidation in which event both common and preferred shareholders would receive the same form of consideration.

Accounting Treatment

The Company has allocated the proceeds from the financing amongst the Series X contingently redeemable convertible preferred shares, the warrants to purchase shares of common stock, and the investors' rights to purchase shares of Series X-1 convertible preferred stock.

- *Outstanding Series X Contingently Redeemable Convertible Preferred Stock* – Due to the contingent redemption feature related to NASDAQ conversion limits that could result in a potential redemption for cash, the Company classified the 17,000 shares of Series X contingently redeemable convertible preferred stock in the mezzanine section (between equity and liabilities) on the accompanying balance sheet. The Company recorded the residual value of these shares at $9.6 million, which is net of allocation of $3.7 million to the fair value of the warrants to purchase common stock and $3.7 million to the fair value of the rights to purchase Series X-1 convertible preferred stock.

- *Warrants to Purchase Common Stock* – The Company determined the warrants are not considered indexed to its own stock because the underlying instruments are not "fixed-for-fixed" and therefore, the warrants should be accounted for as derivatives. The warrants were measured at fair value at inception of $3.7 million and recorded as a liability with a corresponding entry to Series X contingently redeemable convertible preferred stock. In subsequent periods, the fair value of the warrants will be remeasured at each reporting date and the changes to fair value will be recorded as part of other income/expense in the Company's statement of operation until the earlier of exercise or the exercise price becomes fixed. The fair value of the Company's warrant liability is discussed in Note 5 and Note 6. When the number of shares of common stock underlying the warrants becomes fixed, the related warrant liability will be reclassified as stockholders' equity.

- *Rights to Purchase Series X-1 Convertible Preferred Stock* - The Company determined that the investors' rights to purchase future shares of Series X-1 convertible preferred stock is a freestanding instrument. The instrument is treated as equity due to the permanent equity classification of the underlying Series X-1 convertible preferred stock. The right was allocated based on its relative fair value of $3.7 million to the proceeds of the Series X convertible preferred stock and recorded as part of permanent equity.

The following table summarizes the assumptions used in the Monte Carlo simulation model to determine the fair value of the option related to the rights to purchase Series X-1 convertible preferred stock on the date of issuance:

Common stock price	$	3.20
Initial Series X contingently redeemable convertible preferred stock conversion price	$	2.95
Expected volatility (1)		120%
Dividend yield		0%
Risk-free interest rate		0.90%
Expected term (years)		3

(1) The volatility was based on blended historical and implied volatilities.

- *Beneficial Conversion Feature* - Because the conversion price of the shares of Series X contingently redeemable convertible preferred stock was less than the fair value of the Company's common stock at the date of issuance, the in-the-money conversion feature (Beneficial Conversion Feature, or BCF) requires separate financial statement recognition and is measured at the intrinsic value (i.e., the amount of the increase in value that preferred stockholders would realize upon conversion based on the value of the conversion shares on the issuance date). The BCF is recorded as a discount to the Series X convertible preferred shares and is immediately accreted as a deemed preferred stock dividend and, accordingly, an adjustment to net loss to arrive at net loss applicable to common stockholders. During the quarter ended September 30, 2016, the Company recorded a deemed dividend of $8.8 million.

As of the issuance date, and through September 30, 2016, it was not deemed probable that the redemption contingencies in the Series X contingently redeemable preferred stock would result in the stock becoming redeemable. As a result no adjustment is made to the discounts on the Series X convertible preferred stock related to the warrants to purchase common stock and right to purchase series X-1 convertible preferred stock presented in temporary equity. In the event it is deemed probable that the instrument will become redeemable, a deemed dividend will be recorded in respect of these discounts.

Common Stock

On March 14, 2016, the Company filed a universal shelf registration statement with the SEC on Form S-3 (File No. 333-210166) for the proposed offering from time to time of up to $100.0 million of its securities, including common stock, preferred stock, debt securities and/or warrants. In September 2016, the Company utilized $17.0 million of it's shelf registration through the issuance of 17,000 shares of Series X contingently redeemable convertible preferred stock at purchase price of $1,000 per share. As of the date of this report, there is a balance of $43.6 million available for future issuance.

On November 15, 2013, the Company entered into an at-the-market sales agreement (the "Cowen ATM Agreement") with Cowen and Company, LLC ("Cowen") under which the Company from time to time was able to offer and sell shares of its common stock, par value $0.001 per share, having an aggregate offering price of up to $25.0 million through Cowen, as agent. For the three and nine months ended September 30, 2016, the Company sold zero and $2.5 million, respectively, in shares of common stock pursuant to the Cowen ATM Agreement. The Cowen ATM Agreement was terminated on April 21, 2016.

On April 21, 2016, the Company entered into an at-the-market sales agreement with H.C. Wainwright (the "H.C. Wainwright ATM Agreement") under which the Company from time to time may offer and sell shares of its common stock, par value $0.001 per share, having an aggregate offering price of up to $25.0 million through H.C. Wainwright, as agent. For the three and nine months ended September 30, 2016, the Company sold $1.6 million and $2.3 million in shares of common stock pursuant to the H.C. Wainwright ATM Agreement, respectively, leaving a balance of $22.7 million available for future sale pursuant to the H.C. Wainwright ATM Agreement as of September 30, 2016.

On March 12, 2015, the Company executed an equity purchase agreement with LPC, pursuant to which the Company has the right, but not the obligation, to sell to LPC up to an aggregate of $10.0 million in shares of common stock over a period of two years. In July 2015, the Company amended the equity purchase agreement to reduce the amount available for purchase to $6.0 million. On April 27, 2016, the Company amended the equity purchase agreement and increased the amount of common stock available for purchase to $15.0 million. For the three and nine months ended September 30, 2016, the Company sold approximately $0.6 million and $1.6 million in shares of common stock, respectively, pursuant to the equity purchase agreement, leaving a balance of $13.4 million available for future sales as of September 30, 2016. In connection with the sale of shares to LPC, for the three and nine months ended September 30, 2016, the Company issued 3,660 and 24,829 shares, respectively, to LPC as commitment fee pursuant to the equity purchase agreement.

Warrants

In March 2011, the Company issued a seven-year warrant to purchase 40,178 shares of the Company's common stock at an exercise price of $48.00 per share. The warrant was immediately exercisable and expires in March 2018. As of September 30, 2016, the warrant remained outstanding and exercisable.

In September 2016, the Company issued warrants to certain institutional investors to purchase shares of the Company's common stock at an exercise price equal to the Series X contingently redeemable convertible preferred stock's conversion price, plus a 20% premium, and will be exercisable at any time and from time to time after March 13, 2017, and will expire on September 13, 2019. The fair value of the Company's warrant liability is discussed in Note 5 and Note 6. As of September 30, 2016, the warrant remained outstanding but not exercisable.

9. SHARE-BASED COMPENSATION PLANS

2013 Plan

On March 25, 2013, the Company's board of directors adopted the 2013 Stock Option and Incentive Plan (the "2013 Plan"), which was also approved by the Company's stockholders at its annual general meeting on May 16, 2013. The Company initially reserved 1,750,000 shares of its common stock for the issuance of awards under the 2013 Plan, plus all shares remaining available for grant under the Company's 2010 Stock Option and Incentive Plan (the "2010 Plan"), plus any additional shares returned under the 2010 Plan or 2013 Plan as a result of the cancellation, forfeiture or other termination (other than by exercise) of awards issued pursuant to the 2010 Plan or 2013 Plan, subject in all cases to adjustment including reorganization, recapitalization, reclassification, stock dividend, stock split, reverse stock split or other similar change in the Company's capital stock. In May 2015, the Company's shareholders approved an additional 1,790,818 shares of its common stock for issuance under the 2013 Plan. In April 2016, the Company's shareholders approved an additional 1,600,000 shares of its common stock for issuance under the 2013 Plan. Of the shares of common stock reserved for issuance under the 2013 Plan, no more than 750,000 shares will be issued to any individual participant as incentive options, non-qualified options or stock appreciation rights during any calendar year. The 2013 Plan permits the granting of incentive and non-statutory stock options, restricted and unrestricted stock awards, restricted stock units, stock appreciation rights, performance share awards, cash-based awards and dividend equivalent rights to eligible employees, directors and consultants. The option exercise price of an option granted under the 2013 Plan may not be less than 100% of the fair market value of a share of the Company's common stock on the date the stock option is granted. Options granted under the 2013 Plan have a maximum term of 10 years and generally vest over four years. In addition, in the case of certain large stockholders, the minimum exercise price of incentive options must equal 110% of fair market value on the date of grant and the maximum term is limited to five years. Subject to overall Plan limitations, the maximum aggregate number of shares of common stock that may be issued in the form of incentive options shall not exceed 6,250,000 shares of common

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

The terms of awards granted during the three and nine months ended September 30, 2016 and the method for determining the grant date fair value of the awards were consistent with those described in the financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2015.

The following table summarizes stock option activity for the nine months ended September 30, 2016 (in thousands except share and per share information):

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life in Years	Aggregate Intrinsic Value
Balance at December 31, 2015	4,255,981	$ 4.78	8.44	$ 4,323
Granted	2,592,322	$ 3.49		
Exercised	(116,773)	$ 2.20		
Cancelled and expired	(658,857)	$ 4.90		
Forfeited	(90,000)	$ 9.48		
Balance at September 30, 2016	5,982,673	$ 4.19	8.36	$ 1,627
Exercisable at September 30, 2016	2,488,364	$ 4.41	7.36	$ 851

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, 2016, there was $9.9 million of total unrecognized compensation expense related to stock options and is expected to be amortized on a straight-line basis over a weighted-average remaining period of 2.73 years.

The assumptions used in the Black-Scholes option-pricing model to value stock options are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Expected Volatility	97%	94%	98%	94%
Dividend Yield	0%	0%	0%	0%
Risk-Free Interest Rate	1.23%	1.74%	1.45%	1.69%
Expected Term (years)	6.02	6.02	5.93	5.92
Weighted-average fair value per option	$ 2.45	$ 7.29	$ 2.70	$ 5.46
Fair value of awards vested (in thousands)	$ 929	$ 567	$ 3,907	$ 2,695

2010 Employee Stock Purchase Plan ("ESPP")

Effective July 2010, under the terms of the ESPP, eligible employees of the Company may authorize the Company to deduct amounts from their compensation, which amounts are used to enable the employees to purchase shares of the Company's common stock. The Company initially reserved 12,500 shares of common stock for issuance thereunder on January 1, 2011, and on each January 1 thereafter, the number of shares of stock reserved and available for issuance under the Plan shall be cumulatively increased by the lesser of (i) one percent (1%) of the number of shares of common stock issued and outstanding on the immediately preceding December 31 or (ii) 31,250 shares of common stock. On January 1, 2016, in accordance with the ESPP's annual increase provisions, the authorized shares in the ESPP increased by 31,250.

The purchase price per share is 85% of the fair market value of the common stock as of the first date or the ending date of the applicable semi-annual purchase period, whichever is less (the "Look-Back Provision"). The 15% discount and the Look-Back Provision make the ESPP compensatory. The Black-Scholes option pricing model was used to value the employee stock purchase rights. The assumptions used in the Black-Scholes option-pricing model to value the employee stock purchase rights are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Expected Volatility	99%	109%	94%	65%
Dividend Yield	0%	0%	0%	0%
Risk-Free Interest Rate	0.40%	0.09%	0.33%	0.07%
Expected Term (years)	0.50	0.50	0.50	0.50

Stock-Based Compensation Expense

Total stock-based compensation expense, including expense recorded for the ESPP, was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Research and development	$ 454	$ 583	1,330	$ 1,025
General and administrative	932	729	2,613	1,470
Total stock-based compensation	$ 1,386	$ 1,312	$ 3,943	$ 2,495

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

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), which are subject to the "safe harbor" created by those sections. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. All statements other than statements of historical factors are "forward-looking statements" for purposes of these provisions. In some cases you can identify forward-looking statements by terms such as "may," "will," "should," "could," "would," "expect," "plan," "anticipate," "believe," "estimate," "project," "predict," "potential" and similar expressions intended to identify forward-looking statements. Such forward-looking statements are subject to risks, uncertainties and other important factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified below and those discussed in the section titled "Risk Factors" in this report. Furthermore, such forward-looking statements speak only as of the date of this report. Except as required by law, we undertake no obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements.

Overview

Anthera Pharmaceuticals, Inc. is a biopharmaceutical company focused on advancing the development and commercialization of innovative medicines that benefit patients with unmet medical needs. We currently have two compounds in development, liprotamase and blisibimod. We licensed liprotamase from Eli Lilly & Co ("Eli Lilly") in July 2014. Liprotamase is a novel non-porcine investigational Pancreatic Enzyme Replacement Therapy ("PERT") intended for the treatment of patients with Exocrine Pancreatic Insufficiency ("EPI"), often seen in patients with cystic fibrosis and other conditions. We licensed blisibimod from Amgen, Inc. ("Amgen") in December 2007. Blisibimod targets B-cell activating factor (BAFF), which has been shown to be elevated in a variety of B-cell mediated autoimmune diseases, including systemic lupus erythematosus ("SLE"), or lupus, Immunoglobulin A nephropathy, or IgA nephropathy, lupus nephritis, and others.

We were incorporated in September 2004. We have devoted substantially all of our resources to research and development of our product candidates. We have not generated any revenue from the commercial sales of our product candidates, and since inception we have funded our operations through equity offerings, private placements of convertible debt, debt financings, equity investment and cost reimbursement from a former collaborative partner, Zenyaku Kogyo Co., Ltd ("Zenyaku"), and a research award from Cystic Fibrosis Foundation Therapeutics Incorporated ("CFFT"). We will need substantial additional financing to continue development of our product candidates, obtain regulatory approvals, prepare for commercial readiness, and 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 that such funds will be available on terms favorable to us, if at all. In addition to the normal risks associated with drug development companies, we may never successfully complete development of our product candidates, obtain adequate patent protection for our technology, obtain necessary government regulatory approval for our product candidates or achieve commercial viability for any approved product candidates. In addition, we may not be profitable even if we succeed in commercializing our product candidates.

In December 2014, we entered in an exclusive license agreement with Zenyaku for the development and commercialization of blisibimod in Japan and potentially other countries throughout Asia. In September 2015, Zenyaku provided us a notice of its intent to terminate the Zenyaku Agreement, effective January 7, 2016 ("Termination Notice"). The termination was "at will" and Zenyaku alleged no breach of the Zenyaku Agreement by us. There are no termination penalties incurred by us in connection with the early termination of the Zenyaku Agreement by Zenyaku. As a result of the early termination of the Zenyaku Agreement, will not recognize revenues under the Zenyaku Agreement beyond January 2016. In addition, we regained full worldwide rights for blisibimod and we are actively pursuing partnerships with pharmaceutical and biotechnology companies to further advance the development of blisibimod globally.

In March 2015, we received a research award of up to $3 million from CFFT for our development of liprotamase. We retain the right to develop and commercialize liprotamase and will owe royalties to CFFT on net sales of any drug candidate approved and commercialized under the collaboration. The funding is to be disbursed by CFFT to us upon our achievement of milestones specified in the agreement. As of September 30, 2016, there was $0.1 million remaining under the award agreement. At our discretion, we may choose to fund a particular stage of the liprotamase development plan without CFFT funds. Any CFFT funds not expended on the development program of liprotamase must be returned to CFFT and, upon such return, the amounts of such returned funds will not be included as part of the research award for the purpose of calculating royalties or other amounts owed by us to CFFT. To the extent CFFT provides or makes available any information, expertise, know-how or other intellectual property related to cystic fibrosis or the treatment, prevention or cure thereof ("CFFT Know-How") to us, CFFT grants to us a non-exclusive, transferrable, sublicensable, worldwide rights and license under all of CFFT's rights in such CFFT Know-How to assist us to research, develop, commercialize, make or have made, use, sell, have sold, offer for sale, import, export and otherwise exploit the product.

Our Phase 3 Development of Liprotamase in EPI

We initiated the SOLUTION study in the third quarter of 2015. SOLUTION is a Phase 3, randomized, open-label, assessor-blind, non-inferiority, active-comparator study evaluating the efficacy and safety of liprotamase in patients with cystic fibrosis-related exocrine pancreatic insufficiency. This pivotal study, planned for 126 patients in North America, Europe and Israel is intended to evaluate the non-inferiority of liprotamase compared with another commercially available PERT in a population enriched for PERT responders. We reached the enrollment target in August 2016. Topline data is expected at the end of 2016. In September 2016, the Data and Safety Monitoring Board ("DSMB") completed a second safety review of the SOLUTION study and recommended that the study continue without modification to the protocol or charter.

A second, smaller Phase 3 study, SIMPLICITY, in younger pediatric subjects was initiated in the second quarter of 2016. The SIMPLICITY study uses sachets containing a formulation of liprotamase powder for oral solution for ease of administration, and will enroll approximately 46 patients.

We believe the SOLUTION and SIMPLICITY studies may offer a number of potential opportunities for differentiation versus the currently marketed PERTs, including:

- use of biotechnology-derived high-purity enzymes that are produced by fermentation processes rather than from mammalian organs which carry a label warning for viral transmission;
- use of a novel chemically modified lipase drug substance that provides resistance to degradation;
- a formulation containing an appropriate ratio of the three digestive enzymes (lipase, protease and amylase) to potentially maximize relative activity while minimizing the potential for adverse events, such as fibrosing colonopathy;
- a capsule formulation using known excipients that provide lower pill burden and good delivery performance. The pure, high-activity enzyme constituents, and absence of bulky enteric coating give rise to smaller, easy-to-swallow capsules with good disintegration once swallowed, and adequate storage stability compared with porcine PERTs of an equivalent lipase unit dose strength; and
- a sachet formulation containing liprotamase power for oral solution that can be easily dissolved into water or apple juice, and may provide patients, especially young pediatric patients, with an easy-to-swallow dosing option.

During the third quarter of 2016, we initiated the EASY study, which provides continued access to liprotamase for patients who completed the SOLUTION study. We plan to continue the EASY study until the Biologic License Application ("BLA") for liprotamase is approved by the U.S. Food and Drug Administration ("FDA").

Our Phase 3 Development of Blisibimod in Systemic Lupus Erythematosus (Lupus)

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

CHABLIS-SC1 is a Phase 3, multicenter, randomized, double-blind, placebo-controlled study designed to evaluate the efficacy, safety, tolerability and immunogenicity of blisibimod in patients with seropositive, clinically-active lupus (SELENA-SLEDAI $\geq$ 10) who require corticosteroid therapy in addition to standard-of-care for treatment of their disease. The study was designed to randomize approximately 400 patients to receive either 200mg of blisibimod or placebo in addition to their standard-of-care medication for 52 weeks in Asia, Europe, and Latin America. We reached the enrollment target in June 2015. Topline data is expected in the beginning of the fourth quarter of 2016 after the last enrolled patient completes 52 weeks of treatment. The primary endpoint of the CHABLIS-SC1 will be clinical improvement in the SRI-6 response at 52 weeks. Key secondary outcomes from the study, including SRI-8, reduction in the number of lupus flares and steroid use, are intended to further differentiate blisibimod from currently available therapies. To date, enrolled patient demographics and disease characteristics for the CHABLIS-SC1 study are consistent with our goal to enroll patients with higher levels of lupus activity and positive biomarkers despite the stable use of corticosteroids. These characteristics were associated with improved outcomes in both our previous Phase 2 clinical study as well as in large Phase 3 studies conducted with other BAFF-inhibitors, belimumab (Benlysta) and tabalumab.

We believe the CHABLIS development program for blisibimod may offer a number of potential opportunities for differentiation versus the currently marketed BAFF antagonist and other novel B-cell directed therapies, including:

- clinical differentiation:
  - potential for improved clinical response due to selection of patients with high disease activity and use of steroid therapy;
  - an improved clinical efficacy endpoint which requires a larger six-point reduction in the SELENA-SLEDAI;
  - potential for earlier onset of clinical benefit by allowing earlier steroid taper and restriction of background medications;
  - potential to demonstrate reductions in lupus flares;
- mechanism of action, Blisibimod is able to inhibit the activity of both membrane-bound and soluble BAFF;
- potential labeling differentiation: A second study (CHABLIS-7.5) will also aim to enroll patients with positive serology and low complement; as well as assess the ability to reduce background corticosteroid medication usage;
- manufacturing: Blisibimod's novel molecular structure, comprised of 2 identical peptide chains assembled into a covalent dimer, confers manufacturing benefits and lower cost of goods through a bacterial fermentation manufacturing process;
- structure: Blisibimod's 4 BAFF binding domains, compared to the typical 2 domains in a monoclonal antibody give rise to a 350-fold higher affinity for blisibimod (1 picomolar affinity) compared with the reported affinity for the anti-BAFF monoclonal antibody, belimumab (Benlysta); and
- fully human IgG1 Fc domain confers acceptable pharmacokinetic properties to potentially support once-weekly dosing.

An independent Data Safety Monitoring Board ("DSMB") meets regularly over the course of the development program to assess patient safety. During these regular meetings, the DSMB reviews un-blinded safety data which includes adverse events, suspected unexpected serious adverse reactions or SUSARs, deaths, laboratory data, and withdrawal data and compares trends between treatments. After the most recent scheduled meeting in June 2016, the DSMB recommended continuing the CHABLIS-SC1 and BRIGHT-SC clinical studies.

In February 2015, an interim analysis of CHABLIS-SC1 was conducted by an independent un-blinded statistician, who evaluated at a pre-specified time point, the proportion of responders to the systemic lupus erythematous SRI-6 responder index, and recommended the study continue to completion as planned. This futility analysis was not intended to provide any rules for stopping for overwhelming efficacy, for a change in study sample size, or for an alteration of the study design. Rather, the analysis suggested that the observed data conformed with the assumptions upon which the trial was designed. The SRI-6 is a recognized endpoint by the FDA for a previously approved therapeutic. In addition to serving as a registration study for a potential lupus indication, observations in this study are intended to be included in marketing applications for blisibimod in IgA nephropathy and other indications.

A second Phase 3 study, CHABLIS-7.5, is a multicenter randomized, double-blind, placebo-controlled study designed to evaluate the efficacy, safety, tolerability and immunogenicity of blisibimod in patients with seropositive, low complement 3 and 4, clinically-active lupus (SELENA-SLEDAI ≥ 10) who require corticosteroid therapy in addition to standard-of-care for treatment of their disease. We initiated screening into the CHABLIS-7.5 study in June 2016. We expect approximately 350 patients to participate in the CHABLIS-7.5 study. The study's name emphasizes the intent to reduce background corticosteroid medication to ≤7.5 mg prednisone in order to mitigate the risks associated with long-term steroid medication. This study will evaluate the effect of blisibimod on top of standard-of-care medication in patients with severe, seropositive SLE that is inadequately controlled with corticosteroids. Patient eligibility for this study is informed by responder traits identified in the Phase 2 trial with blisibimod as well as the large Phase 3 programs with other BAFF inhibitors, belimumab and tabalumab. These two pivotal studies are anticipated to form the basis of submission for blisibimod as a treatment for active SLE that is not controlled by standard-of-care medication, including corticosteroids.

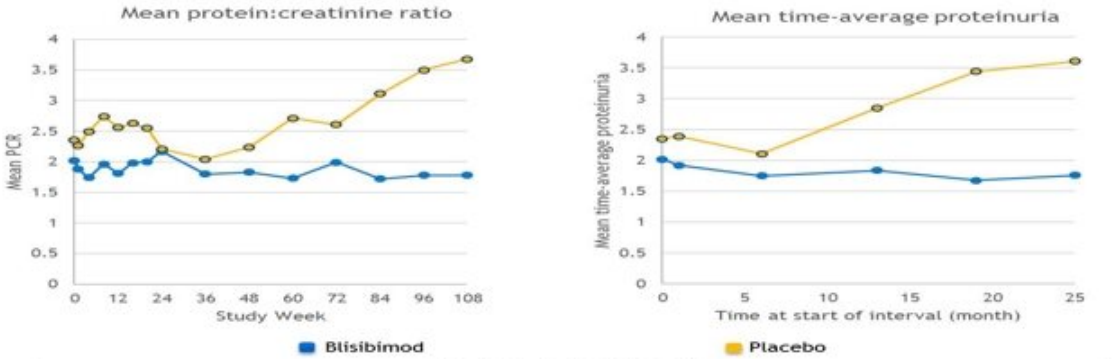
Our Phase 2 Development of Blisibimod for in IgA Nephropathy

The BRIGHT-SC study is a Phase 2 multicenter, randomized, double-blind, placebo-controlled study to evaluate the efficacy, safety, tolerability and immunogenicity of blisibimod in IgA nephropathy. Enrollment criteria are biopsy-proven IgA nephropathy and proteinuria greater than one gram per 24 hours (1g/24hr). Patients must be receiving standard of care medication including angiotensin converting enzyme inhibitors and angiotensin receptor blockers. The BRIGHT-SC study was initiated in the second quarter of 2013. Patients enrolled in the BRIGHT-SC study receive 300mg weekly blisibimod or placebo subcutaneously during the first 8 weeks of therapy, the induction phase, followed by a minimum of 24 weeks of 200mg weekly blisibimod or placebo, the maintenance phase. The BRIGHT-SC clinical study has enrolled patients in Southeast Asia, and the European Union ("EU"). In September 2013, we met with the FDA who agreed to consider accepting proteinuria as an endpoint for Subpart E accelerated approval for blisibimod in IgA nephropathy. In April 2014, we met with the Japan Pharmaceuticals and Medical Devices Agency ("PMDA") to discuss our registration program for blisibimod in IgA nephropathy. In this meeting we gained the PMDA's agreement on the acceptability of proteinuria as the primary efficacy endpoint to support marketing approval in Japan and have amended the BRIGHT-SC study to include the specific data requirements of the PMDA. In December 2014 we met with the European Medicines Agency ("EMA") as part of the scientific advice process for blisibimod. We reached an agreement with the EMA on the acceptability of proteinuria as the primary efficacy variable as well as the requirement for a single study in support a Conditional Marketing Authorization Application ("CMAA") provided that confirmatory evidence from a second study would be available post approval. The EMA also recommended the protocol to collect information on the recommended duration of treatment, duration of response and need for re-treatment.

In March 2015, an interim futility analysis of BRIGHT-SC study was conducted by an independent unblinded statistician, who evaluated several important biomarkers of renal disease in patients who had completed at least 8 weeks of treatment and recommended the study continue to completion as planned.

In June 2016, interim data from the BRIGHT-SC study, which enrolled 57 patients, showed a tendency toward lower proteinuria in blisibimod versus placebo treated patients. While the numerical reduction in proteinuria in blisibimod versus placebo treated patients at week 24 in the BRIGHT-SC study did not meet the predefined statistical primary endpoint of complete or partial response, longer-term data from the study demonstrated an increasingly large separation in proteinuria favoring the blisibimod treated arm compared to the placebo. Additionally, secondary biomarker data from the study, including changes in total B cell counts and changes in immunoglobulins IgA, IgG, and IgM, were highly consistent with previous studies with blisibimod and demonstrated marked reduction after 8 weeks on study. As a result of the increasing proteinuria effect after 24-weeks of dosing, and the demonstration of blisibimod's effect on immunological markers relevant to IgA nephropathy including reductions of B cells, and immunoglobulins including IgA, IgG and IgM, we elected to continue the study for longer term observation.

Effects of blisibimod on proteinuria in subjects with IgA nephropathy enrolled in the Phase 2 BRIGHT-SC Study



Mean Protein:Creatinine ratio															
Week	0	1	4	8	12	16	20	24	36	48	60	72	84	96	108
N (blisibimod)	30	30	30	28	28	28	28	27	23	20	16	15	12	8	5
N (placebo)	27	26	25	24	23	24	22	22	15	13	12	10	8	4	3

We currently plan to conduct an additional analysis in the fourth quarter of 2016 when all of the enrolled subjects have completed a minimum of 48 weeks of treatment.

Revenue

We have not generated any revenue from the commercial sales of our product candidates since our inception and do not expect to generate any revenue from the commercial sales of our product candidates in the near term. However, as a result of the collaborative arrangement that we entered into with Zenyaku in December 2014 for the development of blisibimod, we began recognizing license fee revenue and collaborative revenue in 2015. The license fee revenue from the collaborative arrangement with Zenyaku was initially amortized as revenue over the performance obligation period (product development period) while reimbursement for our FTEs was recorded as collaborative revenues as incurred. In September 2015, we received the Termination Notice from Zenyaku to terminate the collaborative arrangement, effective January 7, 2016. Consequently, we revised the amortization period of our deferred revenue to correspond with the shortened collaboration period and have fully amortized our deferred revenue as of January 7, 2016.

Research and Development Expenses

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

We 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. 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, 2016 and 2015 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Allocated costs:				
Liprotamase	$ 8,386	$ 2,246	$ 19,517	$ 3,664
Blisibimod	3,748	6,492 (1)	10,817	17,194 (1)
Unallocated costs	1,962	1,621	5,352	4,035
Total research and development expenses	$ 14,096	$ 10,359	$ 35,686	$ 24,893

(1) Offset by $0.4 and $1.3 million in reimbursable expense for IgA nephropathy from Zenyaku for the three and nine months ended September 30, 2015 respectively.

We expect our research and development expenses to increase significantly as we continue to develop our product candidates. 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 clinical development programs in order to focus our resources on more promising clinical development 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 product candidates. 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 many research institutions, clinical research organizations and other service providers that conduct and manage clinical studies on our behalf. The financial terms of these agreements are subject to negotiation and vary from contract to contract and may result in uneven payment flows. Generally, these agreements set forth the scope of work to be performed at a fixed fee or unit price. Payments under the contracts are mainly driven by time and materials incurred by these service providers. Expenses related to clinical studies generally are accrued based on time and materials incurred by the service providers and in accordance with the contracts. If timelines or contracts are modified based upon changes to the clinical study design or scope of work to be performed, we modify our estimates of accrued expenses accordingly on a prospective basis.

None of our product candidates has received FDA or foreign regulatory marketing approval. In order to grant marketing approval, the FDA or foreign regulatory agencies must conclude that clinical data establish 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 consolidated financial statements, which have been prepared in accordance with U.S. Generally Accepted Accounting Principles, or GAAP. The preparation of these consolidated 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 accompanying notes to the consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2015, 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 consolidated financial statements.

Revenue Recognition

The Company had a collaboration agreement with Zenyaku which provided for various types of payments from Zenyaku, including development milestones, sales milestones, royalty, and reimbursement for a portion of the Company's internal and external costs. All payments from Zenyaku were nonrefundable. The collaborative arrangement was on a best-efforts basis, did not require scientific achievement as a performance obligation and provided for payment to be made when costs were incurred or services were performed. The collaboration was terminated on January 7, 2016 pursuant to a termination notice from Zenyaku to the Company.

With respect to the collaborative arrangement with Zenyaku, the Company recognized revenue in accordance with FASB Accounting Standards Codification, or ASC 605 " Revenue Recognition ", subtopic ASC 605-25 " Revenue with Multiple Element Arrangements " and subtopic ASC 605-28 " Revenue Recognition-Milestone Method ", which provide accounting guidance for revenue recognition for arrangements with multiple deliverables and guidance on defining the milestone and determining when the use of the milestone method of revenue recognition for research and development transactions is appropriate, respectively. For multiple-element arrangements, each deliverable within a multiple deliverable revenue arrangement is accounted for as a separate unit of accounting if both of the following criteria are met: (1) the delivered item or items have value to the customer on a standalone basis and (2) for an arrangement that includes a general right of return relative to the delivered item(s), delivery or performance of the undelivered item(s) is considered probable and substantially in our control.

The deliverables under the Zenyaku agreement had been determined to be a single unit of accounting and as such any license fee revenues received were recorded as deferred revenue and recognized ratably over the term of the estimated performance period under the agreement, which was the product development period. As a result of an early termination of the Zenyaku agreement, the Company revised the amortization period of its deferred revenue to correspond with the shortened collaboration period in the third quarter of 2015 and had fully amortized its deferred revenue as of January 7, 2016.

For the collaborative research activities, the Company was entitled to reimbursement from Zenyaku for its internal personnel cost at a pre-determined full time equivalent ("FTE") rate. Revenue related to FTE services was recognized as research services were performed over the related performance periods. The Company was required to perform research and development activities as specified in the collaboration agreement. The payments received were not refundable and were based on a contractual reimbursement rate per FTE working on the project. Reimbursement for FTE costs was recorded as collaborative revenue as incurred.

Stock-Based Compensation

We account for stock options and stock purchase rights related to our equity incentive plans under the provisions of ASC 718 which requires the recognition of the fair value of stock-based compensation. The fair value of stock options is estimated using a Black-Scholes option valuation model. This model requires the input of subjective assumptions including expected stock price volatility, expected life and estimated forfeitures of each award. The fair value of equity-based awards is amortized ratably over the requisite service period of the award. Due to the limited amount of historical data available to us, particularly with respect to stock-price volatility, employee exercise patterns and forfeitures, actual results could differ from our assumptions.

Accrued Clinical Expense

We make estimates of our accrued clinical expenses as of each balance sheet date in our consolidated 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 non-clinical development activities.

We base our accruals related to clinical studies on our estimates of the services received and efforts expended pursuant to contracts with many research institutions, clinical research organizations and other service providers that conduct and manage clinical studies on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. Generally, these agreements set forth the scope of work to be performed at a fixed fee or unit price. Payments under the contracts are mainly driven by time and materials incurred by these service providers. In accruing for service fees, we estimate the time and materials incurred by these service providers in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual accordingly. If we do not identify costs that we have begun to incur or if we underestimate or overestimate the level of services performed or the costs of these services, our actual expenses could differ from our estimates.

Fair Value of Financial Instruments with Characteristics of Both Equity and Liability

The Company has issued certain financial instruments, including warrants to purchase common stock and rights to purchase shares of Series X-1 convertible preferred stock, which have the characteristics of both liability and equity. Financial instruments such as warrants that are evaluated to be classified as liabilities are fair valued upon issuance and are remeasured at fair value at subsequent reporting periods with the resulting change in fair value is recorded in other income/(expense). The fair value of warrants is estimated using the Monte Carlo simulation model and requires the input of subjective assumptions including expected stock price volatility, expected life and the Company's assumptions about future announcements of topline clinical data from the Company's clinical studies and their impact to the exercise price of the warrants.

Results of Operations

Comparison of Three Months ended September 30, 2016 and 2015

The following table summarizes our revenues for the three months ended September 30, 2016 and 2015 (in thousands, except percentages)

	Three Months Ended September 30,			
	2016	2015	$ Change	% Change
License fee revenue	$ —	$ 548	$ (548)	(100)%
Collaborative revenue	—	185	(185)	(100)%
Total revenues	$ —	$ 733	$ (733)	(100)%

We began to recognize revenues in 2015 as a result of a collaborative arrangement that we entered into with Zenyaku in December 2014 for the development of blisibimod. The license fee from the collaborative arrangement was amortized over the period of performance (product development period) and recorded as license revenue while reimbursement for our personnel was recorded as collaborative revenue. In September 2015, we received a termination notice from Zenyaku to terminate the collaborative arrangement, effective January 7, 2016. Consequently, we revised the amortization period of the license fee revenue to correspond with the shortened collaboration period and have fully amortized the license fee revenue as of January 7, 2016.

The following table summarizes our research and development expenses for the three months ended September 30, 2016 and 2015 (in thousands, except percentages)

	Three Months Ended September 30,			
	2016	2015	$ Change	% Change
Research and development expenses	$ 14,096	$ 10,359	$ 3,737	36%

Research and development expense increased during the three months ended September 30, 2016 from the same period in 2015 primarily due to cost associated with acceleration of the manufacturing scale-up timeline, including the production of demonstration and registration batches at commercial launch scale for Sollpura™ and the purchase and installation of manufacturing equipment at our contract manufacturers . Additionally, clinical development expense also increased from the prior year due to the initiation of three new clinical studies, namely the CHABLIS-7.5 study with blisibimod in severe lupus patients, the SIMPLICITY study with liprotomase in sachet formulation and the EASY study which provides continued access to Sollpura™ for patients who rolled off the SOLUTION clinical study .

The following table summarizes our general and administrative expenses for the three months ended September 30, 2016 and 2015 (in thousands, except percentages)

	Three Months Ended September 30,			
	2016	2015	$ Change	% Change
General and administrative expenses	$ 2,504	$ 2,091	$ 413	20%

General and administrative expenses increased during the three months ended September 30, 2016 from the same period in 2015 primarily due to higher non-cash stock-based compensation expense recognized as a result of a greater number of unvested stock options.

Comparison of the nine months ended September 30, 2016 and 2015

Revenues

	Nine Months Ended September 30,			
	2016	2015	$ Change	% Change
License fee revenue	$ 139	$ 743	$ (604)	(81)%
Collaborative revenue	6	524	(518)	(99)%
Total revenues	$ 145	$ 1,267	$ (1,122)	(89)%

We began to recognize revenues in 2015 as a result of the collaborative arrangement that we entered into with Zenyaku in December 2014 for the development of blisibimod. During the nine months ended September 30, 2015, we recorded approximately $0.7 million for the amortization of the license fee revenue and $0.5 million for the reimbursement of FTEs. The license fee revenue from the collaborative arrangement is amortized over the period of performance (product development period) while reimbursement for our FTEs is recorded as collaborative revenue. In September 2015, we received a termination notice from Zenyaku to terminate the collaborative arrangement, effective January 7, 2016. Consequently, we revised the amortization period of our deferred revenue to correspond with the shortened collaboration period and have fully amortized our deferred revenue as of January 7, 2016. During the nine months ended September 30, 2016, we recorded approximately $0.1 million for the amortization of the license fee revenue and $6,000 for the reimbursement of FTEs.

Research and Development Expenses

The following table summarizes our research and development expenses for the nine months ended September 30, 2016 and 2015 (in thousands, except percentages):

	Nine Months Ended September 30,			
	2016	2015	$ Change	% Change
Research and development expenses	$ 35,686	$ 24,893	$ 10,793	43%

Research and development expense increased during the nine months ended September 30, 2016 from the same period in 2015 primarily due to cost associated with acceleration of the manufacturing scale-up timeline, including the production of demonstration and registration batches at commercial launch scale for Sollpura™ and the purchase and installation of manufacturing equipment at our contract manufacturers . Additionally, clinical development expense also increased from the prior year due to the initiation of three new clinical studies, namely the CHABLIS-7.5 study with blisibimod in severe lupus patients, the SIMPLICITY study with liprotomase in sachet formulation and the EASY study which provides continued access to Sollpura™ for patients who completed the SOLUTION clinical study .

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the nine months ended September 30, 2016 and 2015 (in thousands, except percentages):

	Nine Months Ended September 30,			
	2016	2015	$ Change	% Change
General and administrative expense	$ 7,318	$ 5,694	$ 1,624	29%

General and administrative expenses increased during the nine months ended September 30, 2016 primarily due to higher non-cash stock-based compensation expense recognized as a result of a greater number of unvested stock options.

Liquidity and Capital Resources

To date, we have funded our operations primarily through private placements of preferred stock and common stock, convertible debt, debt financings and public offerings of common stock, equity investment and cost reimbursement from a collaborative partner, and a research award from CFFT. As of September 30, 2016, we had cash and cash equivalents of approximately $32.6 million.

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

On March 14, 2016, we filed a universal shelf registration statement with the SEC on Form S-3 (File No. 333-210166) for the proposed offering from time to time of up to $100.0 million of our securities, including common stock, preferred stock, debt securities and/or warrants. As of the date of this report there is a balance of $43.6 million available for future issuance under the registration statement.

On April 21, 2016, we entered into an at-the-market sales agreement (the “H.C. Wainwright ATM Agreement”) with H.C. Wainwright & Co., LLC (“H.C. Wainwright”) under which we from time to time may offer and sell shares of our common stock, par value $0.001 per share, having an aggregate offering price of up to $25.0 million through H.C. Wainwright, as agent. As of September 30, 2016, we have sold $2.3 million in shares of common stock pursuant to the H.C. Wainwright ATM Agreement, leaving a balance of $22.7 million available for future sale.

On November 15, 2013, we entered into an at-the-market sales agreement (the “Cowen ATM Agreement”) with Cowen and Company, LLC (“Cowen”) under which we from time to time were able to offer and sell shares of our common stock, par value $0.001 per share, having an aggregate offering price of up to $25.0 million through Cowen, as agent. We had sold $24.3 million in shares of common stock pursuant to the Cowen ATM Agreement prior to terminating the agreement Cowen ATM Agreement on April 21, 2016.

On March 12, 2015, we executed an equity purchase agreement Lincoln Park Capital Fund, LLC ("LPC"), pursuant to which we have the right, but not obligation, to sell to LPC up to an aggregate of $10.0 million in shares of common stock over a period of two years. In July 2015, we amended the Purchase Agreement to reduce the amount available for purchase to $6.0 million. During the quarter ended March 31, 2016, we sold $0.9 million in shares of common stock and issued 11,046 shares of common stock as commitment shares to LPC in lieu of cash commission. On April 27, 2016, we amended the equity purchase agreement and increased the amount of common stock available for purchase to $15.0 million. As of September 30, 2016, we have sold $1.6 million in shares of common stock pursuant to the equity purchase agreement, leaving a balance of $13.4 million available for future sale.

In September 2016, the Company entered into a subscription agreement with certain institutional investors pursuant to which it sold 17,000 units for a purchase price of $1,000 per unit in a registered direct offering. Each unit consists of one share of Series X contingently redeemable convertible preferred stock and a warrant to purchase shares of common stock. Assuming an exercise price equal to $3.54 per share, which is a 20% premium over the closing price of our common stock on September 6, 2016, each unit would include a warrant to purchase up to 70.62 shares of common stock. The offering resulted in gross proceeds of $17.0 million. The subscription agreement provides that the investors have the right, but not the obligation, to make additional investments as follows: within 20 trading days following the Company's initial public announcement of top-line data from the Company's ongoing SOLUTION study, the investors may purchase up to 28,330 shares of convertible Series X-1 preferred stock at a purchase price of $1,000 per share for an aggregate purchase price of $28.3 million ("Additional Investment").

Based on the requirements of Form S-3, however, there are certain factors, such as volume of trading in our common stock and our stock price, which may limit the amount that can be raised in a short period of time through the Purchase Agreement and registration statements described above.

Cash Flows

Comparison of nine Months ended September 30, 2016 and 2015

Cash flows during the nine months ended September 30, 2016 and 2015 consisted of the following (in thousands):

	September 30,	
	2016	**2015**
Net cash used in operating activities	$ (36,691)	$ (21,454)
Net cash used in investing activities	(952)	(80)
Net cash provided by financing activities	23,262	74,657
Total	$ (14,381)	$ 53,123

During the nine months ended September 30, 2016 and 2015, our operating activities used cash of $36.7 million and $21.5 million, respectively, primarily resulting from our net losses and changes in our working capital accounts, adjusted for non-cash items including stock based compensation.

During the nine months ended September 30, 2016, cash used in investing activities was $1.0 million, which was primarily driven by the purchase of capital equipment to support the manufacturing activities for the development of liprotamase. During the nine months ended September 30, 2015, cash used in investing activities was immaterial.

During the nine months ended September 30, 2016, cash provided by financing activities was $23.3 million, which was driven by net proceeds received from the sale of our common stock to LPC pursuant to an equity purchase agreement, sale of common stock to Cowen and H.C. Wainwright pursuant to the Cowen ATM Agreement and the H.C. Wainwright ATM Agreement, and sale of preferred stock pursuant to a subscription agreement. During the same period in 2015, cash provided by financing activities was $74.7 million, which was driven by net proceeds of $11.5 million received from the sale of our common stock through an at-the-market ("ATM") offering program, $53.9 million received from the sale of our common stock through two public offerings, and $9.0 million from the sale of our common stock at a 30% premium to Zenyaku.

Contractual Obligations and Commitments

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

The following table summarizes our estimated scheduled future minimum contractual obligations and commitments as of September 30, 2016 (in thousands):

	Payment Due by Period				
Contractual Obligations	**Less than 1 year**	**1-3 years**	**3-5 years**	**More than 5 years**	**Total**
Facility Lease	$ 267	$ —	$ —	$ —	$ 267

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.

Under the Amgen Agreement, we are obligated to make additional milestone payments upon the achievement of certain development, regulatory and commercial objectives. We are also obligated to pay royalties on future net sales of products that are developed and approved as defined by this collaboration. Our royalty obligations as to a particular licensed product will be payable on a country-by-country basis and licensed on a 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 us or a sublicensee in such country, or (b) 10 years after the first commercial sale of the applicable licensed product in the applicable country.

Under the Lilly Agreement, we are obligated to make milestone payments upon the achievement of certain regulatory and commercial sales milestones. In addition, after sales of the licensed products exceed an aggregate of $100.0 million in the United States, we are obligated to pay tiered royalties on future net sales, ranging from the single digits to the mid-teens, for products that are developed and approved as defined in the Lilly Agreement. Our royalty obligations as to a particular licensed product will be payable, on a licensed product-by-licensed product basis, for the longer of (a) the date of expiration of the last to expire valid claim within the licensed patents that covers the manufacture, use or sale, offer to sell, or import of such licensed product by the Company or a sublicense in such country, or (b) 12 years after the first commercial sale of the applicable licensed product in the applicable country.

Under the research award agreement with CFFT, we are obligated to pay royalties to CFFT as follows: i) a one-time royalty in an amount equal to five times the actual award, payable in three installments between the first and second anniversaries of the first commercial sale of a product; ii) a one-time royalty in an amount equal to the actual award after net product sales reaches $100 million; and iii) in the event of a license, sale or other transfer of the product or a change of control transaction prior to the commercial sale of the product, a milestone payment equal to three times the actual award.

Funding Requirements

To date, we have not generated any revenue from the commercial sales of our product candidates. We expect to incur substantial expenses and generate significant operating losses over the next several years as we continue to advance our product candidates into clinical studies and:

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

As of the filing of this report, we believe our existing cash, anticipated equity investment and access to the capital markets through an equity purchase agreement with LPC and H.C. Wainwright ATM Agreement will enable us to meet our obligations and sustain our operations through at least the next 12 months. However, we may require significant additional funds earlier than we currently expect to conduct additional or extended clinical studies and seek regulatory approval of our product candidates. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical studies.

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

If adequate funds are not available, we may be required to terminate, significantly modify or delay our development programs, 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 rate sensitivity, which is affected by changes in the general level of U.S. interest rates. We are exposed to market risk related to fluctuations in interest rates, market prices, and foreign currency exchange rates. However, since a majority of our investments are in highly liquid money market funds, we do not believe we are subject to any material market risk exposure. As of September 30, 2016, we did not have any material derivative financial instrument. The fair value of our cash and cash equivalents was $32.6 million as of September 30, 2016.

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.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Principal Accounting Officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2016. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities and Exchange Act of 1934, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Securities Exchange Act of 1934 is recorded, processed, summarized, and reported within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Securities Exchange Act of 1934 is accumulated and communicated to that company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. 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.

As required by SEC Rule 13a-15(e), we carried out an evaluation under the supervision and with the participation of our management, including our Chief Executive Officer and Principal Accounting Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the quarter covered by this report. Based on the foregoing, our Chief Executive Officer and Principal Accounting Officer concluded that, as of September 30, 2016, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

There have been no other changes in our internal control over financial reporting during the most recent quarter ended September 30, 2016 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

ITEM 1A. RISK FACTORS

An investment in our securities involves a high degree of risk. We operate in a dynamic and rapidly changing industry that involves numerous risks and uncertainties. The risks and uncertainties described below are not the only ones we face. Other risks and uncertainties, including those that we do not currently consider material, may impair our business. If any of the risks discussed below actually occur, our business, financial condition, operating results or cash flows could be materially adversely affected. This could cause the value of our securities to 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 clinical-stage biotechnology company with two clinical assets in the late stage of development. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. We have no products approved for commercial sale and have not generated any revenue from product sales to date and we continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred losses in each period since our inception in 2004. Substantially all of our losses resulted from costs incurred in connection with our product development programs and from general and administrative costs associated with our operations.

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

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

Our ability to generate product revenue and achieve profitability depends on our ability, alone or with collaborators, to successfully complete the development of our product candidates, conduct clinical studies in patients, obtain the necessary regulatory approvals for our product candidates and commercialize any approved products. Although we recognized collaborative revenues from our license agreement with Zenyaku in the nine months ended September 30, 2016, we cannot guarantee we will recognize collaborative revenue in the future. For the nine months ended September 30, 2016, we recognized collaborative revenue related to the amortization of upfront license fee revenue and reimbursement for our internal full time equivalent ("FTE") employee and certain research and development expenses by Zenyaku. In September 2015, Zenyaku provided us a notice of its intent to terminate the Zenyaku Agreement, effective January 7, 2016. The termination was "at will" and Zenyaku alleged no breach of the Zenyaku Agreement by us. As a result of an early termination the Zenyaku Agreement, we will not recognize revenues under the Zenyaku Agreement beyond January 2016. 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 liprotamase, our product candidate for the treatment of patients with Exocrine Pancreatic Insufficiency, or EPI, and potentially other diseases;
- obtain favorable results for and advance the development of blisibimod, our product candidate for the treatment of B-cell mediated autoimmune diseases, including successfully launching and completing clinical studies in patients with systemic lupus erythematosus, or lupus, IgA nephropathy, or other indications;
- obtain regulatory approval for liprotamase and blisibimod;
- if regulatory approvals are obtained, we will rely on commercial manufacturing of our product candidates with third-party manufacturers;

- if regulatory approvals are obtained, we will need to successfully commercialize the product(s))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 achieve reimbursement with payors.

Our product candidates are subject to the risks of failure inherent in the development of therapeutics based on new technologies. Our 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.

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 will depend on many factors including:

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

- manufacturing campaign for liprotamase and blisibimod clinical materials, including formulation development and product enhancement; as well as the cost to build to commercial scale for our products

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

- the cost, timing and outcomes of regulatory proceedings;

- payments received under any strategic collaborations;

- the filing, prosecution and enforcement of patent claims;

- the costs associated with commercializing our product 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 and access to additional capital through an equity purchase agreement, the H.C. Wainwright ATM Agreement, and an investor option to purchase the Company's preferred stock are sufficient to fund our near term liquidity needs for at least the next 12 months. Changing circumstances may cause us to consume capital significantly faster than we currently anticipate. Additional financing may not be available when we need it or may not be available on terms that are favorable to us. If adequate funds are not available to us on a timely basis, or at all, we may be required to:

- terminate, reduce or delay clinical studies or other development activities for our product candidates; or;

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

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

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

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

In March 2015, we received a research award of up to $3 million from Cystic Fibrosis Foundation Therapeutics Incorporated ("CFFT") for the development of liprotamase. Under the research award agreement, we are obligated to pay royalties to CFFT as follows: i) a one-time royalty in an amount equal to the five times the award, payable in three installments between the first and second anniversaries of the first commercial sale of a product; ii) a one-time royalty in an amount equal to the actual award after net product sales reaches $100 million; and iii) in the event of a license, sale or other transfer of the product or a change of control transaction prior to the commercial sale of the product, a milestone payment equal to three times the actual award.

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

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

As a part of our financing strategy, we have in the past and we may in the future enter into credit agreements with lenders. In connection with these credit agreements, our debt obligations to the lenders could:

- impair our liquidity and make it more difficult for us to satisfy our other obligations;
- require us to dedicate cash flow to payments on our debt obligations, which would reduce the availability of our cash flow to fund working capital, capital expenditures and other corporate requirements;
- impose restrictions on our ability to incur other indebtedness and grant liens on our assets, other than permitted indebtedness and permitted liens, and could impede us from obtaining additional financing in the future for working capital, capital expenditures, acquisitions and general corporate purposes;
- impose restrictions on us with respect to the use of our available cash, including in connection with future acquisitions;
- adversely affect our ability to enter into strategic transactions and similar agreements, or require us to obtain the consent of our lenders;
- make us more vulnerable in the event of a downturn in our business prospects and could limit our flexibility to plan for, or react to, changes in our licensing markets; and
- place us at a competitive disadvantage when compared to our competitors who are not similarly restricted.

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

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, liprotamase and blisibimod, and performing research and development. The company has not demonstrated an ability to obtain regulatory approval for or commercialize a product candidate, and will require substantial increase in new headcount. Consequently, any predictions about our future performance may not be as accurate as they could be if we had a history of successfully developing and commercializing pharmaceutical products.

Risks Associated with Development and Commercialization of Our Product Candidates

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

To date, we have not completed the required clinical trials nor have we submitted to the regulatory agencies the applications required to obtain authorization to market, distribute, sell any products. The success of our business depends primarily upon our ability to develop and commercialize our product candidates successfully.

Our product candidates are prone to the risks of failure inherent in drug development. Before obtaining regulatory approvals for the commercial sale of any product candidates 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 candidates are safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate. Despite our efforts, our product candidates may not:

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

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

Preclinical testing and clinical studies are long, expensive and uncertain processes. We may spend several years completing our testing for any particular product candidate, and failure can occur at any stage. Negative or inconclusive results or adverse medical events during a clinical study could also cause the 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.

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

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

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

- obtaining regulatory approval to commence a clinical study or complying with conditions imposed by a regulatory authority regarding the scope or design of a clinical study;
- reaching agreement on acceptable terms with prospective clinical research organizations, or CROs, and study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and study sites;
- manufacturing, including manufacturing sufficient quantities of product candidates or other materials for use in clinical studies;
- obtaining Institutional Review Board (IRB), approval or the approval of other reviewing entities to conduct a clinical study at prospective sites;
- 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 enrolled in a clinical study, but may withdraw due to treatment protocol, adverse effects, lack of efficacy from the investigational treatment, personal issues or who are lost to further follow-up.

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

- failure to conduct the clinical study in accordance with regulatory requirements or our clinical protocols;
- inspection of the clinical study operations or study sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- unforeseen safety issues or any determination that a clinical study presents unacceptable health risks; and
- lack of adequate funding to continue the clinical study, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional clinical studies and increased expenses associated with the services of our CROs and other third parties.

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

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

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

Success in preclinical testing and early clinical studies does not ensure that later clinical studies will generate adequate data to demonstrate the efficacy and safety of an investigational drug or biologic. A number of companies in the pharmaceutical and biotechnology industries, including those with greater resources and experience, have suffered significant setbacks in Phase 3 clinical studies, even after seeing promising results in earlier clinical studies. Despite the results reported in earlier clinical studies for our product candidates, we do not know whether any Phase 3 or other clinical studies we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market our product candidates. If later stage clinical studies do not produce favorable results, our ability to achieve regulatory approval for any of our product candidates may be adversely impacted. Even if we believe that our product candidates have performed satisfactorily in preclinical testing and clinical studies, we may nonetheless fail to obtain FDA approval for our product candidates.

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

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

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

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

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

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

The market for inflammatory disease therapeutics is especially large and competitive. For lupus, GlaxoSmithKline plc's BAFF antagonist monoclonal antibody, Benlysta®, was approved by the FDA for treatment of lupus. In 2015, new efficacy data with a subcutaneous presentation of Benlysta were presented, along with safety and pharmacokinetics data for an autoinjector for the subcutaneous product. We assume that these presentations will become commercially-available before our product may be registered. Further, we are aware of companies with other products in development that are being tested for potential treatment of lupus: AstraZeneca is conducting 3 Phase 3 trials in lupus and lupus nephritis with their drug candidate, anifrolumab, Merck Serono S.A., whose dual BAFF/APRIL antagonist fusion protein, Atacicept, recently completed a Phase 2/3 clinical study for lupus. In addition, other companies including Janssen, Pfizer, have completed Phase 2 trials in lupus and may continue to advance their clinical development in lupus.

Many of our potential competitors have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of drug candidates, and in obtaining FDA and other regulatory approvals of products and the commercialization of those products. Accordingly, our competitors may be more successful than we may be in obtaining FDA approval for drugs and achieving widespread market acceptance. Our competitors' drugs may be more effective, have fewer adverse effects, be less expensive to develop and manufacture or be more effectively marketed and sold than any product candidates we may commercialize and may render our product candidates obsolete or non-competitive before we can recover the expenses of developing and commercializing our product candidates. We anticipate that we will face intense and increasing competition as new drugs enter the market and advanced technologies become available. These entities may also establish collaborative or licensing relationships with our competitors. Finally, the development of new treatment methods for the diseases we are targeting could render our drugs non-competitive or obsolete. All of these factors could adversely affect our business.

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

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

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

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

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

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

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

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

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

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 blisibimod or liprotamase, if any, may include restrictions on use. Further, the FDA has indicated that long-term safety data on blisibimod may need to be obtained as a post-market requirement. Our product 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 procedures, or cGMP, regulations. If we or a regulatory agency discovers previously unknown problems with our product candidates, such as adverse events of unanticipated severity or frequency, or problems with the facility where the products are manufactured, a regulatory agency may impose restrictions on the products, the manufacturing facility or us, including requiring recall or withdrawal of the products from the market or suspension of manufacturing. If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

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

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

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

New federal legislation or regulatory requirements could affect the requirements for obtaining regulatory approvals of our product candidates or otherwise limit our ability to commercialize any approved products or subject our products to more rigorous post-approval requirements. New legislation, and the additional proposals if enacted, may make it more difficult or burdensome for us to obtain approval of our product candidates, any approvals we receive may be more restrictive or be subject to onerous post-approval requirements, our ability to successfully commercialize approved products may be hindered and our business may be harmed as a result.

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

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

- demonstration of clinical safety and efficacy compared to other products;
- the relative convenience, ease of administration and acceptance by physicians and payors of our product candidates;
- the prevalence and severity of any adverse effects;
- limitations or warnings contained in a product's FDA-approved labeling;
- availability of alternative treatments;

- pricing and cost-effectiveness;
- the effectiveness of our or any future collaborators' sales and marketing strategies;
- our ability to obtain and maintain sufficient third-party coverage or reimbursement from government health care programs, including Medicare and Medicaid; and
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage.

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

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

We are highly dependent on Mr. Paul F. Truex, our Chief Executive Officer, Mr. Craig Thompson, our President and Chief Operating Officer, Dr William Shanahan, our Chief Medical Officer, Dr. Chuck Olson, our Chief Technology Officer, and Ms. Klara Dickinson-Eason, our Chief Regulatory 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 Affordable Care Act, 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 Affordable Care Act until applicable federal and state agencies issue regulations or guidance under the new law. Although it is too early to determine the effect of the Health Care Reform Law, the new law appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and also may increase our regulatory burdens and operating costs. We expect further federal and state proposals and health care reforms to continue to be proposed by legislators, which could limit the prices that can be charged for any product we develop and may limit our commercial opportunity.

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

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

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

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

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

- impairment of our business reputation;
- withdrawal of clinical study participants;
- costs of related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- the inability to commercialize product candidates; and
- decreased demand for product candidates, if approved for commercial sale.

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

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

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

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

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

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

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

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

We rely on our manufacturers to purchase from third-party suppliers the materials necessary to produce drug product for our clinical studies. There are a small number of suppliers, and in some instances, a single supplier for certain capital equipment and raw materials that we use to manufacture drug product. Such suppliers may not sell these raw materials and equipment 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 and equipment 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 product candidates to complete the clinical study, any significant delay in the supply of product candidates or the raw material components thereof for an ongoing clinical study due to the need to replace a third-party manufacturer could considerably delay completion of our clinical studies, product testing and potential regulatory approval. If our manufacturers or we are unable to purchase these raw materials after regulatory approval has been obtained, the commercial launch would be delayed or there would be a shortage in supply of such product candidates, which would impair our ability to generate revenues from the sale of such 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 a product candidate, we may be required to establish large-scale commercial manufacturing capabilities. In addition, as our drug development pipeline increases and matures, we will have a greater need for clinical study and commercial manufacturing capacity. We have no experience manufacturing pharmaceutical products on a commercial scale and some of these suppliers will need to increase their scale of production to meet our projected needs for commercial manufacturing, which may not occur on a timely basis.

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

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

We do not currently have an organization for the sales, marketing, reimbursement 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.

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

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

Risks Related to Our Intellectual Property

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

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

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

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

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

The Amgen agreement provides exclusive and worldwide license rights to develop and commercialize the novel BAFF inhibitor blisibimod, as well as non-exclusive rights to certain technology relating to peptibody compositions and formulations. The Lilly Agreement provides exclusive and worldwide license rights to develop and commercialize liprotamase, as well as non-exclusive rights to certain technology relating to liprotamase compositions and formulations.

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

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 Hatch-Waxman Act provides for an extension of patent term for drug products for a period of up to five years to compensate for time spent in the regulatory approval process.

If we obtain the maximum five-year Hatch-Waxman patent term extension for blisibimod and continue to have rights under the Amgen Agreement with respect to blisibimod, we will have U.S. patent coverage for blisibimod compositions of matter until at least 2027 or 2028, depending on which patent the extension is applied to. If we obtain the maximum five-year Hatch-Waxman patent term extension for liprotamase and continue to have rights under the Lilly Agreement with respect to liprotamase, we will have U.S. patent coverage for liprotamase compositions of matter until 2030 to 2033, depending on which U.S. patent the extension is applied to.

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 (SPC). If we obtain the maximum five-year SPC for blisibimod and continue to have rights under the Amgen Agreement with respect to blisibimod, we will have

European patent coverage for blisibimod compositions of matter until 2027. If we obtain the maximum five-year SPC for liprotamase and continue to have rights under the Lilly Agreement with respect to liprotamase, we will have European patent coverage for liprotamase compositions of matter until 2026 to 2030, depending on which EP patent the extension is applied to.

The Public Health Service Act (PHSA) provides for 12 years of market exclusivity for innovator biologics, significantly longer than the five year period of new chemical entity exclusivity available for small molecule therapeutics. During this 12 year period, a generic applicant is precluded from relying on clinical data from the innovator product to establish safety and efficacy. Since blisibimod has not been previously approved by the FDA, blisibimod should be eligible for 12 years of U.S. data exclusivity. Similarly, since liprotamase contains components that have not been approved previously by the FDA, liprotamase may also be eligible for 12 years of U.S. data exclusivity.

The European Union provides for a 10-year period of data exclusivity for innovator biologics (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 patent(s) covering such biologic expires. A generic version of the approved drug may not be marketed or sold during such market exclusivity period. Blisibimod and liprotamase may be eligible for this 10-year market exclusivity in Europe.

There is no assurance that we will receive the extensions of our patents or other exclusive rights available under the Hatch-Waxman Act or similar foreign legislation. If we fail to receive such Hatch-Waxman extensions or marketing exclusivity rights or if we receive extensions that are materially shorter than expected, our ability to prevent competitors from manufacturing, marketing and selling generic versions of our products will be materially harmed.

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

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

Although our in-licensed and original patents may prevent others from making, using or selling similar products, they do not ensure that we will not infringe the patent rights of third parties. We may not be aware of all patents or patent applications that may impact our ability to make, use or sell our product candidates. For example, because we sometimes identify the mechanism of action or molecular target of a given product candidate after identifying its composition of matter and therapeutic use, we may not be aware until the mechanism or target is further elucidated that a third party has an issued or pending patent claiming biological activities or targets that may cover our product candidates. U.S. patent applications filed after November 29, 2000 are confidential in the U.S. Patent and Trademark Office for the first 18 months after such applications' earliest priority date, and patent offices in non-U.S. countries often publish patent applications for the first time six months or more after filing. Furthermore, we may not be aware of published or granted conflicting patent rights. Any conflicts resulting from patent applications and patents of others could significantly reduce the coverage of our patents and limit our ability to obtain meaningful patent protection. If others obtain patents with conflicting claims, we may need to obtain licenses to these patents or to develop or obtain alternative technology.

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

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

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

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

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

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

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

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

- plans for, progress in and results from clinical studies for our product candidates;
- announcements of new products, services or technologies, commercial relationships, acquisitions or other events by us or our competitors;
- developments concerning proprietary rights, including those pertaining to patents patent applications held by our licensors;
- failure of any of our product candidates, if approved, to achieve commercial success;
- fluctuations in stock market prices and trading volumes of securities of similar companies;
- general market conditions and overall fluctuations in U.S. equity markets;
- variations in our operating results, or the operating results of our competitors;
- changes in our financial guidance or securities analysts' estimates of our financial performance;
- changes in accounting principles;
- sales of large blocks of our common stock, including sales by our executive officers, directors and significant stockholders;
- additions or departures of any of our key personnel;

- announcements related to litigation;
- changing legal or regulatory developments in the United States and other countries; and
- discussion of us or our stock price by the financial press and in online investor communities.

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

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

Our executive officers, directors and greater than 5% stockholders, in the aggregate, own approximately 34.71% of our outstanding common stock. As a result, such persons, acting together, will have the ability to influence our management and affairs and substantially all matters submitted to our stockholders for approval, including the election and removal of directors and approval of any significant transaction. These persons will also have the ability to influence our management and business affairs. This concentration of ownership may have the effect of delaying, deferring or preventing a change in control, impeding a merger, consolidation, takeover or other business combination involving us, or discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of our business, even if such a transaction would benefit other stockholders.

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

As of September 30, 2016, there were 41,955,126 shares of our common stock outstanding. In addition, as of September 30, 2016, we had outstanding options and warrants to purchase 6,022,851 shares of our common stock. Furthermore, we issued 17,000 shares of Series X convertible preferred stock and warrants to purchase our commons stock at a per share price equivalent to 120% of the Series X convertible preferred stock's conversion price. Assuming the Series X convertible preferred stock converts into our common stock at $2.95 per shares (the closing price of our common stock on the September 6, 2016), the Series X convertible preferred stock would be converted into approximately 5,762,712 shares of common stock and the warrants would be exercisable for 1,200,565 shares of common stock. A large portion of these shares and outstanding equity awards are held by a small number of persons and investment funds. Sales by these stockholders or option holders of a substantial number of shares could significantly reduce the market price of our common stock. Moreover, certain holders of shares of common stock will have rights, subject to some conditions, to require us to file registration statements covering the shares they currently hold, or to include these shares in registration statements that we may file for ourselves or other stockholders.

We have registered or will register all common stock that we may issue under our 2013 Stock Option and Incentive Plan (the "2013 Plan"), our Amended and Restated 2010 Stock Option and Incentive Plan (the "2010 Plan") and our Employee Stock Purchase Plan (the "ESPP"). As of September 30, 2016, an aggregate of 508,527 shares of our common stock have been reserved for future issuance under the 2013 Plan, plus any shares cancelled under our 2005 Equity Incentive Plan and 2010 Plan, and an aggregate of 68,677 shares of common stock have been reserved for future issuance under our ESPP. These shares can be freely sold in the public market upon issuance. If a large number of these shares are sold in the public market, the sales could reduce the trading price of our common stock.

In addition, we may sell shares of stock pursuant to an equity purchase agreement with LPC pursuant to which we have the right, but not the obligation, to sell to LPC up to an aggregate of $15.0 million of common stock until April 2017. As of September 30, 2016, there is a balance of $13.4 million available for future sale pursuant to the equity purchase agreement with LPC. We may also sell shares of stock pursuant to the H.C. Wainwright ATM Agreement under which we may from time to time offer and sell up to $25.0 million shares of our common stock. As of September 30, 2016, there is a balance of $22.7 million available for future sale pursuant to the H.C. Wainwright ATM Agreement. Finally, we maintain an effective shelf registration statement on Form S-3 with the SEC for the issuance and sale from time to time of up to approximately $43.6 million of our equity and debt securities.

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

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

Certain investors may not exercise their option to purchase Series X-1 Preferred Stock in the Second Tranche.

On September 6, 2016, as part of a registered direct offering, the Company entered into a subscription agreement with certain institutional investors pursuant to which such investors have the right, but not the obligation, to purchase up to 28,330 shares of convertible Series X-1 convertible preferred stock at a purchase price of $1,000 per share for an aggregate purchase price of $28.3 million. There can be no assurance that such investors will exercise this option to purchase such shares. If we fail to raise sufficient capital in this registered direct offering, we may seek alternative debt, equity or equity-based financing (such as convertible debt) when market conditions permit. Such financing may not be available on favorable terms, or at all.

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

As a public company, we incur significant legal, accounting and other expenses. In addition, our administrative staff are required to perform additional tasks. For example, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, as well as rules subsequently implemented by the SEC and The NASDAQ Global Market, impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. We must also bear all of the internal and external costs of preparing and distributing periodic public reports in compliance with our obligations under the securities laws.

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

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

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

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

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

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

- the requirement of at least 75% of the outstanding common stock to amend any of the foregoing provisions.

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

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

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an “ownership change,” generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period, the corporation’s ability to use its pre-change net operating loss carryforwards, or NOLs, and other pre-change tax attributes (such as research tax credits) to offset its post-change income or taxes may be limited. Our prior equity offerings and other changes in our stock ownership may have resulted in ownership changes. In addition, we may experience subsequent shifts in our stock ownership, including as a result of subsequent offerings, some of which are outside of our control. As a result, if we earn net taxable income, our ability to use our pre-change NOL carryforwards to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

ITEM 6. EXHIBITS

The following exhibits are filed as part of this report:

Number	Description
3.1	Fifth Amended and Restated Certificate of Incorporation (filed as Exhibit 3.6 to the registrant's Registration Statement on Form S-1/A (File No. 333-161930) filed with the SEC February 3, 2010 and incorporated herein by reference).
3.2	Certificate of Amendment to the Fifth Amended and Restated Certificate of Incorporation (filed as Annex A to the registrant's Definitive Proxy Statement on Schedule 14A, filed with the SEC October 20, 2012 and incorporated herein by reference).
3.3	Certificate of Amendment to the Fifth Amended and Restated Certificate of Incorporation filed July 12, 2013 and effective July 15, 2013 (filed as Exhibit 3.1 to the registrant's Current Report on Form 8-K, filed with the SEC on July 16, 2013 and incorporated herein by reference.)
3.4	Amended and Restated Bylaws, as amended on May 21, 2015 (filed as Exhibit 3.4 to the registrant's Form 10-Q filed with the SEC on August 10, 2015 and incorporated herein by reference).
3.5	Certificate of Designation of Preferences, Rights and Limitations of Series X Convertible Preferred Stock (filed as Exhibit 3.1 to the registrant's Form 8-K filed with the SEC on September 12, 2016 and incorporated herein by reference).
3.6	Amended and Restated Certificate of Designation of Preferences, Rights and Limitations of Series X Convertible Preferred Stock (filed as Exhibit 3.1 to the registrant's Form 8-K filed with the SEC on September 15, 2016 and incorporated herein by reference).
3.7	Form of Certificate of Designation of Preferences, Rights and Limitations of Series X-1 Convertible Preferred Stock (filed as Exhibit 3.2 to the registrant's Form 8-K filed with the SEC on September 12, 2016 and incorporated herein by reference).
4.1	Form of Warrant (filed as Exhibit 4.1 to the registrant's Form 8-K filed with the SEC on September 12, 2016 and incorporated herein by reference).
4.2	Specimen Series X Convertible Preferred Stock certificate (filed as Exhibit 4.2 to the registrant's Form 8-K filed with the SEC on September 12, 2016 and incorporated herein by reference).
10.1	Amendment to the LPC Agreement, dated as of April 27, 2016, between Anthera Pharmaceuticals, Inc. and Lincon Park Capital Fund, LLC (filed as exhibit 10.1 to the registrant's Form 8-K filed with the SEC on April 27, 2016 and incorporated herein by reference).
10.2	At Market Issuance Sales Agreement, dated April 21, 2016, between Anthera Pharmaceuticals, Inc. and H.C. Wainwright & Co., LLC (filed as exhibit 10.1 to the registrant's form 8-K filed with the SEC on April 21, 2016 and incorporated herein by reference).
10.3	Subscription Agreement, dated September 6, 2016, between Anthera Pharmaceuticals, Inc. and purchasers affiliated with Biotechnology Value Fund, L.P. and Rock Springs Capital Master Fund LP (filed as Exhibit 10.1 to the registrant's Form 8-K filed with the SEC on September 12, 2016 and incorporated herein by reference).
#10.4	Employment Offer Letter between the Company and Dr. William Shanahan, dated as of April 25, 2016 (filed herewith).
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.LAB	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.

Management contract or compensatory plan, contract or agreement.

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 7, 2016	By:	*<u>/s/ Paul F. Truex</u>* Paul F. Truex Chief Executive Officer
November 7, 2016	By:	*<u>/s/ May Liu</u>* May Liu Senior Vice President, Finance and Administration (Principal Accounting Officer)

Exhibit 10.4

William Shanahan, M.D

Re: Offer of Employment

Dear Bill:

Anthera Pharmaceuticals, Inc. (the "Company") is pleased to extend to you an offer of employment with the Company, as follows:

1. Position . The Company will employ you in the position of Chief Medical Officer (CMO) reporting to the Company's President & COO. Your employment will commence on or about September 1, 2016.

2. Compensation . The Company will compensate you at the rate of $400,000 per annum, pro-rated for any partial month of employment; of which 5% is to be withheld and deposited directly into your 401(k) account sponsored by the Company on a pre-tax basis, up to the annual individual 401 (k) contribution amount permitted by the IRS. The Company will pay you your salary semi-monthly in arrears less customary payroll taxes and withholding taxes. Consideration for salary increases will occur at each year end beginning December 31, 2016. Whether an increase will be given, and if so in what amount, will be decided at the sole discretion of the Company. In addition, you will be eligible for a discretionary target bonus of up to 35% of your base salary based on your achievement of corporate and personal goals as established by the Company. The determination of whether you have achieved the goals, whether you will receive a bonus, and, if so, the bonus amount that will be paid, shall be made by the Company in its sole and absolute discretion.

3. Fringe Benefits . You will be entitled to the customary fringe benefits made available to other employees of the Company in similar positions. Said fringe benefits include a group health insurance program covering you and your dependents (the level of coverage depends on the specific plan you elect), and participation in the Company's 401(k) plan. Eligibility for the Company's health insurance program starts on the first day of the month following a 60-day waiting period from the date of hire. The company provides no defined vacation plan, however, will accommodate reasonable requests for additional time off, in addition to Company/Federal Holidays. The Company's fringe benefits are subject to adjustment from time to time in the sole discretion of the Company.

4. Time out of Office, Vacation, Personal Time Away . The Company has no formal policy regarding attendance, vacation, or sickness. For record keeping and accounting purposes, the Company requires all individuals to provide monthly timesheet of all time in or out of office. In the case of prolonged absences (those of 3 days or more) when possible, individuals should make requests to their managers where a prior notice of absence is provided commensurate with the duration of the absence (i.e. Where possible, longer or planned absences should be requested as far in advance as possible whereas shorter unplanned absences require only appropriate accounting on monthly statements). As a matter of courtesy, when possible, the Company requests that individuals notify their managers of all absences in advance.

5. Stock Options Grant . Subject to the approval of the Company's Board of Directors (the "Board"), you will be granted a stock option ("Option") entitling you to purchase 390,000 shares of Common Stock of the Company (the "Common Stock"). The Option exercise price shall be set at 100% of the fair market value of the Common Stock at the next regularly scheduled meeting of the Board, which shall be determined by the Board in its sole discretion in accordance with the terms of the Plan. The Option shall vest during the course of your employment, with 25% of the shares vesting upon the first anniversary of your date of employment, 75% of the shares vesting in 36 equal monthly installments at the end of each full calendar month that commences thereafter, for so long as you remain employed by the Company, such that subject to your continued employment the stock option shall be fully vested on the fourth anniversary of its vesting start date.

6. Company Policies . You will be expected to comply with all of the Company's policies and practices, particularly including:

    a. You will sign and abide by the Company's "Proprietary Information and Inventions Agreement," pursuant to which you are obligated to, among other things, (i) assign to the Company inventions conceived or developed by you during the duration of your employment with the Company and (ii) maintain the confidentiality of all of the Company's confidential information, and (iii) not use or disclose to any other person any of the Company's confidential information at any time, before, during or after the term of your employment with the Company; and

    b. You will not pursue any activities during the term of your employment with the Company which in any way interferes with the performance of your responsibilities to the Company, or which in any way are adverse to or competitive with the business of the Company. If you should consider pursuing any outside professional activities (whether as a consultant, adviser, or in any other capacity with another organization) during the term of your employment, you agree to disclose them prior to undertaking them so that they can be reviewed for potential conflicts with your responsibilities or the Company's business. However, your ability to serve on external advisory boards shall not be unreasonably prohibited.

7. Employment Eligibility . This offer of employment is conditioned upon your providing evidence of your legal right to work in the U.S. by satisfactorily completing a Form I-9 as required by law.

8. Term . This employment relationship is an "at will" employment which will continue indefinitely unless and until terminated by either party. While it is anticipated that this employment relationship will be a long term and mutually rewarding employment relationship, each party nevertheless reserves the right to terminate the employment relationship at any time, without cause, upon (14) days' prior written notice. Further, upon any breach of this letter by either party, the non-breaching party may terminate immediately.

* * * *

I am excited to have you join the team and I look forward to a long term and mutually beneficial working relationship with you. To evidence your concurrence with the above-stated employment terms, please sign and return to me the enclosed copy of this letter.

Sincerely,

By: */s/ May Liu*
May C. Liu
Senior Vice President
Finance & Administration

ACCEPTED AND AGREED TO AS SET FORTH ABOVE:

Date: August 10, 2016

/s/ *William Shanahan*
William Shanahan

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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

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

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

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

Date: November 4, 2016

/s/ *Paul F. Truex*
Paul F. Truex
Chief Executive Officer

Exhibit 31.2

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

I, May Liu, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 7, 2016

/s/ *May Liu*
May Liu
Senior Vice President, Finance and Administration
(Principal Accounting 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, 2016 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: Chief Executive Officer

November 7, 2016

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, May Liu, 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 ended September 30, 2016 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/ *May Liu*

Name: May Liu
Title: Senior Vice President, Finance and Administration
(Principal Accounting Officer)

November 7, 2016