
**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, 2017**

OR

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

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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company", or an emerging growth company in Rule 12b-2 of the Exchange Act. (Check one):

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

Accelerated filer
Smaller reporting company
Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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, 2017, the number of outstanding shares of the registrant's common stock, par value \$0.001 per share, was 13,849,678.

ANTHERA PHARMACEUTICALS, INC.

FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2017

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PART I — FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

ANTHERA PHARMACEUTICALS, INC.

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

ASSETS	<u>September 30, 2017</u>	<u>December 31, 2016</u> (1)
Current assets:		
Cash and cash equivalents	\$ 6,076	\$ 20,843
Prepaid expenses and other current assets	1,771	1,865
Total current assets	<u>7,847</u>	<u>22,708</u>
Property and equipment — net	521	763
TOTAL	<u>\$ 8,368</u>	<u>\$ 23,471</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,009	\$ 4,782
Accrued clinical expenses	2,105	3,884
Accrued liabilities	111	113
Accrued payroll and related costs	750	1,845
Total current liabilities	<u>3,975</u>	<u>10,624</u>
Warrant liability	4,050	—
Total liabilities	<u>8,025</u>	<u>10,624</u>
Commitments and Contingencies (Note 7)		
Contingently Redeemable Series X Convertible Preferred Stock, \$0.001 par value, 0 and 487 shares issued and outstanding as of September 30, 2017 and December 31, 2016, respectively	—	377
Stockholders' equity (2):		
Series X Convertible Preferred Stock, \$0.001 par value, 5,000,000 shares authorized; 430 and 9,012 shares issued and outstanding as of September 30, 2017 and December 31, 2016, respectively	333	8,614
Common stock, \$0.001 par value, 100,000,000 shares authorized; 11,446,920 and 5,745,536 shares issued and outstanding as of September 30, 2017 and December 31, 2016, respectively	12	6
Additional paid-in capital	424,753	411,404
Accumulated deficit	<u>(424,755)</u>	<u>(407,554)</u>
Total stockholders' equity	<u>343</u>	<u>12,470</u>
TOTAL	<u>\$ 8,368</u>	<u>\$ 23,471</u>

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

(1) Derived from audited Financial Statements.

ANTHERA PHARMACEUTICALS, INC.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
REVENUES:				
License fee	\$ —	\$ —	\$ —	\$ 139
Collaborative revenue	—	—	—	6
Total revenues	—	—	—	145
OPERATING EXPENSES:				
Research and development	\$ 6,104	\$ 14,096	\$ 20,939	\$ 35,686
General and administrative	1,810	2,504	6,338	7,318
Research award	—	—	(100)	(261)
Total operating expenses	7,914	16,600	27,177	42,743
LOSS FROM OPERATIONS	(7,914)	(16,600)	(27,177)	(42,598)
OTHER INCOME (EXPENSE):				
Other (expense)	(43)	(47)	(74)	(109)
Fair value of warrant liability in excess of proceeds from financing	—	—	(600)	—
Change in fair value of warrant liability	1,650	169	10,650	169
Total other income	1,607	122	9,976	60
NET LOSS	\$ (6,307)	\$ (16,478)	\$ (17,201)	\$ (42,538)
Deemed dividends attributable to preferred stock	—	(8,807)	(2,503)	(8,807)
Net loss applicable to common stockholders	\$ (6,307)	\$ (25,285)	\$ (19,704)	\$ (51,345)
Net loss per share applicable to common stockholders —basic and diluted (1)	\$ (0.58)	\$ (4.85)	\$ (2.12)	\$ (10.04)
Weighted-average number of shares used in per share calculation—basic and diluted (1)	10,947,338	5,210,334	9,296,890	5,115,560

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

- (1) All per share amounts and shares of the Company's common stock issued and outstanding for all periods have been retroactively adjusted to reflect the one-for-eight reverse stock split which became effective April 28, 2017.

ANTHERA PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENT OF SERIES X CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY
(in thousands except share and per share amounts)
(unaudited)

	Contingently Redeemable Series X Convertible Preferred Stock		Series X Convertible Preferred Stock		Common Stock (1)		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount			
Balance at December 31, 2016	487	\$ 377	9,012	\$ 8,614	5,745,536	\$ 6	\$ 411,404	\$ (407,554)	\$ 12,470
Issuance of common stock pursuant to exercise of stock options and employee stock purchase plan	-	-	-	-	39,386	-	80	-	80
Share based compensation related to equity awards	-	-	-	-	-	-	2,923	-	2,923
Issuance of common stock and warrants for cash at \$4.00 per share, net of warrant liability of \$14,700	-	-	-	-	3,750,000	-	-	-	-
Issuance of common stock pursuant to an equity purchase agreement, net of issuance cost of \$316	-	-	-	-	1,336,320	1	1,693	-	1,694
Reclassification of contingently redeemable Series X convertible preferred stock	(487)	(377)	487	377	-	-	-	-	377
Conversion of Series X convertible preferred stock into common stock	-	-	(9,069)	(11,161)	575,678	5	11,156	-	-
Deemed dividend attributable to Series X convertible preferred stock	-	-	-	2,503	-	-	(2,503)	-	-
Net loss	-	-	-	-	-	-	-	(17,201)	(17,201)
Balance at September 30, 2017	-	\$ -	430	\$ 333	11,446,920	\$ 12	\$ 424,753	\$ (424,755)	\$ 343

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

- (1) All per share amounts and shares of the Company's common stock issued and outstanding for all periods have been retroactively adjusted to reflect the one-for-eight reverse stock split which became effective April 28, 2017.

ANTHERA PHARMACEUTICALS, INC.

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

	Nine Months Ended September 30,	
	2017	2016
CASH FLOW FROM OPERATING ACTIVITIES:		
Net loss	\$ (17,201)	\$ (42,538)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	246	241
Stock-based compensation expense	2,923	3,943
Fair value of warrant liability in excess of proceeds from financing	600	—
Change in fair value of warrant liability	(10,650)	(169)
Changes in assets and liabilities:		
Accounts receivable	—	326
Prepaid expenses and other assets	93	(358)
Accounts payable	(3,773)	(1,868)
Accrued clinical expenses	(1,782)	3,184
Accrued liabilities	(1)	419
Accrued payroll and related costs	(1,095)	267
Deferred revenue	—	(138)
Net cash used in operating activities	<u>(30,640)</u>	<u>(36,691)</u>
INVESTING ACTIVITIES:		
Property and equipment purchases	—	(952)
Net cash used in investing activities	<u>—</u>	<u>(952)</u>
FINANCING ACTIVITIES:		
Net proceeds from issuance of common stock and warrants pursuant to equity offering	14,099	6,037
Proceeds from issuance of preferred stock, warrants and options, net of offering cost	—	16,920
Net proceeds from issuance of common stock pursuant to equity purchase agreement	1,694	—
Net proceeds from issuance of common stock pursuant to exercise of stock options and employee stock purchase plan	80	305
Net cash provided by financing activities	<u>15,873</u>	<u>23,262</u>
NET DECREASE IN CASH AND CASH EQUIVALENTS	<u>(14,767)</u>	<u>(14,381)</u>
CASH AND CASH EQUIVALENTS — Beginning of period	20,843	46,951
CASH AND CASH EQUIVALENTS — End of period	<u>\$ 6,076</u>	<u>\$ 32,570</u>
SUPPLEMENTAL CASH DISCLOSURES OF CASH FLOW INFORMATION		
Non-cash financing activities:		
Fair value of warrants issued in connection with registered direct offering	<u>\$ 14,700</u>	<u>\$ 3,678</u>
Issuance of common stock as a commitment fee pursuant to an equity purchase agreement	<u>\$ 316</u>	<u>\$ 87</u>

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”) 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, Sollpura and blisibimod. The Company licensed Sollpura from Eli Lilly & Co (“Eli Lilly”) in July 2014. Sollpura 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 or (“BAFF”) which has been shown to be elevated in a variety of B-cell mediated autoimmune diseases, including Immunoglobulin A nephropathy, or IgA nephropathy.

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 EPI and IgA Nephropathy. 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, 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 million through H.C. Wainwright, as agent, which was amended and reduced to \$23 million on March 14, 2017. In June 2017, in connection with the execution of an equity purchase agreement with Lincoln Park Capital, LLC. (“LPC”), the Company filed a prospectus supplement suspending and reducing all offerings pursuant to the H.C. Wainwright ATM agreement.

In March 2017, the Company entered into an underwriting agreement with H.C. Wainwright, pursuant to which the Company sold an aggregate of 30,000,000 shares of its common stock and agreed to issue warrants to purchase an aggregate of 60,000,000 shares of its common stock. On April 28, 2017, with shareholders’ approval, the Company effectuated a one-for-eight reverse split of its outstanding common stock (“Reverse Stock Split”). Subsequent to the Reverse Stock Split, the common stock shares and warrant shares were adjusted to 3,750,000 and 7,500,014, respectively. The financing transaction resulted in proceeds of \$14.1 million.

On June 19, 2017, the Company entered into an equity purchase agreement (the “2017 Purchase Agreement”) with Lincoln Park Capital Fund, LLC. (“LPC”), pursuant to which the Company has the right, at its discretion, to sell up to an aggregate of \$10.0 million in shares of the Company’s common stock and issue up to 181,708 shares of the Company’s common stock as a commitment fee to LPC. The 2017 Purchase Agreement will expire on December 19, 2019.

On October 23, 2017, the Company entered into a definitive agreement with certain accredited investors in connection with a private placement of equity securities, (the “Private Placement”) for potentially \$15 million in gross proceeds. The Private Placement is structured with two closings. The first closing occurred on October 27, 2017 and resulted in gross proceeds of approximately \$2.9million. The second closing, contingent upon the requisite shareholder approval pursuant to Nasdaq Rule 5635(d), is expected to result in gross proceeds of approximately \$12.1 million. The Company plans to obtain such shareholder approval in the first quarter of 2018. See Footnote 10 for further details.

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 will 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, which raises substantial doubt about the Company’s ability to continue as a going concern as of the date of this report and that is not alleviated after consideration management’s plans to mitigate such concerns. The financial statements do not include any adjustments that might result from the outcome of this uncertainty. 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 issuances of equity securities, future partnerships, 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 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, 2016, filed with the SEC on March 16, 2017. 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, 2017 are not necessarily indicative of the results to be expected for the year ending December 31, 2017 or for any other period. The consolidated balance sheet as of December 31, 2016 has been derived from the audited financial statements as of that date but it does not include all the information and notes required by U.S. GAAP.

On April 28, 2017, the Company implemented a one-for-eight reverse split of its outstanding common stock resulting in a reduction of its total common stock issued and outstanding from 80,609,310 shares to 10,076,164 shares. The Reverse Stock Split affected all stockholders of the Company’s common stock equally. The par value of the Company’s common stock and preferred stock remains unchanged at \$0.001 per share and the number of authorized shares of common stock and preferred stock remained unchanged at 100,000,000 and 5,000,000, respectively, after giving effect to the Reverse Stock Split. All references to shares of common stock, stock options, warrants to purchase common stock, the conversion rate of preferred stock and outstanding per share data for all periods presented in the accompanying financial statements and notes thereto have been adjusted to reflect the Reverse Stock Split on a retroactive basis and all share information is rounded down to the nearest whole share after reflecting the reverse split, except where described otherwise.

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 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, the tax provision, stock-based compensation, and warrant liabilities. 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, which have characteristics of both liabilities and equity. Financial instruments such as warrants that are classified as liabilities are fair valued upon issuance and are re-measured 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 valuation models that require the input of subjective assumptions including stock price volatility, expected life, and the probability of future equity issuances and their impact to the price protection feature.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2014-09, Revenue from Contracts with Customers (ASC Topic 606). The standards update outlines a single comprehensive model for entities to utilize to recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration that will be received in exchange for the goods and services. Additional disclosures will also be required to enable users to understand the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. In 2016, the FASB issued accounting standards updates to address implementation issues and to clarify the guidance for identifying performance obligations, licenses and determining if a company is the principal or agent in a revenue arrangement. In August 2015, the FASB issued ASU 2015-14, Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date, which deferred the effective date of ASU 2014-09. The mandatory adoption date of ASC 606 for the Company is now January 1, 2018. There are two methods of adoption allowed, either a “full” retrospective adoption or a “modified” retrospective adoption. The Company expects to adopt the standard on a modified retrospective basis applying the new rules to all contracts existing at January 1, 2018, with an adjustment for the cumulative effect of all changes recognized in beginning retained earnings. Given that the Company is not currently generating revenue and most likely will not be generating revenue at the date of adoption, the adoption of this guidance is not expected to materially impact the Company’s 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. This new standard establishes a right-of-use (ROU) model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the statement of operations. 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. A modified retrospective transition approach is required for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. The Company does not expect the adoption of this standard to have a material impact on its financial statements.

Effective January 1, 2017, the Company adopted ASU No. 2016-09, Compensation-Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting. Among other requirements, the new guidance requires all tax effects related to share-based payments at settlement (or expiration) to be recorded through the income statement. Previously, tax benefits in excess of compensation cost ("windfalls") were recorded in equity, and tax deficiencies ("shortfalls") were recorded in equity to the extent of previous windfalls, and then to the income statement. As required, this change was applied prospectively to all excess tax benefits and tax deficiencies resulting from settlements. Under the new guidance, the windfall tax benefit is to be recorded when it arises, subject to normal valuation allowance considerations. As required, this change was applied on a modified retrospective basis. There was \$0.3 million of unrecognized deferred tax assets attributable to excess tax benefits that were not previously recognized as the Company did not reduce income taxes payable. The cumulative adjustment for the adoption of ASU No. 2016-09 did not have an impact on net equity as the incremental deferred tax assets were fully offset by a corresponding increase in the deferred tax asset valuation allowance.

ASU No. 2016-09 addressed the presentation of employee taxes paid on the statement of cash flows. The Company is now required to present the cost of shares withheld from the employee to satisfy the employees' income tax liability as a financing activity on the statement of cash flows rather than as an operating cash flow. This change is applied on a retrospective basis, as required, but did not impact the statement of cash flows for the nine months ended September 30, 2017.

ASU No. 2016-09 also permits entities to make an accounting policy election related to how forfeitures will impact the recognition of compensation cost for stock-based compensation to either estimate the total number of awards for which the requisite service period will not be rendered, as currently required, or to account for forfeitures as they occur. Upon adoption, the Company elected to not make any changes to the current policy of accounting for forfeitures.

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. The Zenyaku Agreement was mutually terminated in January 2016. Consequently, the Company accelerated the amortization period of its deferred revenue and fully amortized it 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 Sollpura. The Company retains the right to develop and commercialize Sollpura and will owe royalties to CFFT on net sales of any drug candidate approved and commercialized under the collaboration. The funding is disbursed by CFFT to the Company upon the Company's achievement of milestones specified in the grant agreement. At its discretion, the Company may choose to fund a particular stage of the Sollpura development plan without CFFT funds. Any CFFT funds not expended on the development program of Sollpura 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 thereof ("CFFT Know-How") to the Company, CFFT grants to the Company a non-exclusive, transferrable, sub-licensable, 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.

As of March 31, 2017, the Company has fully recognized 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. For the three and nine months ended September 30, 2016, diluted EPS is identical to basic EPS since common equivalent shares are excluded from the calculation, as their effect is anti-dilutive. For the three and nine months ended September 30, 2017, diluted EPS is identical to basic EPS due to all of the Company's outstanding warrants and stock options having exercise prices higher than the Company's average stock price during the period. The effect of preferred shares is excluded during periods with a net loss as their effect is anti-dilutive.

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

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2017</u>	<u>2016</u>	<u>2017</u>	<u>2016</u>
Net loss per share				
Numerator				
Net loss	\$ (6,307)	\$ (16,478)	\$ (17,201)	\$ (42,538)
Deemed dividend attributable to preferred stock	—	(8,807)	(2,503)	(8,807)
Net loss applicable to common stockholders	\$ (6,307)	\$ (25,285)	\$ (19,704)	\$ (51,345)
Denominator				
Weighted average common shares outstanding	10,947,338	5,210,334	9,296,890	5,115,560
Basic and diluted net loss per share	\$ (0.58)	\$ (4.85)	\$ (2.12)	\$ (10.04)

The following outstanding options, warrants, and Series X convertible preferred stock that are potentially dilutive securities were excluded from the computation of diluted net loss per share, as the effect of including them would have been antidilutive.

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2017</u>	<u>2016</u>	<u>2017</u>	<u>2016</u>
Options to purchase common stock	1,240,974	721,252	995,274	654,567
Warrants to purchase common stock	7,774,815	57,805	5,796,789	22,810
Series X convertible preferred stock	27,295	299,755	91,496	98,800
Total	9,043,084	1,078,812	6,883,559	776,177

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 the Company to develop its own assumptions.

The following tables present the Company’s fair value hierarchy for all its financial assets and liabilities (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, 2017 and December 31, 2016 (in thousands):

	<u>September 30, 2017</u>			
	<u>Estimated Fair Value</u>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>
Warrant Liability	\$ 4,050	\$ —	\$ —	\$ 4,050

	<u>December 31, 2016</u>			
	<u>Estimated Fair Value</u>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>
Money market funds	\$ 19,416	\$ 19,416	\$ —	\$ —

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 containing price protection rights 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, 2017
Beginning balance	\$ -
Addition to fair value of warrant liability during the three months ended March 31, 2017	14,700
Decrease in fair value of warrant liability from April 1 to September 30, 2017	(10,650)
Ending balance	<u>\$ 4,050</u>

There were no transfers between Level 1, Level 2 or Level 3 for the nine months ended September 30, 2017 and year ended December 31, 2016.

6. WARRANT LIABILITY

Pursuant to an underwriting agreement entered into in March 2017, the Company issued warrants to purchase 30,000,000 shares of common stock at an initial exercise price of \$0.55 per share ("Tranche 1 Warrants") and warrants to purchase 30,000,000 shares of common stock at an initial exercise price of \$0.50 per share ("Tranche 2 Warrants") to certain investors. On April 28, 2017, the Company implemented a one-for-eight reverse split of its outstanding common stock. The Reverse Stock Split did not change the number of authorized shares of common stock, which remained at 100,000,000, but did increase the number of authorized but unissued shares of common stock, resulting in sufficient authorized shares of common stock to settle the warrants. After giving effect to the Reverse Stock Split, the number of shares issuable upon exercise and the exercise price of the Tranche 1 Warrants were 3,750,007 and \$4.40, respectively, and the number of shares issuable upon exercise and the exercise price of the Tranche 2 Warrants were 3,750,007 and \$4.00, respectively. The Tranche 1 Warrants will expire on April 28, 2022 and the Tranche 2 Warrants expired on October 28, 2017.

The exercise price of the Tranche 1 and Tranche 2 warrants are subject to adjustment in the event of a stock combination, reverse split, or similar transaction involving common stock (each, a "Stock Combination Event") if the average volume weighted average price ("VWAP") of the common stock for the five lowest trading days during the 15 consecutive trading day period ending and including the trading day immediately preceding the 16th trading day after such Stock Combination Event is less than the exercise price of the warrant. In such an event, the exercise price of the warrants is adjusted to the average VWAP. As a result of the Reverse Stock Split, the exercise price for the Tranche 1 and Tranche 2 Warrants were each adjusted to \$1.8918.

The Company accounted for the warrants under ASC Topic 815, *Derivatives and Hedging* ("ASC 815"). The Company determined that, on the date of issuance, the warrants were not considered indexed to its own stock because the underlying instruments were not "fixed-for-fixed" due to the price protection and therefore, the warrants should be accounted for as derivatives. The warrants also permitted the holder to require the Company to settle the warrants for cash in the event of a fundamental transaction, including a sale of the business. At the end of each reporting period, the changes in fair value during the period are recorded as a component of non-operating income (expense) in the consolidated statement of operations. The initial fair value of the liability associated with these warrants was \$14.7 million. As of September 30, 2017, the fair value of the liability associated with these warrants was \$4.1 million. The decrease in fair value of the warrant liability was recorded as non-operating income during the nine months ended September 30, 2017.

The Company estimated the fair value of the warrants using the Monte Carlo simulation model, which combines expected cash outflows with market-based assumptions regarding risk-adjusted yields, stock price volatility, and the probability of future equity events. Inputs used in the valuation of each tranche on issuance date and September 30, 2017 were as follows:

Issuance Date	Tranche 1	Tranche 2
Common stock price	\$ 3.44	\$ 3.44
Exercise price	\$ 4.40	\$ 4.00
Expected Volatility	112.5%	112.5%
Dividend Yield	0%	0%
Risk-Free Interest Rate	2.03%	2.03%
Expected Term (years)	5.0	0.5
September 30, 2017	Tranche 1	Tranche 2
Common stock price	\$ 1.44	\$ 1.44
Exercise price	\$ 1.89	\$ 1.89
Expected Volatility	93.7%	93.7%
Dividend Yield	0%	0%
Risk-Free Interest Rate	1.86%	1.86%
Expected Term (years)	4.6	0.1

For the fair value determination, the Company computed the historical volatility based on daily pricing observations for a period that corresponds to the expected term of the warrants. The expected term for both valuation dates are based on the remaining contractual term of the warrants. The risk-free interest rates are the U.S. Treasury bond rate as of the valuation dates.

The fair value of these warrants also incorporated the Company's assumptions about future equity issuances and their impact to the price protection feature. For the Tranche 1 warrants the valuation factored in one potential reverse split subsequent to the reverse-split on April 28, 2017 and prior to the expiration of the 5-year term. No reverse split was factored in with respect to valuation of the Tranche 2 warrants as they became expired on October 28, 2017.

7. COMMITMENTS AND CONTINGENCIES

Leases

The Company leases its main operating facility in Hayward, California. The lease was for approximately 14,000 square feet and the lease agreement was due to expire in September 2017. On July 20, 2017, the Company terminated the lease agreement and concurrently entered into a sublease agreement for approximately 8,000 square feet of the same facility. The sublease agreement will expire on August 31, 2019.

In April 2016, the Company leased its second operating facility in Pleasanton, California. The lease is for approximately 1,200 square feet and the lease agreement will expire in May 2019.

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 defined by this collaboration. The Company's royalty obligations as to a particular licensed product will be payable, on a country-by-country and licensed product-by-licensed product basis, for the longer of (a) the date of expiration of the last to expire valid claim within the licensed patents that covers the manufacture, use or sale, offer to sell, or import of such licensed product by the Company or a sublicense in such country or (b) 10 years after the first commercial sale of the applicable licensed product in the applicable country.

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 Sollpura, 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 \$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, 2017. 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.

Litigation

On February 13, 2017, a complaint was filed in the United States District Court for the Northern District of California captioned Brian Clevlen v. Anthera Pharmaceuticals, Inc., et al., Case No. 3:17-cv-715, on behalf of a putative class of the Company's stockholders against the Company and certain of its current and former officers. The complaint asserts claims under sections 10(b) and 20(a) of the Securities Exchange Act of 1934 on behalf of all stockholders that purchased the Company's common stock between February 10, 2015 and December 27, 2016. The complaint alleges that the Company made false or misleading statements and/or omissions with respect to the CHABLIS-SC1 trial and SOLUTION study. The complaint seeks unspecified damages, interest, attorneys' fees, costs, and such other relief at the Court may deem just and proper. On April 17, 2017, Urešomir Čorak, a putative stockholder of the Company, filed a motion to be appointed as lead plaintiff, and to have the law firm of Levi & Korsinsky LLP appointed as lead counsel in the action. On April 17, 2017, a group of putative stockholders of the Company, comprised of Kent Roberts, Kent Roberts FBO Evan Roberts, Kent Roberts Parent FBO Owen Roberts, and Bobby King, filed a motion to be appointed as lead plaintiff, to have the law firm of Lifschitz & Miller LLP appointed as lead counsel, and to have the law firm of Reich Radcliffe & Hoover LLP appointed as liaison counsel in the action. On May 18, 2017, the Court appointed Urešomir Čorak as lead plaintiff, and Levi & Korsinsky LLP as lead counsel in the action. On July 17, 2017, lead plaintiff filed a notice of voluntary dismissal of the action without prejudice.

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. As of September 30, 2017, there were 430 shares of Series X Convertible Preferred Stock issued, outstanding and convertible into 27,296 shares of common stock.

In September 2016, the Company entered into a subscription agreement with certain institutional investors pursuant to which it sold 17,000 Series X units for a purchase price of \$1,000 per unit in a registered direct offering (the "Subscription Agreement"). Each unit consists of one share of Series X Convertible Preferred Stock and a warrant to purchase 15.87 shares of common stock. The conversion price for the Series X Convertible Preferred Stock became fixed on November 16, 2016 at \$15.7536 per share, which represented the VWAP of the Company's common stock over the five full trading days following the date of the Company's initial public announcement of topline and/or efficacy data from the CHABLIS-SC1 study on November 10, 2016. The registered direct offering resulted in gross proceeds of \$17.0 million. The holders of Series X Convertible Preferred Stock do not have any voting rights nor the right to elect any members to the board of directors. The Series X Convertible Preferred Stock has a contingent redemption clause. The Company is not required to issue any shares of common stock upon conversion of any shares of Series X Convertible Preferred Stock to the extent that (i) the aggregate issuance of common stock will be greater than 1,048,229 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"). On April 27, 2017, the shareholders approved a proposal to allow holders of Series X Convertible Preferred Stock to convert their shares of Series X Convertible Preferred Stock that converted into common stock in excess of the Threshold Amount which was 30,890 shares of common stock or 487 shares of Series X Convertible Preferred Stock. As a result, the Series X Preferred shares are no longer redeemable by the holder and the shares were reclassified from temporary to permanent equity in the statement of stockholders' equity. As of September 30, 2017, 16,570 shares of Series X Convertible Preferred Stock have been converted into a total of 1,051,823 shares of common stock. The conversion is reflected as a reduction in Series X Convertible Preferred Stock. An aggregate of \$13.4 million discount has been recognized as a deemed dividend in connection with the conversion of Series X Convertible Preferred stock as of September 30, 2017 and no warrants had been exercised.

The Subscription Agreement also provided the investors the right, but not the obligation to make additional investments. These rights expired unexercised on January 26, 2017.

Common Stock

In March 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.

On April 21, 2016, the Company registered \$25.0 million under the registration statement (File No. 333-210166) for the at-the-market sales agreement with H.C. Wainwright (the "H.C. Wainwright ATM Agreement"). On March 14, 2017, the Company amended the H.C. Wainwright ATM Agreement and reduced the amount registered under the registration statement to \$23 million. In June 2017, in connection with the execution of the 2017 Purchase Agreement, the Company filed a prospectus supplement suspending and reducing all offerings pursuant to the H.C. Wainwright ATM agreement.

On April 27, 2016, the Company registered \$14.4 million under the registration statement (File No. 333-210166) for the equity purchase agreement with LPC (the "2015 Purchase Agreement"). On March 12, 2017, upon the expiration of the 2015 Purchase Agreement, \$13.4 million of unused amount became available under the registration statement. On June 19, 2017, the Company entered into a new equity purchase agreement with LPC, the 2017 Purchase Agreement, and registered \$10.3 million under the registration statement (File No. 333-210166). Pursuant to the 2017 Purchase Agreement, the Company has the right, but not the obligation, to sell up to an aggregate of \$10.0 million in shares of common stock and issue up to 181,708 shares of common stock as a commitment fee to LPC over a period of thirty months. Upon executing the 2017 Purchase Agreement, LPC made an initial purchase of 291,036 shares of common stock for gross proceeds of \$0.5 million. As of September 30, 2017, the Company has sold 1,204,411 shares of common stock for an aggregate cash proceeds of \$1.8 million pursuant to the 2017 Purchase Agreement and issued 131,909 shares of common stock to LPC as commitment fee, leaving a balance of \$8.2 million available for future issuance pursuant to the 2017 Purchase Agreement. The 2017 Purchase Agreement will expire on December 19, 2019.

On September 8, 2016, the Company registered \$22.1 million under the registration statement (File No. 333-210166) for a subscription agreement with certain institutional investors for the sale of convertible preferred stock and issuance of warrants in a registered direct offering.

On March 14, 2017, in connection with a registered direct offering of common stock and warrants, the Company registered \$46.5 million under the registration statement (File No. 333-210166) (the "March 2017 Offering"). During the three months ended June 30, 2017, the exercise price of certain warrants issued in connection with the March 2017 Offering was reduced and therefore resulted in \$17.3 million re-allocated back to the shelf registration statement.

As of September 30, 2017, there was a balance of \$14.4 million available for future issuance under the registration statement (File No. 333-210166).

The S-3 registration statement is subject to Instruction I.B.6. of Form S-3, which imposes a limitation on the maximum amount of securities that the Company may sell pursuant to the registration statement during any twelve-month period. When the Company sells securities pursuant to the registration statement, the amount of securities to be sold plus the amount of any securities the Company has sold during the prior twelve months in reliance on Instruction I.B.6. may not exceed one-third of the aggregate market value of its outstanding common stock held by non-affiliates as of a day during the 60 days immediately preceding such sale, as computed in accordance with Instruction I.B.6. Based on this calculation, the Company expects it will be significantly limited, and likely unable to sell additional securities pursuant to its effective registration statement on Form S-3 for a period of twelve months from March 16, 2017, unless and until the market value of the Company's outstanding common stock held by non-affiliates increases significantly. If the Company cannot sell securities under its shelf registration, the Company may be required to utilize more costly and time-consuming means of accessing the capital markets, which could materially adversely affect its liquidity and cash position.

At September 30, 2017, the Company had reserved the following shares for future issuance:

Convertible Series X preferred stock	27,296
Common stock options outstanding	1,179,986
Common stock warrants outstanding	7,774,815
Common stock options available for future grant under stock option plan	128,616
Common stock available for future grant under ESPP plan	449
Total	<u>9,111,162</u>

Warrants

In connection with a venture debt executed in March 2011, the Company issued a seven-year warrant to the lender for the purchase of 5,022 shares of the Company's common stock at an exercise price of \$384.00 per share. The warrant was immediately exercisable and expires in March 2018. As of September 30, 2017, the warrants remained outstanding and exercisable. These warrants are classified in permanent equity on the Company's consolidated Balance Sheet.

In connection with the issuance of Series X convertible preferred stock in September 2016, the Company issued warrants to certain institutional investors to purchase shares of the Company's common stock. On November 16, 2016, the exercise price and number of shares of common stock underlying the warrants became fixed at \$18.90 and 269,779, respectively. The warrants are exercisable at any time and from time to time after March 13, 2017, and will expire on September 13, 2019. As of September 30, 2017, the warrants remained outstanding. These warrants are classified in permanent equity on the Company's consolidated Balance Sheet.

Pursuant to the underwriting agreement for the sale of common stock and warrants in March 2017, the Company issued 30,000,000 warrants ("Tranche 1 Warrants") at an initial exercise price of \$0.55 per share and 30,000,000 ("Tranche 2 Warrants") at an initial exercise price of \$0.50 per share to the investors to purchase shares of the Company's common stock. The Company did not have sufficient authorized but unissued common stock to issue the warrants at the time the underwriting agreement was executed. On April 28, 2017, with shareholders' approval, the Company effectuated a one-for-eight reverse split of its outstanding common stock. Subsequent to the Reverse Stock Split, the Tranche 1 Warrant shares and exercise prices were adjusted to 3,750,007 and \$4.40, respectively, and the Tranche 2 Warrants shares and exercise price were adjusted to 3,750,007 and \$4.00, respectively. Effective as of May 22, 2017, the Tranche 1 and Tranche 2 Warrants' exercise price were further adjusted to \$1.8918 pursuant to Section 2(c) of the warrant agreements, which was the average VWAP of the five (5) lowest trading days during the fifteen (15) consecutive trading days following the April 28, 2018 reverse stock split. The Tranche 1 Warrants will expire on April 28, 2022. The Tranche 2 Warrants expired on October 28, 2017. These warrants are classified as liabilities on the Company's consolidated Balance Sheet until the warrants are exercised or expired.

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 218,750 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 223,852 shares of its common stock for issuance of awards under the 2013 Plan. Of the shares of common stock reserved for issuance under the 2013 Plan, no more than 93,750 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 781,250 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, 2017 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, 2016.

The following table summarizes stock option activity for the nine months ended September 30, 2017 (in thousands except share and per share information):

	<u>Number of Options</u>	<u>Weighted- Average Exercise Price</u>	<u>Weighted- Average Remaining Contractual Life in Years</u>	<u>Aggregate Intrinsic Value</u>
Balance at December 31, 2016	749,517	\$ 29.82	8.19	\$ —
Granted	697,265	\$ 1.69		
Exercised	—	—		
Cancelled and expired	(34,315)	\$ 31.23		
Forfeited	(232,481)	\$ 34.05		
Balance at September 30, 2017	<u>1,179,986</u>	\$ 12.33	8.65	\$ —
Exercisable at September 30, 2017	<u>382,449</u>	\$ 22.51	7.17	\$ —

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, 2017, there was \$4.43 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 2.21 years.

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

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2017</u>	<u>2016</u>	<u>2017</u>	<u>2016</u>
Expected Volatility	109%	97%	134%	98%
Dividend Yield	0%	0%	0%	0%
Risk-Free Interest Rate	2.02%	1.23%	1.89%	1.45%
Expected Term (years)	6.87	6.02	6.07	5.93
Weighted-average fair value per option	\$ 1.31	\$ 19.58	\$ 1.52	\$ 21.62

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 1,562 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) 3,906 shares of common stock. On January 1, 2017, in accordance with the ESPP’s annual increase provisions, the authorized shares in the ESPP increased by 3,906. On April 27, 2017, the Company’s shareholders approved a one-time increase to the ESPP pool by 27,344 shares and increase the number of shares available for issuance under the Plan 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, starting in January 1, 2018.

Under 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 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:

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2017</u>	<u>2016</u>	<u>2017</u>	<u>2016</u>
Expected Volatility	107%	99%	157%	94%
Dividend Yield	0%	0%	0%	0%
Risk-Free Interest Rate	0.88%	0.40%	0.58%	0.33%
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,	
	2017	2016	2017	2016
Research and development	\$ 261	\$ 454	\$ 1,155	\$ 1,330
General and administrative	707	932	1,768	2,613
Total	<u>\$ 968</u>	<u>\$ 1,386</u>	<u>\$ 2,923</u>	<u>\$ 3,943</u>

10. SUBSEQUENT EVENT

On October 23, 2017, the Company entered into a Securities Purchase Agreement (the "Securities Purchase Agreement") for a private placement (the "Private Placement") with a select group of accredited investors (the "Purchasers"). The Private Placement is structured with two closings. Pursuant to the Securities Purchase Agreement, at the initial closing on October 27, 2017 (the "Initial Closing"), Purchasers purchased 2,306,737 shares of the Company's common stock, par value \$0.001, at \$1.25 per share for gross proceeds of approximately \$2.9 million. Each share of common stock was issued with a warrant to purchase 3.0 additional shares of the Company's common stock at an exercise price of \$1.55 per share. The warrants will become exercisable on the six month and one day anniversary of the Initial Closing and will have a term of five years and six months. At the second closing (the "Second Closing"), Purchasers are expected to purchase 7,625,741 shares of the Company's common stock, par value \$0.001, at \$1.25 per share and 2,067,522 shares of the Company's non-voting Class Y Convertible Preferred Stock, par value \$0.001 (the "Class Y Preferred Stock"), at \$1.25 per share, convertible into 2,067,522 shares of Company common stock upon certain conditions. Each share of common stock or Class Y Preferred Stock will be issued with a warrant that is immediately exercisable to purchase 1.0 additional share of the Company's common stock at an exercise price of \$1.25 per share. The warrants issued in the Second Closing will have a term of five years from their date of issuance. Gross proceeds from the Second Closing are expected to be approximately \$12.1 million.

The Company expects that the aggregate number of voting securities to be sold at the Initial Closing and Second Closing of the private placement shall constitute the sale, issuance or potential issuance by the Company of common stock (or securities convertible into or exercisable into common stock) equal to 20% or more of the voting power outstanding before the Private Placement in contravention of Nasdaq Rule 5635(d)(2). Therefore, after the Initial Closing, the Company intends to solicit approval from holders of the currently outstanding shares of the Company immediately prior to the issuance of the securities in connection with the Second Closing and such Second Closing is contingent upon receiving such stockholder approval. The Company plans to obtain such stockholder approval in the first quarter of 2018.

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, Sollpura and blisibimod. We licensed Sollpura from Eli Lilly & Co ("Eli Lilly") in July 2014. Sollpura 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, or BAFF, which has been shown to be elevated in a variety of B-cell mediated autoimmune diseases, including Immunoglobulin A nephropathy.

We were incorporated in September 2004. We have devoted substantially all 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 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"). We will need substantial additional financing to continue to develop our product candidates, obtain regulatory approvals and to fund operating expenses, which we will seek to raise through public or private equity or debt financings, collaborative or other arrangements with third parties or through other sources of financing. We cannot assure you that such funds will be available on terms favorable to us, if at all. In addition to the normal risks associated with 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 March 2015, we received a research award of up to \$3 million from CFFT for our development of Sollpura. We retain the right to develop and commercialize Sollpura 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. At our discretion, we may choose to fund a particular stage of the Sollpura development plan without CFFT funds. Any CFFT funds not expended on the development program of Sollpura 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, sub licensable, 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 Sollpura in EPI

We initiated the Phase 3 SOLUTION study in the third quarter of 2015. SOLUTION was a randomized, open-label, assessor-blind, non-inferiority, active-comparator study evaluating the efficacy and safety of Sollpura in patients with cystic fibrosis-related exocrine pancreatic insufficiency. This pivotal study enrolled 128 patients in North America, Europe and Israel was intended to evaluate the non-inferiority of Sollpura compared with another commercially available PERT in a population of porcine-derived PERT responders. Topline data announced in December 2016 showed that the study narrowly missed the CFA non-inferiority margin of the primary modified Intent to Treat (mITT) analysis by one percent; however, by additional pre-specified analyses of CFA (mITT-Baseline Observation Carried Forward and Per Protocol), Sollpura met the non-inferiority criterion. The study also confirmed that the ratio of the three enzymes in Sollpura demonstrated an appropriate response in the coefficient of nitrogen absorption (CNA). CNA is a measure of protein digestion and absorption and is a key requirement of our planned US Food and Drug Administration ("FDA") regulatory submission. In March 2017, we announced data from the extension phase of the study, which showed that Sollpura demonstrated comparable maintenance in key measurements of height, weight, and body mass index in addition to being well tolerated throughout the 12-week extension period.

Due to the narrow miss of the SOLUTION study and informed by its data, we initiated a new Phase 3 study (RESULT) in the second quarter of 2017. Similar to the SOLUTION study, the RESULT study is a randomized, open-label, non-inferiority, active-comparator study. Approximately 150 cystic fibrosis patients who are porcine PERT responders will be enrolled in the US, Europe and Israel. Based on data from the analysis from the SOLUTION study, we believe that efficacy in the SOLUTION trial was limited by a restrictive dose optimization paradigm in a population whose dose of lipase at baseline had been optimized for porcine PERTs (but not for Sollpura) and that modification of the dosing paradigm may allow for success in the RESULT study. The RESULT study's design is modified from the SOLUTION study design to account for the design limitations in the SOLUTION study by 1) starting Sollpura dosing as 125% of the pre-study PERT dose, 2) allowing for a more "real life" dose adjustment, as needed, based on signs and symptoms throughout the primary treatment phase of the study, and 3) randomizing the use of acid suppression on a 1-to-1 basis, as is seen in cystic fibrosis patients. The study design was discussed with the FDA in the first quarter of 2017. As of September 30, 2017, the RESULT study has screened more than 50% patients. In July 2017, the Company was informed that the RESULT study had been approved by the Cystic Fibrosis Foundation Therapeutics Development Network (CFF-TDN) Protocol Review Committee. In August 2017, the European Cystic Fibrosis Society Clinical Trial Network (ECFS CTN) Executive Committee approved the RESULT study. We believe the approval of the RESULT study by the CFF-TDN and ECFS CTN may expedite patient recruitment in the U.S and EU. The safety of subjects enrolled in this study will be monitored by independent experts appointed by the CFF-TDN. Top line data from the RESULT study, which will be evaluated after assessment of coefficient of fat absorption after 4 weeks of dosing, is expected in Q1 2018.

A second, smaller Phase 3 study, SIMPLICITY, was initiated in the second quarter of 2016. The SIMPLICITY study utilizes sachets containing Sollpura powder for oral solution. The study was designed in two parts (Part A and Part B). Part A which evaluated the safety and general usability of Sollpura powder for oral solution in 15 patients ≥ 7 years of age, was completed in the fourth quarter of 2016. On December 9, 2016, an independent Data Monitoring Committee evaluated the data from Part A and approved progression to Part B, which will enroll pediatric subjects below 7 years of age. Before we proceed with Part B, we plan to amend the SIMPLICITY study to follow a similar dosing approach as the RESULT study and initiate enrollment in Part B after we report topline from the RESULT study.

During the third quarter of 2016, we initiated the EASY study, which provides continued access to Sollpura for patients in the Sollpura arm who completed the SOLUTION study. We plan to modify this study to allow certain patients completing the RESULT study to have continued access until the Biological License Application ("BLA") for Sollpura is approved by the FDA.

We believe our Sollpura studies may offer potential opportunities for differentiation versus the currently marketed porcine-derived PERTs, including:

- Use of biotechnology-derived high-purity enzymes that are produced by fermentation processes rather than from mammalian organs, the latter of which requires a label warning for potential viral transmission;
- ability to manufacture at a fixed ratio of lipase, protease and amylase that is similar to the enzyme secretions from the human pancreas;
- use of a novel, chemically-modified lipase drug substance that provides resistance to degradation at gastric pH, thereby obviating the need for enteric coating;
- lack of enteric coating allows for potentially fewer and smaller, easy to swallow capsules and adequate storage stability compared with porcine PERTs of an equivalent unit dose strength; and
- a sachet formulation containing Sollpura powder for oral solution which can be easily dissolved into water, and finally provides patients, especially young pediatric patients, with an easy-to-swallow dosing option.

Our Phase 2 Development of Blisibimod for in IgA Nephropathy

In June 2013, we initiated a Phase 2 clinical study, ("BRIGHT-SC") of patients with IgA nephropathy in Asia and Eastern Europe. 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 but less than six grams per 24 hours (1g-6g/24hr). Patients must be receiving standard of care medication including angiotensin converting enzyme inhibitors and angiotensin receptor blockers. 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. Patients were treated for up to 2 years, and all patients had the opportunity to complete at least 60 weeks of treatment. The BRIGHT-SC study enrolled 58 patients.

In March 2015, an interim futility analysis of the 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 to continue to completion as planned.

In June 2016, an interim analysis of the BRIGHT-SC study was conducted after all ongoing patients had completed at least 24 weeks of treatment, and the results 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 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 in patients with other diseases and demonstrated marked reduction after 8 weeks on study.

In December 2016, an additional interim analysis of the BRIGHT-SC study was reported after all ongoing patients had completed at least 48 weeks. In this extension analysis there was again a trend toward slowing the progression of proteinuria with blisibimod.

In August 2017, we received orphan drug designation from the U.S. FDA for blisibimod for the treatment of IgA nephropathy. Additionally, in August 2017, we announced top line data from the completed extension of the BRIGTH-SC study in which all patients had the opportunity to complete at least 60 weeks of treatment and some patients were treated for up to 2 years. Throughout the treatment period and for up to one year of additional follow up off treatment, blisibimod appeared to halt disease progression as measured by the mean estimate of 24-hour urinary protein excretion levels. Specifically, in patients treated with blisibimod, the mean change in proteinuria was stable to trending slightly downward, whereas the mean levels increased for patients in the placebo arm. Additionally, blisibimod showed a trend toward preservation of renal function based upon individual rates of change in estimated glomerular filtration rate (eGFR), with an annualized improvement of +6.2mL/min/1.73 m² per year compared to a worsening of -4.8 mL/min/1.73 m² with placebo. As seen with previous interim analyses of the BRIGTH data, serum immunoglobulins IgA, IgG, and IgM, demonstrated marked reduction throughout the treatment period.

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, because 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 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 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.

Research and Development Expenses

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

We 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, 2017 and 2016 (in thousands):

	Three Months Ended		Nine Months Ended September	
	September 30,		30,	
	2017	2016	2017	2016
Allocated costs:				
Liprotamase	\$ 4,365	\$ 8,386	\$ 13,321	\$ 19,517
Blisibimod	387	3,748	2,703	10,817(1)
Unallocated costs	1,352	1,962	4,915	5,352
Total research and development expenses	\$ 6,104	\$ 14,096	\$ 20,939	\$ 35,686

(1) Offset by \$0.4 million in reimbursable expense for IgA nephropathy from a collaborative partner.

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 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 development may vary significantly over the life of a program because 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;
- the duration of patient follow-up, and
- the uncertainty associated with manufacturing of drug products.

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. To grant marketing approval, the FDA or foreign regulatory agencies must conclude that clinical data establishes the safety and efficacy of our product candidates and that the manufacturing facilities, processes and controls are adequate. Despite our efforts, our product candidates may not offer therapeutic or other improvement over existing, comparable drugs, be proven safe and effective in clinical studies, or meet applicable regulatory standards.

Because 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 general and administrative functions, including executive, finance and business development. Other significant costs include professional fees for legal services, including legal services associated with obtaining and maintaining patents, and costs associated with operating as a public company. 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 this Annual Report on Form 10-K for the year ended December 31, 2016, 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.

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.

We account for equity instruments issued to non-employees in accordance with the provisions of ASC 718 and ASC 505, "Equity." As a result, the non-cash charge to operations for non-employee options with service or other performance criteria is affected each reporting period by changes in the estimated fair value of our common stock, as the underlying equity instruments vest. The two factors which most affect these changes are the price of the common stock underlying stock options for which stock-based compensation is recorded and the volatility of the stock price. If our estimates of the fair value of these equity instruments change, it may have the effect of significantly changing compensation expense

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, which have characteristics of both liabilities and equity. Financial instruments such as warrants that are classified as liabilities are fair valued upon issuance and are re-measured 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 valuation models that require the input of subjective assumptions including stock price volatility, expected life, and the probability of future equity issuances and their impact to the price protection feature.

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 adjust if necessary. Examples of estimated accrued clinical expenses include:

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

We base our accruals related to clinical studies on our estimates of the services received and efforts expended pursuant to contracts with many research institutions, 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.

Results of Operations*Comparison of the Three months ended September 30, 2017 and 2016*

The following table summarizes our research and development expenses for the three months ended September 30, 2017 and 2016 (in thousands, except percentages):

	Three months ended September 30,		\$ Change	% Change
	2017	2016		
Research and development expenses	\$ 6,104	\$ 14,096	\$ (7,992)	(57)%

Research and development expense decreased during the three months ended September 30, 2017 from the same period in 2016 primarily due to lower clinical development expenses as a result of the SOLUTION study in cystic fibrosis patients with exocrine pancreatic insufficiency and CHABLIS clinical studies in patients with systemic lupus erythematosus being substantially completed at the end of 2016, which resulted in reductions in clinical trial expense by \$4.9 million and manufacturing/clinical drug supplies by \$1.9 million.

The following table summarizes our general and administrative expenses for the three months ended September 30, 2017 and 2016 (in thousands, except percentages):

	Three Months Ended September 30,		\$ Change	% Change
	2017	2016		
General and administrative expenses	\$ 1,810	\$ 2,504	\$ (694)	(28)%

General and administrative expenses decreased during the three months ended September 30, 2017 as compared to the same period in 2016 primarily due to an approximately one-third reduction in administrative headcount, which resulted in lower payroll and stock-based compensation expense of \$0.4 million. Furthermore, professional services decreased by \$0.2 million as compared to the same period in 2016 due to lower legal fees.

The following table summarizes our non-operating income (expense) for the three months ended September 30, 2017 and 2016 (in thousands, except percentages):

	Three Months Ended September 30,		\$ Change	% Change
	2017	2016		
Other income (expense)	\$ (43)	\$ (47)	\$ 4	9%
Change in fair value of warrant liability	1,650	169	1,481	876%
Total other income (expense)	\$ 1,607	\$ 122	\$ 1,485	1,217%

Other income (expense) recorded for the three months ended September 30, 2017 is comprised of mainly a change in the fair value of warrant liability. We issued common stock warrants to the investors in connection with a public offering of our common stock in March 2017. The fair value of the liability associated with these warrants was \$5.7 million at June 30, 2017. The fair value decreased to \$4.1 million as of September 30, 2017 due to a decrease in the fair value of the common stock underlying the warrant shares. The decrease is recognized as part of non-operating income in the statement of operations during the three months ended September 30, 2017.

Comparison of the nine months ended September 30, 2017 and 2016

	Nine Months Ended September 30,		\$ Change	% Change
	2017	2016		
License fee revenue	\$ —	\$ 139	\$ (139)	(100)%
Collaborative revenue	—	6	\$ (6)	(100)%
Total revenues	\$ —	\$ 145	\$ (145)	(100)%

We began to recognize revenue in 2015 from the collaborative arrangement we entered into with a collaborative partner in December 2014 for the development of blisibimod. In January 2016, we recorded total revenue of \$0.1 million for the amortization of the license fee revenue and for the reimbursement of FTEs. This collaborative arrangement was terminated effective January 7, 2016 and no collaborative revenue has been recognized subsequent to the termination.

The following table summarizes our research and development expenses for the nine months ended September 30, 2017 and 2016 (in thousands, except percentages):

	Nine Months Ended September 30,		\$ Change	% Change
	2017	2016		
Research and development expenses	\$ 20,939	\$ 35,686	\$ (14,747)	(41)%

Research and development expense decreased during the nine months ended September 30, 2017 from the same period in 2016 primarily due to lower clinical development expenses as a result of the SOLUTION study in cystic fibrosis patients with exocrine pancreatic insufficiency and CHABLIS clinical studies in patients with systemic lupus erythematosus were substantially completed at the end of 2016, which resulted in reductions in clinical trial expense by \$9.3 million and manufacturing/clinical drug supplies by \$3.9 million.

The following table summarizes our general and administrative expenses for the nine months ended September 30, 2017 and 2016 (in thousands, except percentages):

	Nine Months Ended September 30,		\$ Change	% Change
	2017	2016		
General and administrative expense	\$ 6,338	\$ 7,318	\$ (980)	(13)%

General and administrative expenses decreased during the nine months ended September 30, 2017 from the same period in 2016 primarily due to an approximately one-third reduction in administrative headcount implemented in January 2017, which resulted in lower payroll and stock-based compensation expense of \$1.3 million.

The following table summarizes our non-operating income (expense) for the nine months ended September 30, 2017 and 2016 (in thousands, except percentages):

	Nine Months Ended September 30,		\$ Change	% Change
	2017	2016		
Other income (expense)	\$ (74)	\$ (109)	\$ 35	(32)%
Fair value of warrant liability in excess of proceeds from financing	(600)	—	(600)	(100)%
Change in fair value of warrant liability	10,650	169	10,481	6,202%
Total other income (expense)	\$ 9,976	\$ 60	\$ 9,916	16,527%

Other income (expense) recorded for the nine months ended September 30, 2017 is comprised of mainly a change in fair value of warrant liability. In connection with a direct offering of our common stock in March 2017, we issued common stock warrants to the investors. The initial fair value of the liability associated with these warrants was \$14.7 million. The fair value decreased to \$4.1 million as of September 30, 2017 due to a decrease in the fair value of the common stock underlying the warrant shares. The decrease is recognized as part of non-operating income in the statement of operations.

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, 2017, we had cash and cash equivalents of approximately \$6.1 million. On October 23, 2017, we entered into a Securities Purchase Agreement for a private placement our common stock and warrants for potentially \$15 million in gross proceeds. The private placement is structured with two closings. The initial closing was completed on October 27, 2017 for gross proceeds of \$2.9 million. The second closing for gross proceeds of \$12.1 million is contingent on stockholder approval pursuant to Nasdaq Rule 5635(d)(2). We intend to solicit stockholder approval in the first quarter of 2018.

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

In March 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 its securities, including common stock, preferred stock, debt securities and/or warrants.

On April 21, 2016, we registered \$25.0 million under the registration statement (File No. 333-210166) for the at-the-market sales agreement with H.C. Wainwright (the "H.C. Wainwright ATM Agreement"). On March 14, 2017, we amended the H.C. Wainwright ATM Agreement and reduced the amount registered under the registration statement to \$23 million. In June 2017, in connection with the execution the 2017 Purchase Agreement, we filed a prospectus supplement suspending and reducing all offerings pursuant to the H.C. Wainwright ATM agreement.

On April 27, 2016, we registered \$14.4 million under the registration statement (File No. 333-210166) for the equity purchase agreement with LPC (the "2015 Purchase Agreement"). On March 12, 2017, upon the expiration of the 2015 Purchase Agreement, \$13.4 million of unused amount became available under the registration statement. On June 19, 2017, we executed an equity purchase agreement with LPC (the "2017 Purchase Agreement") to sell to LPC up to an aggregate of \$10.0 million in shares of common stock and issue up to 181,708 shares of our common stock as a commitment fee to LPC over a period of thirty months. As of September 30, 2017, we have sold 1,204,411 shares of common stock for an aggregate cash proceeds of \$1.8 million pursuant to the 2017 Purchase Agreement and issued 131,909 shares of common stock to LPC as commitment fee, leaving a balance of \$8.2 million available for future issuance pursuant to the 2017 Purchase Agreement. The 2017 Purchase Agreement will expire on December 19, 2019.

On September 8, 2016, we registered \$22.1 million under the registration statement (File No. 333-210166) for a subscription agreement with certain institutional investors for the sale of convertible preferred stock and issuance of warrants in a registered direct offering.

On March 14, 2017, in connection with a registered direct offering of common stock and warrants, we registered \$46.5 million under the registration statement (File No. 333-210166) (the "March 2017 Offering"). During the three months ended September 30, 2017, the exercise price of certain warrants issued in connection with the March 2017 Offering was reduced which resulted in \$17.3 million re-allocated back to the shelf registration statement.

As of September 30, 2017, there was a balance of \$14.4 million available for future issuance under the registration statement.

On October 23, 2017, the Company entered into a definitive agreement with certain accredited investors in connection with a private placement of equity securities (the "Private Placement"). The Private Placement is expected to have two closings. The first closing occurred on October 27, 2017 and resulted in gross proceeds of approximately \$2.9 million. The second closing, contingent upon the requisite shareholder approval pursuant to Nasdaq Rule 5635(d), is expected to result in gross proceeds of \$12.1 million. The Company expects to receive such shareholder approval in the first quarter of 2018. If we are unable to obtain shareholder approval for the transaction, or are otherwise unable to complete the second closing, we will need to seek other sources of financing, and there can be no assurance that we will be able to do so on favorable terms, or at all.

We will need substantial additional financing to continue the development of our 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 us if at all, which raises substantial doubt about our ability to continue as a going concern as of the date of this report and that is not alleviated after consideration of management's plans to mitigate such concerns. The financial statements do not include any adjustments that might result from the outcome of this uncertainty. If adequate funds are not available, we may be required to delay, reduce the scope of, or eliminate one or more of our clinical trials. We plan to meet our capital requirements primarily through issuances of equity securities, future partnerships, debt financing, and in the longer term, revenue from product sales. Failure to generate revenue or raise additional capital would adversely affect our ability to achieve our intended business objectives.

Cash Flows

Comparison of Nine months ended September 30, 2017 and 2016

Cash flows during the nine months ended September 30, 2017 and 2016 consisted of the following (in thousands):

	September 30,	
	2017	2016
Net cash used in operating activities	\$ (30,640)	\$ (36,691)
Net cash used in investing activities	—	(952)
Net cash provided by financing activities	15,873	23,262
Total	\$ (14,767)	\$ (14,381)

During the nine months ended September 30, 2017 and 2016, our operating activities used cash of \$30.6 million and \$36.7 million, respectively, primarily resulting from our net losses and changes in our working capital accounts, adjusted for non-cash items including stock based compensation and change in the fair value of warrant liability.

No cash was provided by nor used in investing activities during the nine months ended September 30, 2017. 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 Sollpura.

During the nine months ended September 30, 2017, cash provided by financing activities was \$15.9 million, which was driven by net proceeds received from the sale of our common stock and warrants. During the same period in 2016, cash provided by financing activities was \$23.3 million, which was driven by net proceeds from the sale of stock pursuant to an equity purchase agreement and an at-the-market sales agreement.

Contractual Obligations and Commitments

We have lease obligations consisting of two operating leases for our operating facilities that expire in August 2019 and May 2019, respectively.

The following table summarizes our estimated scheduled future minimum contractual obligations and commitments as of September 30, 2017 (in thousands):

Contractual Obligations	Payment Due by Period				
	< 1 year	1-3 years	3-5 years	> 5 years	Total
Facility Leases	\$ 191	154	\$ —	\$ —	\$ 345

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 sub-licensee 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.

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 and market prices. 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, 2017, we did not have any material derivative financial instruments. The fair value of our cash and cash equivalents was \$6.1 million as of September 30, 2017.

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, 2017. 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 period covered by this report. Based on the foregoing, our Chief Executive Officer and Principal Accounting Officer concluded that, as of September 30, 2017, 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, 2017 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

On February 13, 2017, a complaint was filed in the United States District Court for the Northern District of California captioned Brian Clevlen v. Anthera Pharmaceuticals, Inc., et al., Case No. 3:17-cv-715, on behalf of a putative class of the Company's stockholders against the Company and certain of its current and former officers. The complaint asserts claims under sections 10(b) and 20(a) of the Securities Exchange Act of 1934 on behalf of all stockholders that purchased the Company's common stock between February 10, 2015 and December 27, 2016. The complaint alleges that the Company made false or misleading statements and/or omissions with respect to the CHABLIS-SC1 trial and SOLUTION study. The complaint seeks unspecified damages, interest, attorneys' fees, costs, and such other relief at the Court may deem just and proper. On April 17, 2017, Urešomir Čorak, a putative stockholder of the Company, filed a motion to be appointed as lead plaintiff, and to have the law firm of Levi & Korsinsky LLP appointed as lead counsel in the action. Also on April 17, 2017, a group of putative stockholders of the Company, comprised of Kent Roberts, Kent Roberts FBO Evan Roberts, Kent Roberts Parent FBO Owen Roberts, and Bobby King, filed a motion to be appointed as lead plaintiff, to have the law firm of Lifschitz & Miller LLP appointed as lead counsel, and to have the law firm of Reich Radcliffe & Hoover LLP appointed as liaison counsel in the action. On May 18, 2017, the Court appointed Urešomir Čorak as lead plaintiff, and Levi & Korsinsky LLP as lead counsel in the action. On July 17, 2017, lead plaintiff filed a notice of voluntary dismissal of the action without prejudice.

ITEM 1A. RISK FACTORS

You should carefully consider the risks described below, together with the other information contained in this Quarterly Report on Form 10-Q, including the consolidated financial statements and the related notes that appear at the end of this report. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected.

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 assets in the clinical 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. As of September 30, 2017, we had an accumulated deficit of \$424.5 million. Substantially all our losses resulted from costs incurred with our product development programs and from general and administrative costs associated with our operations.

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 believe there is substantial doubt about our ability to continue as a going concern as we do not currently have sufficient cash resources to fund our operations through 12 months from the filing date of the Form 10-Q. Our financial statements do not include any adjustments that may result from the outcome of this uncertainty. If we are unable to continue as a viable entity, our stockholders may lose their entire investment.

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 as we:

- continue clinical development of Sollpura and blisibimod;
- manufacture our drug product candidates for use in clinical trials and to support future applications for marketing approval; and
- hire additional clinical, scientific and management personnel, if needed.

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 cost of manufacturing 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.

At September 30, 2017, our capital resources consisted of cash and cash equivalents of \$6.1 million. On October 23, 2017, the Company entered into a definitive agreement with certain accredited investors in connection with a private placement of equity securities (the "Private Placement"). The Private Placement is expected to have two closings. The first closing occurred on October 27, 2017 and resulted in gross proceeds of approximately \$2.9 million. The second closing, contingent upon the requisite shareholder approval pursuant to Nasdaq Rule 5635(d), is expected to result in gross proceeds of \$12.1 million. The Company expects to receive such shareholder approval in the first quarter of 2018. If we are unable to obtain shareholder approval for the transaction, or are otherwise unable to complete the second closing, we will need to seek other sources of financing, and there can be no assurance that we will be able to do so on favorable terms, or at all.

We will need substantial additional financing to continue the development of our 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 us, if at all, which raises substantial doubt about our ability to continue as a going concern as of the date of this report and that is not alleviated after consideration of management's plans to mitigate such concerns. The financial statements do not include any adjustments that might result from the outcome of this uncertainty. If adequate funds are not available, we may be required to delay, reduce the scope of, or eliminate one or more of its clinical trials. We plan to meet our capital requirements primarily through issuances of equity securities, future partnerships, debt financing, and in the longer term, revenue from product sales. Failure to generate revenue or raise additional capital would adversely affect our ability to achieve its intended business objectives.

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.

We will not be able to meet our cash requirements beyond the first quarter of 2018 without obtaining additional capital from external sources if the Second Closing of the Private Placement does not occur, and if we are unable to do so, we may not be able to continue as a going concern.

We anticipate that our cash and cash equivalents of \$6.1 million as of September 30, 2017, together with the proceeds from the First Closing of the Private Placement will meet our cash requirements into the fourth quarter of 2017. If the Second Closing occurs, we anticipate we will be able to meet our cash requirements into the second quarter of 2018. However, in order for us to continue as a going concern beyond the fourth quarter of 2017 (if the Private Placement Second Closing does not occur) or beyond the second quarter of 2018 (if the Private Placement Second Closing does occur), we will be required to obtain capital from external sources.

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. 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 full-time employees ("FTEs") was recorded as collaborative revenues as incurred. 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. Because of an early termination of the Zenyaku Agreement, we did not recognize revenues under the Zenyaku Agreement beyond January 2016.

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 Sollpura, our product candidate for the treatment of patients with low digestive enzyme levels 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 IgA nephropathy, or other indications related to the development of blisibimod;
- obtain regulatory approval for Sollpura and blisibimod;
- if regulatory approvals are obtained, begin the commercial manufacturing of our product candidates with third-party manufacturers;
- launch commercial sales and effectively market our product candidates, either independently or in strategic collaborations with third parties; and
- achieve broad market acceptance of our product candidates in the medical community and with third-party payors.

Our product candidates are subject to the risks of failure inherent in the development of therapeutics based on new technologies. Our product candidates have failed in clinical studies because we were unable to demonstrate that they were effective. Furthermore, our products candidates could fail if they cause unacceptable adverse effects in the patients we treat. Failure of our product candidates in clinical studies will 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. Our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern.

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 Sollpura and blisibimod clinical materials, including data to support the application for marketing approval, formulation development and product enhancement;
- non-clinical activities that we may pursue parallel to our clinical studies;
- 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

The amount of cash and other sources of capital available to us, including the net proceeds from the Private Placement, are not expected to be sufficient to fund our expected needs for the next twelve months, which results in substantial doubt about our ability to continue as a going concern. 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 Sollpura. Pursuant to the Lilly Agreement, we are required to make various milestone payments upon our achievement of certain regulatory and commercial objectives for any Sollpura 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 Sollpura. 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 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, Sollpura and blisibimod, and performing research and development. We have not yet demonstrated an ability to obtain regulatory approval for or commercialize a product candidate. Consequently, any predictions about our future performance may not be as accurate as they could be if we had a history of successfully developing and commercializing pharmaceutical products.

Risks Associated with Development and Commercialization of Our Product Candidates

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

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

Our product candidates are prone to the risks of failure inherent in drug development. Before obtaining regulatory approvals for the commercial sale of any product 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 U.S. FDA and, with respect to approval in other countries, similar regulatory authorities in those countries, that the product candidates are safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate. Despite our efforts, our product candidates may not:

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

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

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

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

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

Delays in the commencement or completion of clinical testing could significantly affect our product development costs. We do not know whether planned clinical studies will begin on time or be completed on schedule, if at all. The commencement and completion of clinical studies can be delayed for numerous 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 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 initiated a clinical study, but may withdraw due to treatment protocol, adverse effects from the therapy, lack of efficacy from the treatment, personal issues or who are lost to further follow-up.

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

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

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

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

Any delays in the development and validation of drug manufacturing processes for commercialization 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 drug manufacturing could significantly affect our readiness to commercialize our drug products. We do not know whether planned manufacturing processes will be successful or be completed on schedule. The development and validation of drug manufacturing processes can be delayed for numerous reasons, including delays related to:

- reaching agreement on acceptable terms with prospective chemical manufacturing organizations, or CMOs, the terms of which can be subject to extensive negotiation;
- lack of availability of raw materials;
- lack of adequate funding to continue the development and validation of drug manufacturing processes;
- inability to demonstrate robustness of the process at our CMOs;
- equipment failure that results in the loss of some or all of a batch of manufactured drug;
- irregularities or errors in shipping between manufacturing facilities or distributors that result in the loss of some or all of a batch of drug; and
- uncontrollable natural forces that may render the CMO temporarily or permanently incapable of manufacturing our drugs.

Drug manufacturing may also be delayed, suspended or changed as a result of advice from regulatory authorities such as the U.S. FDA or other international regulatory authorities due to a number of factors, including:

- failure of the CMO to conform with appropriate quality standards; and
- inspection of the CMO by the U.S. FDA or other regulatory authorities resulting in the imposition of a manufacturing hold.

Additionally, changes in regulatory requirements and policies may occur and we may need to amend our manufacturing plans or processes to reflect these changes. Amendments to the processes may impact the costs, timing or successful completion development and validation of the drug manufacturing processes for commercialization. If we experience delays in completion of, or if we, the U.S. FDA or other regulatory authorities 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, product commercialization may also ultimately lead to the denial of regulatory approval of our product candidates. Also, if product commercialization is delayed, our competitors may be able to bring products to market before we do, and the commercial viability of our product candidates could be significantly reduced.

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

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

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

We are party to the Amgen Agreement, which provides for the exclusive worldwide licenses of the compositions of matter and methods of use for blisibimod, as well as non-exclusive worldwide licenses of compositions of matter and methods of use relating to peptibodies generally. We are also party to the Lilly Agreement, which provides for an exclusive worldwide license of the compositions of matter, formulation, and methods of use patents for Sollpura. 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 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 also highly competitive. There are currently several marketed products for EPI caused by cystic fibrosis, including Creon marketed by AbbVie, Inc., Pancreaze by Janssen Pharmaceuticals, Inc., Pertye by Cornerstone 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; Alcresta Therapeutics markets RELiZORB, a lipase enzyme cartridge designed for use by adults receiving nutrition by enteral tube who have trouble digesting and absorbing ingested fats; and AzurRx Biopharma's MS1819 lipase is currently being tested in a Phase 2 trial in patients with chronic pancreatitis.

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

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

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

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

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

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

Any of these events could prevent us from achieving or maintaining market approval and 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 clinical and drug manufacturing data have been generated and submitted to the appropriate regulatory authorities, and they have reviewed and approved the applications for such product candidate. We cannot assure you that the regulatory agencies will complete their review processes in a timely manner or that we will obtain regulatory approval for any product candidates we develop. Satisfaction of regulatory requirements typically takes many years, is dependent upon the type, complexity and novelty of the product and requires the expenditure of substantial resources. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action or changes in U.S. FDA policy during the period of product development, clinical studies and U.S. FDA regulatory review.

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

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

- issue warning letters or untitled letters;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;

- suspend any ongoing clinical studies;
- refuse to approve pending applications or supplements to applications filed by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products, refuse to permit the import or export of products, or require us to initiate a product recall.

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

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

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

- demonstration of clinical safety and efficacy compared to other products;
- the relative convenience, ease of administration and acceptance by physicians and payors of our product candidates;
- the prevalence and severity of any adverse effects;
- limitations or warnings contained in a product's U.S. FDA-approved labeling;
- availability of alternative treatments;
- pricing and cost-effectiveness;
- the effectiveness of our or any future collaborators' sales and marketing strategies;
- our ability to obtain and maintain sufficient third-party coverage or reimbursement from government health care programs, including Medicare and Medicaid; and
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage.

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

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

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

We rely on our manufacturers to purchase from third-party suppliers the materials necessary to produce drug product for our clinical studies. There are a small number of suppliers, and in some instances, a single supplier for certain capital equipment and raw materials that we use to manufacture drug product. Such suppliers may not sell these raw materials 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 and distribution of pharmaceutical products and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. To market any products that may be approved by the U.S. FDA, we must build our sales, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate product revenue and may not become profitable. We will be competing with many companies that currently have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

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

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

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

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 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.

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

Specifically, in both the United States and some foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the health care system in ways that could affect our ability to sell our products profitably. In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the Health Care Reform Law, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

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

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

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

In some foreign countries, including major markets in the 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.

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. Craig Thompson, our Chief Executive Officer, Dr. William R. Shanahan, our Chief Medical Officer, Dr. Renee Martin, our Senior Vice President, Medical Sciences, 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.

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

We are subject to securities litigation, which is expensive and could divert management attention.

Our share price has been and may continue to be volatile. Companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We are a target of this type of litigation. For example, on February 13, 2017, a complaint was filed in the United States District Court for the Northern District of California captioned Brian Clevlen v. Anthera Pharmaceuticals, Inc., et al., Case No. 3:17-cv-715, on behalf of a putative class of the Company's stockholders against the Company and certain of its current and former officers that was voluntarily dismissed, as discussed in Item 3. Legal Proceedings. Litigation of this type could result in substantial costs and diversion of management's attention and resources, which could adversely impact our business. Any adverse determination in litigation could also subject us to significant liabilities.

Our common stock is currently at risk for delisting from NASDAQ. Delisting could adversely affect the liquidity of our common stock and the market price of our common stock could decrease.

Our common stock is currently listed on The NASDAQ Global Market ("NASDAQ"). NASDAQ has minimum requirements that a company must meet to remain listed on NASDAQ. These requirements include maintaining a minimum closing bid price of \$1.00 per share under Listing Rule 5450(a)(1) and maintaining stockholders' equity at above \$10 million or market value at above \$50 million, pursuant to Nasdaq Listing Rules 5450(a) and 5450(b), respectively. On May 15, 2017, we received a letter from NASDAQ informing us that our most recent Form 10-Q for the period ended March 31, 2017 reported stockholders' equity fell below the minimum of \$10 million for continued inclusion under Listing Rule 5450(b)(1)(A). We submitted a compliance plan to NASDAQ on June 28, 2017. Based on our submission, NASDAQ has determined to grant us an extension until November 13, 2017 to regain compliance with Listing Rule 5450 (b)(1)(A). After the expiration of the extension period, we plan to submit a request to a Hearings Panel (the "Panel") for further extension pursuant to procedures set forth in the Nasdaq Listing 5800 Series. A hearing request will stay the suspension of our stock pending the Panel's decision.

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

If our common stock is not listed on NASDAQ or another national exchange, the trading price of our common stock is below \$5.00 per share and we have net tangible assets of \$6.0 million or less, the open-market trading of our common stock will be subject to the "penny stock" rules promulgated under the Securities Exchange Act of 1934, as amended. If our shares become subject to the "penny stock" rules, broker-dealers may find it difficult to effectuate customer transactions and trading activity in our securities may be adversely affected. Under these rules, broker-dealers who recommend such securities to persons other than institutional accredited investors must:

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

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

Our stock price has been and will likely continue to be volatile, which could result in the decline of the value of your investment in our common stock or class action litigation against us and our management, which could cause us to incur substantial costs and divert management's attention and resources.

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;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- 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;
- delisting from the NASDAQ Global Market; 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. Securities litigation against us, including as discussed elsewhere in this form 10-Q, could result in substantial expenses and the diversion of our management's attention and resources and could harm our business, operating results and financial condition.

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

As of the date of this report, we have 13,849,678 shares of common stock, 10,945,019 shares of warrants, and 1,036,121 shares of stock options outstanding. Furthermore, on October 23, 2017, we entered into a Securities Purchase Agreement for a private placement of securities with a select group of accredited investors. The private placement is structured with two closings. The initial closing was completed on October 27, 2017. The second closing for 7,625,741 shares of our common stock and 2,067,522 shares of our non-voting Class Y Convertible Preferred Stock, convertible into 2,067,522 shares of our common stock upon certain conditions, is subject to stockholders approval, which we plan to obtain in the first quarter of 2018. Each share of common stock or Class Y Preferred Stock will be issued with a warrant that is immediately exercisable to purchase 1.0 additional share of our common stock for a total of 9,693,263 shares of common stock. If the warrants and options were exercised, they will result in significant additional shares becoming available for sale. Sales by these stockholders or option holders of a substantial number of shares could reduce the market price of our common stock. Moreover, certain holders of shares of common stock will have rights, subject to some conditions, to require us to file registration statements covering the shares they currently hold, or to include these shares in registration statements that we may file for ourselves or other stockholders.

In addition, we may sell shares of stock pursuant to the 2017 Purchase Agreement executed in June 2017 under which we have the right, but not obligation, to sell up to an aggregate of \$10.0 million in shares of our common stock and issue up to 181,807 in shares of our common stock as commitment fee to LPC. There is \$8.2 million available for future issuance pursuant to the equity purchase agreement as of September 30, 2017. The 2017 Purchase Agreement will expire on December 19, 2019.

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.

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

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

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

We may be unable to issue securities under our shelf registration statement, which may have an adverse effect on our liquidity.

We have filed a shelf registration statement on Form S-3 with the SEC. The registration statement is subject to Instruction I.B.6. of Form S-3, which imposes a limitation on the maximum amount of securities that we may sell pursuant to the registration statement during any twelve-month period. When we sell securities pursuant to the registration statement, the amount of securities to be sold plus the amount of any securities we have sold during the prior twelve months in reliance on Instruction I.B.6. may not exceed one-third of the aggregate market value of our outstanding common stock held by non-affiliates as of a day during the 60 days immediately preceding such sale, as computed in accordance with Instruction I.B.6. Based on this calculation, we expect that we will be significantly limited, and likely unable to sell additional securities pursuant to our effective registration statement on Form S-3 for a period of twelve months from March 16, 2017, unless and until the market value of our outstanding common stock held by non-affiliates increases significantly. If we cannot sell securities under our shelf registration, we may be required to utilize more costly and time-consuming means of accessing the capital markets, which could materially adversely affect our liquidity and cash position.

Risks Related to Our Intellectual Property

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

We hold license rights to numerous U.S., European ("EP"), and non-EP foreign patents and patent applications relating to blisibimod and Sollpura. Our Sollpura 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., as well as U.S. and Patent Cooperation Treaty ("PCT") patent applications owned by us.

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

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

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

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

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

We depend in part on our licensors to protect the proprietary rights covering blisibimod and Sollpura. 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 Amendments and similar foreign legislation to extend our licensed patent terms and/or we do not obtain market exclusivity for our product candidates, our business will be materially harmed.

The Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments, provides for an extension of patent term for drug compounds for a period of up to five years to compensate for time spent in clinical testing and the regulatory approval process. If the USPTO grants a five-year patent term extension for liprotamase and for blisibimod, and if we continue to have rights under our license agreements with respect to both, our exclusive rights to one of liprotamase's U.S. composition of matter patents could extend until 2030 or 2033, and our exclusive rights to one of blisibimod's U.S. composition of matter patents could extend until 2027 or 2028. In Europe, similar legislative enactments allow patent terms in the European Union to be extended for up to five years through the grant of a Supplementary Protection Certificate. If each European country where we seek such extension grants a five-year extension for liprotamase and for blisibimod, and if we continue to have rights under our license agreements with respect to both, our exclusive rights to liprotamase's European composition of matter patents could extend until 2026 or 2030, and our exclusive rights to blisibimod's European composition of matter patents could extend until 2027 in those European countries.

However, we may not be granted an extension in a particular country if we, for example, fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the applicable time period of the extension or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration of the term of any such extension is less than we request, our competitors, including manufacturers of generic alternatives, may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially.

Further, since neither liprotamase nor blisibimod have been previously approved in the U.S., both may be eligible for 12 years of biologic data exclusivity from the U.S. FDA. During this data exclusivity period, competitors are barred from relying on the innovator biologic's safety and efficacy data to gain approval. Similarly, the European Union provides that companies who receive regulatory approval for a new biologic will have a 10-year period of data exclusivity for that biologic (with the possibility of a further one-year extension) in most EU countries, beginning on the date of such European regulatory approval, regardless of when the European composition of matter patent covering such biologic expires. A generic version of the approved drug may not be marketed or sold during such market exclusivity period. The law governing biologic data exclusivity in the U.S. is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement the Biologics Price Competition and Innovation Act of 2009 may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for liprotamase or blisibimod. For example, there is a risk that the 12-year period of exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider liprotamase or blisibimod to be a reference product for competing products, potentially creating the opportunity for competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for liprotamase or blisibimod in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

There is no assurance that we will receive extensions for our patents under the Hatch-Waxman Amendment or similar foreign legislation, or that we will receive data exclusivity or other exclusive marketing rights. If we fail to receive such extensions or exclusivities, or if we receive extensions or exclusivity periods that are materially shorter than expected, our ability to prevent competitors from manufacturing, marketing and selling biosimilars 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.

ITEM 6. EXHIBITS

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

Number	Description
3.1	Certificate of Designation of Preferences, Rights and Limitations of Class Y Convertible Preferred Stock, dated October 24, 2017 (filed as Exhibit 3.1 to the registrant's Form 8-K filed with the SEC on October 25, 2017 and incorporated herein by reference).
10.1	Securities Purchase Agreement, dated October 23, 2017, by and among the Company and the Purchasers (filed as Exhibit 10.1 to the registrant's Form 8-K filed with the SEC on October 25, 2017 and incorporated herein by reference).
10.2	Registration Rights Agreement, dated October 23, 2017, by and among the Company and the Purchasers (filed as Exhibit 10.2 to the registrant's Form 8-K filed with the SEC on October 23, 2017 and incorporated herein by reference).
10.3	Form of Warrant to Purchase Common Stock (filed as Exhibit 10.3 to the registrant's Form 8-K filed with the SEC on October 23, 2017 and incorporated herein by reference).
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.
32.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as adopted pursuant Section 906 of the Sarbanes-Oxley Act of 2002.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.

SIGNATURES

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

ANTHERA PHARMACEUTICALS, INC.

November 8, 2017

By: /s/ J. Craig Thompson
J. Craig Thompson
Chief Executive Officer
(Principal Executive Officer)

November 8, 2017

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

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

I, J. Craig Thompson, 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 8, 2017

/s/ J. Craig Thompson

J. Craig Thompson
Chief Executive Officer
(Principal Executive Officer)

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

I, May Liu, certify that:

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

Date: November 8, 2017

/s/ May Liu

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

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

I, J. Craig Thompson, 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, 2017 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.

November 8, 2017

By: /s/ J. Craig Thompson
J. Craig Thompson
Chief Executive Officer
(Principal Executive Officer)

**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, 2017 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.

November 8, 2017

By: /s/ May Liu
May Liu
Senior Vice President, Finance & Administration
(Principal Financial Officer)
