Anthera Pharmaceuticals Inc
Form 10-Q
May 15, 2018

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 March 31, 2018

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

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

_____

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 Accelerated filer

Non-accelerated filer	Smaller reporting company
(Do not check if a 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 April 30, 2018 the number of outstanding shares of the registrant’s common stock, par value $0.001 per share, was 26,179,302.

ANTHERA PHARMACEUTICALS, INC.

FORM 10-Q FOR THE QUARTER ENDED MARCH 31, 2018

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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	March 31, 2018	December 31, 2017 (1)
Current assets:		
Cash and cash equivalents	$ 8,086	$ 2,196
Prepaid expenses and other current assets	653	995
Total current assets	8,739	3,191
Property and equipment — net	72	482
TOTAL	$ 8,811	$ 3,673
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,845	$ 1,832
Accrued clinical expenses	756	1,785
Accrued liabilities	45	28
Accrued payroll and related costs	—	1,066
Total current liabilities	2,646	4,711
Warrant liability	704	4,457
Total liabilities	3,350	9,168
Commitments and Contingencies (Note 6)		
Stockholders' equity (deficit) :		
Series X Convertible Preferred Stock, $0.001 par value, 5,000,000 shares authorized; 0 and 430 shares issued and outstanding as of March 31, 2018 and December 31, 2017, respectively	—	333
Common stock, $0.001 par value, 100,000,000 shares authorized; 26,179,302 and 13,854,491 shares issued and outstanding as of March 31, 2018 and December 31, 2017, respectively	26	14
Additional paid-in capital	447,587	428,586
Accumulated deficit	(442,152)	(434,428)
Total stockholders' equity (deficit)	5,461	(5,495)
TOTAL	$ 8,811	$ 3,673

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

(1) Derived from audited Financial Statements.

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ANTHERA PHARMACEUTICALS, INC.

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

	Three Months Ended March 31,	
	2018	2017
OPERATING EXPENSES		
Research and development	7,468	7,801
General and administrative	3,503	2,903
Research award	—	(100)
Total operating expenses	10,971	10,604
LOSS FROM OPERATIONS	(10,971)	(10,604)
OTHER EXPENSE:		
Other income (expense)	(43)	(3)
Fair value of warrant liability in excess of proceeds from financing	—	(600)
Change in fair value of warrant liability	3,290	—
Total other income (expense)	3,247	(603)
NET LOSS	$(7,724)	$(11,207)
Deemed dividends attributable to preferred stock	(1,540)	(2,503)
Net loss applicable to common stockholders	$(9,264)	$(13,710)
Net loss per share applicable to common stockholders — basic and diluted (1)	$(0.42)	$(2.03)
Weighted-average number of shares used in per share calculation — basic and diluted (1)	22,166,869	6,759,567

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.

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

	Series X Convertible Preferred Stock		Class Y Convertible Preferred Stock		Common Stock				
	Shares	Amount	Shares	Amount	Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
Balance at December 31, 2017	430	$ 333	-	$ -	13,854,491	$ 14	$ 428,586	$ (434,428)	$ (5,495)
Issuance of common stock pursuant to employee stock purchase plan	-	-	-	-	27,630	-	40	-	40
Share-based compensation related to equity awards	-	-	-	-	-	-	3,266	-	3,266
Issuance of common stock pursuant to exercise of warrants	-	-	-	-	1,902,683	2	2,992	-	2,994
Issuance of common stock pursuant to an equity purchase agreement, net of issuance cost of $16	-	-	-	-	673,939	1	1,308	-	1,308
Issuance of common stock for cash at $1.25 per share in a private placement, net of issuance cost of $450	-	-	-	-	7,625,741	7	4,771	-	4,779
Issuance of warrants pursuant to a private placement, net of issuance cost of	-	-	-	-	-	-	4,999	-	4,999

$471 Issuance of Class Y convertible preferred stock for cash at $1.25 per share in a private placement	-	-	2,067,522	1,416	-	-	(122)	-	1,294
Beneficial conversion feature on Class Y convertible preferred stock	-	-	-	(1,416)	-	-	1,416	-	-
Deemed dividend attributable to beneficial conversion feature on Class Y convertible preferred stock	-	-	-	1,416	-	-	(1,416)	-	-
Conversion of Class Y convertible preferred stock into common stock	-	-	(2,067,522)	(1,416)	2,067,522	2	1,414	-	-
Conversion of Series X convertible preferred stock into common stock	(430)	(333)	-	-	27,296	-	333	-	-
Net loss	-	-	-	-		-		(7,724)	(7,724)
Balance at March 31, 2018	-	$ -	-	$ -	26,179,302	$ 26	$ 447,587	$ (442,152)	$ 5,461

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.

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ANTHERA PHARMACEUTICALS, INC.

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

	Three Months Ended March 31,	
	2018	2017
CASH FLOW FROM OPERATING ACTIVITIES:		
Net loss	$ (7,724)	$ (11,207)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	161	45
Stock-based compensation expense	3,304	1,086
Fair value of warrant liability in excess of proceeds from financing	—	600
Change in fair value of warrant liability	(3,290)	—
Changes in assets and liabilities:		
Accounts receivable	—	(100)
Prepaid expenses and other assets	342	(256)
Accounts payable	(97)	(2,023)
Accrued clinical expenses	(1,029)	(1,659)
Accrued liabilities	18	695
Accrued payroll and related costs	(1,066)	(1,510)
Net cash used in operating activities	(9,381)	(14,329)
INVESTING ACTIVITIES:		
Proceeds from disposal of property and equipment	358	—
Net cash provided by investing activities	358	—
FINANCING ACTIVITIES:		
Net proceeds from issuance of common stock, preferred stock and warrants pursuant to equity offering	11,075	14,100
Net proceeds from issuance of common stock pursuant to an equity purchase agreement	1,307	—
Net proceeds from issuance of common stock pursuant to exercise of warrants	2,531	—
Net proceeds from issuance of common stock pursuant to exercise of stock options and employee stock purchase plan	—	38
Net cash provided by financing activities	14,913	14,138
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	5,890	(191)
CASH AND CASH EQUIVALENTS — Beginning of period	2,196	20,843
CASH AND CASH EQUIVALENTS — End of period	$ 8,086	$ 20,652
SUPPLEMENTAL CASH DISCLOSURES OF CASH FLOW INFORMATION		
Non-cash financing activities:		
Issuance of common stock as a commitment fee pursuant to an equity purchase agreement	$ 16	$ —
Fair value of warrants issued in connection with equity offering	$ —	$ 14,700

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

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

1. BUSINESS OF THE COMPANY

Description of Business

Anthera Pharmaceuticals, Inc. ("the Company") is a biopharmaceutical company headquartered in Hayward, California. The Company currently licenses two compounds, 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.

Since incorporation, the Company has been primarily performing research and development activities, including clinical trials, manufacturing of clinical drugs, filing patent applications, hiring personnel, and raising capital to support and expand these activities.

On March 12, 2018, the Company announced that the RESULT Phase 3 clinical trial of Sollpura for the treatment of patients with EPI did not meet its primary endpoint of non-inferiority to porcine PERT. All ongoing clinical trials of Sollpura were concluded by the end of April 2018. The Company has also discontinued the development of blisibimod.

Liquidity and Need for Additional Capital

The Company has never generated net income from operations, and, at March 31, 2018, had an accumulated deficit of $442.2 million, primarily as a result of research and development and general and administrative expenses. Due to the RESULT clinical trial not meeting its primary endpoint, in April 2018, the Company began a formal process of evaluating strategic alternatives and implemented a number of cost reduction measures, including a 90% reduction in its workforce and termination of major vendor contracts, which substantially reduced the Company's capital needs in the foreseeable future.

As of March 31, 2018, the Company had cash and cash equivalents of approximately $8.1 million. The Company's current cash balance is not expected to fund its operations through the next twelve months. As such, in April 2018, the Company began to wind down its activities. The Company also decided to discontinue further development of Sollpura and blisibimod and devote its time and resources to identifying and evaluating strategic alternatives. The process is aimed at identifying opportunities to diversify the Company's pipeline, including through potential strategic combinations. If a strategic transaction is not consummated, the Company may be required to dissolve or liquidate. The Company cannot be certain if any future financing will be available on terms favorable to the Company, if at all. 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 will terminate all strategic transaction efforts and eliminate all remaining personnel.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

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, 2017, filed with the SEC on March 5, 2018. 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 months ended March 31, 2018 are not necessarily indicative of the results to be expected for the year ending December 31, 2018 or for any other period. The consolidated balance sheet as of December 31, 2017 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.

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.

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Use of Estimates

The preparation of these 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, tax provision, stock-based compensation, warrant liabilities, and computation of beneficial conversion features. The Company bases its estimates on historical experience and on various other market specific and other relevant assumptions that it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ significantly from these estimates.

Financial Instruments with Characteristics of Both Equity and Liabilities

The Company has issued certain financial instruments, including warrants to purchase common stock, 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.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (“FASB”), or other standard setting bodies and adopted by us as of the specified effective date. Unless otherwise discussed, the impact of recently issued standards that are not yet effective is not expected to have a material impact on the Company’s financial position or results of operations upon adoption.

In July 2017, the FASB issued ASU 2017-11, Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480) and Derivatives and Hedging (Topic 815): I. Accounting for Certain Financial Instruments with Down Round Features; II. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception, (ASU 2017-11). Part I of this update addresses the complexity of accounting for certain financial instruments with down round features. Down round features are features of certain equity-linked instruments (or embedded features) that result in the strike price being reduced on the basis of the pricing of future equity offerings. Current accounting guidance creates cost and complexity for entities that issue financial instruments (such as warrants and convertible instruments) with down round features that require fair value measurement of the entire instrument or conversion option. Part II of this update addresses the difficulty of navigating Topic 480, Distinguishing Liabilities from Equity, because of the existence of extensive pending content in the FASB Accounting Standards Codification. This pending content is the result of the indefinite deferral of accounting requirements about mandatorily redeemable financial instruments of certain nonpublic entities and certain mandatorily redeemable noncontrolling interests. The amendments in Part II of this update do not have an accounting effect. This ASU is effective for fiscal years, and interim periods within those years, beginning after December 15, 2018. The Company is currently assessing the potential impact of adopting ASU 2017-11 on its financial statements and related disclosures, but does not expect it to have a significant impact.

In May 2017, the FASB issued, ASU-2017-09, Compensation—Stock Compensation (Topic 718). This guidance clarifies when changes to the terms and conditions of share-based awards must be accounted for as modifications. The guidance does not change the accounting treatment for modifications. The Company adopted this guidance from January 1, 2018 and it did not have a material impact on its consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842). This ASU is a comprehensive new leases standard that amends various aspects of existing guidance for leases and requires additional disclosures about leasing arrangements. The new standard requires that all lessees recognize the assets and liabilities that arise from leases on the balance sheet and disclose qualitative and quantitative information about its leasing arrangements. The classification criteria for distinguishing between finance leases and operating leases are substantially similar to the classification criteria for distinguishing between capital leases and operating leases in the previous lease guidance. The ASU is effective for annual periods beginning after December 15, 2018, including interim periods within those fiscal years, and earlier adoption is permitted. In the financial statements in which the ASU is first applied, leases shall be measured and recognized at the beginning of the earliest comparative period presented with an adjustment to equity. The Company is currently evaluating the impact of the adoption of this guidance on its consolidated financial condition, results of operations and cash flows.

In May 2014, the 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 adopted the standard from January 1, 2018, however, given that the Company is not generating revenue and has no revenue contracts, the adoption of this guidance did not impact its consolidated financial statements.

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3. 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. In addition, in computing the dilutive effect of convertible securities, the numerator is adjusted to add back any convertible preferred dividends. Diluted EPS is identical to basic EPS since common equivalent shares are excluded from the calculation, as their effect is anti-dilutive.

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

	Three Months Ended March 31	
	2018	2017
Net loss per share		
Numerator		
Net loss	$ (7,724)	$ (11,207)
Deemed dividend attributable to preferred stock	(1,540)	(2,503)
Net loss applicable to common stockholders	$ (9,264)	$ (13,710)
Denominator		
Weighted average common shares outstanding	22,166,869	6,759,567
Basic and diluted net loss per share	$ (0.42)	$ (2.03)

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.

	Three Months Ended March 31,	
	2018	2017
Total options to purchase common stock	6,724,345	750,355
Total warrants to purchase common stock	18,725,764	274,801
Series X convertible preferred stock	—	30,930
Total	25,450,109	1,056,086

4. FAIR VALUE OF FINANCIAL INSTRUMENTS

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

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

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

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

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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 March 31, 2018 and December 31, 2017 (in thousands):

	March 31, 2018 Estimated Fair Value	Level 1	Level 2	Level 3
Assets:				
Money market funds	$7,989	7,989	$ —	$ —
Liabilities:				
Warrant Liability	$704	$—	$ —	$ 704

	December 31, 2017 Estimated Fair Value	Level 1	Level 2	Level 3
Assets:				
Money market funds	$2,097	$2,097	$ —	$—
Liabilities:				
Warrant liability	$4,457	$—	$ —	$4,457

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):

	March 31, 2018
Beginning balance at December 31, 2017	$ 4,457
Decrease in fair value of warrant liability from January 1 to March 31, 2018	(3,290)
Balance reclassified to additional paid-in capital upon exercise of warrants	(463)
Ending balance	$ 704

There were no transfers between Level 1, Level 2 or Level 3 for the three months ended March 31, 2018 and year ended December 31, 2017.

5. 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 the 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 27, 2017.

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The exercise price of the Tranche 1 Warrants is 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 Warrants was adjusted to $1.8918.

The Company accounted for the warrants under ASC Topic 815, Derivatives and Hedging (“ASC 815”) pursuant to the following features:

1. On the date of issuance, the warrants were not considered indexed to the Company’s own stock because the underlying instruments were not “fixed-for-fixed” due to the exercise price being subject to adjustment in a Stock Combination Event.

2. The warrants permit the holder to require the Company to settle the warrants for cash in an amount equal to the Black-Scholes value of the warrants 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. The Tranche 2 warrants, which expired in October 2017 were out of the money and had a fair value of zero upon expiration. As of March 31, 2018, the fair value of the liability associated with the Tranche 1 Warrants decreased to $0.7 million from $4.5 million as of December 31, 2017 due to a decrease in the fair value of the common stock underlying the warrant shares, as well as reduction in the number of outstanding warrants pursuant to exercises by the warrant holders. The decrease in fair value of the warrant liability was recorded as non-operating income during the three months ended March 31, 2018. The Company estimated the fair value of the warrants using the Black-Scholes model with the following valuation assumptions

March 31, 2018	
Common stock price	$0.32
Exercise price	$1.89
Expected volatility	132.1%
Dividend yield	0 %
Risk-free interest rate	2.53 %
Expected term (years)	4.08

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 all valuation dates were based on the remaining contractual terms of the warrants. The risk-free interest rates were the U.S. Treasury bond rate as of the valuation months and years.

6. COMMITMENTS AND CONTINGENCIES

Leases

The Company subleases its main operating facility in Hayward, California. The lease is for approximately 8,000 square feet and the sublease agreement will expire on August 31, 2019. In April 2016, the Company leased its second operating facility in Pleasanton, California for approximately 1,200 square feet, which was subsequently terminated early by the Company in February 2018.

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.

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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 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 March 31, 2018. 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.

7. 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 and 2,067,522 shares of its authorized and unissued preferred stock as Series X Convertible Preferred stock and Class Y Convertible Preferred stock, respectively.

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. As of March 31, 2018, all 17,000 shares of Series X convertible preferred stock have been converted into shares of common stock.

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 investors (the "Purchasers"). The Private Placement was structured with two closings. Pursuant to the Securities Purchase Agreement, at the second closing on January 9, 2018, (the "Second Closing"), the Purchasers purchased 7,625,741 shares of the Company's common stock at $1.25 per share and 2,067,522 shares of the Company's non-voting Class Y Convertible Preferred Stock ("Class Y Convertible Preferred Stock") at $1.25 per share, convertible into 2,067,522 shares of Company common stock upon certain conditions. In the event of the Company's liquidation, dissolution or winding up, holders of Class Y Preferred Stock will participate pari passu with the holders of the Company's common stock in any distribution of proceeds, pro rata based on the number of shares held by each such holder. The Preferred Shares will generally have no voting rights. As of March 31, 2018, all 2,067,522 shares of Class Y Convertible Preferred Stock have been converted into shares of common stock.

Accounting Treatment

The Company has allocated the proceeds from the Private Placement amongst the Class Y Preferred Stock, common stock, and the warrants to purchase shares of common stock based on the relative fair values, as all the instruments are equity classified.

- Beneficial Conversion Feature - Because the conversion price of the shares of Class Y Preferred Stock was less than the fair value of the Company's common stock at the date of issuance, the in-the-money conversion feature (Beneficial Conversion Feature, or BCF) requires separate financial statement recognition and is measured at the intrinsic value (i.e., the amount of the increase in value that preferred stockholders would realize upon conversion based on the value of the conversion shares on the issuance date in excess of the amount allocated to the Class Y Preferred Stock for accounting purposes). The BCF is recorded as a discount to the Class Y Convertible Preferred Stock and is immediately accreted as a deemed preferred stock dividend and, accordingly, an adjustment to net loss to arrive at net loss applicable to common stockholders. During the quarter ended March 31, 2018, the Company recorded a deemed dividend of $1.5 million.

Common Stock

In March 2018, the Company filed a universal shelf registration statement with the SEC on Form S-3 for the proposed offering from time to time of up to $100.0 million of its securities, including common stock, preferred stock, warrants and/or units. As of March 31, 2018, the balance of $100.0 million is available for future issuance under the registration statement.

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 to sell securities pursuant to its effective registration statement on Form S-3 for a period of twelve months from March 5, 2018, unless and until the market value of the Company's outstanding common stock held by non-affiliates increases to above $75 million. If the Company cannot sell securities under its shelf registration statement, 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.

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In June 2017, the Company executed an equity purchase agreement with Lincoln Park Capital, LLP. ("LPC") (the "2017 Equity 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 valued at $0.3 million as a commitment fee to LPC over a period of thirty months. As of March 31, 2018, the Company has sold an aggregate of 1,870,411 shares of common stock for net proceeds of $3.1 million and issued an aggregate of 139,848 shares of common stock as commitment fee to LPC and maximized the number of shares of common stock it can sell to LPC pursuant to Nasdaq Rule 5635(d)(2).

On October 23, 2017, the Company entered into a Securities Purchase Agreement ("SPA") for a private placement of equity securities (the "Private Placement") with a select group of accredited investors (the "Purchasers"). The Private Placement was structured with two closings. The first closing occurred on October 27, 2017 ("Initial Closing") and resulted in net proceeds of approximately $2.7 million. The second closing ("Second Closing") was conditioned upon and subject to the Company receiving the requisite shareholder approval pursuant to Nasdaq Rule 5635(d), which was obtained on January 5, 2018. The Second Closing subsequently occurred on January 9, 2018 and resulted in incremental allocated proceeds of $11.1 million. Pursuant to the SPA, at the Initial Closing, the Purchasers purchased 2,306,737 shares of the Company's common stock at $1.25 per share. 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. At the Second Closing, the Purchasers purchased 7,625,741 shares of the Company's common stock at $1.25 per share and 2,067,522 shares of the Company's non-voting Class Y Convertible Preferred Stock (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 was issued with a warrant that was immediately exercisable to purchase 1.0 additional share of the Company's common stock at an exercise price of $1.25 per share. The financial instrument represented by the obligation to issue Class Y Preferred Stock and warrants upon shareholder approval is equity classified. The Company accounted for the Initial Closing in October 2017 and the Second Closing in January 2018. For both closings, the Company allocated the net proceeds based on the relative fair value method. As of March 31, 2018, all of the 2,067,522 shares of Class Y Convertible Preferred Stock were converted into 2,067,522 shares of common stock.

At March 31, 2018, the Company had reserved the following shares for future issuance:

Common stock options outstanding	6,724,345
Common stock warrants outstanding	18,725,764
Common stock options available for future grant under stock option plan	584,257
Common stock available for future grant under ESPP plan	504,069
Total	26,538,435

Warrants

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 March 31, 2018, 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 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. 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 Warrant 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 the terms of the warrant agreements. A total of 96,021 Tranche 2 Warrants were exercised on October 5, 2017 and the remaining 3,653,986 Tranche 2 Warrants expired on October 27, 2017. During the three months ended March 31, 2018, a total of 236,318 Tranche 1 Warrants were exercised at $1.8918 per share, leaving a balance of 3,507,626 Tranche 1 Warrants outstanding and exercisable as of March 31, 2018 with an expiry date of April 28, 2022. These warrants are classified as liabilities on the Company's consolidated Balance Sheet until the warrants are exercised or expired, (see Note 5).

Pursuant to the Private Placement for the sale of common stock and warrants in October 2017, the Company issued warrants to certain institutional investors to purchase shares of the Company's common stock. The Private Placement was structured with two closings. The Initial Closing occurred in October 2017, which resulted in the Company issuing 6,920,211 warrants ("Initial Closing Warrants") to the investors at an exercise price of $1.55 per share and a term of five years and six months. As of March 31, 2018, the Initial Closing Warrants remained outstanding. The Second Closing occurred in January 2018 and resulted in the Company issuing 9,693,263 warrants ("Second Closing Warrants") to the investors at an exercise price of $1.25 per share and a term of five years. During the three-month period ended March 31, 2018, a total of 1,665,115 Second Closing Warrants were exercised at an exercise price of $1.25, leaving a balance of 8,028,148 outstanding. Warrants from both closings are classified in equity pursuant to the accounting guidance prescribed under ASC Topic 815, ASC Topic 480 Distinguishing Liabilities from Equity and ASC 825 Financial Instruments – Registration Payment Arrangements. The Company measured the fair value of the warrants from the Initial and Second Closing using the Black-Scholes option pricing model on issuance date based on the following assumptions:

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	Initial Closing	Second Closing
Common stock price	$ 1.72	$ 1.50
Exercise price	$ 1.55	$ 1.25
Expected volatility	110 %	113 %
Dividend yield	0 %	0 %
Risk-free interest rate	1.98 %	2.18 %
Expected term (years)	5.5	5.0

For the fair value determination, the Company computed the historical volatility based on daily pricing observations for a period that corresponds to the expected terms of the warrants, which were based on the contractual terms of the warrants. The risk-free interest rates were the U.S. Treasury bond rate as of the valuation month and year.

8. SHARE-BASED COMPENSATION PLANS

2018 Plan

In December 2017, the Company's Board of Directors adopted the 2018 Stock Option and Incentive Plan (the "2018 Plan"), which was also approved by the Company's stockholders at a special meeting of the shareholders on January 5, 2018. The Company initially reserved 6,000,000 shares of its common stock for the issuance of awards under the 2018 Plan, plus all shares remaining available for grant under the Company's 2013 Stock Option and Incentive Plan (the "2013 Plan"), plus any additional shares returned under the 2010 Plan and 2013 Plan as a result of the cancellation, forfeiture or other termination (other than by exercise) of awards issued pursuant to the 2010 Plan and 2013 Plan, subject in all cases to adjustment including reorganization, recapitalization, reclassification, stock dividend, stock split, reverse stock split or other similar change in the Company's capital stock. Of the shares of common stock reserved for issuance under the 2018 Plan, no more than 2,000,000 shares can be issued to any individual participant as incentive options, non-qualified options or stock appreciation rights during any calendar year. The 2018 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 2018 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 2018 Plan have a maximum term of 10 years and generally vest over four years. In addition, in the case of certain large stockholders, the minimum exercise price of incentive options must equal 110% of fair market value on the date of grant and the maximum term is limited to five years. Subject to overall Plan limitations, the maximum aggregate number of shares of common stock that may be issued in the form of incentive options shall not exceed 6,000,000 shares of common stock. The 2018 Plan does not allow the option holders to exercise their options prior to vesting.

The terms of awards granted during the three months ended March 31, 2018 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, 2017.

The following table summarizes stock option activity for the three months ended March 31, 2018 (in thousands except share and per share information):

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life in Years	Aggregate Intrinsic Value

Balance at December 31, 2017	1,066,121	$ 10.04	8.68	$ 18
Granted	6,190,674	$ 1.65		
Exercised	—	—		
Cancelled and expired	(4,257)	$ 30.43		
Forfeited	(528,283)	$ 1.65		
Balance at March 31, 2018	6,724,345	$ 2.96	9.50	$ —
Exercisable at March 31, 2018	2,576,796	$ 4.01	9.23	$ —

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 March 31, 2018, there was $7.42 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 2.28 years.

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

	Three Months Ended March 31,			
	2018		2017	
Expected Volatility	106	%	106	%
Dividend Yield	0	%	0	%
Risk-Free Interest Rate	2.24	%	2.12	%
Expected Term (years)	5.82		6.02	
Weighted-average fair value per option	$ 1.35		$ 4.20	

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. On each January 1, the number of shares of stock reserved and available for issuance under the Plan is increased by the lesser of (i) one percent (1%) of the number of shares of common stock issued and outstanding on the immediately preceding December 31 or (ii) 31,250 shares of common stock.

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. There were no participants in the ESPP as at March 31, 2018.

Stock-Based Compensation Expense

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

	Three Months Ended March 31,	
	2018	2017
Research and development	$ 1,168	$ 396
General and administrative	2,098	690
Total	$ 3,266	$ 1,086

10. SUBSEQUENT EVENTS

On April 12, 2018, the Board of Directors of the Company approved and commenced a management and administrative personnel reorganization plan furthering its on-going efforts to effectively align Company resources. In connection with this plan, the Company eliminated all non-essential salaried positions by April 30, 2018. The Company expects to record exit charges, in the form of termination benefits of approximately $1.2 million in connection therewith.

The Company has decided to discontinue further development of Sollpura and blisibimod and devote its time and resources to identifying and evaluating strategic alternatives. The process is aimed at identifying opportunities to diversify the Company’s pipeline, including through potential strategic combinations. If a strategic transaction is not consummated, the Company may be required to dissolve or liquidate.

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

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

Overview

Anthera Pharmaceuticals, Inc. is a biopharmaceutical company that has historically focused on advancing the development and commercialization of innovative medicines that benefit patients with unmet medical needs. We currently license two compounds, 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 and others.

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 and a research award from Cystic Fibrosis Foundation Therapeutics Incorporated ("CFFT").

On March 12, 2018, the Company announced that the RESULT Phase 3 clinical trial of Sollpura for the treatment of patients with EPI did not meet its primary endpoint of non-inferiority to porcine PERT. All ongoing clinical trials of Sollpura were concluded by the end of April 2018.

Financial Overview

We have never generated net income from operations, and, at March 31, 2018, we had an accumulated deficit of $442.2 million, primarily as a result of research and development and general and administrative expenses. Due to the RESULT clinical trial not meeting its primary endpoint, in April 2018, we began a formal process of evaluating strategic alternatives and implemented a number of cost reduction measures, including a 90% reduction in our workforce and termination of major vendor contracts, which substantially reduced our capital needs in the foreseeable future.

As of March 31, 2018, we had cash and cash equivalents of approximately $8.1 million. Our current cash balance is not expected to fund our operations through the next twelve months. As such, in April 2018, we began to wind down our activities. We also decided to discontinue further development of Sollpura and blisibimod and devote our time and resources to identifying and evaluating strategic alternatives. The process is aimed at identifying opportunities to diversify our pipeline, including through potential strategic combinations. If a strategic transaction is not consummated, we may be required to dissolve or liquidate. We cannot be certain if any future financing will be available on terms favorable to us, if at all. If adequate funds are not available, we will terminate all strategic transaction efforts and eliminate all remaining personnel.

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, manufacturing and distribution of clinical drugs, and overhead allocations consisting of various administrative and facilities-related costs. Research and development expenses are separated into two main categories: clinical development and pharmaceutical development. Historically, our clinical development costs have included costs for preclinical and clinical studies. Pharmaceutical development costs consist of expenses incurred relating to clinical studies and product formulation and manufacturing.

The product candidates have been developed 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.

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The following table shows our total research and development expenses for the three months ended March 31, 2018 and 2017 (in thousands):

	Three Months Ended March 31,	
	2018	2017
Allocated costs:		
Sollpura	$5,212	$4,701
Blisibimod	129	1,250
Unallocated costs	2,127	1,850
Total research and development expense	$7,468	$7,801

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.

Critical Accounting Policies and Estimates

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

While our significant accounting policies are more fully described in the accompanying notes to the consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2017, 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.

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 stock combination events and their impact to the exercise price.

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:

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·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.

Our expenses related to clinical studies and manufacturing are based on estimates of the services received and efforts expended pursuant to contracts with many research institutions, clinical research organizations, contract manufacture organizations, and other service providers. 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 and manufacturing activities 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 on scope of work to be performed, we modify our estimates of accrued expenses accordingly on a prospective basis.

Results of Operations

Comparison of Three Months Ended March 31, 2018 and 2017

The following table summarizes our research and development expenses for the three months ended March 31, 2018 and 2017 (in thousands, except percentages):

	Three months ended March 31,			
	2018	2017	$ Change	% Change
Research and development expenses	$ 7,468	$ 7,801	$ (333)	(4)%

Research and development expense decreased during the three months ended March 31, 2018 from the same period in 2017 primarily due to a $1.0 million decrease in regulatory related expense, offset by a $0.3 million increase in clinical trial expense and a $0.3 million increase in payroll.

The following table summarizes our general and administrative expenses for the three months ended March 31, 2018 and 2017 (in thousands, except percentages):

	Three Months Ended March 31,			
	2018	2017	$ Change	% Change
General and administrative expenses	$ 3,503	$ 2,903	$ 600	21 %

General and administrative expenses increased during the three months ended March 31, 2018 from the same period in 2017 primarily due to higher stock-based compensation expense of $1.4 million due to higher number of options vested in 2018, offset by a decrease in professional services by $0.6 million.

The following table summarizes our non-operating income (expense) for the three months ended March 31, 2018 and 2017 (in thousands, except percentages):

	Three Months Ended March 31,			
	2018	2017	$ Change	% Change
Other income (expense)	$ (43)	$ (3)	$ (40)	1,333 %
Fair value of warrant liability in excess of proceeds from financing	—	(600)	600	100 %
Change in fair value of warrant liability	3,290	—	3,290	100 %
Total other income (expense)	$ 3,247	$ (603)	$ 3,850	638 %

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Other income (expense) recorded for the three months ended March 31, 2018 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. We accounted for the warrants under ASC Topic 815, Derivatives and Hedging (“ASC 815”). The fair value of the warrant liability is remeasured at the end of each reporting period with the change in fair value during the period recorded as a component of non-operating income (expense) in the consolidated statement of operations. As of March 31, 2018, the fair value of the warrant liability decreased from $4.5 million to $0.7 million due to a decrease in the fair value of the common stock underlying the warrant shares, as well as reduction in the number of outstanding warrants pursuant to exercises by the warrant holders. The decrease in fair value of the warrant liability was recorded as non-operating income during the three months ended March 31, 2018.

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 Cystic Fibrosis Foundation Therapeutics Incorporated ("CFFT").

On March 12, 2018, we announced that the RESULT Phase 3 clinical trial of Sollpura for the treatment of patients with EPI did not meet its primary endpoint of non-inferiority to porcine PERT. All ongoing clinical trials of Sollpura were concluded by the end of April 2018, and we began a formal process of evaluating strategic alternatives. Our expected cash needs for the foreseeable future have been significantly reduced with our current initiatives, termination of personnel and major vendor contracts.

As of March 31, 2018, the Company had cash and cash equivalents of approximately $8.1 million. The Company’s current cash balance is not expected to fund its operations through the next twelve months. As such, in April 2018, the Company began to wind down its activities. The Company also decided to discontinue further development of Sollpura and blisibimod and devote its time and resources to identifying and evaluating strategic alternatives. The process is aimed at identifying opportunities to diversify the Company’s pipeline, including through potential strategic combinations. If a strategic transaction is not consummated, the Company may be required to dissolve or liquidate. The Company cannot be certain if any future financing will be available on terms favorable to the Company, if at all. 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 will terminate all strategic transaction efforts and eliminate all remaining personnel.

Cash Flows

Comparison of Three months ended March 31, 2018 and 2017

Cash flows during the nine months ended March 31, 2018 and 2017 consisted of the following (in thousands):

	March 31,	
	2018	2017
Net cash used in operating activities	$(9,381)	$(14,329)
Net cash provided by investing activities	358	—
Net cash provided by financing activities	14,913	14,138
Total	$5,890	$(191)

During the three months ended March 31, 2018 and 2017, our operating activities used cash of $9.4 million and $14.3 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.

During the three months ended March 31, 2018, cash provided by investing activities was $0.4 million which was driven by the sale of capital equipment to a contract manufacturer. No cash was provided by nor used in investing activities during the three months ended March 31, 2017.

During the three months ended March 31, 2018, cash provided by financing activities was $14.9 million, which was driven by net proceeds received from the sale of our common stock and warrants. During the same period in 2017, cash provided by financing activities was $14.1 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 a lease obligation consisting of one operating lease for our facility that expires in August 2019.

The following table summarizes our estimated scheduled future minimum contractual obligations and commitments as of March 31, 2018 (in thousands):

	Payment Due by Period				
Contractual Obligations	< 1 year	1-3 years	3-5 years	> 5 years	Total
Facility Leases	$158	53	$ —	$ —	$211

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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.

In December 2007, the Company and Amgen Inc. ("Amgen") entered into a worldwide, exclusive license agreement (the "Amgen Agreement") to develop and commercialize blisibimod in any indication. Under the Amgen Agreement, we are obligated to make additional milestone payments upon the achievement of certain development, regulatory and commercial objectives. We are also obligated to pay royalties on future net sales of products that are developed and approved as defined by this collaboration. Our royalty obligations as to a particular licensed product will be payable on a country-by-country basis and licensed on a product-by-licensed-product basis, for the longer of (a) the date of expiration of the last-to-expire valid claim within the licensed patents that covers the manufacture, use or sale, offer to sell or import of such licensed product by us or a sublicensee in such country, or (b) 10 years after the first commercial sale of the applicable licensed product in the applicable country.

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. 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 March 31, 2018, we did not have any material derivative financial instruments. The fair value of our cash and cash equivalents was $8.1 million as of March 31, 2018.

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 March 31, 2018. 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 March 31, 2018, 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 March 31, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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PART II — OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

None

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 Evaluation of Strategic Alternatives

Our business to date has been almost entirely dependent on the success of Sollpura and blisibimod, and we have decided to discontinue further development of Sollpura and blisibimod and devote our time and resources to identifying and evaluating strategic alternatives, which may not be successful.

To date, we have invested substantially all of our efforts and financial resources in the research and development of Sollpura and blisibimod. On March 12, 2018, we announced that the RESULT Phase 3 clinical trial of Sollpura for the treatment of patients with EPI did not meet its primary endpoint of non-inferiority to porcine PERT. All ongoing clinical trials of Sollpura were concluded by the end of April 2018, and we began a formal process of evaluating strategic alternatives. The process is aimed at identifying opportunities to diversify our pipeline, including through potential strategic combinations. There can be no assurance that our process to identify and evaluate potential strategic alternatives will result in any definitive offer to consummate a strategic transaction, or if made what the terms thereof will be or that any transaction will be approved or consummated. If any definitive offer to consummate a strategic transaction is received, there can be no assurance that a definitive agreement will be executed or that, if a definitive agreement is executed, the transaction will be consummated. In addition, there can be no assurance that any transaction, involving our company and/or assets, that is consummated would enhance shareholder value. There also can be no assurance that we will conduct further drug research or development activities in the future.

Any such strategic transaction may require us to incur non-recurring or other charges, may increase our near-and long-term expenditures and may pose significant integration challenges or disrupt our management or business, which could adversely affect our operations and financial results. For example, these transactions may entail numerous operational and financial risks, including:

·exposure to unknown liabilities;

·incurrence of substantial debt or dilutive issuances of equity securities to pay for acquisitions;

·write-downs of assets or goodwill or impairment charges;

- incurrence of amortization expenses;

- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and;

- inability to retain key employees of our company or any acquired businesses.

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If we do not successfully consummate a strategic transaction, our Board of Directors may decide to pursue a dissolution and liquidation of our company. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities.

There can be no assurance that the process to identify a strategic transaction will result in a successfully consummated transaction. If no transaction is completed, our Board of Directors may decide to pursue a dissolution and liquidation of our company. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such decision and, ultimately, such liquidation, since the amount of cash available for distribution continues to decrease as we fund our operations while we evaluate our strategic alternatives. In addition, if our Board of Directors were to approve and recommend, and our stockholders were to approve, a dissolution and liquidation of our company, we would be required under Delaware corporate law to pay our outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions in liquidation to our stockholders. Our commitments and contingent liabilities may include (i) obligations under our employment and related agreements with certain employees that provide for severance and other payments following a termination of employment occurring for various reasons, including a change in control of our company; (ii) potential litigation against us, and other various claims and legal actions arising in the ordinary course of business; and (iii) non-cancelable facility lease obligations. As a result of this requirement, a portion of our assets may need to be reserved pending the resolution of such obligations. In addition, we may be subject to litigation or other claims related to a dissolution and liquidation of our company. If a dissolution and liquidation were pursued, our Board of Directors, in consultation with its advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of our common stock could lose all or a significant portion of their investment in the event of a liquidation, dissolution or winding up of our company.

Risks Related to Our Financial Condition and Capital Requirements

We have incurred significant losses since our inception.

We are a clinical-stage biotechnology company with two assets. Investment in a biopharmaceutical company 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 March 31, 2018, we had an accumulated deficit of $442.2 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 potential future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital.

Our current cash balance is not sufficient to fund our operations for the next twelve months.

We anticipate that our cash and cash equivalents of $8.1 million as of March 31, 2018 will not be sufficient to fund our operations for next twelve months from the filing of this report. Changing circumstances may cause us to consume capital significantly faster than we currently anticipate. If adequate funds are not available to us on a timely basis, or at all, we may be required to cease our operations and terminate all personnel.

The substantial doubt about our ability to continue as a going concern as of the date of this report 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.

Risks Related to the Development and Commercialization of our Product Candidate

The termination of our Phase 3 product candidate, Sollpura, could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospect.

The termination of our late stage product candidate, Sollpura, could adversely affect our commercial prospect and financial condition. We do not currently have funds to continue the development of our second product candidate, blisibimod. The lack of funding will delay the commencement and completion of clinical studies for blisibimod in a number of ways, 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; and

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

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 FDA or other regulatory authorities, the IRB or other reviewing entities, or any of our clinical study sites suspend or terminate any of our clinical studies, the commercial prospects for our product candidates may be harmed and our ability to generate product revenues will be delayed. In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical studies may also ultimately lead to the denial of regulatory approval of our product candidates. Also, if one or more clinical studies are delayed, our competitors may be able to bring products to market before we do, and the commercial viability of our product candidates could be significantly reduced.

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

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

If we breach the license agreement for blisibimod, we could lose the ability to continue the development and commercialization of blisibimod.

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. The agreement requires 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 licensor 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 licensor. Our licensor 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 agreement could result in our loss of exclusive rights and may lead to a complete termination of our product development and any commercialization efforts for our product candidates.

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

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

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

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

Although we are not currently conducting any clinical studies, undesirable adverse effects caused by our product candidates could cause us, IRBs or other reviewing entities, clinical study sites, or regulatory authorities to interrupt, delay or halt clinical studies and could result in the denial of regulatory approval by the FDA or other regulatory authorities.

If serious adverse events related to our product candidates are observed in any 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 or revoke the licenses for 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 FDA policy during the period of product development, clinical studies and FDA regulatory review.

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

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

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- issue warning letters or untitled letters;

- seek an injunction or impose civil or criminal penalties or monetary fines;

- suspend or withdraw regulatory approval or revoke a license;

- 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 FDA or other regulatory authorities will depend upon the acceptance of these products by the medical community, including physicians, patients and health care payors. The degree of market acceptance of our approved products will depend on a number of factors, including:

- demonstration of clinical safety and efficacy compared to other products;

- the relative convenience, ease of administration and acceptance by physicians and payors of our product candidates;

- the prevalence and severity of any adverse effects;

- limitations or warnings contained in a product's FDA-approved labeling;

- availability of alternative treatments;

- pricing and cost-effectiveness;

- the effectiveness of our or any future collaborators' sales and marketing strategies;

- our ability to obtain and maintain sufficient third-party coverage or reimbursement from government health care programs, including Medicare and Medicaid; and

- the willingness of patients to pay out-of-pocket in the absence of third-party coverage.

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

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;

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·withdrawal of clinical study participants;

·costs of related litigation;

·distraction of management's attention from our primary business;

·substantial monetary awards to patients or other claimants;

·the inability to commercialize product candidates; and

·decreased demand for product candidates, if approved for commercial sale.

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

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

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

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.

In the United States, there have been and continue to be a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our drug candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any drug candidates for which we obtain marketing approval. For example, in 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or the Affordable Care Act, or the ACA, was passed, which substantially changed the way health care is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. The provisions of the ACA of importance to the pharmaceutical and biotechnology industry are, among others, the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, which is apportioned among these entities according to their market share in certain government healthcare programs;

- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for branded and generic drugs, respectively;

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- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts to negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;

- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations, unless the drug is subject to discounts under the 340B drug discount program;

- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;

- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability;

- expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;

- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;

- new requirements under the federal Physician Payments Sunshine Act for drug manufacturers to report information related to payments and other transfers of value made to physicians and teaching hospitals as well as ownership or investment interests held by physicians and their immediate family members;

- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;

- creation of the Independent Payment Advisory Board, which, if and when impaneled, will have authority to recommend certain changes to the Medicare program that could result in reduced payments for prescription drugs; and

- establishment of a Center for Medicare and Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, however, there have been modifications and challenges to numerous aspects of the ACA:

- In 2012, the U.S. Supreme Court heard challenges to the constitutionality of the individual mandate and the viability of certain provisions of the Healthcare Reform Act. The Supreme Court's decision upheld most of the Healthcare Reform Act and determined that requiring individuals to maintain "minimum essential" health insurance coverage or pay a penalty to the Internal Revenue Service was within Congress's constitutional taxing authority. However, as a result of tax reform legislation passed in late December 2017, the individual mandate has been eliminated. The long ranging effects of the elimination of the individual mandate on the viability of the ACA are unknown at this time.

- On January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices.

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On October 13, 2017, President Trump signed an Executive Order terminating the cost-sharing subsidies that reimburse insurers under the ACA. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017.

- CMS has recently proposed regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces.

In 2018, litigation, regulation, and legislation related to the ACA are likely to continue, with unpredictable and uncertain results. The full impact of the ACA, any law repealing. replacing, and/or modifying elements of it, and the political uncertainty surrounding any repeal or replacement legislation on our business remains unclear.

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In addition, other legislative changes have been proposed and adopted that, directly or indirectly, affect or are likely to affect, the pharmaceutical industry and the commercialization of our products, including: the Budget Control Act of 2011; the American Taxpayer Relief Act of 2012; the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, also called the Medicare Modernization Act ("MMA"); and the Middle Class Tax Relief and Job Creation Act of 2012. We expect that any of these, as well as any healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products.

Individual U.S. state governments have also become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures. 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, attempts to repeal, replace, or modify the ACA, additional prescription drug coverage legislation, 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.

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We are subject to healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and others will play a primary role in the recommendation and prescription of our product candidates, if approved. Our future arrangements with third-party payors will expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our product candidates, if we obtain marketing approval. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- The federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or paying remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as Medicare and Medicaid.

- The federal false claims laws impose criminal and civil penalties, including those from civil whistleblower or qui tam actions pursuant to the federal False Claims Act, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease, or conceal an obligation to pay money to the federal government.

- The federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information.

- The federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services.

- The federal transparency requirements, sometimes referred to as the “Sunshine Act,” under the Patient Protection and Affordable Care Act, require manufacturers of drugs, devices, biologics, and medical supplies to report to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests.

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information.

- Federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

- Analogous state laws and regulations, such as state anti-kickback and false claims laws and transparency laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information

related to payments to physicians and other healthcare providers or marketing expenditures and drug pricing.

Ensuring that our future business arrangements with third-parties comply with applicable healthcare laws and regulations could be costly. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations, including anticipated activities to be conducted by our sales team, were found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines and exclusion from government funded healthcare programs, such as Medicare and Medicaid, any of which could substantially disrupt our operations. If any of the physicians or other providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

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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. 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 Capital Market ("NASDAQ"). NASDAQ has minimum requirements that a company must meet to remain listed on NASDAQ. To be listed under the Equity Standard 5505(a) and 5505(b) (1), a company must maintain a minimum closing bid price of $1.00 per share, stockholders' equity at no less than $2.5 million, and publicly held shares of at least 500,000 by at least 300 holders with market value of at least $1 million. To be listed under the Market Value of Listed Securities Standard 5505(a) and 5505(b) (2), a company must maintain the same minimum closing bid price, publicly held shares and public holders as the Equity Standard, and must maintain a market value of listed securities of no less than $35 million, but does not need to maintain a minimum shareholders' equity requirement. We currently do not meet the minimum closing bid price requirement of both listing standards.

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

If our common stock is not listed on NASDAQ or another national exchange, the trading price of our common stock is below $5.00 per share and we have net tangible assets of $6.0 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:

- 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;
- 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;

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- 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; 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, 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 NASDAQ 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-K, 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 by the selling stockholders could cause our stock price to decline.

Sales of a substantial number of shares of our common stock by the selling stockholders in the public market or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities, even if there is no relationship between such sales and the performance of our business.

As of April 30, 2018, there were 26,179,302 shares of our common stock outstanding. In addition, we had outstanding options and warrants to purchase 25,450,109 shares of our common stock that, if converted and exercised, will result in these additional shares becoming available for sale. A large portion of these shares and outstanding equity awards are held by a small number of persons and investment funds. Sales by these stockholders or option holders in the public market or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities, even if there is no relationship between such sales and the performance of our business.

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 may seek additional capital through a combination of private and public equity offerings, debt financings and collaboration, strategic and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest may be diluted, and the terms may include liquidation or

other preferences that adversely affect your rights as a stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring debt, making capital expenditures or declaring dividends. If we raise additional funds through collaboration, strategic alliance and licensing arrangements with third-parties, we may have to relinquish valuable rights to our technologies or product candidates or grant licenses on terms that are not favorable to us.

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

As a public company, we incur significant legal, accounting and other expenses that we would not incur as a private company. 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 Capital Market, impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. We must also bear all of the internal and external costs of preparing and distributing periodic public reports in compliance with our obligations under the securities laws.

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

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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 of Directors 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 ownership changes within the meaning of Section 382 ownership of the Internal Revenue Code during 2012 and in January 2018, 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. 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 and the current market value of our outstanding common stock, we expect that we will be significantly limited to selling additional securities pursuant to our effective registration statement on Form S-3, 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.

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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 U.S. numerous 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, 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.

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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 Amendment 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 Amendment 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 Sollpura and for blisibimod and if we continue to have rights under our license agreements with respect to both, our exclusive rights to one of Sollpura’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 grants a five-year extension for Sollpura and for blisibimod and if we continue to have rights under our license agreements with respect to both, our exclusive rights to Sollpura’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 Sollpura nor blisibimod have been previously approved in the U.S., both may be eligible for 12 years of biologic data exclusivity from the 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 Sollpura 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 Sollpura 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 Sollpura 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.

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There is no assurance that we will receive extensions for our patents available 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 of our products will be materially harmed.

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

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

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

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

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

Our commercial success will depend in part on our ability to manufacture, use, sell and offer to sell our product candidates and proposed product candidates without infringing patents or other proprietary rights of third-parties. Although we are not currently aware of any litigation or other proceedings or third-party claims of intellectual property infringement related to our product candidates, the pharmaceutical industry is characterized by extensive litigation regarding patents and other intellectual property rights. Other parties may obtain patents in the future and

allege that the use of our technologies infringes these patent claims or that we are employing their proprietary technology without authorization. Likewise, third-parties may challenge or infringe upon our or our licensors' existing or future patents.

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

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

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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	Fifth Amended and Restated Certificate of Incorporation, as amended (filed as Exhibit 3.1 to the registrant's 10-Q filed with the SEC on May 10, 2017 and incorporated herein by reference).
3.2	Amended and Restated Bylaws, as amended on May 21, 2015 (filed as Exhibit 3.4 to the registrant's Form 10-Q filed with the SEC on August 10, 2015 and incorporated herein by reference).
4.1	Form of Tranche 1 Warrant (filed as Exhibit 4.1 to the registrant's Form 8-K filed with the SEC on March 16, 2017 and incorporated herein by reference).
#10.1	Amended and Restated Employment Agreement by and between the Company and Craig Thompson, dated January 5, 2018 (Filed as Exhibit 10.35 to the Company's Annual Report on Form 10-K, filed with the SEC on March 5, 2018 and incorporated herein by reference).
#10.2	Amended and Restated Employment Agreement by and between the Company and May Liu, dated January 5, 2018 (Filed as Exhibit 10.36 to the Company's Annual Report on Form 10-K, filed with the SEC on March 5, 2018 and incorporated herein by reference).
#10.3	Employment Agreement by and between the Company and William Shanahan, M.D., dated January 5, 2018 (Filed as Exhibit 10.37 to the Company's Annual Report on Form 10-K, filed with the SEC on March 5, 2018 and incorporated herein by reference).
#10.4	Employment Agreement by and between the Company and Renee Martin, Ph.D., dated January 5, 2018 (Filed as Exhibit 10.38 to the Company's Annual Report on Form 10-K, filed with the SEC on March 5, 2018 and incorporated herein by reference).
#10.5	Employment Agreement by and between the Company and Patrick Murphy, dated January 5, 2018 (Filed as Exhibit 10.39 to the Company's Annual Report on Form 10-K, filed with the SEC on March 5, 2018 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.

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SIGNATURES

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

ANTHERA PHARMACEUTICALS, INC.

May 15, 2018 By: /s/ J. Craig Thompson
J. Craig Thompson
Chief Executive Officer
(Principal Executive Officer)

May 15, 2018 By: /s/ May Liu
May Liu
Senior Vice President, Finance and Administration
(Principal Accounting Officer)