Anthera Pharmaceuticals Inc
Form 10-Q
August 09, 2016

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 June 30, 2016

OR

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

For the transition period from to

Commission file number: 001-34637

ANTHERA PHARMACEUTICALS, INC.
(Exact Name of Registrant as Specified in Its Charter)

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

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

_____

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting

company" in Rule 12b-2 of the Exchange Act. (Check one):

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

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

As of July 31, 2016 the number of outstanding shares of the registrant's common stock, par value $0.001 per share, was 41,427,352

ANTHERA PHARMACEUTICALS, INC.

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

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PART I — FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

ANTHERA PHARMACEUTICALS, INC.

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

	June 30, 2016	December 31, 2015 (1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 28,500	$ 46,951
Accounts receivable	261	326
Prepaid expenses and other current assets	1,178	585
Total current assets	29,939	47,862
Property and equipment — net	778	263
TOTAL	$ 30,717	$ 48,125
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 4,228	$ 5,259
Accrued clinical expenses	4,199	1,377
Accrued liabilities	449	98
Accrued payroll and related costs	1,305	1,596
Deferred revenue – current	—	138
Total current liabilities	10,181	8,468
Total liabilities	10,181	8,468
Commitments and Contingencies (Note 6)		
Stockholders' equity:		
Common stock, $0.001 par value, 100,000,000 shares authorized; 41,285,033 and 40,004,037 shares issued and outstanding as of June 30, 2016 and December 31, 2015, respectively	41	40
Additional paid-in capital	398,586	391,648
Accumulated deficit	(378,091)	(352,031)
Total stockholders' equity	20,536	39,657
TOTAL	$ 30,717	$ 48,125

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 per share data)
(unaudited)

	Three months ended June 30,		Six months ended June 30,	
	2016	2015	2016	2015
REVENUES:				
License fee revenue	$—	$146	$139	$195
Collaborative revenue	—	143	6	339
Total revenues	—	289	145	534
OPERATING EXPENSES:				
Research and development	$11,966	$8,539	$21,590	$14,534
General and administrative	2,576	1,696	4,814	3,603
Research award	(261)	(1,100)	(261)	(1,100)
Total operating expenses	14,281	9,135	26,143	17,037
LOSS FROM OPERATIONS	(14,281)	(8,846)	(25,998)	(16,503)
OTHER INCOME (EXPENSE):				
Other income (expense)	(53)	(49)	(62)	(52)
NET LOSS	$(14,334)	$(8,895)	$(26,060)	$(16,555)
Net loss per share—basic and diluted	$(0.35)	$(0.25)	$(0.64)	$(0.52)
Weighted-average number of shares used in per share calculation—basic and diluted	41,032,544	35,817,794	40,541,219	31,729,152

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

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ANTHERA PHARMACEUTICALS, INC.

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

	Six Months Ended June 30,	
	2016	2015
CASH FLOW FROM OPERATING ACTIVITIES:		
Net loss	$ (26,060)	$ (16,555)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	146	140
Stock-based compensation expense	2,557	1,183
Changes in assets and liabilities:		
Accounts receivable	65	(551)
Prepaid expenses and other assets	(593)	(275)
Accounts payable	(1,031)	3,049
Accrued clinical expenses	2,822	385
Accrued liabilities	352	76
Accrued payroll and related costs	(151)	(9)
Deferred revenue	(138)	(195)
Net cash used in operating activities	(22,031)	(12,752)
INVESTING ACTIVITIES:		
Property and equipment purchases	(662)	(80)
Net cash used in investing activities	(662)	(80)
FINANCING ACTIVITIES:		
Proceeds from issuance of common stock, net of offering costs	3,947	38,469
Proceeds from issuance of common stock to Zenyaku Kogyo Co., Ltd.	—	7,000
Proceeds from issuance of common stock pursuant to exercise of stock options	295	179
Net cash provided by financing activities	4,242	45,648
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(18,451)	32,816
CASH AND CASH EQUIVALENTS — Beginning of period	46,951	2,639
CASH AND CASH EQUIVALENTS — End of period	$ 28,500	$ 35,455
SUPPLEMENTAL CASH DISCLOSURES OF CASH FLOW INFORMATION		
Non-cash financing activities:		
Issuance of common stock in the form of a waiver of a fee otherwise payable to Amgen under the Amgen Agreement	$ —	$ 1,000
Issuance of common stock as a commitment fee pursuant to an equity purchase agreement	$ 76	$ 60

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. ORGANIZATION AND SIGNIFICANT ACCOUNTING POLICIES

Organization

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

Liquidity and Need for Additional Capital

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

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

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

To fully execute its business plan, the Company will need to complete certain research and development activities and clinical studies. Further, the Company's product candidates will require regulatory approval prior to commercialization. These activities may span many years and require substantial capital to complete and may ultimately be unsuccessful. Any delays in completing these activities could adversely impact the Company. The

Company will need substantial additional financing to continue development of its product candidates, obtain regulatory approvals, and prepare for commercial readiness if the clinical trials are successful; such financing may not be available on terms favorable to the Company, if at all. If adequate funds are not available, the Company may be required to delay, reduce the scope of, or eliminate one or more of its clinical trials. The Company plans to meet its capital requirements primarily through future partnerships, issuances of equity securities, debt financing, and in the longer term, revenue from product sales. Failure to generate revenue or raise additional capital would adversely affect the Company's ability to achieve its intended business objectives.

Basis of Presentation

The accompanying unaudited Condensed Consolidated Financial Statements have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC") for Quarterly Reports on Form 10-Q and do not contain all of the information and footnotes required by U.S. generally accepted accounting principles ("U.S. GAAP") for complete financial statements. The accompanying unaudited Condensed Consolidated financial statements and notes thereto should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2015, filed with the SEC on March 14, 2016. In the opinion of management, the accompanying unaudited Condensed Consolidated financial statements reflect all adjustments, which include only normal recurring adjustments necessary to present fairly the Company's interim consolidated financial information. The results for the three and six months ended June 30, 2016 are not necessarily indicative of the results to be expected for the year ending December 31, 2016 or for any other period. The consolidated balance sheet as of December 31, 2015 has been derived from the audited financial statements as of that date but it does not include all of the information and notes required by U.S. GAAP.

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The Company has evaluated events and transactions subsequent to the balance sheet date and has disclosed all events or transactions that occurred subsequent to the balance sheet date but prior to filing this Quarterly Report on Form 10-Q that would require recognition or disclosure in the unaudited Condensed Consolidated Financial Statements.

Use of Estimates

The preparation of these condensed consolidated financial statements in conformity with U.S. GAAP requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, expenses and related disclosures. On an ongoing basis, management evaluates its estimates, including critical accounting policies or estimates related to clinical trial accruals, tax provision, and stock-based compensation. The Company bases its estimates on historical experience and on various other market specific and other relevant assumptions that it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ significantly from these estimates.

Recent Accounting Pronouncements

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

In November 2015, the FASB issued guidance on the classification of deferred taxes, Accounting Standards Update No. 20154-17 ("ASU 2015-17"), Balance Sheet Classification of Deferred Taxes. ASU 2015-17 eliminates the guidance in Topic 740, Income Taxes, that required an entity to separate deferred tax liabilities and assets between current and noncurrent amounts in a classified balance sheet. The amendments require that all deferred tax liabilities and assets of the same tax jurisdiction or a tax filing group, as well as any related valuation allowance, be offset and presented as a single amount in a classified balance sheet. The amendments are effective for public business entities for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2016. Early adoption is permitted as of the beginning of any interim period or annual reporting period. The Company does not expect the adoption of this guidance to materially affect its consolidated financial statements.

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

In March 2016, the FASB issued ASU No. 2016-09, Compensation—Stock Compensation (Topic 718). This standard makes several modifications to Topic 718 related to the accounting for forfeitures, employer tax withholding on share-based compensation and the financial statement presentation of excess tax benefits or deficiencies. ASU

2016-09 also clarifies the statement of cash flows presentation for certain components of share-based awards. The standard is effective for interim and annual reporting periods beginning after December 15, 2016, although early adoption is permitted. The adoption of ASU 2015-17 is not expected to have a significant impact on the Company's consolidated financial position or results of operations.

2. COLLABORATIVE AGREEMENT

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

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3. RESEARCH AWARD

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

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

For the three and six months ended June 30, 2016 and 2015, the Company recognized approximately $0.3 million and $1.1 million, respectively, from CFFT in connection with achieving certain milestones specified in the award agreement and included it as part of operating expense. As of June 30, 2016, there was $100,000 remaining under the research award.

4. NET LOSS PER SHARE

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Net loss per share				
Numerator				
Net loss	$ (14,334)	$ (8,895)	$ (26,060)	$ (16,555)
Denominator				
Weighted average common shares outstanding	41,032,544	35,817,794	40,541,219	31,729,152
Basic and diluted net loss per share	$ (0.35)	$ (0.25)	$ (0.64)	$ (0.52)

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

	As of June 30,	
	2016	2015
Options to purchase common stock	5,880,160	3,482,848
Warrants to purchase common stock	40,178	556,838
Restricted Stock Units	—	937
Total	5,920,338	4,040,623

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5. FAIR VALUE OF FINANCIAL INSTRUMENTS

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

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

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

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

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

	June 30, 2016			
	Estimated Fair Value	Level 1	Level 2	Level 3
Money market funds	$24,773	$24,773	$ —	$ —

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

There were no transfers between Level 1, Level 2 or Level 3 for the six months ended June 30, 2016 and year-ended 2015.

6. COMMITMENTS AND CONTINGENCIES

Leases

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

Other Commitments

In December 2007, the Company and Amgen entered into a worldwide, exclusive license agreement (the "Amgen Agreement") to develop and commercialize blisibimod in any indication, including for the treatment of systemic lupus erythematosus ("lupus"). Under the terms of the Amgen Agreement, the Company paid a nonrefundable, upfront license fee of $6.0 million. As there was no future alternative use for the technology, the Company expensed the license fee in research and development expenses during 2007. Under the terms of the Amgen Agreement, the Company is obligated to make additional milestone payments to Amgen of up to $33.0 million upon the achievement of certain development and regulatory milestones. The Company is also obligated to pay tiered royalties on future net sales of products, ranging from the high single digits to the low double digits, which are developed and approved as set forth in the Amgen Agreement. The Company's royalty obligations as to a particular licensed product will be payable, on a country-by-country and licensed product-by-licensed product basis, for the longer of (a) the date of expiration of the last to expire valid claim within the licensed patents that covers the manufacture, use or sale, offer to sell, or import of such licensed product by the Company or a sublicense in such country or (b) 10 years after the first commercial sale of the applicable licensed product in the applicable country.

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

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

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

7. STOCKHOLDERS' EQUITY

Preferred Stock

The Company's Fifth Amended and Restated Certificate of Incorporation designates 5,000,000 shares of the Company's capital stock as undesignated preferred stock. There were no preferred shares issued or outstanding as of June 30, 2016.

Common Stock

On March 14, 2016, the Company filed a universal shelf registration statement with the SEC on Form S-3 (File No. 333-210166) for the proposed offering from time to time of up to $100.0 million of its securities, including common stock, preferred stock, debt securities and/or warrants. As of the date of this report, there is a balance of $60.6 million available for future issuance.

On November 15, 2013, the Company entered into an at-the-market sales agreement (the "Cowen ATM Agreement") with Cowen and Company, LLC ("Cowen") under which the Company from time to time was able to offer and sell shares of its common stock, par value $0.001 per share, having an aggregate offering price of up to $25.0 million through Cowen, as agent. For the three and six months ended June 30, 2016, the Company sold $1.6 million and $2.5

million, respectively, in shares of common stock pursuant to the Cowen ATM Agreement. The Cowen ATM Agreement was terminated on April 21, 2016.

On April 21, 2016, the Company entered into an at-the-market sales agreement with H.C. Wainwright (the "H.C. Wainwright ATM Agreement") under which the Company from time to time may offer and sell shares of its common stock, par value $0.001 per share, having an aggregate offering price of up to $25.0 million through H.C. Wainwright, as agent. For the three and six months ended June 30, 2016, the Company sold $0.7 million in shares of common stock pursuant to the H.C. Wainwright ATM Agreement, leaving a balance of $24.3 million available for future sale pursuant to the H.C. Wainwright ATM Agreement as of June 30, 2016.

On March 12, 2015, the Company executed an equity purchase agreement with LPC, pursuant to which the Company has the right, but not the obligation, to sell to LPC up to an aggregate of $10.0 million in shares of common stock over a period of two years. In July 2015, the Company amended the equity purchase agreement to reduce the amount available for purchase to $6.0 million. On April 27, 2016, the Company amended the equity purchase agreement and increased the amount of common stock available for purchase to $15.0 million. For the three and six months ended June 30, 2016, the Company sold approximately $0.2 million and $1.0 million in shares of common stock, respectively, pursuant to the equity purchase agreement, leaving a balance of $14.0 million available for future sales as of June 30, 2016.

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Warrants

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

8. SHARE-BASED COMPENSATION PLANS

2013 Plan

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

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

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

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life in Years	Aggregate Intrinsic Value
Balance at December 31, 2015	4,255,981	$ 4.78	8.44	$ 4,323
Granted	2,180,322	$ 3.55		
Exercised	(111,765)	$ 2.21		
Cancelled and expired	(354,378)	$ 4.53		
Forfeited	(90,000)	$ 9.48		
Balance at June 30, 2016	5,880,160	$ 4.32	8.10	$ 1,551
Exercisable at June 30, 2016	2,478,736	$ 4.56	6.61	$ 713

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 June 30, 2016, there was $10.2 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 2.76 years.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Expected Volatility	98 %	97 %	98 %	95 %
Dividend Yield	0 %	0 %	0 %	0 %
Risk-Free Interest Rate	1.32 %	1.52 %	1.49 %	1.63 %
Expected Term (years)	5.86	5.59	5.92	5.76
Weighted-average fair value per option	$ 2.74	$ 4.18	$ 2.69	$ 3.02
Fair value of awards vested	$ 894	$ 398	$ 2,978	$ 1,711

2010 Employee Stock Purchase Plan (“ESPP”)

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

The purchase price per share is 85% of the fair market value of the common stock as of the first date or the ending date of the applicable semi-annual purchase period, whichever is less (the “Look-Back Provision”). The 15% discount

and the Look-Back Provision make the ESPP compensatory. The Black-Scholes option pricing model was used to value the employee stock purchase rights. The assumptions used in the Black-Scholes option-pricing model to value the employee stock purchase rights are as follows:

	Three Months Ended June 30,				Six Months Ended June 30,			
	2016		2015		2016		2015	
Expected Volatility	88	%	52	%	88	%	52	%
Dividend Yield	0	%	0	%	0	%	0	%
Risk-Free Interest Rate	0.24	%	0.06	%	0.24	%	0.06	%
Expected Term (years)	0.50		0.50		0.50		0.50	

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Stock-Based Compensation Expense

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Research and development	$448	$240	876	$442
General and administrative	991	440	1,681	741
Total stock-based compensation	$1,439	$680	$2,557	$1,183

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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," "expect," "plan," "anticipate," "believe," "estimate," "project," "predict," "potential" and similar expression identify forward-looking statements. Such forward-looking statements are subject to risks, uncertainties and other important factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified below and those discussed in the section titled "Risk Factors" in this report. Furthermore, such forward-looking statements speak only as of the date of this report. Except as required by law, we undertake no obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements.

Overview

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

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

In December 2014, we entered in an exclusive license agreement with Zenyaku for the development and commercialization of blisibimod in Japan and potentially other countries throughout Asia. In September 2015, Zenyaku provided us a notice of its intent to terminate the Zenyaku Agreement, effective January 7, 2016 ("Termination Notice"). The termination was "at will" and Zenyaku alleged no breach of the Zenyaku Agreement by

us. There are no termination penalties incurred by us in connection with the early termination of the Zenyaku Agreement by Zenyaku. As a result of the early termination of the Zenyaku Agreement, will not recognize revenues under the Zenyaku Agreement beyond January 2016. In addition, we regained full worldwide rights for blisibimod and we are actively pursuing partnerships with pharmaceutical and biotechnology companies to further advance the development of blisibimod globally.

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

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Our Phase 3 Development of Liprotamase in EPI

We initiated the SOLUTION study in the third quarter of 2015. SOLUTION is a Phase 3, randomized, open-label, assessor-blind, non-inferiority, active-comparator study evaluating the efficacy and safety of liprotamase in patients with cystic fibrosis-related exocrine pancreatic insufficiency. This pivotal study, planned for 126 patients in North America, Europe and Israel is intended to evaluate the non-inferiority of liprotamase compared with another commercially available PERT in a population enriched for PERT responders. We closed screening in the SOLUTION study in the second quarter of 2016 and expect the study to become fully enrolled in the third quarter of 2016 in the United States. A second, smaller Phase 3 study, SIMPLICITY, in younger pediatric subjects was initiated in the second quarter of 2016. The SIMPLICITY study uses sachets containing a formulation of liprotamase powder for oral solution for ease of administration, and will enroll approximately 46 patients. We believe the SOLUTION and SIMPLICITY studies may offer a number of potential opportunities for differentiation versus the currently marketed PERTs, including:

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

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

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

CHABLIS-SC1 is a Phase 3, multicenter, randomized, double-blind, placebo-controlled study designed to evaluate the efficacy, safety, tolerability and immunogenicity of blisibimod in patients with seropositive, clinically-active lupus (SELENA-SLEDAI ≥ 10) who require corticosteroid therapy in addition to standard-of-care for treatment of their disease. The study was designed to randomize approximately 400 patients to receive either 200mg of blisibimod or placebo in addition to their standard-of-care medication for 52 weeks in Asia, Europe, and Latin America. We reached the enrollment target in June 2015. Topline data is expected in the beginning of the fourth quarter of 2016 after the last enrolled patient completes 52 weeks of treatment. The primary endpoint of the CHABLIS-SC1 will be clinical improvement in the SRI-6 response at 52 weeks. Key secondary outcomes from the study, including SRI-8, reduction in the number of lupus flares and steroid use, are intended to further differentiate blisibimod from currently

available therapies. To date, enrolled patient demographics and disease characteristics for the CHABLIS-SC1 study are consistent with our goal to enroll patients with higher levels of lupus activity and positive biomarkers despite the stable use of corticosteroids. These characteristics were associated with improved outcomes in both our previous Phase 2 clinical study as well as in large Phase 3 studies conducted with other BAFF-inhibitors, belimumab (Benlysta) and tabalumab.

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

·clinical differentiation:

Øpotential for improved clinical response due to selection of patients with high disease activity and use of steroid therapy;

Øan improved clinical efficacy endpoint which requires a larger six-point reduction in the SELENA-SLEDAI;

Øpotential for earlier onset of clinical benefit by allowing earlier steroid taper and restriction of background medications;

Øpotential to demonstrate reductions in lupus flares;

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- mechanism of action, Blisibimod is able to inhibit the activity of both membrane-bound and soluble BAFF;

- potential labeling differentiation: A second study (CHABLIS-7.5) will also aim to enroll patients with positive serology and low complement; as well as assess the ability to reduce background corticosteroid medication usage;

- manufacturing: Blisibimod's novel molecular structure, comprised of 2 identical peptide chains assembled into a covalent dimer, confers manufacturing benefits and lower cost of goods through a bacterial fermentation manufacturing process;

- structure: Blisibimod's 4 BAFF binding domains, compared to the typical 2 domains in a monoclonal antibody give rise to a 350-fold higher affinity for blisibimod (1 picomolar affinity) compared with the reported affinity for the anti-BAFF monoclonal antibody, belimumab (Benlysta); and

- fully human IgG1 Fc domain confers acceptable pharmacokinetic properties to potentially support once-weekly dosing.

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

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

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

Two articles regarding the effects of blisibimod in lupus were published in the second quarter of 2016. The first, authored by Professor Michele Petri of, Johns Hopkins University, summarized the observed improvements in patient-reported fatigue in patients with lupus enrolled in the Phase 2b PEARL-SC clinical trial (published in Lupus, June 26 2016). The second article, authored by Dr. Morton Scheinberg reviewed the nonclinical, pharmacokinetic and

clinical research findings related to blisibimod, and provided insight into the trial design and enrollment characteristics of patients in the Phase 3 CHABLIS-SC trial (published in Expert Opinion on Biological Therapy, 16:5, 723-733, April 2016).

Our Phase 2 Development of Blisibimod for in IgA Nephropathy

The BRIGHT-SC study is a Phase 2 multicenter, randomized, double-blind, placebo-controlled study to evaluate the efficacy, safety, tolerability and immunogenicity of blisibimod in IgA nephropathy. Enrollment criteria are biopsy-proven IgA nephropathy and proteinuria greater than one gram per 24 hours (1g/24hr). Patients must be receiving standard of care medication including angiotensin converting enzyme inhibitors and angiotensin receptor blockers. The BRIGHT-SC study was initiated in the second quarter of 2013. Patients enrolled in the BRIGHT-SC study receive 300mg weekly blisibimod or placebo subcutaneously during the first 8 weeks of therapy, the induction phase, followed by a minimum of 24 weeks of 200mg weekly blisibimod or placebo, the maintenance phase. The BRIGHT-SC clinical study has enrolled patients in Southeast Asia, and the European Union (“EU”).

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In September 2013, we met with the FDA who agreed to consider accepting proteinuria as an endpoint for Subpart E accelerated approval for blisibimod in IgA nephropathy. In April 2014, we met with the Japan Pharmaceuticals and Medical Devices Agency ("PMDA") to discuss our registration program for blisibimod in IgA nephropathy. In this meeting we gained the PMDA's agreement on the acceptability of proteinuria as the primary efficacy endpoint to support marketing approval in Japan and have amended the BRIGHT-SC study to include the specific data requirements of the PMDA. In December 2014 we met with the European Medicines Agency ("EMA") as part of the scientific advice process for blisibimod. We reached an agreement with the EMA on the acceptability of proteinuria as the primary efficacy variable as well as the requirement for a single study in support a Conditional Marketing Authorization Application ("CMAA") provided that confirmatory evidence from a second study would be available post approval. The EMA also recommended the protocol to collect information on the recommended duration of treatment, duration of response and need for re-treatment.

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

In June 2016, interim data from the BRIGHT-SC study, which enrolled 57 patients, showed a tendency toward lower proteinuria in blisibimod versus placebo treated patients. While the numerical reduction in proteinuria in blisibimod versus placebo treated patients at week 24 in the BRIGHT-SC study did not meet the predefined statistical primary endpoint of complete or partial response, longer-term data from the study demonstrated an increasingly large separation in proteinuria favoring the blisibimod treated arm compared to the placebo. Additionally, secondary biomarker data from the study, including changes in total B cell counts and changes in immunoglobulins IgA, IgG, and IgM, were highly consistent with previous studies with blisibimod and demonstrated marked reduction after 8 weeks on study. As a result of the increasing proteinuria effect after 24-weeks of dosing, and the demonstration of blisibimod's effect on immunological markers relevant to IgA nephropathy including reductions of B cells, and immunoglobulins including IgA, IgG and IgM, we elected to continue the study until the last subject completes 48 weeks of observation.

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

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

Revenue

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

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Research and Development Expenses

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

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

The following table shows our total research and development expenses for the three and six months ended June 30, 2016 and 2015 (in thousands):

	Three Months Ended June 30,			Six Months Ended June 30,		
	2016	2015		2016	2015	
Allocated costs:						
Liprotamase	$ 6,805	$ 804		$ 11,131	$ 1,418	
Blisibimod	3,386	6,524	(1)	7,069	10,702	(1)
Unallocated costs	1,775	1,211		3,390	2,414	
Total research and development expenses	$ 11,966	$ 8,539		$ 21,590	$ 14,534	

(1) Offset by $0.4 million in reimbursable expense for IgA nephropathy from Zenyaku.

We expect our research and development expenses to increase significantly as we continue to develop our product candidates. We intend to fund our clinical studies with existing cash and proceeds from potential future debt and equity offerings.

We expect that a large percentage of our research and development expenses in the future will be incurred in support of our current and future clinical development programs. These expenditures are subject to numerous uncertainties in timing and cost to completion. As we obtain results from clinical studies, we may elect to discontinue or delay clinical studies for certain clinical development programs in order to focus our resources on more promising clinical development programs. Completion of clinical studies may take several years or more, but the length of time generally varies according to the type, complexity, novelty and intended use of product candidates. The cost of clinical studies may vary significantly over the life of a program as a result of differences arising during clinical development, including:

- the number of sites included in the studies;

- the length of time required to enroll suitable patient subjects;

- the number of patients that participate in the studies;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients; and
- the duration of patient follow-up.

Our expenses related to clinical studies are based on estimates of the services received and efforts expended pursuant to contracts with many research institutions, clinical research organizations and other service providers that conduct and manage clinical studies on our behalf. The financial terms of these agreements are subject to negotiation and vary from contract to contract and may result in uneven payment flows. Generally, these agreements set forth the scope of work to be performed at a fixed fee or unit price. Payments under the contracts are mainly driven by time and materials incurred by these service providers. Expenses related to clinical studies generally are accrued based on time and materials incurred by the service providers and in accordance with the contracts. If timelines or contracts are modified based upon changes to the clinical study design or scope of work to be performed, we modify our estimates of accrued expenses accordingly on a prospective basis.

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None of our product candidates has received FDA or foreign regulatory marketing approval. In order to grant marketing approval, the FDA or foreign regulatory agencies must conclude that clinical data establish the safety and efficacy of our product candidates and that the manufacturing facilities, processes and controls are adequate. Despite our efforts, our product candidates may not offer therapeutic or other improvement over existing, comparable drugs, be proven safe and effective in clinical studies, or meet applicable regulatory standards.

As a result of the uncertainties discussed above, we are unable to determine the duration and completion costs of our development projects or when and to what extent we will receive cash inflows from the commercialization and sale of an approved product candidate, if ever.

General and Administrative Expenses

General and administrative expenses consist primarily of compensation for employees in executive and operational functions, including clinical, chemical manufacturing, regulatory, finance and business development. Other significant costs include professional fees for legal services, including legal services associated with obtaining and maintaining patents. We will continue to incur significant general and administrative expenses as a public company, including costs for insurance, costs related to the hiring of additional personnel, payment to outside consultants, lawyers and accountants and complying with the corporate governance, internal controls and similar requirements applicable to public companies.

Critical Accounting Policies and Estimates

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

While our significant accounting policies are more fully described in the accompanying notes to the consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2015, we believe that the following accounting policies are the most critical to aid you in fully understanding and evaluating our reported financial results and affect the more significant judgments and estimates that we use in the preparation of our consolidated financial statements.

Revenue Recognition

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

With respect to the collaborative arrangement with Zenyaku, the Company recognized revenue in accordance with FASB Accounting Standards Codification, or ASC 605 " Revenue Recognition ", subtopic ASC 605-25 " Revenue with

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

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

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

Stock-Based Compensation

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

Accrued Clinical Expense

We make estimates of our accrued clinical expenses as of each balance sheet date in our consolidated financial statements based on facts and circumstances known to us at that time. This process involves reviewing open contracts and purchase orders, communicating with our applicable personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual cost. The majority of our service providers invoice us at least monthly in arrears for services performed. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. Examples of estimated accrued clinical expenses include:

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

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

Results of Operations

Comparison of Three Months ended June 30, 2016 and 2015

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

	Three Months Ended June 30,			
	2016	2015	$ Change	% Change
License fee revenue	$ —	$ 146	$ (146)	(100)%
Collaborative revenue	—	143	(143)	(100)%
Total revenues	$ —	$ 289	$ (289)	(100)%

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

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

	Three Months Ended June 30,			
	2016	2015	$ Change	% Change
Research and development expenses	$ 11,966	$ 8,539	$ 3,427	40 %

Research and development expense increased during the three months ended June 30, 2016 from the same period in 2015 primarily due to higher clinical development expenses of $2.8 million to support our ongoing clinical programs, the acceleration of enrollment in our SOLUTION clinical study, the initiation of two new Phase 3 studies, namely the SIMPLICITY study with liprotomase in sachet formulation and the CHABLIS-7.5 study with blisibimod in severe lupus patients, and manufacturing costs associated with Sollpura™.

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

	Three Months Ended June 30,			
	2016	2015	$ Change	% Change
General and administrative expenses	$ 2,576	$ 1,696	$ 880	52 %

General and administrative expenses increased during the three months ended June 30, 2016 from the same period in 2015 primarily due to higher non-cash stock-based compensation expense of $0.6 million recognized during the three months ended June 30, 2016 as a result of a greater number of unvested stock options.

Comparison of the six months ended June 30, 2016 and 2015

Revenues

	Six Months Ended June 30,			
	2016	2015	$ Change	% Change
License fee revenue	$ 139	$ 195	$ (56)	(29)%
Collaborative revenue	6	339	(333)	(98)%
Total revenues	$ 145	$ 534	$ (389)	(73)%

We began to recognize revenues in 2015 as a result of the collaborative arrangement that we entered into with Zenyaku in December 2014 for the development of blisibimod. During the six months ended June 30, 2015, we recorded approximately $0.2 million for the amortization of the license fee revenue and $0.3 million for the reimbursement of FTEs. The license fee revenue from the collaborative arrangement is amortized over the period of performance (product development period) while reimbursement for our FTEs is recorded as collaborative revenue. In September 2015, we received a termination notice from Zenyaku to terminate the collaborative arrangement, effective January 7, 2016. Consequently, we revised the amortization period of our deferred revenue to correspond with the shortened collaboration period and have fully amortized our deferred revenue as of January 7, 2016. During the six months ended June 30, 2016, we recorded approximately $0.1 million for the amortization of the license fee revenue and $6,000 for the reimbursement of FTEs.

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Research and Development Expenses

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

	Six Months Ended June 30,			
	2016	2015	$ Change	% Change
Research and development expenses	$ 21,590	$ 14,534	$ 7,056	49 %

Research and development expense increased during the six months ended June 30, 2016 from the same period in 2015 primarily due to higher clinical development expenses of $6.2 million to support our ongoing clinical programs, the acceleration of enrollment in our Solution clinical study, and initiation of two new Phase 3 studies, namely the SIMPLICITY study with liprotomase in sachet formulation and the CHABLIS-7.5 study with blisibimod in severe lupus patients, and manufacturing costs associated with Sollpura™. Furthermore, during the six months ended June 30, 2016, higher non-cash stock-based compensation expense of $0.4 million was recognized as result of a greater number of unvested stock options.

General and Administrative Expenses

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

	Six Months Ended June 30,			
	2015	2015	$ Change	% Change
General and administrative expense	$ 4,814	$ 3,603	$ 1,211	34 %

General and administrative expenses increased during the six months ended June 30, 2016 primarily due to higher non-cash stock-based compensation expense of $0.9 million recognized during the six months ended June 30, 2016 as a result of a greater number of unvested stock options.

Liquidity and Capital Resources

To date, we have funded our operations primarily through private placements of preferred stock and common stock, convertible debt, debt financings and public offerings of common stock, equity investment and cost reimbursement from a collaborative partner, and a research award from CFFT. As of June 30, 2016, we had cash and cash equivalents of approximately $28.5 million.

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

On March 14, 2016, we filed a universal shelf registration statement with the SEC on Form S-3 (File No. 333-210166) for the proposed offering from time to time of up to $100.0 million of our securities, including common stock, preferred stock, debt securities and/or warrants. As of the date of this report there is a balance of $60.6 million available for future issuance under the registration statement.

On November 15, 2013, we entered into an at-the-market sales agreement (the “Cowen ATM Agreement”) with Cowen and Company, LLC (“Cowen”) under which we from time to time were able to offer and sell shares of our common stock, par value $0.001 per share, having an aggregate offering price of up to $25.0 million through Cowen, as

agent. We had sold $24.3 million in shares of common stock pursuant to the Cowen ATM Agreement prior to terminating the agreement Cowen ATM Agreement on April 21, 2016.

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On April 21, 2016, we entered into an at-the-market sales agreement (the "H.C. Wainwright ATM Agreement") with H.C. Wainwright & Co., LLC ("H.C. Wainwright") under which we from time to time may offer and sell shares of our common stock, par value $0.001 per share, having an aggregate offering price of up to $25.0 million through H.C. Wainwright, as agent. As of June 30, 2016, we have sold $0.7 million in shares of common stock pursuant to the H.C. Wainwright ATM Agreement, leaving a balance of $24.3 available for future sale.

On March 12, 2015, we executed an equity purchase agreement Lincoln Park Capital Fund, LLC ("LPC"), pursuant to which we have the right, but not obligation, to sell to LPC up to an aggregate of $10.0 million in shares of common stock over a period of two years. In July 2015, we amended the Purchase Agreement to reduce the amount available for purchase to $6.0 million. During the quarter ended March 31, 2016, we sold $0.9 million in shares of common stock and issued 11,046 shares of common stock as commitment shares to LPC in lieu of cash commission. On April 27, 2016, we amended the equity purchase agreement and increased the amount of common stock available for purchase to $15.0 million. As of June 30, 2016, we have sold $1.0 million in shares of common stock pursuant to the equity purchase agreement, leaving a balance of $14.0 million available for future sale.

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

Cash Flows

Comparison of Six Months ended June 30, 2016 and 2015

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

	June 30,	
	2016	2015
Net cash used in operating activities	$(22,031)	$(12,752)
Net cash used in investing activities	(662)	(80)
Net cash provided by financing activities	4,242	45,648
Total	$(18,451)	$32,816

During the six months ended June 30, 2016 and 2015, our operating activities used cash of $22.0 million and $12.8 million, respectively, primarily resulting from our net losses and changes in our working capital accounts, adjusted for non-cash items including stock based compensation.

During the six months ended June 30, 2016, cash used in investing activities was $0.7 million, which was primarily driven by the purchase of capital equipment to support the manufacturing activities for the development of liprotamase. During the six months ended June 30, 2015, cash used in investing activities was immaterial.

During the six months ended June 30, 2016, cash provided by financing activities was $4.2 million, which was driven by net proceeds received from the sale of our common stock to LPC pursuant to an equity purchase agreement and to Cowen and H.C. Wainwright pursuant to the Cowen ATM Agreement and the H.C. Wainwright ATM Agreement. During the same period in 2015, cash provided by financing activities was $45.6 million, which was driven by net proceeds of $11.5 million from the at-the-market sales agreement with Cowen, $26.9 million received from the sale of our common stock through a public offering and $7.0 million from the sale of our common stock to our former collaborative partner, Zenyaku.

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Contractual Obligations and Commitments

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

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

	Payment Due by Period				
Contractual Obligations	Less than 1 year	1-3 years	3-5 years	More than 5 years	Total
Facility Lease	$233	$ 59	$ —	$ —	$292

The above amounts exclude potential payments to be made under our license agreements to our licensors that are based on the progress of our product candidates in development, as these payments are not determinable.

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

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

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

Funding Requirements

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

- prepare for commercial supply and commercial readiness;
- hire additional clinical, scientific and management personnel; and
- implement new operational, financial and management information systems.

Our future capital uses and requirements depend on numerous forward-looking factors. These factors include the following:

- the progress of clinical studies of our product candidates;
- the time and costs involved in obtaining regulatory approvals;
- delays that may be caused by evolving requirements of regulatory agencies;
- the costs involved in filing and prosecuting patent applications and enforcing or defending patent claims;
- our ability to establish, enforce and maintain selected strategic alliances; and

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- the acquisition of technologies, product candidates and other business opportunities that require financial commitments.

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

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

If adequate funds are not available, we may be required to terminate, significantly modify or delay our development programs, or obtain funds through collaborators that may require us to relinquish rights to our technologies or product candidates that we might otherwise seek to develop or commercialize independently. We may elect to raise additional funds even before we need them if the conditions for raising capital are favorable.

Off-Balance Sheet Arrangements

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

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. We are exposed to market risk related to fluctuations in interest rates, market prices, and foreign currency exchange rates. However, since a majority of our investments are in highly liquid money market funds, we do not believe we are subject to any material market risk exposure. As of June 30, 2016, we did not have any material derivative financial instruments. The fair value of our cash and cash equivalents was $28.5 million as of June 30, 2016.

Our investment policy is to limit credit exposure through diversification and investment in highly rated securities. We actively review, along with our investment advisors, current investment ratings, company specific events and general economic conditions in managing our investments and in determining whether there is a significant decline in fair value that is other-than-temporary.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Principal Accounting Officer, evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2016. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities and Exchange Act of 1934, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Securities Exchange Act of 1934 is recorded, processed, summarized, and reported within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Securities Exchange Act of 1934 is accumulated and communicated to that company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

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

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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 June 30, 2016 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

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

ITEM 1A. RISK FACTORS

An investment in our securities involves a high degree of risk. We operate in a dynamic and rapidly changing industry that involves numerous risks and uncertainties. The risks and uncertainties described below are not the only ones we face. Other risks and uncertainties, including those that we do not currently consider material, may impair our business. If any of the risks discussed below actually occur, our business, financial condition, operating results or cash flows could be materially adversely affected. This could cause the value of our securities to decline, and you may lose all or part of your investment.

Risks Related to Our Financial Condition and Capital Requirements

We have incurred significant losses since our inception and anticipate that we will incur continued significant losses for the foreseeable future.

We are a clinical-stage biotechnology company with two clinical assets in the late stage of development. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. We have no products approved for commercial sale and have not generated any revenue from product sales to date and we continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred losses in each period since our inception in 2004. Substantially all of our losses resulted from costs incurred in connection with our product development programs and from general and administrative costs associated with our operations.

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

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

Our ability to generate product revenue and achieve profitability depends on our ability, alone or with collaborators, to successfully complete the development of our product candidates, conduct clinical studies in patients, obtain the necessary regulatory approvals for our product candidates and commercialize any approved products. Although we recognized collaborative revenues from our license agreement with Zenyaku in the six months ended June 30, 2016, we cannot guarantee we will recognize collaborative revenue in the future. For the six months ended June 30, 2016, we recognized collaborative revenue related to the amortization of upfront license fee revenue and reimbursement for our internal full time equivalent ("FTE") employee and certain research and development expenses by Zenyaku. In September 2015, Zenyaku provided us a notice of its intent to terminate the Zenyaku Agreement, effective January 7,

2016. The termination was "at will" and Zenyaku alleged no breach of the Zenyaku Agreement by us. As a result of an early termination the Zenyaku Agreement, we will not recognize revenues under the Zenyaku Agreement beyond January 2016. We have not generated any revenue from our development-stage product candidates, and we do not know when, or if, we will generate any revenue. The commercial success of our development-stage product candidates will depend on a number of factors, including, but not limited to, our ability to:

- obtain favorable results for and advance the development of liprotamase, our product candidate for the treatment of patients with Exocrine Pancreatic Insufficiency, or EPI, and potentially other diseases;

- obtain favorable results for and advance the development of blisibimod, our product candidate for the treatment of B-cell mediated autoimmune diseases, including successfully launching and completing clinical studies in patients with systemic lupus erythematosus, or lupus, IgA nephropathy, or other indications;

- obtain regulatory approval for liprotamase and blisibimod;

- if regulatory approvals are obtained, begin the commercial manufacturing of our product candidates with third-party manufacturers;

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- launch commercial sales and effectively market our product candidates, either independently or in strategic collaborations with third parties; and

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

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

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

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

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

- manufacturing campaign for liprotamase and blisibimod clinical materials, including formulation development and product enhancement;

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

- the cost, timing and outcomes of regulatory proceedings;

- payments received under any strategic collaborations;

- the filing, prosecution and enforcement of patent claims;

- the costs associated with commercializing our product candidates if they receive regulatory approval, including the cost and timing of developing sales and marketing capabilities, or entering into strategic collaboration with others relating to the commercialization of our product candidates; and

- revenues received from approved products, if any, in the future

As of the date of this report, we anticipate that our existing cash and access to additional capital through an equity purchase agreement and the H.C. Wainwright ATM Agreement are sufficient to fund our near term liquidity needs for at least the next 12 months. Changing circumstances may cause us to consume capital significantly faster than we currently anticipate. Additional financing may not be available when we need it or may not be available on terms that are favorable to us. If adequate funds are not available to us on a timely basis, or at all, we may be required to:

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

- terminate, reduce or delay our (i) establishment of sales and marketing capabilities, (ii) pursuit of strategic collaborations with others relating to the sales, marketing and commercialization of our product candidates or (iii)

other activities that may be necessary to commercialize our product candidates, if approved for sale.

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

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

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

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

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

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

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

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

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

Our limited operating history makes it difficult to evaluate our business and prospects.

We were incorporated in September 2004. Our operations to date have been limited to organizing and staffing our company, acquiring product and technology rights, conducting product development activities for our primary product candidates, liprotamase and blisibimod, and performing research and development. We have not yet demonstrated an ability to obtain regulatory approval for or commercialize a product candidate. Consequently, any predictions about our future performance may not be as accurate as they could be if we had a history of successfully developing and commercializing pharmaceutical products.

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Risks Associated with Development and Commercialization of Our Product Candidates

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

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

Our product candidates are prone to the risks of failure inherent in drug development. Before obtaining regulatory approvals for the commercial sale of any product candidates for a target indication, we must demonstrate with substantial evidence gathered in preclinical and well- controlled clinical studies, and, with respect to approval in the United States, to the satisfaction of the FDA and, with respect to approval in other countries, similar regulatory authorities in those countries, that the product candidates are safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate. Despite our efforts, our product candidates may not:

·offer therapeutic or other improvement over existing, comparable therapeutics;

·be proven safe and effective in clinical studies;

·meet applicable regulatory standards;

·be capable of being produced in sufficient quantities at acceptable costs;

·be successfully commercialized; or

·obtain favorable reimbursement.

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

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

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

candidates may be delayed and their value maybe be reduced.

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

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

- obtaining regulatory approval to commence a clinical study or complying with conditions imposed by a regulatory authority regarding the scope or design of a clinical study;

- reaching agreement on acceptable terms with prospective clinical research organizations, or CROs, and study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and study sites;

- manufacturing, including manufacturing sufficient quantities of product candidates or other materials for use in clinical studies;

- obtaining Institutional Review Board (IRB), approval or the approval of other reviewing entities to conduct a clinical study at prospective sites;

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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;
- severe or unexpected drug-related adverse effects experienced by patients in a clinical study; and
- retaining patients who have enrolled in a clinical study, but may withdraw due to treatment protocol, adverse effects, lack of efficacy from the investigational treatment, personal issues or who are lost to further follow-up.

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

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

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

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

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

Success in preclinical testing and early clinical studies does not ensure that later clinical studies will generate adequate data to demonstrate the efficacy and safety of an investigational drug or biologic. A number of companies in the

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

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

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

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

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

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

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

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

Many of our potential competitors have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of drug candidates, and in obtaining FDA and other regulatory approvals of products and the commercialization of those products. Accordingly, our competitors may be

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

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

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

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

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

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

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

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

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

Even if we project positive clinical results and file for regulatory approval, we cannot commercialize any product candidate until the appropriate regulatory authorities have reviewed and approved the applications for such product

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

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

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

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

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

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

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

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

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

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

- our ability to obtain and maintain sufficient third-party coverage or reimbursement from government health care programs, including Medicare and Medicaid; and
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage.

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

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

We are highly dependent on Mr. Paul F. Truex, our Chief Executive Officer, Mr. Craig Thompson, our President and Chief Operating Officer, Dr. James Pennington, our Interim Chief Medical Officer, Dr. Chuck Olson, our Chief Technology Officer, and Ms. Klara Dickinson-Eason, our Chief Regulatory Officer, and the other principal members of our executive team. The loss of the services of any of these persons might impede the achievement of our research, development and commercialization objectives. Recruiting and retaining qualified scientific personnel and possibly sales and marketing personnel will also be critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific personnel from universities and research institutions. Failure to succeed in clinical studies may make it more challenging to recruit and retain qualified scientific personnel. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

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

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

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

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

Also in the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, also called the Medicare Modernization Act, or MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for drugs. In addition, this legislation authorized Medicare Part D prescription drug plans to use formularies where they can limit the number of drugs that will be covered in any therapeutic class. As a result of this legislation and the expansion of federal coverage of drug products, we expect that

there will be additional pressure to contain and reduce costs. These cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for any approved products and could seriously harm our business. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors.

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

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

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

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

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

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

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

Our research and development activities involve the controlled use of potentially hazardous substances, including toxic chemical and biological materials. We could be held liable for any contamination, injury or other damages resulting from these hazardous substances. In addition, our operations produce hazardous waste products. While third parties are responsible for disposal of our hazardous waste, we could be liable under environmental laws for any

required cleanup of sites at which our waste is disposed. Federal, state, foreign and local laws and regulations govern the use, manufacture, storage, handling and disposal of these hazardous materials. If we fail to comply with these laws and regulations at any time, or if they change, we may be subject to criminal sanctions and substantial civil liabilities, which may harm our business. Even if we continue to comply with all applicable laws and regulations regarding hazardous materials, we cannot eliminate the risk of accidental contamination or discharge and our resultant liability for any injuries or other damages caused by these accidents.

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

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

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

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

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

We rely on our manufacturers to purchase from third-party suppliers the materials necessary to produce drug product for our clinical studies. There are a small number of suppliers, and in some instances, a single supplier for certain capital equipment and raw materials that we use to manufacture drug product. Such suppliers may not sell these raw materials and equipment to our manufacturers at the times we need them or on commercially reasonable terms. We do not have any control over the process or timing of the acquisition of these raw materials and equipment by our manufacturers. Moreover, we currently do not have any agreements for the commercial production of these raw materials. Although we generally do not begin a clinical study unless we believe we have a sufficient supply of product candidates to complete the clinical study, any significant delay in the supply of product candidates or the raw material components thereof for an ongoing clinical study due to the need to replace a third-party manufacturer could considerably delay completion of our clinical studies, product testing and potential regulatory approval. If our manufacturers or we are unable to purchase these raw materials after regulatory approval has been obtained, the commercial launch would be delayed or there would be a shortage in supply of such product candidates, which would impair our ability to generate revenues from the sale of such product candidates.

Because of the complex nature of our compounds, our manufacturers may not be able to manufacture our compounds at a cost or in quantities or in a timely manner necessary to make commercially successful products. If we successfully commercialize a product candidate, we may be required to establish large-scale commercial manufacturing capabilities. In addition, as our drug development pipeline increases and matures, we will have a greater need for clinical study and commercial manufacturing capacity. We have no experience manufacturing pharmaceutical products on a commercial scale and some of these suppliers will need to increase their scale of production to meet our projected needs for commercial manufacturing, which may not occur on a timely basis.

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

to incur additional regulatory costs.

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

We do not currently have an organization for the sales, marketing and distribution of pharmaceutical products and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. In order to market any products that may be approved by the FDA, we must build our sales, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate product revenue and may not become profitable. We will be competing with many companies that currently have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

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Guidelines and recommendations published by various organizations may adversely affect the use of any products for which w

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

Risks Related to Our Intellectual Property

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

We hold license rights to numerous United States, European ("EP"), and non-EP foreign patents and patent applications relating to blisibimod and liprotamase. Our liprotamase portfolio is made up of exclusively licensed patents and patent applications from Eli Lilly. Our blisibimod portfolio is made up of exclusively and non-exclusively licensed patents and patent applications from Amgen, Inc.

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

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

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

- we or our licensors were the first to make the inventions covered by each of our pending patent applications;
- we or our licensors were the first to file patent applications for these inventions;
- others will not independently develop similar or alternative technologies or duplicate any of our technologies;
- any of our or our licensors' pending patent applications will result in issued patents;

- any of our or our licensors' patents will be valid or enforceable;
- any patents issued to us or our licensors and collaborators will provide a basis for commercially viable products, will provide us with any competitive advantages or will not be challenged by third parties;
- we will develop additional proprietary technologies or product candidates that are patentable; or
- the patents of others will not have an adverse effect on our business.

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

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

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

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

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

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

Our success will depend in part on the ability of us or our licensors to obtain, maintain and enforce patent protection for their intellectual property, in particular, those patents to which we have secured exclusive rights. We or our licensors may not successfully prosecute the patent applications which we have licensed. Even if patents issue in respect of these patent applications, we or our licensors may fail to maintain these patents, may determine not to pursue litigation against other companies that are infringing these patents or may pursue such litigation less aggressively than we would. Without protection for the intellectual property we license, other companies might be able to offer substantially identical products for sale, which could adversely affect our competitive business position and harm our business prospects.

If we do not obtain protection under the Hatch-Waxman Act and similar foreign legislation to extend our licensed patent terms and to obtain market exclusivity for our product candidates, our business will be materially harmed.

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

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

In Europe, similar legislative enactments allow patent terms in the European Union to be extended for up to five years through the grant of a Supplementary Protection Certificate (SPC). If we obtain the maximum five-year SPC for blisibimod and continue to have rights under the Amgen Agreement with respect to blisibimod, we will have European patent coverage for blisibimod compositions of matter until 2027. If we obtain the maximum five-year SPC for liprotamase and continue to have rights under the Lilly Agreement with respect to liprotamase, we will have European patent coverage for liprotamase compositions of matter until 2026 to 2030, depending on which EP patent the extension is applied to.

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

The European Union provides for a 10-year period of data exclusivity for innovator biologics (with the possibility of a further one-year extension) in most EU countries, beginning on the date of such European regulatory approval, regardless of when the European patent(s) covering such biologic expires. A generic version of the approved drug may not be marketed or sold during such market exclusivity period. Blisibimod and liprotamase may be eligible for this 10-year market exclusivity in Europe.

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

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

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

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

We may not be able to obtain any licenses or other rights to patents, technology or know-how from third parties necessary to conduct our business as described in this report and such licenses, if available at all, may not be available on commercially reasonable terms. Any failure to obtain such licenses could delay or prevent us from developing or

commercializing our product candidates or proposed product candidates, which would harm our business. Litigation or patent interference proceedings may be necessarily brought against third parties, as discussed below, to enforce any of our patents or other proprietary rights or to determine the scope and validity or enforceability of the proprietary rights of such third parties.

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

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

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

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

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

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

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

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

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

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

Our executive officers, directors and greater than 5% stockholders, in the aggregate, own approximately 35.28% of our outstanding common stock. As a result, such persons, acting together, will have the ability to influence our management and affairs and substantially all matters submitted to our stockholders for approval, including the election and removal of directors and approval of any significant transaction. These persons will also have the ability to influence our management and business affairs. This concentration of ownership may have the effect of delaying, deferring or preventing a change in control, impeding a merger, consolidation, takeover or other business combination involving us, or discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of our business, even if such a transaction would benefit other stockholders.

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

As of June 30, 2016, there were 41,285,033 shares of our common stock outstanding. In addition, as of June 30, 2016, we had outstanding options and warrants to purchase 5,920,338 shares of our common stock that, if 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 of a substantial number of shares could significantly reduce the market price of our common stock. Moreover, certain holders of shares of common stock will have rights, subject to some conditions, to require us to file registration statements covering the shares they currently hold, or to include these shares in registration statements that we may file for ourselves or other stockholders.

We have registered or will register all common stock that we may issue under our 2013 Stock Option and Incentive Plan (the "2013 Plan"), our Amended and Restated 2010 Stock Option and Incentive Plan (the "2010 Plan") and our Employee Stock Purchase Plan (the "ESPP"). As of June 30, 2016, an aggregate of 616,048 shares of our common stock have been reserved for future issuance under the 2013 Plan, plus any shares cancelled under our 2005 Equity Incentive Plan and 2010 Plan, and an aggregate of 68,677 shares of common stock have been reserved for future issuance under our ESPP. These shares can be freely sold in the public market upon issuance. If a large number of these shares are sold in the public market, the sales could reduce the trading price of our common stock.

In addition, we may sell shares of stock pursuant to an equity purchase agreement with LPC pursuant to which we have the right, but not the obligation, to sell to LPC up to an aggregate of $13.96 million of common stock until April 2017. We may also sell shares of stock pursuant to the H.C. Wainwright ATM Agreement under which we may from time to time offer and sell up to $25.0 million shares of our common stock. As of June 30, 2016, there is a balance of $24.3 million available for future sale pursuant to the at-the-market sales agreement with H.C. Wainwright. Finally, we maintain an effective shelf registration statement on Form S-3 with the SEC for the issuance and sale from time to time of up to approximately $60.6 million of our equity and debt securities.

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

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

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

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

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

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

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

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

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

- a classified and staggered board of directors whose members can only be dismissed for cause;
- the prohibition on actions by written consent of our stockholders;
- the limitation on who may call a special meeting of stockholders;
- the establishment of advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted upon at stockholder meetings;
- the ability of our board of directors to issue preferred stock without stockholder approval, which would increase the number of outstanding shares and could thwart a takeover attempt; and
- the requirement of at least 75% of the outstanding common stock to amend any of the foregoing provisions.

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

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

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

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ITEM 6. EXHIBITS

The following exhibits are filed as part of this report:

Number	Description
3.1	Fifth Amended and Restated Certificate of Incorporation (filed as Exhibit 3.6 to the registrant's Registration Statement on Form S-1/A (File No. 333-161930) filed with the SEC February 3, 2010 and incorporated herein by reference).
3.2	Certificate of Amendment to the Fifth Amended and Restated Certificate of Incorporation (filed as Annex A to the registrant's Definitive Proxy Statement on Schedule 14A, filed with the SEC October 20, 2012 and incorporated herein by reference).
3.3	Certificate of Amendment to the Fifth Amended and Restated Certificate of Incorporation filed July 12, 2013 and effective July 15, 2013 (filed as Exhibit 3.1 to the registrant's Current Report on Form 8-K, filed with the SEC on July 16, 2013 and incorporated herein by reference.)
3.4	Amended and Restated Bylaws, as amended on May 21, 2015 (filed as Exhibit 3.4 to the registrant's Form 10-Q filed with the SEC on August 10, 2015 and incorporated herein by reference).
10.1	Amendment to the LPC Agreement, dated as of April 27, 2016, between Anthera Pharmaceuticals, Inc. and Lincon Park Capital Fund, LLC (filed as exhibit 10.1 to the registrant's Form 8-K filed with the SEC on April 27, 2016 and incorporated herein by reference).
10.2	At Market Issuance Sales Agreement, dated April 21, 2016, between Anthera Pharmaceuticals, Inc. and H.C. Wainwright & Co., LLC (filed as exhibit 10.1 to the registrant's form 8-K filed with the SEC on April 21, 2016 and incorporated herein by reference).
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.
32.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as adopted pursuant Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.

101.DEF XBRL Taxonomy Extension Definition Linkbase Document.

101.LAB XBRL Taxonomy Extension Label Linkbase Document.

101.PRE XBRL Taxonomy Extension Presentation Linkbase Document.

Management contract or compensatory plan, contract or agreement.

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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.

August 9, 2016 By: /s/ Paul F. Truex
Paul F. Truex
Chief Executive Officer

August 9, 2016 By: /s/ May Liu
May Liu
Senior Vice President, Finance and Administration
(Principal Accounting Officer)