Anthera Pharmaceuticals Inc
Form 10-K
March 05, 2018

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)
ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2017
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 (Zip Code)
(Address of Principal Executive Offices)

(510) 856-5600
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Name of Each Exchange on Which Registered
Common Stock, par value $0.001 per share	The Nasdaq Capital Market

Securities registered pursuant to Section 12(g) of the Act:
None
Indicate by a check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by a check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes No

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 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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this FORM 10-K or any amendment to this FORM 10-K.

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

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

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

The aggregate market value of the registrant’s common stock held by non-affiliates as of June 30, 2017 was approximately $17.1 million based upon the closing sales price of the registrant’s common stock as reported on the Nasdaq Global Market. Shares of common stock held by each executive officer and director and by each person who owns 10 percent or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for any other purpose.

As of February 28, 2018, the number of outstanding shares of the registrant’s common stock, par value $0.001 per share, was 23,397,497.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant’s Proxy Statement for the registrant’s 2017 Annual Meeting of Stockholders will be filed with the Securities and Exchange Commission within 120 days after the registrant’s fiscal year ended December 31, 2017 and are incorporated by reference in Part III of this report.

ANTHERA PHARMACEUTICALS, INC.

FORM 10-K FOR THE FISCAL YEAR ENDED

DECEMBER 31, 2017

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Unless the context otherwise requires, we use the terms “Anthera Pharmaceuticals,” “Anthera,” “we,” “us,” “the Company” and “our” in this Annual Report on Form 10-K refer to Anthera Pharmaceuticals, Inc. and its subsidiaries. We use various trademarks, service marks and trade names in our business, including without limitation “Anthera Pharmaceuticals” and “Anthera.” This report also contains trademarks, services marks and trade names of other businesses that are the property of their respective holders.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, including the section entitled “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” contains forward-looking statements regarding future events and our future results that are subject to the safe harbors created under the Securities Act of 1933, as amended (the “Securities Act”), and the Securities Exchange Act of 1934, as amended (the “Exchange Act”). Forward-looking statements relate to future events or our future financial performance. We generally identify forward-looking statements by terminology such as “may,” “will,” “would,” “should,” “expects,” “plans,” “anticipates,” “could,” “intends,” “target,” “projects,” “contemplates,” “predicts,” “assume,” “intend,” “potential,” “continue” or other similar words or the negative of these terms. These statements are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. The outcome of the events described in these forward-looking statements is subject to risks, uncertainties and other factors described in “Risk Factors” and elsewhere in this report. Accordingly, you should not place undue reliance upon these forward-looking statements. We cannot assure you that the events and circumstances reflected in the forward-looking statements will be achieved or occur, the timing of events and circumstances and actual results could differ materially from those projected in the forward-looking statements. Forward-looking statements contained in this report include, but are not limited to, statements about:

- the progress of, timing of and amount of expenses associated with our research, development and commercialization activities;
- the timing, conduct and success of our clinical studies for our product candidates;
- our ability to obtain U.S. and foreign regulatory approval for our product candidates and the ability of our product candidates to meet existing or future regulatory standards;
- our expectations regarding federal, state and foreign regulatory requirements;
- the therapeutic benefits and effectiveness of our product candidates;
- the accuracy of our estimates of the size and characteristics of the markets that may be addressed by our product candidates;
- our ability to manufacture sufficient amounts of our product candidates for clinical studies and products for commercialization activities;
- our intention to seek to establish strategic collaborations or partnerships for the development or sale of our product candidates;
- our expectations as to future financial performance, expense levels and liquidity sources;
- the timing of commercializing our product candidates;

- our ability to compete with other companies that are or may be developing or selling products that are competitive with our product candidates;
- anticipated trends and challenges in our potential markets;
- our ability to attract and retain key personnel; and
- other factors discussed elsewhere in this report.

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The forward-looking statements made in this report relate only to events as of the date on which the statements are made. We have included important factors in the cautionary statements included in this report, particularly in the section entitled “Risk Factors” that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make. Except as required by law, we do not assume any intent to update any forward-looking statements after the date on which the statements are made, whether as a result of new information, future events or circumstances or otherwise.

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PART I

ITEM 1. BUSINESS

Overview

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

Sollpura

The exocrine pancreas is responsible for synthesis and secretion of digestive enzymes, including lipase, protease, and amylase. In addition, the pancreas secretes bicarbonate into the duodenum to neutralize the very high acidity of stomach contents. EPI occurs when diseases such as cystic fibrosis ("CF") and chronic pancreatitis ("CP") impede or destroy the exocrine function of the pancreas. A reduction in, or absence of, the normally secreted pancreatic digestive enzymes causes lipids, proteins, and carbohydrates to enter the distal gastrointestinal ("GI") tract in un-absorbable forms, leading to GI pain and distention, mal-digestion, and steatorrhea. Without appropriate therapy, patients with EPI may experience malnutrition, poor growth, weight loss, reduced quality of life, and, in severe cases, increased morbidity and early death.

PERT is currently the mainstay of treatment for nutrient malabsorption in patients with digestive enzyme deficiencies known as EPI and orally delivered porcine PERTs have been available for many years for its treatment. As the porcine-derived proteins contained in the PERTs pass through the low pH environment of the stomach, they are protected by the enteric coating until they reach a pH of approximately 5.6 or greater in the duodenum and then are rapidly released. Due to the bulk imposed by the enteric coating, most patients have to take 10-20 capsules per day in order to maintain their nutritional requirement. Patient-to-patient differences in the acidity of the upper intestine makes dissolution of enterically-coated products variable, and gives rise to alterations in the rate and extent to which enzymes are released from these products. Poor stability and variability in terms of potency and pharmaceutical properties have also been identified as important factors contributing to a poor response of some patients to PERTs.

Current PERTs are Suboptimal

Sollpura is a novel, non-porcine PERT that contains three biotechnology-derived digestive enzymes: a lipase, a protease and an amylase. Through enzyme cross-linking, the lipase enzyme in Sollpura is more stable than the porcine-derived lipase in the low pH environment of the stomach and therefore Sollpura does not have an enteric polymer coating. Furthermore, since the three enzymes in Sollpura are biotechnology-derived, Sollpura does not contain porcine proteins or purines that may be associated with a risk of viral transmission or allergic reaction to proteins of porcine origin. The individual enzyme components of Sollpura are formulated at a fixed ratio of lipase, protease, and amylase. The Sollpura enzyme dose ratio was selected from nonclinical efficacy studies conducted using a canine model of pancreatic insufficiency which demonstrated that the lipase enzyme in Sollpura was efficacious when administered at >500 units/kg per meal, and the protease doses >1000 units/kg per meal. The

suitability of the enzyme ratio in Sollpura is further supported by the observation that Sollpura and Creon were equi-effective in pigs with surgically-induced pancreatic insufficiency.

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Sollpura – a Potentially Transformative Therapy for EIP

We believe Sollpura has the potential to become the first soluble, stable and non-porcine derived enzyme product and offer a novel solution to patients who are unable to maintain appropriate nutritional health. Sollpura's chemical characteristics, unlike currently available PERTs, make it ideal for powder formulation as either a capsule, or sachet of powder for oral solution which can be conveniently administered in solution in a small volume of water.

Our Phase 3 Development of Sollpura in EPI

We initiated a Phase 3 study of Sollpura ("RESULT") in patients with EPI due to cystic fibrosis in May 2017. The RESULT study is a randomized, open-label, assessor-blind, non-inferiority, active-comparator study evaluating the non-inferiority of Sollpura with respect to Coefficient of Fat Absorption ("CFA") compared to a commercially available PERT in a population of porcine-derived PERT responders. The RESULT study's design is modified from a previous Phase 3 study's ("SOLUTION") design to account for the design limitations in the SOLUTION study by 1) starting Sollpura dosing as 125% of the pre-study PERT dose, 2) allowing for a more "real life" dose adjustment, as needed, based on signs and symptoms throughout the primary treatment phase of the study, and 3) a shorter treatment duration of 4 weeks, with 3 weeks of dose optimization and 1 week of stable dosing. Patients are then followed in a 20-week extension period for the collection of longer term safety and efficacy (e.g., growth, maintenance of body weight) data. The RESULT study design was discussed with the United States Food and Drug Administration ("FDA") prior to initiation. Furthermore, the study had been approved by the Cystic Fibrosis Foundation Therapeutics Development Network ("CFFTDN") Protocol Review Committee, and the European Cystic Fibrosis Society Clinical Trial Network Executive Committee.

The RESULT study enrolled 140 patients in North America, Eastern and Western Europe and Israel. In December 2017 and January 2018, pre-specified interim futility analyses of the RESULT study were conducted by a Data Monitoring Committee ("DMC") comprised of experts appointed by the CFFTDN when approximately 25% and 50% of patients had completed the 4-week treatment period; in each instance, the committee recommended the study to continue to completion as planned. We expect to report topline data from the RESULT study in March 2018.

A second, smaller Phase 3 study ("SIMPLICITY") aimed at expanding the treatment age of patients to include patients age 28 days to seven years old, and enabling potential marketing approval for the sachet presentation of Sollpura, was initiated in the second quarter of 2016. The SIMPLICITY study utilizes sachets containing Sollpura powder for oral solution. The study is designed in two parts (Part A and Part B). Part A which evaluated the safety and general usability of Sollpura powder for oral solution in 15 patients ≥7 years of age, was completed in the fourth quarter of 2016. On December 9, 2016, an independent Data Monitoring Committee evaluated the data from Part A and approved progression to Part B, which will enroll pediatric subjects below 7 years of age. Before we proceed with Part B, we plan to amend the SIMPLICITY study to follow a similar dosing approach as in the RESULT study and initiate enrollment in Part B in the second quarter of 2018.

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Furthermore, during the third quarter of 2016, we initiated the EASY study, which provides continued access to Sollpura for patients in the Sollpura arm who completed the SOLUTION study. We have amended this study to also allow Sollpura-assigned patients completing the RESULT study at a lipase dose greater than 10,000 units/kg/day to have continued access until the Biological License Application ("BLA") for Sollpura is approved by the FDA.

Lastly, prior to the RESULT study, we conducted another Phase 3 study ("SOLUTION") in patients with EPI. The SOLUTION study was also a randomized, open-label, assessor-blind, non-inferiority, active-comparator study evaluating the efficacy and safety of Sollpura. This pivotal study enrolled 128 patients in North America, Europe and Israel. Top line data announced in December 2016 showed that the study narrowly missed the CFA non-inferiority margin of the primary mITT analysis by one percent; however, by additional pre-specified analyses of CFA (mITT-Baseline Observation Carried Forward and Per Protocol), Sollpura met the non-inferiority criterion. The study also demonstrated that the ratio of the three enzymes in Sollpura provided an appropriate response in coefficient of nitrogen absorption ("CNA"). In March 2017, we announced data from the extension phase of the study, which showed that Sollpura demonstrated comparable maintenance in key measurements of height, weight, and body mass index in addition to being well tolerated throughout the 12-week extension period.

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

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

Blisibimod

BAFF, or B-cell Activating Factor (also known as B lymphocyte stimulator or BLyS), is a member of a tumor necrosis family of natural human proteins and is critical to the development, maintenance and survival of multiple B-cell lineages as well as plasma cells – all of which are critical to the human immune response. B-cells and plasma cells are a vital part of the human immune system, producing natural antibody responses to invading pathogens such as viruses, bacteria and other dangerous antigens. Abnormally high elevations of BAFF, B-cells and plasma cells have been associated with several autoimmune diseases, including lupus and IgA nephropathy. BAFF is primarily expressed by macrophages, monocytes and dendritic cells and interacts with three different receptors on B-cells and plasma cells including BAFF receptor, or BAFF-R, B-cell maturation antigen, or BCMA, and transmembrane activator and cyclophilin ligand interactor, or TACI. The potential role of BAFF inhibition and associated reductions in B-cell and plasma cell numbers in lupus and rheumatoid arthritis has been validated in multiple clinical studies with blisibimod and other BAFF antagonists.

Blisibimod, a peptibody directed against BAFF, was developed as an alternative to antibodies and is produced in Escherichia coli bacterial culture, as opposed to antibodies that are typically produced in mammalian cell culture. A peptibody is a novel fusion protein that is distinct from an antibody with several potential advantages, including ease of manufacture, potency and relatively small molecular weight. Blisibimod inhibits both soluble and membrane-bound BAFF.

Our Phase 2 Development of Blisibimod for Immunoglobulin A Nephropathy

IgA is a human antibody that helps the body fight infections. IgA nephropathy may occur when plasma cells express excessive amounts of under-glycosylated IgA and subsequent immune complexes containing this immunogenic protein are deposited in the kidneys. These IgA containing immune complexes deposit in the mesangium of glomeruli in the kidney and are proinflammatory. As a result, kidney glomeruli become inflamed and damaged, leading to leakage of blood and protein into urine. According to a recent publication in the New England Journal of Medicine (Wyatt & Julian, 2013), primary IgA nephropathy occurs at any age, most commonly with clinical onset in the second and third decades of life, and a large number of cases eventually progress to renal failure. In patients with IgA nephropathy, levels of BAFF are significantly higher than in healthy individuals, and elevated levels of BAFF are associated with histological severity of disease in kidney tissue. In IgA nephropathy, plasma cells express immunogenic IgA that forms immune complexes that deposit in renal tissue and lead to renal inflammation and damage that can progress to renal failure and end-stage renal disease. Significant reductions in B-cell counts were observed in clinical studies of patients with lupus with blisibimod with concomitant decreases in proteinuria, serum immunoglobulins and autoantibodies, and increases in complement C3. We believe inhibition of BAFF may reduce B-cell proliferation, maturation, and survival, thereby reducing serum levels of IgA and targeting antibodies, and therefore reduce progressive renal damage in patients with IgA nephropathy.

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In June 2013, we initiated a Phase 2 clinical study, ("BRIGHT-SC") of patients with IgA nephropathy in Asia and Eastern Europe. The BRIGHT-SC study was 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 included biopsy-proven IgA nephropathy and proteinuria greater than one gram but less than six grams per 24 hours (1g-6g/24hr). Patients must have been receiving standard of care medication including angiotensin converting enzyme inhibitors and/or angiotensin receptor blockers. Patients enrolled in the BRIGHT-SC study received 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 study enrolled 58 patients. In August 2017, we reported top line data from the completed extension of the BRIGHT-SC study in which all patients had the opportunity to complete at least 60 weeks of treatment and some patients were treated for up to two years. Throughout the treatment period and for up to one year of additional follow up off treatment, blisibimod appeared to halt disease progression as measured by the mean estimate of urinary protein:creatinine levels ("proteinuria"). Specifically, in patients treated with blisibimod, the mean change in proteinuria was stable to trending slightly downward, whereas the mean levels increased for patients in the placebo arm. Additionally, blisibimod showed a trend toward preservation of renal function based upon individual rates of change in estimated glomerular filtration rate ("eGFR"), with an annualized improvement of +6.2mL/min/1.73 m^2 per year compared to a worsening of -4.8 mL/min/1.73 m^2 with placebo as seen in the graph below. Furthermore, serum immunoglobulins IgA, IgG, and IgM, demonstrated marked reduction throughout the treatment period.

Market Opportunity

Sollpura for the treatment of Exocrine Pancreatic Insufficiency (EPI)

According to our estimate, EPI is a disease that affects an estimated 130,000 patients in the United States. The most common causes of EPI are chronic pancreatitis and cystic fibrosis, the former a longstanding inflammation of the pancreas altering the organ's normal structure and function that can result from malnutrition, heredity, or (in the western world especially), behavior (alcohol use and smoking), and the latter a recessive hereditary disease most common in Europeans and Ashkenazi Jews where the molecular culprit is an altered, CFTR-encoded chloride channel. In children, another common cause is Shwachman-Bodian-Diamond syndrome, a rare autosomal recessive genetic disorder resulting from mutation in the SBDS gene.

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Blisibimod for the treatment of IgA Nephropathy

According to the National Organization for Rare Diseases, primary IgA nephropathy occurs at any age, most commonly with clinical onset in the second and third decades of life and a large number of cases eventually progress to renal failure. There is also a striking geographic variation in the prevalence of IgA nephropathy throughout the world. In the United States, IgA nephropathy is considered an orphan disease as it is believed to affect approximately 130,000 people annually. In August 2017, the FDA granted orphan drug designation for blisibimod for the treatment of IgA. The prevalence of IgA nephropathy varies throughout the world, with the highest prevalence in Asia (Singapore, Japan and China), Australia, Finland and southern Europe (20 to 40% of all glomerulonephritis). In Asia, routine urinalyses are performed for school children and renal biopsies for patients with asymptomatic hematuria, and the reported prevalence of the disease is much higher. For example, in Japan, IgA nephropathy is estimated to affect over 350,000 people annually. According to the National Kidney and Urologic Diseases Information Clearinghouse, 25% of adults with IgA nephropathy eventually develop total kidney failure.

Manufacturing Strategy

Sollpura

We completed technology transfer for pharmaceutical ingredient (“API”) manufacturing and drug product manufacturing in 2016, and estimate that we will complete process validation for the fermentation and associated down-stream purification for all three enzyme APIs in 2019. In parallel, commercial scale capsule and sachet drug product manufacturing process validation is anticipated to be completed in 2019.

Regulatory Strategy

Sollpura

The RESULT study protocol has been reviewed by the FDA prior to initiation. We believe that the design of RESULT provides adequate evaluation of efficacy and safety of Sollpura to respond to the FDA’s 2011 complete response letter. The RESULT study should also address the 2005 EMA protocol assistance comments, which were consistent with the FDA’s request for an active comparator trial. We anticipate completing the Phase 3 clinical trials with Sollpura (the RESULT and SIMPLICITY studies) in 2018, and process validation for commercial manufacture of Sollpura APIs and drug product in 2019, with a target submission date of the Biologics Licence Application (“BLA”) in 2019.

IgA Nephropathy

In September 2013, we met with the FDA who agreed to consider accepting proteinuria as a surrogate endpoint under a Subpart E approval for blisibimod for treatment of 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. In December 2014 we met with the European Medicines Agency (“EMA”) as part of the scientific advice process for blisibimod, and reached agreement on the acceptability of proteinuria as the primary efficacy variable, as well as the sufficiency of a single study to support a Conditional Marketing Authorization Application (“CMAA”) provided that confirmatory evidence from a second study would be available post approval. The EMA also recommended that the protocol provide information on the required duration of treatment, duration of response and need for re-treatment. Given the observed effects of blisibimod on proteinuria in patients with lupus, we are currently evaluating our options for investigating the effects of blisibimod in B-cell associated glomerulonephritides.

Historical Clinical Studies by Licensor - Sollpura

Sollpura was studied from 2002 to 2009 in seven clinical trials, in which a total of 492 unique subjects received at least 1 dose of Sollpura. Three Phase 1 trials were conducted, 1 in healthy volunteers and 2 in subjects with EPI due to CF. Two short-term trials, the Phase 2 Study TC-2A, and the Phase 3 Study 726 evaluated the efficacy of Sollpura in subjects ≥7 years of age with EPI due to CF. Two long-term Phase 3 safety and tolerability trials were also conducted: Study 767 in subjects with EPI due to CF and Study 810 in subjects with EPI due to chronic pancreatitis/pancreatectomy. Completed clinical trials demonstrated that dietary fat and nitrogen (protein) absorption are significantly increased in patients with cystic fibrosis and EPI who received Sollpura. In 2013, Eli Lilly gained agreement from the FDA on the design of a pivotal trial that would provide adequate evaluation of efficacy and safety.

The dose-ranging Phase 1 study TC-1B evaluated five dose levels across a 50-fold range, from 100-to-5000 lipase units (U) per kg per meal in CF-EPI subjects. In this study, greater improvements in nutrients absorption, as measured using the percent change from baseline in the coefficient of fat absorption (CFA) and CNA, were observed at doses of 500 lipase U per kg per meal and higher.

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Study TC-2A, a Phase 2, randomized, double-blind, parallel group, dose-finding trial, was conducted in 125 pediatric and adult subjects with CF-related EPI who were treated with Sollpura for 28 days in one of three dosing regimens containing 6,500 U, 32,500 U, and 130,000 U lipase administered per meal or snack. Observed mean CFAs at the end of study were 56.2%, 67.0%, and 69.7% in the 6,500, 32,500, and 130,000 U dose groups, respectively (one-way ANOVA p = 0.0032) with significant improvements in mean changes from baseline (one-way ANOVA p = 0.0005) and mean changes from baseline off-enzyme CFA to on treatment were 1.2%, 11.4% and 17.3%, respectively (1-way ANOVA p=0.0005). Pairwise comparison of the CFA values showed that statistically greater improvements were observed at the higher doses of Sollpura compared with the lowest dose of 6,500 U. Similar improvements in the CNA, were observed with Sollpura at the two highest dose levels.

Study 726, a Phase 3, placebo-controlled, parallel design, multinational clinical, evaluated the effects of a single capsule of Sollpura (containing 32,500 U lipase, with protease and amylase in fixed ratios) or placebo administered with every meal or snack in subjects with cystic fibrosis-related EPI. Among the 138 subjects enrolled in this study, treatment with Sollpura resulted in a statistically significant improvement in the change from baseline in the CFA of 21.2% with Sollpura compared with 6.0% with placebo (p = 0.0011). The median body weight of subjects in this trial was 50 kg, for which the corresponding Sollpura dose was 650 U lipase/kg/meal or snack.

Two one-year studies were conducted to evaluate the safety and effects on nutritional status of Sollpura. Study 810 evaluated adult subjects with EPI due to CP or after pancreatectomy. Among the 214 subjects who were treated, an average dose of 5.5 capsules (containing 32,500 U lipase, with protease and amylase in fixed ratios) of Sollpura per day maintained nutritional status as assessed by serial measurement of height and weight, including age-appropriate growth and weight gain in children. Mean BMI z-scores for subjects in Study 767 were maintained over time on study (mean BMI z-score at baseline, Months 3, 6, and 12 were -0.503, -0.637, -0.688, and -0.655, respectively).

Historical Clinical Studies – Blisibimod

To date, five randomized, clinical studies have been conducted with blisibimod in patients with lupus: two Phase 1 dose-ranging studies by our licensor, Amgen; and two double-blind, placebo-controlled dose-ranging clinical outcomes studies, PEARL-SC (Phase 2b) and CHABLIS-SC1 (Phase 3), and a Phase 2 Open-Label Extension study (OLE) by the Company. All five clinical studies evaluated the efficacy and safety of multiple doses of subcutaneous blisibimod versus placebo in patients with active and seropositive lupus. The PEARL-SC study was completed in June 2012 and the CHABLIS-SC1 study was completed in November 2016. Both studies failed to meet the primary endpoints and we elected to stop further development of blisibimod for the treatment of lupus.

In the CHABLIS-SC1 study, the primary endpoint compared the effects of blisibimod and placebo at Week 52 using the SLE Responder Index-6 (SRI-6): ≥6-point improvement in SELENA-SLEDAI, no new BILAG 1A or 2B domain scores, and <0.3-point increase in Physician's Global Assessment. Compared with placebo, a higher proportion of subjects on blisibimod met the SRI-6 criteria from Week 16 through Week 52. However, this effect was not statistically significant at the primary endpoint analysis at Week 52. There was a statistically-significant steroid sparing effect among subjects randomized to blisibimod wherein 17.2% of subjects in the blisibimod group achieved corticosteroid dose of less than or equivalent to 7.5 mg prednisone compared with 8.9% in the control group (p=0.019). In subjects with baseline urinary protein:creatinine ratio (UPCR) ≥0.5 g/g, significantly higher proportions of blisibimod subjects achieved >50% reduction in UPCR, and/or UPCR <0.5 g/g. Reductions in SLE autoantibodies and B cells, and increases in complement C3 and C4 were observed with blisibimod. We believe that these data support the further research with blisibimod patients with B-cell associated glomerulonephritides including IgA nephropathy, lupus with renal manifestations, and membranous glomerulonephritis. As a result of the outcomes of the CHABLIS-SC1 trial, at the end of 2016 we elected to discontinue the Phase 3 CHABLIS-7.5 study, which was initiated in June 2016.

Research and Development

Since our inception in 2004, we have focused primarily on developing our product candidates, which currently include Sollpura for EPI and blisibimod for IgA nephropathy and potentially other glomerulonephritides. In the years ended December 31, 2017, 2016, and 2015, we incurred $28.6 million, $46.5 million and $33.5 million, respectively, of research and development expense.

Our Strategy

Our objective is to develop and commercialize our product candidates to treat serious diseases associated with inflammation, including enzyme replacement therapies and renal disease. To achieve these objectives, we intend to initially focus on the following activities.

Advance Clinical Development of Sollpura

We are advancing the development of Sollpura in a Phase 3 registration program in patients with cystic fibrosis-related EPI. If our Phase 3 clinical study is successful, we intend to commercialize Sollpura in the U.S. and seek strategic corporate partners whose capabilities complement ours to launch Sollpura outside of U.S.

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Seek Collaborative Corporate Partner for Blisibimod

We have received orphan drug designation for blisibimod for the treatment of IgA nephropathy. We plan to opportunistically enter into collaborations with third parties for the development of blisibimod in renal disease and other B-cell associated glomerulonephritides.

Developing Commercial Strategies Designed to Maximize Our Product Candidates' Market Potential

Our product candidates are focused on highly-specialized physician segments, such as cystic fibrosis specialists and nephrologists. We believe that we can build a small, focused sales force capable of marketing our products effectively in acute care and orphan indications.

Competition

Our industry is highly competitive and subject to rapid and significant technological change. Our potential competitors include large pharmaceutical and biotechnology companies, specialty pharmaceutical and generic drug companies, academic institutions, government agencies and research institutions. Our primary competitors who market PERTs approved in the U.S. or are developing PERTs in the U.S. are described in further detail below. We believe that key competitive factors that will affect the development and commercial success of our product candidates are efficacy, safety and tolerability profile, reliability, convenience of dosing, price and reimbursement.

Compound	Stage	Company	Indications	Notes
Creon	Approved	Abbvie	EPI, CF, CP, pancreatectomy	Ÿ Porcine, enteric coated
Pancreaze	Approved	Janssen/J&J	EPI, CF and other	Ÿ Porcine, enteric coated
Zenpep	Approved	Allergan	EPI, CF, CP	Ÿ Porcine, enteric coated
Viokace	Approved	Allergan	EPI, CP and pancreatectomy in adults	Ÿ Porcine, enteric coated, in combination with proton pump inhibitor
Pertzye	Approved	Chiesi	EPI, CF	Ÿ Porcine, enteric coated
MS1819	Phase 2a	AzurRx	EPI, CP	Ÿ Lipase only

Intellectual Property

Our policy is to pursue, maintain and defend patent rights, developed internally and licensed from third parties, to protect the technology, inventions and improvements that are commercially important to the development of our business. We also rely on trade secrets that may be important to the development of our business.

Our success will depend significantly on our ability to:

- obtain and maintain patent and other proprietary protection for the technology, inventions and improvements we consider important to our business;

- defend our patents;

- preserve the confidentiality of our trade secrets; and

- operate our business without infringing the patents and proprietary rights of third parties.

Sollpura

As of the date of this report, our Sollpura portfolio is made up of exclusively licensed patents and patent applications from Eli Lilly, including:

- Two issued U.S. patents;

- Four issued European ("EP") patents, each validated in one or more of Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Great Britain, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Monaco, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and Turkey;

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· 16 issued non-EP foreign patents in Australia, Canada, China, Hong Kong, India, Israel, Japan, Mexico, Russia, South Korea and Ukraine; and

· One pending non-EP foreign patent application.

We hold exclusive worldwide licenses from Eli Lilly to all of these patents and patent applications. The exclusively licensed U.S. patents are currently scheduled to expire in March 2025 and July 2028. Depending upon the timing, duration and specifics of FDA approval of Sollpura, one of these U.S. patents may be eligible for a patent term restoration of up to five years under Hatch-Waxman Act. See "—Regulatory Matters— Patent Term Restoration and Marketing Exclusivity." This could extend the expiration date of the selected U.S. Patent to as late as March 2030 or July 2033, depending on which patent the term restoration is applied to. We intend to pursue pediatric exclusivity as well, which could add an additional six months to the patent term. The four exclusively licensed EP patents are currently scheduled to expire between February 2021 and October 2025. One of these patents may be eligible for a Supplementary Protection Certificate of up to five years, which could extend the expiration date to between February 2026 and October 2030.

Blisibimod

As of the date of this report, our blisibimod patent portfolio includes:

· Four issued U.S. patents;

· One pending U.S. non-provisional patent application;

· Three issued European (EP) patents, each validated in one or more of Albania, Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Monaco, the Netherlands, Portugal, Romania, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom;

· One pending EP patent application;

· 23 issued non-EP foreign patents in Australia, Bulgaria, Canada, China, the Czech Republic, Estonia, Eurasia (validated in all nine Eurasian countries), Hong Kong, Hungary, Israel, Japan, Mexico, New Zealand, Norway, the Philippines, Poland, Serbia, Singapore, Slovakia, South Korea and South Africa; and

· Four pending non-EP foreign patent applications in Brazil, Hong Kong, Mexico, and Poland.

We hold exclusive worldwide licenses from Amgen to all of these patents and patent applications. In addition, we hold a non-exclusive worldwide license to one issued U.S. patent, one pending U.S. non-provisional patent application, one EP patent, one pending EP patent application, and over 50 non-EP foreign patents and pending patent applications relating to general peptibody compositions and formulations.

The four exclusively licensed U.S. patents are currently scheduled to expire in May 2022, March 2023 and November 2023. Depending upon the timing, duration and specifics of FDA approval of blisibimod, one of these U.S. patents (or another patent issuing from a related patent application) is expected to be eligible for a patent term restoration of up to five years under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Act. See "—Regulatory Matters— Patent Term Restoration and Marketing Exclusivity." This could extend the expiration date of the U.S. Patent to as late as May 2027, March 2028 or November 2028, depending on which patent the term restoration is applied to. We intend to pursue pediatric exclusivity as well, which could add an additional six months to the patent term. The exclusively licensed EP patents are currently scheduled to expire in May

2022. One of these patents is expected to be eligible for a Supplementary Protection Certificate of up to five years, which could extend the expiration date to May 2027.

The U.S. patent system permits the filing of provisional and non-provisional patent applications. A non-provisional patent application is examined by the United States Patent and Trademark Office, or USPTO, and can mature into a patent once the USPTO determines that the claimed invention meets the standards for patentability. A provisional patent application is not examined, and automatically expires 12 months after its filing date. As a result, a provisional patent application cannot mature into a patent. The requirements for filing a provisional patent application are not as strict as those for filing a non-provisional patent application. Provisional applications are often used, among other things, to establish an early filing date for a subsequent non-provisional patent application.

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The filing date of a non-provisional patent application is used by the USPTO to determine what information is prior art when it considers the patentability of a claimed invention. If certain requirements are satisfied, a non-provisional patent application can claim the benefit of the filing date of an earlier filed provisional patent application. As a result, the filing date accorded by the provisional patent application may remove information that otherwise could preclude the patentability of an invention.

We are aware of two third-party issued U.S. patents that contain broad claims related to BLyS or BAFF binding polypeptides. Based on our analyses, if these patents were asserted against us, we do not believe that blisibimod would be found to infringe any valid claim of these patents. If we were to challenge the validity of either of these issued U.S. patents in court, we would need to overcome the presumption of validity that attaches to every U.S. 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 possibly requiring 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.

Current License Agreements

Eli Lilly and Company

In July 2014, we entered into a worldwide, exclusive license agreement with Eli Lilly (the "Lilly Agreement"), to develop and commercialize Sollpura, a Phase 3 novel investigational PERT for the treatment of patients with EPI, often seen in patients with cystic fibrosis and other conditions. Under the terms of the Lilly Agreement, we were not required to make any up-front payment but are obligated to make milestone payments of up to $33.5 million for capsule products and $9.5 million for reformulated products upon the achievement of certain regulatory and commercial sales milestones, none of which have been achieved as of December 31, 2017. 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 of products, 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 us or a sublicense in such country, or (b) 12 years after the first commercial sale of the applicable licensed product in the applicable country.

Amgen

In December 2007, we entered into a license agreement with Amgen, which was amended in October 2009 and November 2014 (as amended, the "Amgen Agreement"), pursuant to which we obtained an exclusive worldwide license to certain technology and compounds relating to blisibimod, as well as a non-exclusive worldwide license to technology relating to certain peptibody compositions of matter and formulations. The licensed patents included a specific set of previously filed U.S. and foreign patents and applications, as well as any applications filed after the execution date by Amgen and covering licensed know-how. During the period of the agreement, we are responsible for the filing, prosecution, defense and maintenance of all exclusively licensed blisibimod patents and applications. Amgen retains the right to review all documents relating to said filing, prosecution, defense and maintenance, and we are required to incorporate all reasonable comments or suggestions that Amgen makes with regard to these documents.

Pursuant to the terms of the Amgen Agreement, we have paid $6.0 million in license fees to Amgen for blisibimod. In addition, we are required to make various milestone payments upon the achievement of certain development, regulatory and commercial objectives, including payment upon commencement of the first Phase 3 clinical study for any blisibimod formulation in the United States or European Union. We are also 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. Furthermore, we are required to make tiered quarterly royalty payments on net sales, which increase as a percentage from the high single digits to the low double digits as net sales increase. Our royalty payment obligations for a particular product in a particular country begin on the date of the first commercial sale of the licensed product in that country, and end upon the later of 10 years from the date of first commercial sale in that country or the expiration date of the last valid claim of a licensed patent that covers the manufacture, use or sale, offer to sell or import of the product.

The Amgen Agreement will remain in effect until we elect to terminate, or until termination for material breach by either party or insolvency on our part. Under these terms, Amgen can terminate the agreement if we fail to meet our obligations, resulting in a loss of our exclusive rights to the licensed technology.

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In connection with a collaborative arrangement with Zenyaku Kogyo Co., Ltd ("Zenyaku") for the development of IgA nephropathy that was executed in December 2014 and terminated in January 2016, we amended the Amgen Agreement in November 2014 to (i) adjust certain royalty and milestone payment obligations payable to Amgen in light of our collaboration with Zenyaku and (ii) provide that the sublicense granted by us to Zenyaku shall survive the termination of the Amgen Agreement. Under this amendment, we also agreed to grant Amgen that number of shares of our common stock equal to $1.0 million divided by the volume weighted average price of our common stock for 20 trading days prior to issuance. We 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.

Manufacturing and Supply

We currently rely on contract manufacturers to produce drug substances and drug products required for our clinical studies under current GMP with oversight by our internal managers. We plan to continue to rely upon contract manufacturers and, potentially, collaboration partners to manufacture commercial quantities of our product candidates if and when approved for marketing by the FDA. Our contract manufacturers obtain the raw materials for the drug substances and drug products required for our clinical studies from a variety of sources. We believe that this will provide a sufficient supply of these raw materials and drug product to meet our needs for the foreseeable future. We do not have in place long term supply agreements with respect to all of the components of any of our pharmaceutical systems, however, and are subject to the risk that we may not be able to procure all required components in adequate quantities with acceptable quality, within acceptable time frames or at reasonable cost.

Our research and development activities involve the controlled use of potentially hazardous substances, including toxic chemical and biological materials. Accordingly, we are subject to federal, state and local laws governing the use, handling and disposal of these materials. We believe that our safety procedures for handling and disposing of these materials comply in all material respects with the standards prescribed by local, state and federal regulations.

Sales and Marketing

Given our stage of development, we have not developed a commercial organization or distribution capabilities. We expect that we would develop these capabilities once we receive Phase 3 data in contemplation of FDA approval and the commercial launch of our product candidates. In order to commercialize our product candidates, we plan to develop these capabilities internally or through collaboration with third parties. In selected therapeutic areas where we feel that any approved products can be commercialized by a specialty sales force that calls on a limited and focused group of physicians, we may seek to commercialize the product candidates alone. We also plan to seek commercialization partners for products in international markets.

We intend to build the commercial infrastructure necessary to bring our product candidates to market. In addition to a specialty sales force, sales management, internal sales support and an internal marketing group, we will need to establish capabilities to manage key accounts, such as managed care organizations, group-purchasing organizations, specialty pharmacies and government accounts. We may also choose to employ medical sales liaisons personnel to support our products.

Regulatory Matters

Government Regulation and Product Approval

Government authorities in the United States at the federal, state and local level and other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling,

packaging, storage, record-keeping, promotion, advertising, distribution, marketing, export and import of products such as those we are developing. Our product candidates must be approved by the FDA through either the new drug application, or NDA, process, or the biologics license application, or BLA, process before they may legally be marketed in the United States. Both of our drug candidates, Sollpura and blisibimod, are biologically manufactured and will go through the BLA process for approval if successful in Phase 3.

United States Drug Development Process

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and implementing regulations and biological products under both the FDCA and the Public Health Service Act, or the PHSA, and implementing regulations. The process of obtaining regulatory approvals and compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process, or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, withdrawal of an approval, license revocation, a clinical hold, untitled or warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. The process required by the FDA before a drug or biological product may be marketed in the United States generally involves the following:

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- completion of preclinical laboratory tests, animal studies and formulation studies according to Good Laboratory Practices regulations;

- submission to the FDA of an IND, which must become effective before human clinical studies may begin;

- performance of adequate and well-controlled human clinical studies according to Good Clinical Practices, or GCP, to establish the safety and efficacy of the proposed drug or biological product for its intended use;

- submission to the FDA of an NDA for a new drug or BLA for a biological product;

- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug or biological product is produced to assess compliance with cGMP; and

- FDA review and approval of the NDA or BLA.

The testing and approval process requires substantial time, effort and financial resources and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, if at all. Once a pharmaceutical or biological product candidate is identified for development, it enters the preclinical testing stage. Nonclinical tests include laboratory evaluations of product chemistry, toxicity, formulation and stability, as well as animal studies to assess its potential safety and efficacy. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data and any available clinical data or literature, to the FDA as part of the IND. The sponsor includes a protocol detailing, among other things, the objectives of the initial clinical study, dosing procedures, subject selection and exclusion criteria, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated if the initial clinical study lends itself to an efficacy evaluation. Some nonclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA places the clinical study on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical study can begin. Clinical holds may also be imposed by the FDA at any time before or during clinical studies due to safety concerns or non-compliance.

All clinical studies must be conducted under the supervision of one or more qualified investigators in accordance with GCP regulations. These regulations include the requirement that all research subjects provide informed consent. Further, an institutional review board, or IRB, must review and approve the plan for any clinical study before it commences at any institution. An IRB considers, among other things, whether the risks to individuals participating in the studies are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the information regarding the clinical study and the consent form that must be provided to each clinical study subject or to his or her legal representative and must monitor the clinical study until completed. Each new clinical protocol and any amendments to the protocol must be submitted to the FDA for review, and to the IRBs for approval.

Human clinical studies are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1. The product is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.

- Phase 2. Involves studies in a limited patient population to identify possible adverse effects and safety risks to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage and schedule.

- Phase 3. Clinical studies are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical study sites. These studies are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for product labeling.

Progress reports detailing the results of the clinical studies must be submitted at least annually to the FDA. Safety reports must be submitted to the FDA and the investigators within 15 days after the sponsor determines the information qualifies for reporting for serious and unexpected suspected adverse reactions, findings from other studies or animal or in vitro testing that suggest a significant risk in humans, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator's brochure. A sponsor also must notify FDA of any unexpected fatal or life-threatening suspected adverse reaction within 7 days after the sponsor's receipt of the information. Phase 1, Phase 2 and Phase 3 testing may not be completed successfully within any specified period, if at all. The FDA, a data safety monitoring board, or the sponsor may suspend or terminate a clinical study at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical study at its institution if the clinical study is not being conducted in accordance with the IRB's requirements or if the drug or biological product has been associated with unexpected serious harm to patients.

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Concurrent with clinical studies, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidates and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidates do not undergo unacceptable deterioration over their shelf life.

U.S. Review and Approval Processes

The results of product development, preclinical studies and clinical studies, along with descriptions of the manufacturing process, analytical tests conducted on the drug or biological product, proposed labeling and other relevant information, are submitted to the FDA as part of an NDA for a new drug or BLA for a biological product, requesting approval to market the product. The submission of an NDA or BLA is subject to the payment of a substantial user fee; a waiver of such fee may be obtained under certain limited circumstances.

In addition, under the Pediatric Research Equity Act of 2003, or PREA, as amended, an NDA or BLA or supplement to an NDA or BLA must contain data to assess the safety and effectiveness of the drug or biological product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers. A sponsor who is planning to submit a marketing application for a drug that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration is required to submit an initial Pediatric Study Plan, or PSP, within sixty days of an end-of-Phase 2 meeting or, if there is no end-of-Phase 2 meeting as early as practicable before the initiation of the Phase 3 or Phase 2/3 study. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from nonclinical studies, early phase clinical trials, and/or other clinical development programs. Unless otherwise required by regulation, PREA does not apply to any drug or biological product for an indication for which orphan designation has been granted.

The FDA reviews all NDAs and BLAs submitted to ensure that they are sufficiently complete for substantive review before it accepts them for filing. The FDA may request additional information rather than accept a NDA or BLA for filing. In this event, the NDA or BLA must be re-submitted with the additional information. The re-submitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP- compliant to assure and preserve the product's identity, strength, quality and purity. The FDA reviews a BLA to determine, among other things, whether the product is safe, has an acceptable purity profile and is adequately potent, and whether its manufacturing meets standards designed to assure the product's continued identity, sterility, safety, purity and potency. Before approving an NDA or BLA, the FDA will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The FDA may refer the NDA or BLA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. An advisory committee is a panel of experts who provide advice and recommendations when requested by the FDA on matters of importance that come before the agency. The FDA is not bound by the recommendation of an advisory committee but

it generally follows such recommendations.

The approval process is lengthy and difficult and the FDA may refuse to approve an NDA or BLA if the applicable regulatory criteria are not satisfied or may require additional clinical data or other data and information. Even if such data and information is submitted, the FDA may ultimately decide that the NDA or BLA does not satisfy the criteria for approval. Data obtained from clinical studies are not always conclusive and the FDA may interpret data differently than we interpret the same data. The FDA will issue a complete response letter if the agency decides not to approve the NDA or BLA in its present form. The complete response letter usually describes all of the specific deficiencies in the NDA or BLA identified by the FDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical studies. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the NDA or BLA, addressing all of the deficiencies identified in the letter, or withdraw the application

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If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may require Phase 4 testing which involves clinical studies designed to further assess a drug or biological product's safety and effectiveness after NDA or BLA approval and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized.

Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of FDA approval of the use of our product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Amendment. The Hatch-Waxman Amendment permits a patent term restoration of up to five years as compensation for patent term lost during the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA or BLA plus the time between the submission date of an NDA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we intend to apply for restorations of patent terms for some of our currently owned or licensed patents to add patent life beyond their current expiration dates, depending on the expected length of the clinical studies and other factors involved in the filing of the relevant NDA or BLA.

Market exclusivity provisions under the FDCA can also delay the submission or the approval of certain competitor applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application, or ANDA, or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical studies necessary to demonstrate safety and effectiveness. The Patient Protection and Affordable Care Act provides 12 years of data exclusivity for innovator biologics. During this exclusivity period, competitors are barred from relying on the innovator's safety and efficacy data to gain FDA approval. Therefore, a competitor seeking to obtain marketing approval during this exclusivity period would be required to conduct its own preclinical and clinical studies.

Pediatric exclusivity is another type of exclusivity in the United States. Pediatric exclusivity, if granted, adds an additional six months to an existing exclusivity or statutory delay in approval resulting from a patent certification. This six-month exclusivity, which runs from the end of other exclusivity protection or patent delay, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making a drug or biological product available in the U.S. for this type of disease or condition will be recovered from sales of the product. Orphan product designation must be requested before submitting an NDA or BLA. After the FDA grants orphan product designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug or biological product for the same indication, except in very limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity by means of greater effectiveness, greater safety, or by providing a major contribution to patient care, for seven years. Competitors, however, may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product, but for a different indication for which the orphan product has exclusivity. Orphan product exclusivity could also block the approval of one of our products for seven years if a competitor obtains approval of the same drug or biological product as defined by the FDA or if any of our product candidates is determined to be contained within the competitor’s product for the same indication or disease. If a drug or biological product designated as an orphan product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan product exclusivity.

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The FDA also administers a clinical research grants program, whereby researchers may compete for funding to conduct clinical studies to support the approval of drugs, biologics, medical devices and medical foods for rare diseases and conditions. A product does not have to be designated as an orphan product to be eligible for the grant program. An application for an orphan grant should propose one discrete clinical study to facilitate FDA approval of the product for a rare disease or condition. The clinical study may address an unapproved new product or an unapproved new use for a product already on the market.

Expedited Development and Review Programs

The FDA has a fast track program that is intended to expedite or facilitate the process for reviewing new drugs and biological products that are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. For a fast track product, the FDA may consider for review on a rolling basis sections of the NDA or BLA before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA or BLA, the FDA agrees to accept sections of the NDA or BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA or BLA.

A fast track product may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. A fast track product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug or biological product designated for priority review in an effort to facilitate the review. Additionally, a fast track product may be eligible for accelerated approval. Drug or biological products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval, which means that they may be approved on the basis of adequate and well- controlled clinical studies establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. As a condition of approval, the FDA may require that a sponsor of a drug or biological product receiving accelerated approval perform adequate and well-controlled post-marketing clinical studies. Fast track designation, priority review and accelerated approval do not change the standards for approval but may expedite the development or approval process.

Sponsors may request that their drug be designated as a Breakthrough Therapy. The goal of this program is to expedite the development and review of a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition if preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA actions to expedite the development of a Breakthrough Therapy include (a) holding meetings with the sponsor and the review team throughout the development of the drug, (b) providing timely advice to and interactive communication with the sponsor regarding the development of the drug to ensure that the development program to gather the nonclinical and clinical data necessary for approval is as efficient as practicable, (c) involving senior managers and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review, (d) assigning a cross-disciplinary project lead for the FDA review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor and (e) taking steps to ensure that the design of the clinical trials is as efficient as practicable, when scientifically appropriate, such as by minimizing the number of patients exposed to a potentially less efficacious treatment.

Post-Approval Requirements

Any drug or biological products for which we receive FDA approvals are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, complying with certain electronic records and signature requirements and complying with FDA promotion and advertising requirements. The FDA strictly regulates labeling, advertising, promotion and other types of information on products that are placed on the market. Drugs and biological products may be promoted only for the approved indications and in accordance with the provisions of the approved label. Further, manufacturers of drugs and biological products must continue to comply with cGMP requirements, which are extensive and require considerable time, resources and ongoing investment to ensure compliance. In addition, changes to the manufacturing process generally require prior FDA approval before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

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Drug and biological product manufacturers and other entities involved in the manufacturing and distribution of approved drugs or biological products are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. The cGMP requirements apply to all stages of the manufacturing process, including the production, processing, sterilization, packaging, labeling, storage and shipment of the drug or biological product. Manufacturers must establish validated systems to ensure that products meet specifications and regulatory standards, and test each product batch or lot prior to its release.

Manufacturers of biological products must also report to the FDA any deviations from cGMP that may affect the safety, purity or potency of a distributed product; or any unexpected or unforeseeable event that may affect the safety, purity or potency of a distributed product. The regulations also require investigation and correction of any deviations from cGMP and impose documentation requirements.

We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products. Future FDA and state inspections may identify compliance issues at the facilities of our contract manufacturers that may disrupt production or distribution or may require substantial resources to correct.

The FDA may withdraw a product approval if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. Further, the failure to maintain compliance with regulatory requirements may result in administrative or judicial actions, such as fines, warning letters, holds on clinical studies, product recalls or seizures, product detention or refusal to permit the import or export of products, refusal to approve pending applications or supplements, restrictions on marketing or manufacturing, injunctions or civil or criminal penalties.

In addition, from time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA.

In addition to new legislation, the FDA regulations and policies are often revised or reinterpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether further legislative or FDA regulation or policy changes will be enacted or implemented and what the impact of such changes, if any, may be.

Foreign Regulation

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical studies and commercial sales and distribution of our products to the extent we choose to sell any products outside of the United States. Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence clinical studies or marketing of the product in those countries. The approval process varies from country to country and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical studies, product licensing, pricing and reimbursement vary greatly from country to country.

In the European Union, our products are subject to extensive regulatory requirements, which provide, among other things, that no medicinal product may be placed on the market of a European Union member state unless a marketing authorization has been issued by the European Medicines Agency or a national competent authority. European Union member states require regulatory clearance by both the national competent authority and a favorable ethics committee opinion prior to the commencement of a clinical study.

Under the European Union regulatory systems, we may submit marketing authorization applications either under a centralized or decentralized procedure. The centralized procedure provides for the grant of a single marketing authorization that is valid for all European Union member states. The centralized procedure is compulsory for medicines produced by certain biotechnological processes, products with a new active substance indicated for the treatment of certain diseases such as neurodegenerative disorder or diabetes and products designated as orphan medicinal products, and optional for those products which are highly innovative or for which a centralized process is in the interest of patients. The decentralized procedure of approval provides for approval by one or more other, or concerned, member states of an assessment of an application performed by one member state, known as the reference member state. Under the decentralized approval procedure, an applicant submits an application, or dossier, and related materials (draft summary of product characteristics, draft labeling and package leaflet) to the reference member state and concerned member states. The reference member state prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. Within 90 days of receiving the reference member state's assessment report, each concerned member state must decide whether to approve the assessment report and related materials. If a member state cannot approve the assessment report and related materials on the grounds of potential serious risk to public health, the disputed points may eventually be referred to the European Commission, whose decision is binding on all member states.

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Reimbursement

Sales of pharmaceutical products depend significantly on the availability and adequacy of third-party reimbursement. Third-party payors include government health administrative authorities, including, at the federal and state level, managed care providers, private health insurers and other organizations. We anticipate third-party payors will provide reimbursement for our product although we cannot predict the level of reimbursement such third-party payors will provide for our products. Third-party payors are increasingly challenging the price and examining the cost-effectiveness of medical products and services. In addition, significant uncertainty exists as to the reimbursement status of newly approved health care products. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of our products. Our product candidates may not be considered cost-effective. It is time consuming and expensive for us to seek reimbursement from third-party payors. Reimbursement may not be available or sufficient to allow us to sell our product on a competitive and profitable basis.

In addition, the U.S. Congress and state legislatures from time to time propose and adopt initiatives aimed at cost containment, which could impact our ability to sell our products profitably. For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, contains provisions that may reduce the profitability of drug products through increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, and mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs. Adoption of general controls and measures, coupled with the tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for pharmaceutical drugs.

The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of the Department of Health and Human Services as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. Effective in 2010, the ACA made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate on most branded prescription drugs from 15.1% of average manufacturer price, or AMP, to 23.1% of AMP, and adding a new rebate calculation for "line extensions" (i.e., new formulations, such as extended release formulations) of solid oral dosage forms of branded products, creating a new methodology by which rebates owed by are calculated for drugs that are inhaled, infused, instilled, implanted or injected, as well as potentially impacting their rebate liability by modifying the statutory definition of AMP. The ACA also expanded the universe of Medicaid utilization subject to drug rebates by requiring pharmaceutical manufacturers to pay rebates on Medicaid managed care utilization as of 2010 and by expanding the population potentially eligible for Medicaid drug benefits (phased-in by 2014). Pricing and rebate programs must also comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990.
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The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the MMA, imposed new requirements for the distribution and pricing of prescription drugs for Medicare beneficiaries, and included a major expansion of the prescription drug benefit under a new Medicare Part D. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities that will provide coverage of outpatient prescription drugs. Part D prescription drug plans include both stand-alone prescription drug benefit plans and prescription drug coverage as a supplement to Medicare Advantage plans. Unlike Medicare Part A and B, Part D coverage is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. While all Medicare drug plans must give at least a standard level of coverage set by Medicare, Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs

within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee.

Government payment for some of the costs of prescription drugs may increase demand for products for which we receive marketing approval. However, any negotiated prices for our products covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain. Moreover, 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 payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payors.

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For a drug product to receive federal reimbursement under the Medicaid or Medicare Part B programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. The required 340B discount on a given product is calculated based on the AMP and Medicaid rebate amounts reported by the manufacturer. As of 2010, the ACA expanded the types of entities eligible to receive discounted 340B pricing, although under the current state of the law these newly eligible entities (with the exception of children's hospitals) will not be eligible to receive discounted 340B pricing on orphan drugs. As 340B drug pricing is determined based on AMP and Medicaid rebate data, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discount to increase. The American Recovery and Reinvestment Act of 2009 provides funding for the federal government to compare the effectiveness of different treatments for the same illness. The plan for the research was published in 2012 by the Department of Health and Human Services, the Agency for Healthcare Research and Quality and the National Institutes for Health, and periodic reports on the status of the research and related expenditures are made to Congress. Although the results of the comparative effectiveness studies are not intended to mandate coverage policies for public or private payors, it is not clear what effect, if any, the research will have on the sales of our drug candidates, if any such drug or the condition that they are intended to treat are the subject of a trial. It is also possible that comparative effectiveness research demonstrating benefits in a competitor's drug could adversely affect the sales of our drug candidate. If third-party payors do not consider our drugs to be cost-effective compared to other available therapies, they may not cover our drugs after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our drugs on a profitable basis.

In recent years, additional laws have resulted in direct or indirect reimbursement reductions for certain Medicare providers, including:

- The Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2025 unless additional Congressional action is taken.

- The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

- The Middle Class Tax Relief and Job Creation Act of 2012 required that the Centers for Medicare & Medicaid Services reduce the Medicare clinical laboratory fee schedule by 2% in 2013, which served as a base for 2014 and subsequent years. In addition, effective January 1, 2014, CMS also began bundling the Medicare payments for certain laboratory tests ordered while a patient received services in a hospital outpatient setting.

These laws, and future state and federal healthcare reform measures may be adopted in the future, any of which may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

As noted above, the marketability of any products for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. We expect that an increasing emphasis on cost containment measures in the United States will continue to increase the pressure on pharmaceutical pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.There are also

laws that govern a company's eligibility to participate in Medicare and Medicaid reimbursements. For example, a company may be debarred from participation if it is found to have violated federal anti-kickback laws, which could have a significant effect on a company's ability to operate its business. These laws are discussed below.

The cost of pharmaceuticals continues to generate substantial governmental and third-party payor interest. We expect that the pharmaceutical industry will experience pricing pressures due to the trend toward managed healthcare, the increasing influence of managed care organizations, and additional legislative proposals. Indeed, we expect that there will continue to be a number of federal and state proposals to implement governmental pricing controls and limit the growth of healthcare costs, including the cost of prescription drugs. At the present time, Medicare is prohibited from negotiating directly with pharmaceutical companies for drugs. However, Congress is considering passing legislation that would lift the ban on federal negotiations. While we cannot predict whether such legislative or regulatory proposals will be adopted, the adoption of such proposals could harm our business, financial condition and results of operations.

Some third-party payors also require pre-approval of coverage for new or innovative drug therapies before they will reimburse healthcare providers that use such therapies. While we cannot predict whether any proposed cost-containment measures will be adopted or otherwise implemented in the future, the announcement or adoption of these proposals could have a material adverse effect on our ability to obtain adequate prices for our product candidates and operate profitably.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. In some countries, pricing negotiations with governmental authorities can take six to 12 months or longer after the receipt of marketing approval. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidates to other available therapies. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for our product.

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Other Healthcare Laws

For our product and any product candidates which may obtain regulatory approval and are marketed in the United States, our arrangements with third-party payors, healthcare providers, and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any products for which we obtain marketing approval. In addition, we may be subject to health information privacy and security regulation by U.S. federal and state governments and foreign jurisdictions in which we conduct our business. In the United States, these laws include, without limitation, state and federal anti-kickback, false claims, physician transparency, and patient data privacy and security laws and regulations, including but not limited to those described below:

- The federal Anti-Kickback Statute makes it illegal for any person, including a prescription drug manufacturer (or a party on its behalf) to, knowingly and willfully offer, solicit, receive, or pay remuneration, directly or indirectly, in cash or in kind, that is intended to induce or reward the referral of an individual for or the purchase or recommendation of an item or for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs. Violations of this law are punishable by up to five years in prison, criminal fines, administrative civil money penalties and exclusion from participation in federal healthcare programs. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it

- The federal False Claims Act imposes civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities (including manufacturers) for, among other things, knowingly presenting, or causing to be presented false or fraudulent claims for payment by a federal healthcare program or making a false statement or record material to payment of a false claim or avoiding, decreasing or concealing an obligation to pay money to the federal government. Penalties for a False Claims Act violation include three times the actual damages sustained by the government, plus mandatory civil penalties of between $10,957and $21,916 for each separate false claim, the potential for exclusion from participation in federal healthcare programs and the potential implication of various federal criminal statutes. The government may deem manufacturers to have "caused" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. Claims which include items or services resulting from a violation of the federal Anti-Kickback Statute are false or fraudulent claims for purposes of the False Claims Act. Our future marketing and activities relating to the reporting of wholesaler or estimated retail prices for our products, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state and third-party reimbursement for our products, and the sale and marketing of our product and any future product candidates, are subject to scrutiny under this law.

- Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly or willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (“HITECH”), and their respective implementing regulations, which imposes, among other things, specified requirements on covered entities and their business associates, relating to the privacy and security of individually identifiable health information, including mandatory contractual terms and required implementation of technical safeguards of such information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties applicable to business associates, and gave state attorneys general new authority to file civil actions for damage or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys’

fees and costs associated with pursuing federal civil actions.

- The Physician Payments Sunshine Act, enacted as part of the ACA, as amended by the Health Care and Education Reconciliation Act of 2010, which imposed new annual reporting requirements for certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program for certain payments and other "transfers of value" provided to physicians and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members.

- Analogous state and foreign fraud and abuse laws and regulations, such as state anti-kickback and false claims laws, which may be broader in scope and apply regardless of payor. Such laws are enforced by various state agencies and through private actions. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant federal government compliance guidance, require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, and restrict marketing practices or require disclosure of marketing expenditures. State and foreign laws also govern the privacy and security of health information in certain circumstances. Such data privacy and security laws may differ from one another in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have scrutinized interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other related governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, disgorgement ,exclusion of drugs from government funded healthcare programs, such as Medicare and Medicaid, reputational harm, additional oversight and reporting obligations if we become subject to a corporate integrity agreement or similar settlement to resolve allegations of non-compliance with these laws and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to similar actions, penalties and sanctions. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company’s attention from the business.

Employees

As of December 31, 2017, we had 21 employees. All of our employees are engaged in administration, finance, clinical, manufacturing, regulatory and business development functions. None of our employees are represented by a labor union, and we believe that our relations with our employees are good.

Other Available Information

We are subject to the information requirements of the Exchange Act. Therefore, we file periodic reports, proxy statements and other information with the Securities and Exchange Commission (SEC), which may be obtained by visiting the Public Reference Room of the SEC at 100 F Street, NE, Washington, D.C. 20549 or by calling the SEC at 1-800-SEC-0330. In addition, the SEC maintains a website (www.sec.gov) that contains reports, proxy and information statements, and other information regarding issuers that file electronically.

We were incorporated in Delaware in 2004. The mailing address of our headquarters is 25801 Industrial Blvd, Suite B, Hayward, CA 94545, and our telephone number at that location is 510-856-5600. Our website is www.anthera.com. Through a link on the “Investors” section of our website (under “SEC Filings” in the “Financial Information” section), we make available, free of charge, the following filings as soon as reasonably practicable after they are electronically filed with or furnished to the SEC: our Annual Reports on Form 10-K; Quarterly Reports on Form 10-Q; Current Reports on Form 8-K; and any amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act. Information contained on, or that can be accessed through, our website does not constitute part of this Annual Report on Form 10-K.

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ITEM 1A. RISK FACTORS

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

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

Risks Related to Our Financial Condition and Capital Requirements

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

We are a clinical-stage biotechnology company with two assets in the clinical stage of development. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. We have no products approved for commercial sale and have not generated any revenue from product sales to date and we continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred losses in each period since our inception in 2004. As of December 31, 2017, we had an accumulated deficit of $434.4 million. Substantially all our losses resulted from costs incurred with our product development programs and from general and administrative costs associated with our operations.

Our historical losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital. In addition, if we obtain regulatory approval for our product candidates, we may incur significant sales, marketing, in-licensing and outsourced manufacturing expenses as well as continued product development expenses. As a result, we expect to continue to incur significant losses over the next several years as we continue to advance our product candidates into clinical studies and as we:

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

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

- the progress of clinical studies of our product candidates;
- the cost of manufacturing our product candidates;

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

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

Our ability to generate product revenue and achieve profitability depends on our ability, alone or with collaborators, to successfully complete the development of our product candidates, conduct clinical studies in patients, obtain the necessary regulatory approvals for our product candidates and commercialize any approved products. We have not generated any revenue from the commercial sales of our product candidates since our inception and do not expect to generate any revenue from the commercial sales of our product candidates in the near term. However, as a result of the collaborative arrangement that we entered into with Zenyaku in December 2014 for the development of blisibimod, we began recognizing license fee revenue and collaborative revenue in 2015. The license fee revenue from the collaborative arrangement with Zenyaku was initially amortized as revenue over the performance obligation period (product development period) while reimbursement for our full-time employees ("FTEs") was recorded as collaborative revenues as incurred. In September 2015, Zenyaku provided us a notice of its intent to terminate the Zenyaku Agreement, effective January 7, 2016. The termination was "at will" and Zenyaku alleged no breach of the Zenyaku Agreement by us. Because of an early termination of the Zenyaku Agreement, we did not recognize revenues under the Zenyaku Agreement beyond January 2016.

The commercial success of our development-stage product candidates will depend on a number of factors, including, but not limited to, our ability to:

- obtain favorable results for and advance the development of Sollpura, our product candidate for the treatment of patients with low digestive enzyme levels and potentially other diseases;

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

- obtain regulatory approval for Sollpura and blisibimod;

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

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

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

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

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

We anticipate that our cash and cash equivalents of $2.2 million as of December 31, 2017, together with the net proceeds of $11.1 million from the second closing of a private placement of our equity securities and $3.1 million from warrant exercises and sale of common stock pursuant to an equity purchase agreement subsequent to December

31, 2017 will not be sufficient to fund our operations for next twelve months from the filing of this report, which results in substantial doubt about our ability to continue as a going concern. Changing circumstances may cause us to consume capital significantly faster than we currently anticipate. If adequate funds are not available to us on a timely basis, or at all, we may be required to:

- delay our regulatory submission for Sollpura;

- significantly modify, reduce the scope of, delay ongoing clinical studies and manufacturing activities for Sollpura;

- 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 substantial doubt about our ability to continue as a going concern as of the date of this report is not alleviated after consideration of management's plans to mitigate such concerns. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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If we are unable to continue as a viable entity, our stockholders may lose their entire investment. In order for us to continue as a going concern beyond our current projected cash runway of the second quarter of 2018, we will be required to obtain capital from external sources, and there can be no assurance that we will be able to do so on favorable 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. Furthermore, we may elect to raise additional funds even before we need them if the conditions for raising capital are favorable.

We plan to meet our capital requirements primarily through issuances of equity securities, potential partnerships, debt financing, and in the longer term, revenue from product sales. We may be forced to obtain funds through collaborations with potential collaborators that may require us to relinquish rights to our technologies or product candidates that we may otherwise seek to develop or commercialized independently. Failure to generate revenue or raise additional capital would adversely affect our ability to achieve our intended business objectives.

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 campaigns for clinical materials, including data to support the application for marketing approval, formulation development and product enhancement;
- non-clinical activities that we may pursue parallel to our clinical studies;
- the filing, prosecution and enforcement of patent claims;
- the costs associated with commercializing our product candidates if they receive regulatory approval, including the cost and timing of developing sales and marketing capabilities, or entering into strategic collaboration with others relating to the commercialization of our product candidates; and
- revenues received from approved products, if any, in the future.

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

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

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

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

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

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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.

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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 IRB, approval or the approval of other reviewing entities to conduct a clinical study at prospective sites;
- recruiting and enrolling patients to participate in clinical studies for a variety of reasons, including size of patient population, nature of clinical study protocol, the availability of approved effective treatments for the relevant disease and competition from other clinical study programs for similar indications;
- severe or unexpected drug-related adverse effects experienced by patients in a clinical study; and
- retaining patients who have initiated a clinical study, but may withdraw due to treatment protocol, adverse effects from the therapy, lack of efficacy from the treatment, personal issues or who are lost to further follow-up.

Clinical studies may also be delayed, suspended or terminated as a result of ambiguous or negative interim results, or results that are inconsistent with earlier results. In addition, a clinical study may be suspended or terminated by us, the FDA, the IRB or other reviewing entity overseeing the clinical study at issue, at 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 for re-examination, which may impact the costs, timing or successful completion of a clinical study. If we experience delays in completion of, or if we, the FDA or other regulatory authorities, the IRB or other reviewing entities, or any of our clinical study sites suspend or terminate any of our clinical studies, the commercial prospects for our product candidates may be harmed and our ability to generate product revenues will be delayed. In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical studies may also ultimately lead to the denial of regulatory approval of our product candidates. Also, if one or more clinical studies are delayed, our competitors may be able to bring products to market before we do, and the commercial viability of our product candidates could be significantly reduced.

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

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

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

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

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

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

The pharmaceutical industry is highly competitive and subject to rapid and significant technological change. Our potential competitors include large pharmaceutical and more established biotechnology companies, specialty pharmaceutical and generic drug companies, academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. All 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 also highly competitive. There are currently several marketed products for EPI caused by cystic fibrosis in the U.S., including Creon marketed by AbbVie, Inc., Pancreaze by Janssen Pharmaceuticals, Inc., Zenpep and Viokace by Allergan, and Pertzye by Chiesi. We are also aware of companies with other products in development that are being tested for potential treatment of EPI caused by cystic fibrosis: AzurRx Biopharma's MS1819 lipase is currently being tested in a Phase 2 trial in patients with chronic pancreatitis; and Alcresta Therapeutics markets RELiZORB, a lipase enzyme cartridge designed for use by adults receiving nutrition by enteral tube who have trouble digesting and absorbing ingested fats.

Many of our potential competitors have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of drug candidates, and in obtaining FDA and other regulatory approvals of products and the commercialization of those products. Accordingly, our competitors may be more successful than we may be in obtaining FDA and other regulatory approvals for drugs and achieving widespread market acceptance. Our competitors' drugs may be more effective, have fewer adverse effects, be less expensive to develop and manufacture or be more effectively marketed and sold than any product candidates we may

commercialize and may render our product candidates obsolete or non-competitive before we can recover the expenses of developing and commercializing our product candidates. We anticipate that we will face intense and increasing competition as new drugs enter the market and advanced technologies become available. These entities may also establish collaborative or licensing relationships with our competitors. Finally, the development of new treatment methods for the diseases we are targeting could render our drugs non-competitive or obsolete. All of these factors could adversely affect our business.

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

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.

Sollpura, 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 Sollpura which, if successful, could result in regulatory approval of Sollpura. There are still open items from the CRL that we will need to address with the FDA. While we plan to make reasonable efforts to accommodate and address the FDA's inquiries and requests, 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 Sollpura in patients with EPI.

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If serious adverse events 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 or revoke the licenses for the products;

- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications;

- we may be required to change the way the products are administered, conduct additional clinical studies or change the labeling of the products;

- we could be sued and held liable for harm caused to patients; and

- our reputation may suffer.

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

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

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

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

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

manufacturing facility or us, including requiring recall or withdrawal of the products from the market or suspension of manufacturing. If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

·issue warning letters or untitled letters;

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

·suspend or withdraw regulatory approval or revoke a license;

·suspend any ongoing clinical studies;

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· refuse to approve pending applications or supplements to applications filed by us;

· suspend or impose restrictions on operations, including costly new manufacturing requirements; or

· seize or detain products, refuse to permit the import or export of products, or require us to initiate a product recall.

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

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

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

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

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

· the prevalence and severity of any adverse effects;

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

· availability of alternative treatments;

· pricing and cost-effectiveness;

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

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

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

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

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

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

- impairment of our business reputation;
- 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.

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

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

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

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

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

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

We have relied upon a small number of third-party manufacturers and active pharmaceutical ingredient formulators for the manufacture of our material for preclinical and clinical testing purposes and intend to continue to do so in the future. We also expect to rely upon third parties to produce materials required for the commercial production of our

product candidates if we succeed in obtaining necessary regulatory approvals. If we are unable to arrange for third-party manufacturing sources, or to do so on commercially reasonable terms, we may not be able to complete development of our product candidates or market them.

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

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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.

Any delays in the development and validation of drug manufacturing processes for commercialization could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospect.

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

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

- uncontrollable natural forces that may render the CMO temporarily or permanently incapable of manufacturing our drugs.

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

- failure of the CMO to conform with appropriate quality standards; and

- inspection of the CMO by the FDA or other regulatory authorities resulting in the imposition of a manufacturing hold.

Additionally, changes in regulatory requirements and policies may occur and we may need to amend our manufacturing plans or processes to reflect these changes. Amendments to the processes may impact the costs, timing or successful completion development and validation of the drug manufacturing processes for commercialization. If we experience delays in completion of, or if we, the FDA or other regulatory authorities suspend or terminate any of our clinical studies, the commercial prospects for our product candidates may be harmed and our ability to generate product revenues will be delayed. In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, product commercialization may also ultimately lead to the denial of regulatory approval of our product candidates. Also, if product commercialization is delayed, our competitors may be able to bring products to market before we do, and the commercial viability of our product candidates could be significantly reduced.

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

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

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

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

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

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

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

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

biotechnology industry are, among others, the following:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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Individual U.S. state governments have also become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures. The continuing efforts of government and other third-party payors to contain or reduce the costs of health care through various means may limit our commercial opportunity. It will be time-consuming and expensive for us to go through the process of seeking reimbursement from Medicare and private payors. Our products may not be considered cost-effective, and government and third- party private health insurance coverage and reimbursement may not be available to patients for any of our future products or sufficient to allow us to sell our products on a competitive and profitable basis. Our results of operations could be adversely affected by the MMA, attempts to repeal, replace, or modify the ACA, additional prescription drug coverage legislation, and by other health care reforms that may be enacted or adopted in the future. In addition, increasing emphasis on managed care in the United States will continue to put pressure on the pricing of pharmaceutical products. Cost control initiatives could decrease the price that we or any potential collaborators could receive for any of our future products and could adversely affect our profitability.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Our share price has been and may continue to be volatile. Companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We are a target of this type of litigation. For

example, on February 13, 2017, a complaint was filed in the United States District Court for the Northern District of California captioned Brian Clevlen v. Anthera Pharmaceuticals, Inc., et al., Case No. 3:17- cv-715, on behalf of a putative class of the Company's stockholders against the Company and certain of its current and former officers that was voluntarily dismissed, as discussed in Item 3. Legal Proceedings. Litigation of this type could result in substantial costs and diversion of management's attention and resources, which could adversely impact our business. Any adverse determination in litigation could also subject us to significant liabilities.

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

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

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

Although our common stock is listed for trading on the Nasdaq Capital 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 Capital Market in particular, have experienced substantial price and volume volatility that is often seemingly unrelated to the operating performance of particular companies. These broad market fluctuations may cause the trading price of our common stock to decline. In the past, securities class action litigation has often been brought against a company after a period of volatility in the market price of its common stock. Securities litigation against us, including as

discussed elsewhere in this Form 10-K, could result in substantial expenses and the diversion of our management's attention and resources and could harm our business, operating results and financial condition.

Future sales of our common stock by the selling stockholders could cause our stock price to decline.

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

As of February 28, 2018, there were 23,397,497 shares of our common stock outstanding. In addition, we had outstanding 2,067,522 shares of Class Y Convertible Preferred Stock that are convertible into 2,067,522 shares of common stock, and options and warrants to purchase 26,520,407 shares of our common stock that, if converted and exercised, will result in these additional shares becoming available for sale. A large portion of these shares and outstanding equity awards are held by a small number of persons and investment funds. Sales by these stockholders or option holders in the public market or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities, even if there is no relationship between such sales and the performance of our business.

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

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

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

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

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

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

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

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

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

·a classified and staggered board of directors whose members can only be dismissed for cause;

·the prohibition on actions by written consent of our stockholders;

- the limitation on who may call a special meeting of stockholders;

- the establishment of advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted upon at stockholder meetings;

- the ability of our board of directors to issue preferred stock without stockholder approval, which would increase the number of outstanding shares and could thwart a takeover attempt; and

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

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

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

Generally, a change of more than 50% in the ownership of a corporation's stock, by value, over a three-year period constitutes an ownership change for U.S. federal income tax purposes. An ownership change may limit a company's ability to use its net operating loss carryforwards attributable to the period prior to such change. We underwent ownership changes within the meaning of Section 382 ownership of the Internal Revenue Code during 2012 and in January 2018, as such, our net operating loss carryforwards are limited. In addition, the pre-change R&D tax credits have also been limited for federal tax purposes. If we earn net taxable income, our ability to use our pre-change net operating loss carryforwards to offset U.S. federal taxable income will be subject to limitations, which will result in increased future tax liability to us.

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

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

Risks Related to Our Intellectual Property

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

We hold license rights to U.S. numerous European ("EP"), and non-EP foreign patents and patent applications relating to blisibimod and Sollpura. Our Sollpura portfolio is made up of exclusively licensed patents and patent applications from Eli Lilly. Our blisibimod portfolio is made up of exclusively and non-exclusively licensed patents and patent applications from Amgen, as well as U.S. and Patent Cooperation Treaty ("PCT") patent applications owned by us.

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

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

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

·we or our licensors were the first to make the inventions covered by each of our pending patent applications;

·we or our licensors were the first to file patent applications for these inventions;

·others will not independently develop similar or alternative technologies or duplicate any of our technologies;

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- any of our or our licensors' pending patent applications will result in issued patents;

- any of our or our licensors' patents will be valid or enforceable;

- any patents issued to us or our licensors and collaborators will provide a basis for commercially viable products, will provide us with any competitive advantages or will not be challenged by third parties;

- we will develop additional proprietary technologies or product candidates that are patentable; or

- the patents of others will not have an adverse effect on our business.

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

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

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

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

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

We depend in part on our licensors to protect the proprietary rights covering blisibimod and Sollpura. Our licensors are responsible for maintaining certain issued patents and prosecuting certain patent applications. We have limited, if any, control over the amount or timing of resources that our licensors devote on our behalf or the priority they place on maintaining these patent rights and prosecuting these patent applications to our advantage. Our licensors may also

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

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

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

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

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

Further, since neither Sollpura nor blisibimod have been previously approved in the U.S., both may be eligible for 12 years of biologic data exclusivity from the FDA. During this data exclusivity period, competitors are barred from relying on the innovator biologic's safety and efficacy data to gain approval.

Similarly, the European Union provides that companies who receive regulatory approval for a new small biologic will have a 10-year period of data exclusivity for that biologic (with the possibility of a further one-year extension) in most EU countries, beginning on the date of such European regulatory approval, regardless of when the European composition of matter patent covering such biologic expires. A generic version of the approved drug may not be marketed or sold during such market exclusivity period. The law governing biologic data exclusivity in the U.S. is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement the Biologics Price Competition and Innovation Act of 2009 may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for Sollpura or blisibimod. For example, there is a risk that the 12-year period of exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider Sollpura or blisibimod to be a reference product for competing products, potentially creating the opportunity for competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for Sollpura or blisibimod in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

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

products will be materially harmed.

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

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

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

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

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

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

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

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

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We lease our main operating facility in Hayward, California. We occupy approximately 8,000 square feet under a facility sublease agreement that expires in August 2019. We believe our existing facility is adequate for our current needs and that any additional space we need will be available in the future on commercially reasonable terms.

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

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

ITEM 4. MINE SAFETY DISCLOSURE

Not applicable.

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PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Price Range of Common Stock

Our common stock was listed on The Nasdaq Global Market under the symbol "ANTH" from our initial public offering ("IPO") until January 26, 2018. Since January 26, 2018, the Company has been listed on The Nasdaq Capital Market under the symbol "ANTH". Prior to the IPO, there was no public market for our common stock. The following table sets forth, for the periods indicated, the high and low intraday sales prices of our common stock as reported by The Nasdaq Global Market:

	High	Low
First Quarter 2016	$39.20	$18.24
Second Quarter 2016	$35.20	$21.52
Third Quarter 2016	$32.00	$22.40
Fourth Quarter 2016	$27.36	$5.12
First Quarter 2017	$6.24	$3.04
Second Quarter 2017	$3.52	$1.54
Third Quarter 2017	$1.71	$1.20
Fourth Quarter 2017	$2.43	$1.34

Holders of our Common Stock

As of December 31, 2017, an aggregate of 13,854,491 shares of our common stock were issued and outstanding and were held by 55 registered holders, based on information provided by the Company's transfer agent. A significantly larger number of stockholders may be "street name" or beneficial holders, whose shares of record are held by banks, brokers and other financial institutions.

Dividend Policy

We have never declared or paid any cash dividends on our common stock. We currently intend to retain any future earnings to finance the growth and development of our business. Therefore, we do not anticipate declaring or paying any cash dividends in the foreseeable future. Any future determination as to the declaration and payment of dividends, if any, will be at the discretion of our board of directors and will depend on then-existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant.

Securities Authorized for Issuance under Equity Compensation Plans

The information regarding securities authorized for issuance under equity compensation plans is included in Part III, Item 12 of this report.

Recent Sales of Unregistered Securities

During the year ended December 31, 2017, we did not issue or sell any unregistered securities not previously disclosed in a Quarterly Report on Form 10-Q or in a Current Report on Form 8-K.

Issuer Purchases of Equity Securities

We did not repurchase any securities during the quarter or year ended December 31, 2017.

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ITEM 6. SELECTED FINANCIAL DATA (in thousands, except share and per share data)

The following tables reflect selected consolidated summary financial data for each of the last five fiscal years and are derived from our audited financial statements. This data should be read in conjunction with Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" and Part II, Item 8, "Financial Statements and Supplementary Data", appearing elsewhere in this Annual Report on Form 10-K.

	Year Ended December 31,				
	2017	2016	2015	2014	2013
	(in thousands, except share and per share data)				
Statement of Operations Data:					
REVENUES					
License revenue	$—	$139	$2,562	$—	$—
Collaborative revenue	—	6	623	—	—
Total revenues	—	145	3,185	—	—
Operating expenses					
Research and development	$28,594	$46,512	$33,498	$21,839	$21,684
General and administrative	7,938	11,071	7,568	6,620	6,563
Research award (1)	(100)	(261)	(2,638)	—	—
Total operating expenses	36,432	57,322	38,428	28,459	28,247
LOSS FROM OPERATIONS	(36,432)	(57,177)	(35,243)	(28,459)	(28,247)
OTHER INCOME (EXPENSE)					
Other income (expense)	(85)	(90)	23	(96)	(15)
Interest expense	—	—	—	(1,049)	(2,599)
Change in fair value of warrant liability	10,243	1,744	—	—	—
Fair value of warrant liability in excess of proceeds from financing	(600)	—	—	—	—
Total other income (expense)	9,558	1,654	23	(1,145)	(2,614)
NET LOSS	$(26,874)	$(55,523)	$(35,220)	$(29,604)	$(30,861)
Deemed dividends attributable to preferred stock	(2,503)	(10,914)	—	—	—
Net loss applicable to common stockholders	(29,377)	$(66,437)	$(35,220)	$(29,604)	$(30,861)
Net loss per share — basic and diluted (2)	$(2.86)	$(12.87)	$(7.91)	$(10.88)	$(13.52)
Weighted average shares used in net loss per share -- basic and diluted (3)	10,278,391	5,163,784	4,453,905	2,722,034	2,283,427

	December 31,				
	2017	2016	2015	2014	2013
	(in thousands)				
Balance Sheet Data:					
Cash, cash equivalents and short-term investments	$2,196	$20,843	$46,951	$2,639	$25,946
Restricted cash	—	—	—	—	10,000
Working capital	(1,520)	12,084	39,394	(2,729)	18,743
Total assets	3,673	23,471	48,125	3,490	37,417
Total notes payable	—	—	—	—	17,875
Total liabilities	9,168	10,624	8,468	5,751	22,659

Contingently redeemable & convertible preferred stock	—	377	—	—	—
Convertible preferred stock	333	8,614	—	—	—
Common stock and additional paid-in capital	428,600	411,410	391,688	314,550	301,965
Accumulated deficit	(434,428)	(407,554)	(352,031)	(316,811)	(287,207)
Total stockholders' equity (deficit)	(5,495)	12,470	39,657	(2,261)	14,758

(1) In March 2015, we received a research award of up to $3 million from CFFT for our development of Sollpura. The research award was receivable by the Company upon the achievement of certain milestones specified in the award agreement. As of December 31, 2017 the entire award has been received and recognized as a component of Operating Expenses in each of the years ended December 31, 2017, 2016, and 2015.

(2) Diluted earnings per share, or EPS, is identical to basic EPS since common equivalent shares are excluded from the calculation, as their effect is anti-dilutive.

(3) Weighted average shares used in net loss per basic and diluted share have been adjusted to reflect a 1-for-8 reverse stock split effectuated by the Company on April 28, 2017.

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ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis should be read together with our consolidated financial statements and the related notes set forth under "Item 8. Consolidated Financial Statements and Supplementary Data." This discussion contains forward-looking statements reflecting our current expectations that involve risks and uncertainties. See "Special Note Regarding Forward-Looking Statements" for a discussion of the uncertainties, risks and assumptions associated with these statements. Actual results and the timing of events could differ materially from those discussed in our forward-looking statements as a result of many factors, including those set forth under "Risk Factors" and elsewhere in this report.

Overview

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

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

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

Our Phase 3 Development of Sollpura in EPI

In May 2017, we initiated a Phase 3 study of Sollpura ("RESULT") in patients with EPI due to cystic fibrosis. The RESULT study is a randomized, open-label, assessor-blind, non-inferiority, active-comparator study evaluating the non-inferiority of Sollpura with respect to Coefficient of Fat Absorption (“CFA”) compared to a commercially available PERT in a population of porcine-derived PERT responders. The RESULT study’s design is modified from a previous Phase 3 study’s (“SOLUTION”) design to incorporate learnings from that study by 1) starting Sollpura dosing at 125% of the pre-study PERT dose, 2) allowing for a more “real life” dose adjustment, as needed, based on signs and symptoms throughout the first three weeks of the primary treatment phase of the study, and 3) providing a shorter primary treatment duration of 4 weeks, with 3 weeks of dose optimization and 1 week of stable dosing before measuring CFA. Patients are then followed in a 20-week extension period for the collection of longer term safety and efficacy (e.g., growth, maintenance of body weight) data. The RESULT study design was discussed with the FDA prior to initiation. Furthermore, the study had been approved by the Cystic Fibrosis Foundation Therapeutics Development Network (“CFFTDN”) Protocol Review Committee, and the European Cystic Fibrosis Society Clinical Trial Network Executive Committee.

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The RESULT study enrolled 140 patients in North America, Eastern and Western Europe and Israel. In December 2017 and January 2018, pre-specified interim futility analyses of the RESULT study were conducted by a Data Monitoring Committee ("DMC") comprised of experts appointed by the CFFTDN when approximately 25% and 50% of patients had completed the 4-week primary treatment period; in each instance, the committee recommended the study to continue to completion as planned.

A second, smaller Phase 3 study ("SIMPLICITY") aimed at expanding the treatment age of patients to include patients age from 28 days to seven years old, and potentially enabling marketing approval for the sachet presentation of Sollpura, was initiated in the second quarter of 2016. The SIMPLICITY study utilizes sachets containing Sollpura powder for oral solution. The study is designed in two parts (Part A and Part B). Part A which evaluated the safety and general usability of Sollpura powder for oral solution in 15 patients ≥7 years of age, was completed in the fourth quarter of 2016. On December 9, 2016, an independent Data Monitoring Committee evaluated the data from Part A and approved progression to Part B, which will enroll pediatric subjects below 7 years of age. Assuming the RESULT study is successful, before we proceed with Part B, we plan to amend the SIMPLICITY study to follow a similar dosing approach as the RESULT study and initiate enrollment in Part B in the second quarter of 2018.

Furthermore, during the third quarter of 2016, we initiated the EASY study, which provides continued access to Sollpura for patients in the Sollpura arm who completed the SOLUTION study. We have amended this study to also allow Sollpura-assigned patients completing the RESULT study at a lipase dose greater than 10,000 units/kg/day to have continued access until the Biological License Application ("BLA") for Sollpura is approved by the FDA.

Lastly, prior to the RESULT study, we conducted another Phase 3 study ("SOLUTION") in patients with EPI. The SOLUTION study was also a randomized, open-label, assessor-blind, non-inferiority, active-comparator study evaluating the efficacy and safety of Sollpura. This pivotal study enrolled 128 patients in North America, Europe and Israel. Top line data announced in December 2016 showed that the study narrowly missed the CFA non-inferiority margin of the primary mITT analysis by one percent; however, by additional pre-specified analyses of CFA (mITT-Baseline Observation Carried Forward and Per Protocol), Sollpura met the non-inferiority criterion. The study also demonstrated that the ratio of the three enzymes in Sollpura provided an appropriate response in CNA. In March 2017, we announced data from the extension phase of the study, which showed that Sollpura demonstrated comparable maintenance in key measurements of height, weight, and body mass index in addition to being well tolerated throughout the 12-week extension period.

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

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

Our Phase 2 Development of Blisibimod for in IgA Nephropathy

In June 2013, we initiated a Phase 2 clinical study, (“BRIGHT-SC”) of patients with IgA nephropathy in Asia and Eastern Europe. The BRIGHT-SC study was 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 included biopsy-proven IgA nephropathy and proteinuria greater than one gram but less than six grams per 24 hours (1g-6g/24hr). Patients must have been receiving standard of care medication including angiotensin converting enzyme inhibitors and/or angiotensin receptor blockers. Patients enrolled in the BRIGHT-SC study received 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 study enrolled 58 patients. In August 2017, we reported top line data from the completed extension of the BRIGHT-SC study in which all patients had the opportunity to complete at least 60 weeks of treatment and some patients were treated for up to two years. Throughout the treatment period and for up to one year of additional follow up off treatment, blisibimod appeared to halt disease progression as measured by the mean estimate of urinary protein:creatinine levels ("proteinuria"). Specifically, in patients treated with blisibimod, the mean change in proteinuria was stable to trending slightly downward, whereas the mean levels increased for patients in the placebo arm. Additionally, blisibimod showed a trend toward preservation of renal function based upon individual rates of change in estimated glomerular filtration rate (“eGFR”), with an annualized improvement of +6.2mL/min/1.73 m^2 per year compared to a worsening of -4.8 mL/min/1.73 m^2 with placebo as seen in the graph below. Furthermore, serum immunoglobulins IgA, IgG, and IgM, demonstrated marked reduction throughout the treatment period.

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Revenue

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

Research and Development Expenses

Since our inception, we have focused our activities on our product candidates' development programs. We expense research and development costs as they are incurred. Research and development expenses consist of personnel costs, including salaries, benefits and stock-based compensation, clinical studies performed by contract research organizations, or CROs, manufacturing and distribution of clinical drugs, and overhead allocations consisting of various administrative and facilities-related costs. Clinical study expenses are separated into two main categories: clinical development and pharmaceutical development. Historically, our clinical development costs have included costs for preclinical and clinical studies. 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 2017, 2016 and 2015 (in thousands):

	Year Ended December 31,		
	2017	2016	2015
Allocated costs:			
Blisibimod (1)	$3,396	$13,222	$21,082
Sollpura	18,265	26,113	6,682
Unallocated costs	6,933	7,177	5,734
Total research and development expense	$28,594	$46,512	$33,498

(1) During the year ended December 31, 2015, Blisibimod expense included reimbursed development costs totaling $1.5 million pursuant to the Zenyaku agreement.

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 and manufacturing activities. These expenditures are subject to numerous uncertainties in timing and cost to completion, including:

·the number of clinical 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;

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- the duration of patient follow-up;

- acquisition of the equipment and expertise to manufacture our drug; and

- manufacturing challenges including costs of raw materials, purchase and maintenance of equipment, and costs associated with measurement of drug quality.

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

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

General and Administrative Expenses

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

Critical Accounting Policies and Estimates

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

While our significant accounting policies are more fully described in the accompanying notes to the consolidated financial statements included in this Annual Report on Form 10-K for the year ended December 31, 2017, we believe that the following accounting policies are the most critical to aid you in fully understanding and evaluating our reported financial results and affect the more significant judgments and estimates that we use in the preparation of our consolidated financial statements.

Stock-Based Compensation

We account for stock options and stock purchase rights related to our equity incentive plans under the provisions of ASC 718 which requires the recognition of the fair value of stock-based compensation. The fair value of stock options is estimated using a Black-Scholes option valuation model. This model requires the input of subjective

assumptions including expected stock price volatility, expected life and estimated forfeitures of each award. The fair value of equity-based awards is amortized ratably over the requisite service period of the award. Due to the limited amount of historical data available to us, particularly with respect to stock-price volatility, employee exercise patterns and forfeitures, actual results could differ from our assumptions.

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

The Company has issued certain financial instruments, including warrants to purchase common stock, which have characteristics of both liabilities and equity. Financial instruments such as warrants that are classified as liabilities are fair valued upon issuance and are re-measured at fair value at subsequent reporting periods with the resulting change in fair value recorded in other income/(expense). The fair value of warrants is estimated using valuation models that require the input of subjective assumptions including stock price volatility, expected life, and the probability of future stock combination events and their impact to the exercise price.

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Accrued Clinical Expense

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

·fees paid to CROs in connection with clinical studies;

·fees paid to investigative sites in connection with clinical studies;

·fees paid to contract manufacturers in connection with the production of clinical study materials; and

·fees paid to vendors in connection with preclinical development activities.

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

Results of Operations

Comparison of Years Ended December 31, 2017 and 2016

Revenue

The following table summarizes our revenues for the years ended December 31, 2017 and 2016 (in thousands, except percentages):

	2017	2016	$ Change	% Change
License revenue	$ —	$139	$ (139)	(100)%
Collaborative revenue	—	6	(6)	(100)%
Total revenues	$ —	$145	$ (145)	(100)%

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

Research and Development Expense

The following table summarizes our research and development expenses for the years ended December 31, 2017 and 2016 (in thousands, except percentages):

	2017	2016	$ Change	% Change
Research and development expense	$28,594	$46,512	$(17,918)	(39)%

Research and development expense decreased during the year ended December 31, 2017 from 2016 primarily due to lower clinical development expenses as a result of the SOLUTION and CHABLIS studies being substantially complete in 2016 and the SIMPLICITY study being on hold since 2016. The BRIGHT and CHABLIS 7.5 studies were completed during 2017 and the RESULT study in cystic fibrosis patients with exocrine pancreatic insufficiency study was initiated in 2017. The change in clinical development activities result in reductions in expenses by $16.2 million.

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General and Administrative Expense

The following table summarizes our general and administrative expenses for the years ended December 31, 2017 and 2016 (in thousands, except percentages):

	2017	2016	$ Change	% Change
General and administrative expenses	$7,938	$11,071	$(3,133)	(28)%

General and administrative expenses decreased during the year ended December 31, 2017 from 2016 primarily due to an approximately one-third reduction in administrative headcount implemented in January 2017, which lowered payroll and stock-based compensation expense by $3.4 million.

Research Award

The following table summarizes our research award for the years ended December 31, 2017 and 2016 (in thousands, except percentages):

	2017	2016	$ Change	% Change
Research Award	$(100)	$(261)	$ (161)	(62)%

Research award decreased in the year ended December 31, 2017 from 2016 primarily due to the timing of achieving certain milestones specified in the award agreement. We have fully recognized the research award in 2017.

Other Income (Expense)

The following table summarizes our other income (expenses) for the years ended December 31, 2017 and 2016 (in thousands, except percentages):

	2017	2016	$ Change	% Change
Other income (expense)	$(85)	$(90)	$ 5	6 %
Fair value of warrant liability in excess of proceeds from financing	(600)	—	(600)	(100)%
Change in fair value of warrant liability	10,243	1,744	8,499	487 %
Total other income (expense)	$9,558	$1,654	$ 7,904	478 %

Other income (expense) recorded in the year ended December 31, 2017 is comprised of mainly a $10.2 million change in fair value of warrant liability associated with a direct offering of our common stock and warrants in March 2017. The initial fair value of the liability associated with the warrants was $14.7 million. The fair value decreased to $4.5 million as of December 31, 2017 primarily due to a decrease in the fair value of the common stock underlying the warrant shares. The decrease of $10.2 million is recognized as part of non-operating income in the year ended December 31, 2017. In the year ended December 31, 2016, we recorded $1.7 million for changes in the fair value of warrant liability associated with a direct offering of preferred stock and warrants that we executed in September 2016. The exercise price and number of warrant shares were not known on the date issuance. As such, we estimated an initial fair value of $3.7 million for the warrant liability with certain assumptions. In November 2016, the exercise price and number of shares of common stock underlying the warrants became fixed. The Company re-measured the fair value of the warrants and derived a fair value of $1.9 million. The decrease of $1.7 million was recognized as part of non-operating income in the year ended December 31, 2016.

Comparison of Years Ended December 31, 2016 and 2015

Revenue

The following table summarizes our revenues for the years ended December 31, 2016 and 2015 (in thousands, except percentages):

	2016	2015	$ Change	% Change
License revenue	$139	$2,562	$ (2,423)	(95)%
Collaborative revenue	6	623	(617)	(99)%
Total revenues	$145	$3,185	$ (3,040)	(96)%

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Revenue decreased in the year ended December 31, 2016 primarily due to the termination of a collaborative partnership with Zenyaku. 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 year ended December 31, 2015, we recorded $2.6 million for the amortization of the license fee and $0.6 million for the reimbursement of FTEs. License fee from the collaborative arrangement was amortized over the period of performance (product development period) while reimbursement for our FTEs 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 our deferred revenue to correspond with the shortened collaboration period and fully amortized the deferred revenue as of January 7, 2016.

Research and Development Expense

The following table summarizes our research and development expenses for the years ended December 31, 2016 and 2015 (in thousands, except percentages):

	2016	2015	$ Change	% Change
Research and development expense	$46,512	$33,498	$13,014	39 %

Research and development expenses increased in 2016 from 2015 primarily due to costs associated with acceleration of the manufacturing scale-up timeline, including the production of demonstration and registration batches at commercial launch scale for Sollpura™. Additionally, clinical development expense also increased from prior year due to the initiation of three new clinical studies, namely the CHABLIS-7.5 study with blisibimod in severe lupus patients, the SIMPLICITY study with Sollpura in sachet formulation and the EASY study which provides continued access to Sollpura™ for patients who rolled off the SOLUTION clinical study.

General and Administrative Expense

The following table summarizes our general and administrative expenses for the years ended December 31, 2016 and 2015 (in thousands, except percentages):

	2016	2015	$ Change	% Change
General and administrative expenses	$11,071	$7,568	$ 3,503	47 %

General and administrative expenses increased in 2016 from 2015 primarily due to higher non-cash stock-based compensation expense recognized in 2016 as a result of options issued in 2016 and higher expense related to professional services to support the growth of the Company.

Research Award

The following table summarizes our research award for the years ended December 31, 2016 and 2015 (in thousands, except percentages):

	2016	2015	$ Change	% Change
Research Award	$(261)	$(2,638)	$(2,377)	(91)%

Research award decreased in 2016 from 2015 primarily due to the timing of achieving certain milestones specified in the award agreement. We achieved a majority of the milestones in 2015 and as a result we recognized $2.6 million out of total of $3.0 million in research award from CFFT for the year ended December 31, 2015.

Other Income (Expense)

The following table summarizes our other income (expenses) for the years ended December 31, 2016 and 2015 (in thousands, except percentages):

	2016	2015	$ Change	% Change
Other income (expense)	$(90)	$ 23	$ (113)	(491)%
Change in fair value of warrant liability	1,744	—	1,744	100 %
Total other income (expense)	$1,654	$ 23	$ 1,631	7,092 %

Other income (expense) recorded in 2016 included change in fair value of warrant liability, interest earned on our cash and cash equivalents and the net impact of realized gain or loss from foreign currency exchange fluctuations. In connection with the subscription agreement for the sale of convertible preferred stock entered in September 2016, we issued common stock warrants to certain institutional investors. The initial fair value of the liability associated with these warrants was $3.7 million, and the fair value decreased to $1.9 million when the number of shares of common stock underlying the warrants became fixed in November 2016. The changes in the fair value of the warrants is recognized in the statement of operations in the year ended December 31, 2016. Other income (expense) recorded in 2015 was mainly a result of interest earned on our cash and cash equivalents and the net impact of realized gain or loss from foreign currency exchange fluctuations.

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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 December 31, 2017, we had cash and cash equivalents of approximately $2.2 million. In January 2018, we completed the second closing of a private placement that was executed in October 2017 for net proceeds of $11.1 million. In February 2018, we received net proceeds of $3.1 million from warrant exercises and sale of common stock pursuant to an equity purchase agreement.

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

In March 2016, we filed a universal shelf registration statement with the SEC on Form S-3 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. Between April 2016 and February 2018, we issued $3.3 million of our common stock (including shares issued for commitment fee) pursuant to equity purchase agreements with Lincoln Park Capital under the registration statement. In September 2016, we sold $22.1 million of our preferred stock to institutional investors in a registered direct offering. In March 2017 we sold $15.0 million of common stock and warrants to purchase common stock with an aggregate exercise price of $31.5 million. After completion of these offerings, up to a maximum offering price of $17.4 million of our common stock, preferred stock, debt securities, warrants and/or units remain available under our shelf registration statement on Form S-3. Pursuant to Instruction I.B.6 to Form S-3, we may not sell more than the equivalent of one-third of our public float during any 12 consecutive months so long as our public float is less than $75 million, which will limit our ability to raise funds using our shelf registration statement.

We will need substantial additional financing to continue the development of our product candidates, obtain regulatory approvals, and prepare for commercial readiness if our clinical trials are successful. We believe our current capital is only sufficient to fund our operating plan through the second quarter of 2018. We currently do not have arrangements to obtain additional financing. Any such financing could be difficult to obtain on favorable terms or at all, which raises substantial doubt about our ability to continue as a going concern as of the date of this report and that is not alleviated after consideration of management’s plans to mitigate such concerns. The financial statements do not include any adjustments that might result from the outcome of this uncertainty. If adequate funds are not available, we may be required to delay our development programs. This would include, amongst other things, eliminating or reducing the scope of one more of our clinical trials, delaying BLA submission for Sollpura, delaying manufacturing activities, and reducing headcount. Even if we raise additional funds by issuing equity or equity-linked securities, such financings may only be available on unattractive terms and, in such event, the market price of our common stock may decline and further dilution to our existing stockholders will result. In addition, the expectation of future dilution as a result of our offering of securities convertible into equity securities may cause our stock price to decline.

Cash Flows

Comparison of Years Ended December 31, 2017 and 2016

Cash flows during the years ended December 31, 2017 and 2016 consisted of the following (in thousands):

	2017	2016
Net cash used in operating activities	$(36,900)	$(48,919)
Net cash used in investing activities	—	(766)
Net cash provided by financing activities	18,253	23,577
Net decrease in cash and cash equivalents	$(18,647)	$(26,108)

During the year ended December 31, 2017, our operating activities used cash of $36.9 million, compared to $48.9 million in 2016. The decrease in cash used for operating activities in 2017 was mainly attributable to lower research and development expense due to the completion of our Phase 3 CHABLIS-SC1 clinical study by the end of 2016 and discontinuation of our Phase 3 CHABLIS-7.5 in early 2017. The CHABLIS studies enrolled more than 400 patients with systemic lupus erythematous ("SLE") across multiple geographies in Asia, Europe and Latin America.

During the year ended December 31, 2017, no cash was used in investing activities, compared to $0.8 million in 2016. Cash used in investing activities was higher in 2016 mainly due to the purchase of capital equipment to support the manufacturing activities for the development of Sollpura.

During the year ended December 31, 2017, cash provided by financing activities was $18.3 million, compared to $23.6 million in 2016. Proceeds raised in 2017 are comprised of mainly $14.1 million from the sale of our common stock through a direct offering in March, $2.2 million from the first closing of a private placement of our securities in October and $1.8 million from the sale of common stock pursuant the 2017 Equity Purchase Agreement. Proceeds raised in 2016 are comprised of mainly $16.8 million from the sale of preferred stock and warrants, and net proceeds of $6.4 million from the sale of common stock pursuant the 2015 Equity Purchase Agreement and the H.C. Wainwright ATM Agreement.

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Comparison of Years Ended December 31, 2016 and 2015

Cash flows during the years ended December 31, 2016 and 2015 consisted of the following (in thousands):

	2016	2015
Net cash used in operating activities	$(48,919)	$(30,907)
Net cash used in investing activities	(766)	(80)
Net cash provided by financing activities	23,577	75,299
Net increase (decrease) in cash and cash equivalents	$(26,108)	$44,312

During the years ended December 31, 2016 and 2015, our operating activities used cash of $48.9 million and $30.9 million, respectively. The increase in cash used for operating activities in 2016 was mainly attributable to higher research and development expense due to costs associated with acceleration of the manufacturing scale-up timeline, the purchase and installation of manufacturing equipment at our contract manufacturers, and the initiation of three new clinical studies in 2016.

During the year ended December 31, 2016, cash used in investment activities was $0.8 million, which was primarily driven by the purchase of capital equipment to support the manufacturing activities for the development of Sollpura. During the year ended December 31, 2015, cash used in investing activities was immaterial.

During the year ended December 31, 2016, cash provided by financing activities was $23.6 million, which was driven by net proceeds received from the sale of our common stock pursuant to an equity purchase agreement, sale of common stock pursuant to at-the-market (“ATM”) sales agreements, and sale of preferred stock and warrants to purchase our common stock pursuant to a subscription agreement. During the year ended December 31, 2015, cash provided by financing activities was $75.3 million, which was driven by net proceeds of $12.1 million received from the sale of our common stock through an ATM program, $53.9 million received from the sale of our common stock through two public offerings, and $9.0 million from the sale of our common stock at a 30% premium to a collaborative partner.

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Contractual Obligations and Commitments

We have lease obligations consisting of two operating leases for our operating facilities that expire in May and July 2019, respectively. The following table summarizes our estimated scheduled future minimum contractual obligations and commitments as of December 31, 2017 (in thousands):

	Payment Due by Period				
Contractual Obligations	< 1 year	1-3 years	3-5 years	> 5 years	Total
Facility Leases	$ 191	$ 106	$ —	$ —	$297

In February 2018, the Company early terminated the lease agreement for its Pleasanton office and reduced its future lease payment by approximately $42,000.

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

We have been a clinical-stage company since inception and have not generated any revenue from product sales. We expect to incur substantial expenses and generate significant operating losses over the next several years as we continue to advance our product candidates. 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 cost of manufacturing our drugs;
- the costs involved in filing and prosecuting patent applications and enforcing or defending patent claims;

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- our ability to establish, enforce and maintain selected strategic alliances; and

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

The Company's cash balance of $2.2 million as of December 31, 2017, together with the net proceeds of $11.1 million from the Second Closing of the Private Placement and $3.1 million from the exercise of warrants and sale of common stock pursuant to an equity purchase agreement subsequent to December 31, 2017 is expected to fund the Company's operations through the first half of 2018. Therefore, there is substantial doubt about the Company's ability to continue as a going concern within one year after the date the financial statements are issued. The Company's current cash position is sufficient to enable it to complete its Phase 3 clinical study of Sollpura (the "RESULT" study) in patients with exocrine pancreatic insufficiency due to cystic fibrosis, which study's topline data is expected in March 2018. If the RESULT study meets its primary endpoint, the Company plans to raise sufficient capital following the study's readout and use the proceeds to fund the preparation of its Biologics License Application ("BLA") for Sollpura, continuation of its manufacturing of drug products and general corporate purpose.

The Company cannot ascertain any future financing will be available on terms favorable to the Company, if at all. The financial statements do not include any adjustments that might result from the outcome of this uncertainty. If adequate funds are not available, the Company will be required to delay its development programs. This would include, amongst other things, eliminating or reducing the scope of one more of our clinical trials, delaying BLA submission for Sollpura, delaying manufacturing activities, and reducing headcount. The Company plans to meet its capital requirements for the next twelve months primarily through issuances of equity securities, potential partnerships and debt financing. Failure to raise additional capital would adversely affect the Company's ability to achieve its intended business objectives.

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 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. We are exposed to market risk related to fluctuations in interest rates and market prices. However, since a majority of our investments are in highly liquid money market funds, we do not believe we are subject to any material market risk exposure. As of December 31, 2017, we did not have any material derivative financial instruments. The fair value of our cash and cash equivalents was $2.2 million as of December 31, 2017.

ITEM 8. CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The consolidated financial statements required by this item are set forth beginning in Item 15 of this report and are incorporated herein by reference.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable.

ITEM 9A. 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 December 31, 2017. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities and Exchange Act of 1934, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Securities Exchange Act of 1934 is recorded, processed, summarized, and reported within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Securities Exchange Act of 1934 is accumulated and communicated to that company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

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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 year covered by this report. Based on the foregoing, our Chief Executive Officer and Principal Accounting Officer concluded that, as of December 31, 2017, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Report on Internal Control over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act. Internal control over financial reporting is a process, effected by an entity's board of directors, management and other personnel, designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with GAAP. Internal control over financial reporting includes those policies and procedures which pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of assets; provide reasonable assurance that transactions are recorded as necessary to permit preparation of consolidated financial statements in accordance with GAAP; provide reasonable assurance that receipts and expenditures are being made only in accordance with management's and or the board of directors' authorization; and provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our consolidated financial statements. Because of its inherent limitations, internal control over financial reporting may not prevent or detect material errors in our consolidated financial statements. Also, projection of any evaluation of the effectiveness of our internal control over financial reporting to future periods is subject to the risk that controls may become inadequate because of changes in conditions, because the degree of compliance with our policies and procedures may deteriorate.

Management, including our chief executive officer and principal accounting officer, assessed the effectiveness of our internal control over financial reporting as of December 31, 2017. In making its assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in Internal Control-Integrated Framework (2013). Based on the results of our evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2017. We reviewed the results of management's assessment with the Audit Committee of our board of directors.

For the year ended December 31, 2017, our independent registered public accounting firm, BDO USA, LLP was not required to report on the effectiveness of internal control over financial reports due to the exemptions allowed to smaller reporting companies under the Wall Street Reform and Consumer Protection Act of 2009.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting during the most recent quarter ended December 31, 2017 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

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PART III

ITEM 10. Directors, Executive Officers and Corporate Governance

The names of the current executive officers and directors of the Company, their ages as of January 31, 2018, and certain other information about them are set forth below (unless set forth elsewhere in this report).

Name	Age	Position
Executive Officers		
Craig Thompson	51	President, Chief Executive Officer and Director
William R. Shanahan, M.D.	69	Chief Medical Officer
May Liu	42	Senior Vice President, Finance and Administration
Renee Martin, Ph.D.	49	Senior Vice President, Medical Sciences
Non-Employee Directors		
Paul F. Truex	49	Executive Chairman of the Board
Brent V. Furse(2)(3)	49	Director
Christopher S. Henney, Ph.D.(1)(2)	76	Director
Brian R. Mueller(2)	44	Director
David E. Thompson(1)(3)	70	Director
Philip T. Sager, M.D.(1)(3)	62	Director

(1) Member of our nominating and corporate governance committee.
(2) Member of our audit committee.
(3) Member of our compensation committee.

Executive Officers

J. Craig Thompson. Mr. Thompson was appointed to serve as the Company’s President effective January 7, 2016 and to serve on the board of directors and as the Company’s Chief Executive Officer effective December 6, 2016. Mr. Thompson has over 20 years of experience in pharmaceutical development and commercialization. Most recently he served as the Chief Operating Officer for Tetraphase Pharmaceuticals from February 2014 to December 2015, where he oversaw the development and implementation of the commercial strategy as well as the business development and commercial manufacturing. Prior to Tetraphase Pharmaceuticals, from January 2011 to December 2014, Mr. Thompson served as the Chief Commercial Officer for Trius Therapeutics resulting in the acquisition of Trius by Cubist Pharmaceuticals for over $700 million. Prior to Trius Therapeutics, Mr. Thompson held various positions of increasing responsibility with Pfizer from November 2003 to December 2010, with his last position as Vice President of Marketing, Specialty Care. Prior to Pfizer he held various positions of increasing responsibility at Merck and Co, Inc. from April 1993 to November 2003. Mr. Thompson holds a Bachelor's degree in Commerce from McMaster University and a Master’s degree in Business Administration from the University of Notre Dame.

William R. Shanahan, M.D. Dr. Shanahan has served as Chief Medical Officer since August 2016. Dr. Shanahan served as the Chief Medical Officer of Arena Pharmaceuticals, Inc. from 2004 to June 2016 and served as its Senior Vice President from June 2010 to June 2016. Dr. Shanahan also served as Vice President of Arena Pharmaceuticals Inc. from March 2004 to June 2010. He served as Tanox Inc.'s Chief Medical Officer from August 2000 until March 2004 and served as Vice President, Drug Development of Isis Pharmaceuticals from 1994 to August 2000. Prior to that, he was Director of Clinical Research at Pfizer Central Research where he directed the clinical development of new anti-inflammatory pharmacologic agents from 1990 to 1994. At Searle Research and Development, he held Associate Director and Director of Clinical Research positions. In addition, at the University of Connecticut School of Medicine he held various positions in the Division of Rheumatology including a full-time faculty position as Assistant

Professor and a voluntary and part-time position as Clinical Associate Professor. Dr. Shanahan holds an A.B. degree from Dartmouth College, an M.D. degree from the University of California, San Francisco, and a J.D. degree from Loyola University, Chicago.

May Liu. Ms. Liu has served as our Senior Vice President, Finance and Administration since June 2013 and as our Principal Accounting Officer since May 2013. Prior to that, she served as our Vice President, Finance from January 2011 to June 2013, and as our Corporate Controller from October 2007 to January 2011. Ms. Liu joined us as our Director of Finance in April 2007. Prior to joining us, Ms. Liu served as SEC Reporting and Technical Accounting Manager at Renovis, Inc., a clinical-stage pharmaceutical company, from October 2005 to March 2007. Ms. Liu has been a Certified Public Accountant since 2007 and was a part of Ernst & Young LLP's audit and assurance practice from 2000 to 2005, focusing primarily in the life science industry. Ms. Liu holds a B.S. in business administration with a concentration in accounting from San Francisco State University.

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Renee Martin, Ph.D. Dr. Martin served as our Senior Vice President, Medical Sciences since April 2016 and as our Vice President, Nonclinical and Translational Sciences from November 2011 to March 2016. Prior to that, she served as our Senior Director of Clinical and Translational Sciences in March 2010 to October 2011. Prior to joining Anthera, Dr. Martin spent over 14 years from October 1996 to March 2010 at Roche Pharmaceuticals in both drug discovery and drug development. Counting her time at Roche, Dr. Martin has over 24 years of experience in the pharmaceutical industry, including a 4-year postgraduate research position from May 1992 through October 1996 at Wellcome/GlaxoWellcome Research Laboratories in the UK. Dr. Martin holds a B.A. in Natural Sciences from Cambridge University, UK and a Ph.D. in Pharmacology from King's College University of London, UK.

Non-Employee Directors

Our certificate of incorporation provides for a Board of Directors that is divided into three classes, categorized as Class I, Class II, and Class III. The term for each class is three years, staggered over time. Class I consists of Messrs. Thompson, Furse and Thompson; Class II consists of Dr. Sager; Class III consists of Messrs. Truex and Muller and Dr. Henney.

Paul F. Truex. Mr. Truex has served as Executive Chairman of the Board since December 2016. Mr. Truex previously served as our Director, Chief Executive Officer and President from our inception in September 2004 until January 2016 and as our Director and Chief Executive Officer from September 2004 to December 2016. He was responsible for negotiating our product licenses for both blisibimod, our anti-BAFF peptibody program from Amgen, Inc. and Sollpura™ (liprotamase), a novel enzyme product, from Eli Lilly and Company. Prior to founding Anthera, Mr. Truex served as a founder, Director, President and Chief Executive Officer of Peninsula Pharmaceuticals, Inc. ("Peninsula"), from the commencement of its operations in October 2001. During that time, Mr. Truex negotiated both of Peninsula's product agreements with Shionogi & Co., Ltd. (Doribax®, doripenem) and Takeda Chemical Industries (Teflaro®, ceftaroline). Peninsula was acquired by Johnson and Johnson for $245 million in an all cash transaction. The remaining entity, Cerexa was subsequently acquired for $480 million in cash by Forest Laboratories. Prior to Peninsula, Mr. Truex was Vice President of Commercial Development for Versicor, Inc. (acquired by Pfizer) from April 2000 to September 2001 where he directed early commercial efforts for Versicor's infectious disease portfolio and participated in Versicor's initial public offering. From July 1997 to April 2000, Mr. Truex worked at Eli Lilly and Company ("Eli Lilly") where he served in various marketing and sales roles during the launch of three different products for the primary care physician market (Actos®' Evista®' and Humalog 75/25®). His business development experience included the Lilly ICOS LLC joint venture's two major product divestitures and numerous small research collaborations. Mr. Truex obtained his M.B.A. in marketing and finance from Indiana University and a B.A. in economics from the University of Waterloo. Mr. Truex is currently the Chairman and a director of Milestone Pharmaceuticals, Inc., and a director at CymaBay Therapeutics Inc., (Nasdaq: CBAY). He previously served on the board of directors of Trius Therapeutics Inc (acquired by Cubist Pharmaceuticals, Inc. in July 2013), LQT Therapeutics, and Protagonist Therapeutics, Inc (Nasdaq: PTGX) and Eiger BioPharmaceuticals (Nasdaq: EIGR).

Brent V. Furse. Mr. Furse has served as a member of our board since April 2016. Mr. Furse has over 25 years of healthcare commercial leadership experience with extensive experience in the areas of sales and marketing, commercial product launch and partnerships. Mr. Furse currently serves as President and Chief Executive Officer for GeNo, LLC, a biopharmaceutical company that is developing novel products for the acute care hospital market. Prior to GeNo, he served as President of Cardiorentis AG, an acute care cardiovascular company, from 2000 to 2015 Mr. Furse served as Executive Vice President and Chief Operational Officer at The Medicines Company (Nasdaq: MDCO). Prior to The Medicines Company, he worked in the cardiovascular divisions of Schering-Plough and Bristol-Myers Squibb and for the National Center for Chronic Disease Prevention at the Centers for Disease Control. Mr. Furse holds a Bachelor of Science from Keenesaw State University and holds an M.B.A. from Mercer University.

Christopher S. Henney, Ph.D. Dr. Henney served as the Chairman of our Board of Directors from August 2008 until December 2016 and has been a member of our Board of Directors since April 2005. Dr. Henney has served as Chairman and Chief Executive Officer of Dendreon Corporation, a biotechnology company he co-founded, from 1995 until his retirement in July 2004. Dr. Henney founded Immunex Corp. and ICOS Corp. and served as an executive officer and director in both companies. Dr. Henney is currently the Chairman and a director of Cascadian Therapeutics (formerly Oncothyreon, Inc.) (Nasdaq: CASC) and has served as its interim President and Chief Executive Officer from January 11, 2016 until April 2016. Dr. Henney is also a Vice-Chairman and a director of Cyclacel Pharmaceuticals, Inc. (Nasdaq: CYCC), and a director of Prothena Corporation (Nasdaq: PRTA). Dr. Henney served as a director of AVI BioPharma Inc. from March 2009 until June 2010, and as a director of Mymetics Corporation from March 2012 until November 2012. Dr. Henney holds a B.Sc. with honors in medical biochemistry, a Ph.D. in experimental pathology and a D.Sc. for contributions to the field of immunology, all from the University of Birmingham, England. In 2012, Dr. Henney was elected to the International Biotechnology CEOs Hall of Fame.

Brian R. Mueller. Mr. Mueller has served as a member of our Board since June 2014, and currently serves as Group Vice President, Corporate Controller and Chief Accounting Officer of BioMarin Pharmaceutical Inc. (Nasdaq: BMRN). From March 2009 to March 2014, Mr. Mueller served as BioMarin's Vice President, Corporate Controller. Prior to joining BioMarin in 2002, Mr. Mueller spent a combination of seven years in public accounting with Arthur Andersen, LLP and KPMG, LLP in the audit and business advisory services practices of both firms. Mr. Mueller holds a B.S. in Accountancy from Northern Illinois University in DeKalb, Illinois, and is a member of the American Institute of Certified Public Accountants.

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Philip T. Sager, M.D. Dr. Sager was appointed to serve on our Board in June 2014. Dr. Sager is a Fellow of the American College of Cardiology, a Fellow of the American Heart Association and a Fellow of the Heart Rhythm Society. Dr. Sager has been a member of the International Conference on Harmonization ("ICH") E14 Discussion Group since 2014, a full voting member of the United States Food and Drug Administration Cardiovascular and Renal Drugs Advisory Committee from 2011 until July 2016 and has been the Chair of such Committee since 2016. Dr. Sager has also been a member of the Executive Committee of the Cardiac Safety Research Consortium since 2016, and served as Chair of the Scientific Programs Committee and Scientific Oversight Committee at various times. Dr. Sager has served as a Consulting or Adjunct Professor of Medicine at the Stanford University School of Medicine since 2013 and provided pharmaceutical device and diagnostics consulting service independently since 2010. From 2009 through 2010, Dr. Sager was Vice President, Clinical Research and Head, CV/Metabolic Development for Gilead Sciences, a biotechnology company. Dr. Sager holds an M.D. from Yale University School of Medicine and B.S. degrees in chemistry and biology from the Massachusetts Institute of Technology.

David E. Thompson. Mr. Thompson has served as a member of our Board of Directors since November 2005. Mr. Thompson served as Vice President of Corporate Strategy Business Development for Eli Lilly and Company from January 2001 until his retirement in July 2005. Thereafter, he was a partner at VantagePoint Venture Partners from 2006 through 2008. Mr. Thompson holds a B.S. and an M.B.A. from Michigan State University.

There are no family relationships between any of our directors or executive officers.

Board of Directors' Role in Risk Management

The Board of Directors has overall responsibility for the oversight of the Company's risk management process, which is designed to support the achievement of organizational objectives, including strategic objectives, to improve long-term organizational performance and enhance shareholder value. Risk management includes not only understanding company-specific risks and the steps management implements to manage those risks, but also what level of risk is acceptable and appropriate for the Company. Management is responsible for establishing our business strategy, identifying and assessing the related risks and implementing appropriate risk management practices. The Board of Directors reviews our business strategy and management's assessment of the related risk, and discusses with management the appropriate level of risk for the Company. For example, the Board of Directors meets with management at least quarterly to review, advise and direct management with respect to strategic business risks, litigation risks and risks related to the Company's acquisition strategy, among others. The Board also delegates oversight to Board committees to oversee selected elements of risk as set forth below.

The Board of Directors has delegated day-to-day responsibility for administering and interpreting the Company's Code of Business Conduct and Ethics to the Company's Principal Accounting Officer as compliance officer. Our written Code of Business Conduct and Ethics applies to all of our directors and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions. The Code of Ethics is available on our website at http://www.anthera.com in the For Investors section under "Corporate Governance."

As part of its oversight of the Company's financial reporting process and audits of the Company's financial statements, our Audit Committee is responsible for reviewing financial risk exposures, including monitoring the quality and integrity of the Company's financial statements, the effectiveness of internal control over financial reporting, compliance with legal or regulatory requirements, the performance of the internal audit function and the performance and independence of the Company's independent registered public accounting firm, among other responsibilities as set forth in the Audit Committee Charter. The Audit Committee receives periodic internal control and related assessments from the Company's finance department. In addition, our Audit Committee ensures that the Company's business is conducted with the highest standards of ethical conduct in compliance with applicable laws and regulations by

monitoring our Code of Business Conduct and Ethics Policy and our Employee Feedback Hotline, and the Audit Committee discusses other risk assessment and risk management policies of the Company periodically with management.

Our Compensation Committee participates in the design of compensation structures that create incentives that encourage a level of risk-taking behavior consistent with the Company's business strategy.

Our Nominating and Corporate Governance Committee oversees governance-related risks by working with management to develop and recommend to the Board corporate governance guidelines applicable to the Company, making recommendations regarding director nominees and membership on Board committees and overseeing the annual evaluation of the Board and management.

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Compensation Plans Risk Assessment

As part of its oversight function, our Board of Directors and our Compensation Committee in particular, along with our management team, considers potential risks when reviewing and approving various compensation plans, including executive compensation. Based on this review, our Board of Directors has concluded that such compensation plans, including executive compensation, do not encourage risk taking to a degree that is reasonably likely to have a materially adverse impact on us or our operations.

Board of Directors and Committees of the Board

During 2017, the Board of Directors held a total of eight meetings. All directors attended at least 75% of the total number of Board meetings and meetings of Board committees on which the director served during the time he served on the Board or such committees.

The Board of Directors has determined each of the following current directors is an "independent director" as such term is defined in Nasdaq Rule 5605(a)(2) and Section 10A of the Exchange Act: Messrs. Truex, Furse, Mueller, David Thompson and Drs. Henney and Sager.

The Board of Directors has a standing Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee. Each of our Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee is composed entirely of independent directors in accordance with current Nasdaq listing standards. Furthermore, our Audit Committee meets the enhanced independence standards established by the Sarbanes-Oxley Act of 2002 and related rulemaking of the SEC. The Board of Directors has further determined that Brian R. Mueller, Chairman of the Audit Committee of the Board of Directors, is an "Audit Committee Financial Expert," as such term is defined in Item 407(d)(5) of Regulation S-K promulgated by the SEC. Copies of our Audit Committee, Nominating and Corporate Governance Committee and Compensation Committee charters and our corporate governance guidelines are available, free of charge, on our website at http://www.anthera.com.

Audit Committee. The Audit Committee appoints, approves the compensation of, and assesses the independence of our independent registered public accounting firm and pre-approves auditing and permissible non-audit services, and the terms of such services, to be provided by our independent registered public accounting firm. The Audit Committee is also responsible for reviewing and discussing with management and the independent registered public accounting firm our annual and quarterly financial statements and related disclosures and preparing the report required by the rules of the SEC to be included in our annual proxy statement. The Audit Committee also coordinates the oversight and reviews the adequacy of our internal control over financial reporting and establishes policies and procedures for the receipt and retention of accounting-related complaints and concerns. Currently, the Audit Committee is comprised of Mr. Mueller (Chair), Dr. Henney and Mr. Furse. During 2017, the Audit Committee held five meetings.

Compensation Committee. The Compensation Committee annually reviews and approves our goals and objectives relevant to compensation of our Chief Executive Officer, evaluates our Chief Executive Officer in light of such goals and determines the compensation of our Chief Executive Officer. The Compensation Committee also reviews and approves the compensation of all our other officers, oversees and administers our incentive-based compensation and equity plans and reviews and makes recommendations to our Board of Directors with respect to director compensation. The Compensation Committee also produces an annual report on executive compensation for inclusion in our proxy statement. Currently, the Compensation Committee is comprised of Mr. Furse (Chair), Mr. David Thompson and Dr. Philip Sager. During 2017, the Compensation Committee held five meetings.

Nominating and Corporate Governance Committee. The Nominating and Corporate Governance Committee is responsible for developing and recommending to our Board of Directors individuals to be nominated as directors and

committee members. This includes establishing procedures for identifying and evaluating director candidates (including nominees recommended by stockholders). The Nominating and Corporate Governance Committee is also responsible for developing and recommending to our Board of Directors corporate governance guidelines, as well as overseeing the evaluation of our Board of Directors, committees of the Board and management. Currently, the Nominating and Corporate Governance Committee is comprised of Dr. Sager (Chair), Dr. Henney, and Mr. David Thompson. During 2017, the Nominating and Corporate Governance Committee held one meeting.

Board Leadership

The positions of Executive Chairman of the Board and Chief Executive Officer are presently separated and the Chairman and Chief Executive positions have historically been separated at Anthera. Separating these positions allows our Chief Executive Officer to focus on our day-to-day business, while allowing the Executive Chairman of the Board to lead the Board of Directors in its fundamental role of providing advice to, and independent oversight of, management. Our Board of Directors recognizes the time, effort and energy that the Chief Executive Officer is required to devote to his position in the current business environment, as well as the commitment required to serve as our Executive Chairman, particularly as the Board of Directors' oversight responsibilities continue to grow. Our Board of Directors also believes that this structure ensures a greater role for the independent directors in the oversight of our Company and active participation of the independent directors in setting agendas and establishing priorities and procedures for the work of our Board of Directors. Our Board of Directors believes its administration of its risk oversight function has not affected its leadership structure.

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While our bylaws and corporate governance guidelines do not require that our Chairman and Chief Executive Officer positions be separate, our Board of Directors believes that having separate positions and having an independent outside director serve as Chairman is the appropriate leadership structure for us at this time and demonstrates our commitment to good corporate governance. Our separated Chairman and Chief Executive Officer positions are augmented by the independence of six of our seven directors, and our three entirely independent Board committees that provide appropriate oversight in the areas described above. At executive sessions of independent directors, these directors speak candidly on any matter of interest, without the Chief Executive Officer or other executives present. The independent directors met five times in 2016 without management present. We believe this structure provides consistent and effective oversight of our management and the Company.

Compensation Committee Interlocks and Insider Participation

None of the members of the Compensation Committee is or has at any time during the past fiscal year been an officer or employee of the Company. None of the members of the Compensation Committee has formerly been an officer of the Company. None of our executive officers serve or in the past fiscal year has served as a member of the board of directors or Compensation Committee of any other entity that has one or more executive officers serving as a member of our Board of Directors or Compensation Committee.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our officers and directors, and persons who own more than 10% of a registered class of our equity securities, to file reports of ownership and changes in ownership (Forms 3, 4 and 5) with the SEC. Officers, directors and greater than 10% stockholders are required to furnish us with copies of all such forms which they file.

To our knowledge, based solely on our review of such reports or written representations from certain reporting persons, we believe that all of the filing requirements applicable to our officers, directors, greater than 10% beneficial owners and other persons subject to Section 16 of the Exchange Act were complied with during the year ended December 31, 2017.

ITEM 11. Executive Compensation

Director Compensation

Effective January 1, 2017, each of our non-employee directors receives a $40,000 annual retainer fee instead of per-meeting fees. In consideration for their services, the Executive Chairman of the Board receives an additional $60,000, the Chairman of our Board of Directors receives an additional $40,000, the Chairman of our Audit Committee receives an additional $15,000, the Chairman of our Compensation Committee receives an additional $14,000, and the Chairman of our Nominating and Corporate Governance Committee receives an additional $8,000, each on an annual basis. Other members of the Audit Committee, Compensation Committee, and Nominating and Corporate Governance Committee each receives additional annual cash retainers of $7,500, $6,000 and $4,000, respectively. In addition, our director compensation program provides for the grant of non-qualified stock options to our non-employee directors in amounts based on the aggregate fair value of such grants. Pursuant to the program, each new non-employee director receives a non-qualified stock option, which vests monthly over three years with equal monthly installments, to purchase shares of our common stock equal in value to approximately $150,000. In addition, each non-employee director receives an annual grant of non-qualified stock options, which vest monthly over one year with equal monthly installments, to purchase shares of our common stock equal in value to approximately $120,000. The number of shares subject to such options are determined based on the aggregate fair value, divided by the fair value per share, calculated using the Black-Scholes option pricing model on the grant

date. All members of our Board of Directors are eligible to receive full reimbursement for travel expenses arising from their attendance at our Board meetings

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2017 Director Compensation Table

The following table sets forth information with respect to the compensation earned by our non-employee directors during the fiscal year ended December 31, 2017.

Name	Fees Earned or Paid in Cash ($) (1)	Option Awards ($)(2)	Total ($)
Paul Truex (Executive Chairman) (3)	$ 100,000	$ —	$100,000
Brent V. Furse (4)	$ 56,833	$ —	$56,833
Christopher S. Henney, Ph.D. (5)	$ 51,500	$ —	$51,500
Brian R. Mueller (6)	$ 55,000	$ —	$55,000
Philip T. Sager, M.D. (7)	$ 54,000	$ —	$54,000
David E. Thompson (8)	$ 50,000	$ —	$50,000
Steven B. Engle (9)	$ 17,550	$ —	$17,550

(1) This column reflects retainer fees earned in 2017. Director retainer fees are generally paid in arrears. However, fees earned in the fourth quarter of 2017 were paid in the fourth quarter of 2017.

(2) During the year ended December 31, 2017, there were no option awards granted to the directors due to insufficient stock options available for grant in the Company's 2013 Stock Option and Equity Incentive Plan.

(3) Mr. Truex held 83,032 shares underlying stock options as of December 31, 2017.

(4) Mr. Furse held 9,381 shares underlying stock options as of December 31, 2017.

(5) Dr. Henney held 30,296 shares underlying stock options as of December 31, 2017.

(6) Mr. Mueller held 12,998 shares underlying stock options as of December 31, 2017.

(7) Dr. Sager held 14,248 shares underlying stock options as of December 31, 2017.

(8) Mr. Thompson held 24,614 shares underlying stock options as of December 31, 2017.

(9) Mr. Engle held 14,248 shares of underlying stock options as of December 31, 2017 and did not stand for reelection at the 2017 Annual Meeting of Shareholders and retired from the Board of Directors effective as of April 27, 2017.

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2017 Summary Compensation Table

The following table provides information regarding the total compensation for services rendered in all capacities that was earned during the fiscal year indicated by our current principal executive officer and our other two most highly compensated executive officers as of December 31, 2017. We refer to these officers as our named executive officers.

Name and Principal Position as of December 31, 2017	Year	Salary $	Bonus ($) (2)	Stock Awards ($)	Option Awards ($) (3)	Non-Equity Incentive Plan Compensation ($)	All Other Compensation ($)	Total ($)
J. Craig Thompson	2017	$460,000	$255,300	$ —	$173,077	$ —	$ —	$888,377
CEO and Director	2016	$397,538	$136,017	$ —	$1,786,299	$ —	$ —	$2,319,854
William R. Shanahan, M.D., SVP Chief Medical Officer. (1)	2017	$400,000	$152,460	$ —	$111,295	$ —	$ —	$663,755
	2016	$151,515	$44,439	$ —	$957,921		$ —	$1,153,875
Renee Martin, Ph.D.	2017	$298,636	$99,222	$ —	$98,365	$ —	$ —	$496,223
SVP, Medical Sciences	2016	$278,750	$72,336	$ —	$417,115	$ —	$ —	$768,201

(1) Dr. Shanahan joined the Company on August 15, 2016.

(2) Annual performance cash bonus awards earned in the respective year based on personal and corporate achievements of development and corporate objectives.

(3) During 2017 and 2016, we granted stock options to our named executive officers and the grant date fair value is calculated in accordance with FASB ASC 718. See Note 10 to our financial statements included in our Annual Report for the year ended December 31, 2017 for a discussion of the assumptions made in determining the valuation of option awards.

Narrative Disclosure to Summary Compensation Table

Base Salary. The base salaries of our named executive officers are primarily established based on the scope of their responsibilities and performance, taking into account comparable company data from our compensation consultants and based upon our Compensation Committee's understanding of compensation paid to similarly situated executives, and adjusted as necessary to recruit or retain specific individuals. We typically review the base salaries of our named executive officers annually. The salaries for our named executive officers are as follows:

Named Executive Officer	Annual Base Salary Effective as of December 31, 2017
Craig Thompson, Chief Executive Officer and Director	$ 460,000
William R. Shanahan, M.D., Chief Medical Officer	$ 400,000
Renee Martin, Ph.D., Senior Vice President, Medical Sciences	$ 315,000

Cash Bonuses. The Board of Directors adopted the Company's Executive Incentive Bonus Plan, or the Bonus Plan, which applies to certain key executives, or the Executives, that are recommended by the Compensation Committee and selected by the Board. The Bonus Plan provides for bonus payments based upon the attainment of performance targets established by the Board and related to financial and operational metrics with respect to the Company or any of its subsidiaries, or the Performance Goals, which would include the achievement of clinical study or operational milestones, results of clinical studies and achievement of specified financial metrics or objectives. Each Executive is given a targeted bonus opportunity set for each performance period. The maximum bonus payable to an Executive under the Bonus Plan is 125% of the Executive's bonus opportunity. The Performance Goals are measured at the end of each fiscal year after the Company's financial reports have been published or such other appropriate time as the Board shall determine. If the Performance Goals are met, payments are made within 30 days thereafter, and if met for the previous fiscal year, not later than March 31.

Equity Incentive Compensation. We generally grant stock options to our employees, including our named executive officers, in connection with their initial employment with us. We also typically grant stock options on an annual basis as part of annual performance reviews of our employees. In exercising its discretion to determine the amount of each grant for recommendation to our Board of Directors, the Compensation Committee generally took into account each individual's contributions towards the achievement of our annual corporate goals.

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Other Compensation. We currently maintain broad-based benefits that are provided to all employees, including health insurance, life and disability insurance, dental insurance and a 401(k) plan. As discussed below in "Employment Agreements with Certain Executive Officers," we have entered into employment agreements with certain executive officers providing for benefits upon termination of their employment, including the acceleration of vesting of restricted stock and options. Our goal in providing severance benefits is to offer sufficient cash continuity protection such that our executives will focus their full time and attention on the requirements of the business rather than the potential implications of their respective positions. We prefer to have certainty regarding the potential severance amounts payable to the named executive officers under certain circumstances, rather than negotiating severance at the time that a named executive officer's employment terminates.

Outstanding Equity Awards at Fiscal Year-End

The following table sets forth certain information with respect to outstanding equity awards as of December 31, 2017 with respect to our named executive officers.

	Option Awards			
Name	Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Unexercisable (#)	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price ($)	Option Expiration Date
J. Craig Thompson	22,760 (1)	24,740 (1)	—	$ 29.60	1/7/2026
	—		21,250 (2)	$ 28.16	6/9/2026
	6,250 (3)	18,750 (3)	—	$ 11.76	12/6/2026
	3,125 (4)	9,375 (4)	—	$ 5.12	3/3/2027
	33,853 (5)	47,397 (5)	—	$ 1.63	5/20/2027
			—		
William R. Shanahan	16,250 (6)	32,501 (6)	—	$ 25.36	8/15/2026
M.D.	31,250 (5)	43,750 (5)	—	$ 1.63	5/20/2027
			—		
Renee Martin, Ph.D.	20,312 (5)	28,438 (5)	—	$ 1.63	5/20/2027
	2,031 (7)	17,469 (7)	—	$ 1.60	7/18/2027

(1) This stock option vests over four years as follows: 25% of the stock options shall vest one year following the vesting commencement date, with the remaining 75% of the stock options vesting in 36 equal monthly installments thereafter. The vesting commencement date is January 7, 2016

(2) The option shall have a term of two years and vest as follows: 10,625 shares will vest upon the completion of a transaction with an expected realized value of at least $100 million; 10,625 remaining shares shall vest upon the completion of a transaction with an expected realized value of at least $200 million.

(3)

This stock option vests over four years as follows: 25% of the stock options shall vest one year following the vesting commencement date, with the remaining 75% of the stock options vesting in 36 equal monthly installments thereafter. The vesting commencement date is December 6, 2016.

(4) This stock option vests monthly in 48 equal installments. The vesting commencement date is December 6, 2016.

(5) This stock option vests monthly in 36 equal monthly installments. Vesting of 25% of this option shall be accelerated on interim data of 75% patients enrolled in the Company's RESULT Phase 3 clinical trial, whichever is earlier. Following an acceleration of vesting of the options, the remaining unvested options shall vest in equal monthly installments through the remaining vesting period such that the entire award becomes fully vested 36 months from the vesting commencement date. The vesting commencement date is May 20, 2017.

(6) This stock options vests over four years as follows: 25% of the shares vest one year following the vesting commencement date, with the remaining 75% vest in 36 equal monthly installments thereafter. The vesting commencement date is August 15, 2016.

(7) This stock option vests monthly in 48 equal installments. The vesting commencement date is July 18, 2017.

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Employment Agreements with Certain Executive Officers

On January 25, 2016, we entered into employment agreements with Craig Thompson and May Liu. On January 5, 2018, we amended the employment agreement with Mr. Thompson and Ms. Liu (the "Amended Agreement") and also entered into employment agreements (together with the Amended Agreement, the "Agreements") with Drs. William Shanahan and Renee Martin, and Patrick Murphy, who was appointed to serve as the Company's Senior Vice President, Manufacturing on January 1, 2018 (collectively, the "Executives").

The Agreements provide for an annual base salary (the "Base Salary"), subject to annual review and increase as determined by the Board. In addition, each executive is considered for a bonus target from time to time, in an amount of up to a percentage of the executive's then-current base salary (the "Bonus Percentage"), and is also eligible to participate in the Company's long-term incentive equity program and receive annual equity grants as determined by the Board.

Pursuant to the Agreements, each Executive's employment is at-will. In the event that the Executive's employment is terminated by the Executive for Good Reason or by the Company without Cause (as such terms are defined below), the Executive will be entitled to receive (i) the amount of his or her accrued but unpaid Base Salary and unpaid and documented expense reimbursements as of the date of termination, (ii) any vested benefits the Executive may have under any employee benefit plan, which shall be paid in accordance with the terms of such employee benefit plans, as of the date of termination, (iii) continued payment of the Executive's Base Salary for a period following such termination (the "Severance Period") plus his or her annual target incentive compensation for such Severance Period, (iv) acceleration of vesting of all equity awards that would have vested within twelve months following such termination, (v) continuation of health benefits for twelve months after termination, and (vi) outplacement services, in the case of each of (iii), (iv), (v), and (vi), subject to the execution of a separation agreement and release. The receipt of any severance payments or benefits is subject to the Executive not violating such Executive's post-employment contractual obligations.

The employment agreements define "Cause" as the: (i) commission by the Executive of any felony or certain misdemeanors, or conduct that would reasonably expected to cause the Company or any of its subsidiaries and affiliates any material injury or reputational harm if the Executive's employment continued; (ii) willful disclosure of trade secrets or other confidential information relating to the Company; (iii) continued failure by the Executive to perform his or her duties after demand by the Board (other than as a result of incapacity); (iv) conduct by the Executive constituting a material act of misconduct in connection with the performance of the Executive's duties, including without limitation, misappropriation of funds or property of the Company or any of its subsidiaries or affiliates, or participation in releasing false or materially misleading financial statements or submission of false certifications to the Securities and Exchange Commission (the "SEC"); (v) breach by the Executive of any of the provisions contained in the employment agreements or any other agreement between the parties; (vi) material violation by the Executive of the Company's written employment practices; or (vii) failure to cooperate with internal, regulatory or law enforcement investigations after demand by the Board, or the destruction or failure to preserve documents in connection with such investigations.

The employment agreements define Good Reason as the Executive's compliance with certain procedures specified in the Agreements, including notice and a cure period, after the occurrence of any of the following events: (i) a substantial reduction in the Executive's duties, responsibilities, or authority or a title change, each without the Executive's consent; (ii) a material reduction in the Base Salary or Bonus Percentage; (iii) the relocation of the Company's office under certain circumstances; or (iv) the material breach of the Agreement by the Company.

The current Base Salary for each Executive remains as follows: Mr. Thompson, $460,000; Dr. Shanahan, $400,000 and Ms. Liu, $300,000. The Base Salary for Dr. Martin and Mr. Murphy is $315,000.

The current Bonus Percentage for each Executive remain as follows: Mr. Thompson, 50%; Dr. Shanahan, 35%; Ms. Liu and Dr. Martin, 30%. The Bonus Percentage for Mr. Murphy is 25%.

The Amended Agreements increased the Severance Period from nine months to twelve months, in the case of Mr. Thompson, and from six months to nine months, in the case of Ms. Liu. The Severance Period for each of the other Executives is nine months.

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ITEM 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth certain information as of January 31, 2018 regarding the beneficial ownership of our common stock by the following persons:

- each person who, to our knowledge, owns more than 5% of our common stock;
- each of our named executive officers;
- each director; and
- all of our executive officers and directors as a group.

Unless otherwise indicated in the footnotes to the following table, each person named in the table has sole voting and investment power. The address for each of our named executive officers and directors is c/o Anthera Pharmaceuticals, Inc., 25301 Industrial Boulevard, Suite B, Hayward, CA. Shares of common stock subject to options, warrants or other rights currently exercisable or exercisable within 60 days of January 31, 2018, are deemed to be beneficially owned and outstanding for computing the share ownership and percentage of the stockholder holding the options, warrants or other rights, but are not deemed outstanding for computing the percentage of any other stockholder. As of January 31, 2018, we had 21,507,862 shares of common stock outstanding.

Name and Address of Beneficial Owner	Amount and Nature of Beneficial Ownership	Percent of Class
Named Executive Officers and Directors		
Craig Thompson (1)	634,783	2.95%
William R. Shanahan, M.D. (2)	220,703	1.03%
Renee Martin, Ph.D.(3)	128,398	*
Paul F. Truex (4)	167,448	*
Christopher S. Henney, Ph.D.(5)	125,223	*
Brent Furse (6)	98,953	*
Brian R. Mueller (7)	105,865	*
Philip T. Sager, M.D. (8)	105,865	*
David E. Thompson (9)	118,381	*
All named executive officers and directors as a group (9 persons)	1,705,619	7.36%
Owners of More than 5% of Our Common Stock		
Biotechnology Value Fund, LP and associated entities (10)	2,408,029	11.20%
683 Capital Management, LLC and associated entities (11)	2,603,191	11.48%

*Represents beneficial ownership of less than 1% of the shares of common stock.

(1) Includes (i) 19,848 shares of common stock, and ii) options to purchase 614,935 shares of common stock that are exercisable within 60 days of January 31, 2018, owned of record by Mr. Thompson

(2) Includes options to purchase 220,703 shares of common stock which are exercisable within 60 days of January 31, 2018, owned of record by Dr. Shanahan.

(3) Includes (i) 3,118 shares of common stock and (ii) options to purchase 125,280 shares of common stock which are exercisable within 60 days of January 31, 2018, owned of record by Ms. Martin.

(4) Includes (i) 16,793 shares of common stock, all of which are owned of record by the 2005 Truex Family Trust U/D/T 04/20/2005 and (ii) options to purchase an additional 150,655 shares of common stock that are exercisable within 60 days of January 31, 2018, owned of record by Mr. Truex.

(5) Includes (i) 3,163 shares of common stock and (ii) options to purchase an additional 122,060 shares of common stock that are exercisable within 60 days of January 31, 2018, owned of record by Dr. Henney.

(6) Includes options to purchase 98,953 shares of common stock that are exercisable within 60 days of January 31, 2018, owned of record by Mr. Furse.

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(7) Includes (i) 1,250 shares of common stock and (ii) options to purchase 104,615 shares of common stock that are exercisable within 60 days of January 31, 2018, owned of record by Mr. Mueller.

(8) Includes options to purchase 105,865 shares of common stock that are exercisable within 60 days of January 31, 2018, owned of record by Dr. Sager.

(9) Includes (i) 2,003 shares of common stock and (ii) options to purchase 116,378 shares of common stock that are exercisable within 60 days of January 31, 2018, owned of record by Mr. Thompson.

(10) Includes (A)(i) 110,276 shares of common stock underlying warrants issued in connection with a subscription agreement dated September 6, 2016 and held by Biotechnology Value Fund, L.P., (ii) 72,078 shares of common stock underlying warrants issued in connection with a subscription agreement dated September 6, 2016 and held by Biotechnology Value Fund II, L.P., (iii) 21,455 shares of common stock underlying warrants issued in connection with a subscription agreement dated September 6, 2016 and held by Biotechnology Value Trading Fund OS, L.P., and (iv) 34,230 shares of common stock underlying warrants issued in connection with a subscription agreement dated September 6, 2016 and held by MSI BVF SPV, LLC; (B)(i) 249,024 shares of common stock underlying warrants issued on March 17, 2017 and held by Biotechnology Value Fund, L.P., (ii) 162,901 shares of common stock underlying warrants issued on March 17, 2017 and held by Biotechnology Value Fund II, L.P., (iii) 42,652 shares of common stock underlying warrants issued on March 17, 2017 and held by Biotechnology Value Trading Fund OS, L.P., (iv) 51,458 shares of common stock underlying warrants issued on March 17, 2017 and held by Investment 10, LLC, and (v) 43,964 shares of common stock underlying warrants issued on March 17, 2017 and held by MSI BVF SPV, LLC; and (C)(i) 422,263 shares of common stock underlying warrants issued on January 9, 2018 and held by Biotechnology Value Fund, L.P., (ii) 285,911 shares of common stock underlying warrants issued on January 9, 2018 and held by Biotechnology Value Fund II, L.P., (iii) 75,296 shares of common stock underlying warrants issued on January 9, 2018 and held by Biotechnology Value Trading Fund OS, L.P., (iv) 44,677 shares of common stock issued on January 9, 2018 and held by Investment 10, LLC, and (v) 53,879 shares of common stock issued on January 9, 2018 and held by MSI BVF SPV, LLC. Excludes (i) 301,461 shares of common stock underlying warrants issued on October 27, 2017 and held by Biotechnology Value Fund, L.P., (ii) 204,117 shares of common stock underlying warrants issued on October 27, 2017 and held by Biotechnology Value Fund II, L.P., (iii) 53,754 shares of common stock underlying warrants issued on October 27, 2017 and held by Biotechnology Value Trading Fund OS, L.P., (iv) 31,893 shares of common stock underlying warrants issued on October 27, 2017 and held by Investment 10, LLC, and (v) 38,463 shares of common stock underlying warrants issued on October 27, 2017 and held by MSI BVF SPV, LLC.

(11) The number of shares of common stock that may be deemed to be beneficially owned by 683 Capital Management, LLC (“683 LLC”) is based solely on information disclosed in a Schedule 13G filed on January 8, 2018 on behalf of 683 Capital Management, LLC. As of January 18, 2018, 683 Capital Partners, LP (“683 LP”) may be deemed to beneficially own 1,440,000 shares of Common Stock and 1,163,191 shares of Common Stock underlying warrants. 683 LLC, as the investment manager of 683 LP may be deemed to beneficially own the 1,440,000 shares of Common Stock beneficially owned by 683 LP. Ari Zweiman, as the Managing Member of 683 LLC, may be deemed to beneficially own the 1,440,000 shares of Common Stock beneficially owned by 683 LLC. Excludes 830,427 shares of common stock underlying warrants issued on October 27, 2017 and held by 683 LP.

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Equity Compensation Plan Information

The following table provides information regarding our equity compensation plan in effect as of December 31, 2017.

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted Average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plan (excluding securities referenced in column (a) (c)
Equity compensation plans approved by security holders:	1,066,121	$ 10.04	242,481
Equity compensation plans not approved by security holders	N/A	N/A	N/A
Total	1,066,121	$ 10.04	242,481

ITEM 13. Certain Relationships and Related Transactions, and Director Independence

Commission regulations define the related person transactions that require disclosure to include any transaction, arrangement or relationship, since January 1, 2017, in which the amount involved exceeds the lesser of $120,000 or 1% of the average of our total assets at year-end in which we were or are to be a participant and in which a related person had or will have a direct or indirect material interest. A related person is: (i) an executive officer, director or director nominee of the Company, (ii) a beneficial owner of more than 5% of our common stock, (iii) an immediate family member of an executive officer, director or director nominee or beneficial owner of more than 5% of our common stock, or (iv) any entity that is owned or controlled by any of the foregoing persons or in which any of the foregoing persons has a substantial ownership interest or control.

For the period from January 1, 2017, through the date of this report, described below are certain transactions or series of transactions between us and certain related persons. Information relating to employment agreements entered into by the Company and its executive officers and executive officer and director compensation can be found under the heading “Executive Compensation”.

Private Placement

On October 23, 2017, the Company entered into a securities purchase agreement with a group of 21 accredited investors (the “Purchasers”), pursuant to which the Company issued shares of its common stock, Class Y Convertible Preferred Stock, and warrants to purchase shares of common stock for gross proceeds of approximately $15,000,000 in a private offering with two closings (the “Private Placement”). Purchasers in the Private Placement included entities affiliated with Biotechnology Value Fund, L.P and 683 Capital Management, LLC.

Director Independence

Our determination of the independence of our directors is made using the definition of “independent” contained in the listing standards of the NASDAQ Stock Market. On the basis of information solicited from each director, the board has determined that each of Messrs. Furse, Mueller, and D. Thompson, and Drs. Henney and Sager are independent

within the meaning of such rules.

Indemnification of Officers and Directors

Section 145 of the Delaware General Corporation Law, or the DGCL, authorizes a corporation to indemnify its directors and officers against liabilities arising out of actions, suits and proceedings to which they are made or threatened to be made a party by reason of the fact that they have served or are currently serving as a director or officer to a corporation. The indemnity may cover expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by the director or officer in connection with any such action, suit or proceeding. Section 145 permits corporations to pay expenses (including attorneys' fees) incurred by directors and officers in advance of the final disposition of such action, suit or proceeding. In addition, Section 145 provides that a corporation has the power to purchase and maintain insurance on behalf of its directors and officers against any liability asserted against them and incurred by them in their capacity as a director or officer, or arising out of their status as such, whether or not the corporation would have the power to indemnify the director or officer against such liability under Section 145.

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We have adopted provisions in our restated certificate of incorporation and amended and restated bylaws that limit or eliminate the personal liability of our directors to the fullest extent permitted by the DGCL, as it now exists or may in the future be amended. Consequently, a director will not be personally liable to us or our stockholders for monetary damages or breach of fiduciary duty as a director, except for liability for:

- any breach of the director's duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- any unlawful payments related to dividends or unlawful stock purchases, redemptions or other distributions; or
- any transaction from which the director derived an improper personal benefit.

These limitations of liability do not alter director liability under the federal securities laws and do not affect the availability of equitable remedies such as an injunction or rescission.

In addition, our bylaws provide that:

- we will indemnify our directors, officers and, in the discretion of our board of directors, certain employees to the fullest extent permitted by the DGCL, as it now exists or may in the future be amended; and
- we will advance reasonable expenses, including attorneys' fees, to our directors and, in the discretion of our board of directors, to our officers and certain employees, in connection with legal proceedings relating to their service for or on behalf of us, subject to limited exceptions.

We have entered into indemnification agreements with each of our directors and certain of our executive officers. These agreements provide that we will indemnify each of our directors, certain of our executive officers and, at times, their affiliates to the fullest extent permitted by Delaware law. We will advance expenses, including attorneys' fees (but excluding judgments, fines and settlement amounts), to each indemnified director, executive officer or affiliate in connection with any proceeding in which indemnification is available and we will indemnify our directors and officers for any action or proceeding arising out of that person's services as a director or officer brought on behalf of the Company or in furtherance of our rights. Additionally, certain of our directors may have certain rights to indemnification, advancement of expenses or insurance provided by their affiliates, which indemnification relates to and might apply to the same proceedings arising out of such director's services as a director referenced herein. Nonetheless, we have agreed in the indemnification agreements that the Company's obligations to those same directors are primary and any obligation of the affiliates of those directors to advance expenses or to provide indemnification for the expenses or liabilities incurred by those directors are secondary. We also maintain a general liability insurance policy which covers certain liabilities of directors and officers of our Company arising out of claims based on acts or omissions in their capacities as directors or officers, including liabilities under the Securities Act of 1933, as amended.

ITEM 14. Principal Accountant Fees and Services

The following is a summary of fees billed by BDO USA, LLP for fiscal years ended December 2017 and 2016:

Fees billed by BDO USA, LLP	2017	2016
Audit Fees(1)	$391,308	$491,272
Audit-Related Fees	—	—
Tax Fees	—	—
All Other Fees	—	—
Total	$391,308	$491,272

(1) Includes service fees associated with the annual audit of our financial statements, the reviews of our interim financial statements and the issuance of consent and comfort letters in connection with registration statement.

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PART IV

ITEM 15. EXHIBITS AND CONSOLIDATED FINANCIAL

STATEMENT SCHEDULES

The following documents are filed as part of this report:

(1) Index list to Consolidated Financial Statements:

(2) Consolidated financial statement Schedules

All other schedules are omitted because they are not required or the required information is included in the consolidated financial statements or notes thereto.

(3) Exhibits

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

ITEM 16. Form 10-K Summary

None.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Shareholders and Board of Directors
Anthera Pharmaceuticals, Inc.
Hayward, California

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Anthera Pharmaceuticals, Inc. (the “Company”) as of December 31, 2017 and 2016, the related consolidated statements of operations, Series X Convertible Preferred Stock and Stockholders’ Equity (Deficit), and cash flows for each of the three years in the period ended December 31, 2017 and the related notes (collectively referred to as the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2017 and 2016, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2017, in conformity with accounting principles generally accepted in the United States of America.

Going Concern Uncertainty

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has suffered recurring losses from operations and has a net capital deficiency that raise substantial doubt about its ability to continue as a going concern. Management’s plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (“PCAOB”) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

We have served as the Company's auditor since 2013.

/s/ BDO USA, LLP

San Francisco, California

March 5, 2018

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ANTHERA PHARMACEUTICALS, INC.

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

	December 31,	
	2017	2016
ASSETS		
Current assets:		
Cash and cash equivalents	$2,196	$20,843
Prepaid expenses and other current assets	995	1,865
Total current assets	3,191	22,708
Property and equipment — net	482	763
TOTAL	$3,673	$23,471
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$1,832	$4,782
Accrued clinical expenses	1,785	3,884
Accrued payroll	1,066	1,845
Other accrued liabilities	28	113
Total current liabilities	4,711	10,624
Warrant liability	4,457	—
Total liabilities	9,168	10,624
Commitments and Contingencies (Note 8)		
Contingently Redeemable Series X Convertible Preferred Stock, $0.001 par value, 0 and 487 shares issued and outstanding as of December 31, 2017 and 2016, respectively	—	377
Stockholders' equity (deficit):		
Series X Convertible Preferred Stock, $0.001 par value, 5,000,000 shares authorized; 430 and 9,012 shares issued and outstanding as of December 31, 2017 and 2016, respectively	333	8,614
Common stock, $0.001 par value, 100,000,000 shares authorized; 13,854,491 shares and 5,745,536 shares issued and outstanding as of December 31, 2017 and 2016, respectively	14	6
Additional paid-in capital	428,586	411,404
Accumulated deficit	(434,428)	(407,554)
Total stockholders' equity (deficit)	(5,495)	12,470
TOTAL	$3,673	$23,471

See accompanying notes to consolidated financial statements.

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ANTHERA PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share data)

	Years ended December 31,		
	2017	2016	2015
REVENUES:			
License revenue	$—	$139	$2,562
Collaborative revenue	—	6	623
Total revenues	—	145	3,185
OPERATING EXPENSES:			
Research and development	$28,594	$46,512	$33,498
General and administrative	7,938	11,071	7,568
Research award	(100)	(261)	(2,638)
Total operating expenses	36,432	57,322	38,428
LOSS FROM OPERATIONS	(36,432)	(57,177)	(35,243)
OTHER INCOME (EXPENSE):			
Other income (expense)	(85)	(90)	23
Fair value of warrant liability in excess of proceeds from financing	(600)	—	—
Change in fair value of warrant liability	10,243	1,744	—
Total other income (expense)	9,558	1,654	23
NET LOSS	$(26,874)	$(55,523)	$(35,220)
Deemed dividends attributable to preferred stock	(2,503)	(10,914)	—
Net loss applicable to common stockholders	$(29,377)	$(66,437)	(35,220)
Net loss per share applicable to common stockholders—basic and diluted (1)	$(2.86)	$(12.87)	$(7.91)
Weighted-average number of shares used in per share calculation—basic and diluted (1)	10,278,391	5,163,784	4,453,905

See accompanying notes to consolidated financial statements.

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

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

	Contingently Redeemable Series X Convertible Preferred Stock		Series X Convertible Preferred Stock		Common Stock (1)				
	Shares	Amount	Shares	Amount	Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
Balance at December 31, 2014	-	$ -	-	$ -	2,875,652	$ 3	$ 314,547	$ (316,811)	$ (2,261)
Issuance of common stock upon release of restricted stock units	-	-	-	-	64	-	3	-	3
Issuance of common stock pursuant to exercise of stock options and employee stock purchase plan	-	-	-	-	17.583	-	410	-	410
Issuance of common stock pursuant to an equity purchase agreement, net of issuance cost of $60	-	-	-	-	7,417	-	75	-	75
Issuance of common stock pursuant to an at-market issuance sales agreement, net of issuance cost of $379	-	-	-	-	401,066	1	12,057	-	12,058
Issuance of common stock for cash at average $5.62 per share, net of	-	-	-	-	1,277,778	1	53,755	-	53,756

issuance cost of $3,744									
Issuance of common stock to collaborative partner for cash	-	-	-	-	368,351	3	6,300	-	6,300
Issuance of common stock to settle a license fee obligation	-	-	-	-	52,594	-	1,000	-	1,000
Share-based compensation related to equity awards	-	-	-	-	-	-	3,536	-	3,536
Net loss	-	-	-	-	-	-	-	(35,220)	(35,220)
Balance at December 31, 2015	-	$-	-	$-	5,000,505	$5	$391,683	$(352,031)	$39,657
Issuance of common stock pursuant to exercise of stock options and employee stock purchase plan	-	-	-	-	16,909	-	304	-	304
Share based compensation related to equity awards	-	-	-	-	-	-	6,880	-	6,880
Issuance of common stock pursuant to an at-market issuance sales agreement, net of issuance costs of $277	-	-	-	-	187,623	-	4,850	-	4,850
Issuance of common stock pursuant to an equity purchase agreement, net of issuance costs of $87	-	-	-	-	64,354	-	1,579	-	1,579
Issuance of Series X convertible preferred stock, net of issuance	17,000	16,844		-	-	-	-	-	-

costs of $156									
Investors' right to acquire future shares of Series X-1 convertible preferred stock	-	(3,583)	-	3,583	-	-	-	-	3,583
Reclassification of Series X convertible preferred stock from temporary to permanent equity	(16,513)	(9,206)	16,513	9,206	-	-	-	-	9,206
Conversion of Series X convertible preferred stock into common stock		-	(7,501)	(5,456)	476,145	1	5,455	-	-
Beneficial conversion feature on Series X convertible preferred stock	-	(8,831)		(802)	-	-	9,633	-	8,831
Deemed dividend attributable to Series X convertible preferred stock	-	8,831	-	2,083	-	-	(10,914)	-	(8,831)
Issuance and reclassification of warrants related to Series X convertible preferred stock	-	(3,678)	-		-	-	1,934	-	1,934
Net loss	-	-	-	-	-	-	-	(55,523)	(55,523)
Balance at December 31, 2016	487	$377	9,012	$8,614	5,745,536	$6	$411,404	$(407,554)	$12,470
Issuance of common stock pursuant to exercise of employee stock purchase plan	-	-	-	-	39,386	-	80	-	80
Issuance of common stock pursuant to					100,834	-	190	-	190

exercise of warrants									
Share based compensation related to equity awards	-	-	-	-	-	-	4,379	-	4,379
Issuance of common stock pursuant to an equity purchase agreement, net of issuance cost of $316	-	-	-	-	1,336,320	1	1,693	-	1,694
Issuance of common stock and warrants for cash at $4.00 per share, net of warrant liability of $14,700	-	-	-	-	3,750,000	-	-	-	-
Issuance of common stock and warrants for cash at $1.25 per share, net of issuance cost of $694	-	-	-	-	2,306,737	2	626	-	628
Issuance of warrants in connection with a private placement of common stock	-	-	-	-	-	-	1,561	-	1,561
Reclassification of Series X convertible preferred stock from temporary to permanent equity	(487)	(377)	487	377	-	-	-	-	377
Conversion of Series X convertible preferred stock into common stock	-	-	(9,069)	(11,161)	575,678	5	11,156	-	-
Deemed dividend attributable to Series X	-	-	-	2,503	-	-	(2,503)	-	-

convertible preferred stock									
Net loss	-	-	-	-	-	-	-	(26,874)	(26,874)
Balance at December 31, 2017	-	$ -	430	$ 333	13,854,491	$ 14	$ 428,586	$ (434,428)	$ (5,495)

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

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ANTHERA PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31,		
	2017	2016	2015
Cash flows from operating activities:			
Net loss	$(26,874)	$(55,523)	$(35,220)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	281	266	285
Stock-based compensation expense	4,379	6,739	3,541
Change in fair value of warrant liability	(10,243)	(1,744)	—
Fair value of warrant liability in excess of proceeds from financing	600	—	—
Changes in operating assets and liabilities:			
Accounts receivable	—	326	(326)
Prepaid expenses and other current assets	870	(1,280)	(202)
Accounts payable	(2,950)	(477)	3,027
Accrued clinical expenses	(2,099)	2,507	138
Accrued payroll	(779)	390	527
Other accrued liabilities	(85)	15	(113)
Deferred revenue	—	(138)	(2,564)
Net cash used in operating activities	(36,900)	(48,919)	(30,907)
Cash flows from investing activities:			
Property and equipment purchases	—	(766)	(80)
Net cash used in investing activities	—	(766)	(80)
Cash flows from financing activities:			
Net proceeds from issuance of preferred stock, warrants and options	—	16,844	—
Net proceeds from issuance of common stock pursuant to an equity purchase agreement	1,694	1,579	75
Net proceeds from issuance of common stock pursuant to an at-market issuance sales agreement	—	4,850	12,058
Net proceeds from issuance of common stock and warrants pursuant to equity offerings	16,289	—	—
Net proceeds from issuance of common stock pursuant to equity offerings	—	—	53,756
Net proceeds from issuance of common stock to collaborative partner	—	—	9,000
Net proceeds from issuance of common stock pursuant to exercise of warrants	190	—	—
Net proceeds from issuance of common stock pursuant to exercise of stock options and employee stock purchase plan	80	304	410
Net cash provided by financing activities	18,253	23,577	75,299
Net increase (decrease) in cash and cash equivalents	(18,647)	(26,108)	44,312
Cash and cash equivalents, beginning of period	20,843	46,951	2,639

Cash and cash equivalents, end of period	$2,196	$20,843	$46,951
SUPPLEMENTAL CASH FLOW INFORMATION			
Issuance of common stock as a commitment fee pursuant to an equity purchase agreement	$316	$87	$60
Issuance of common stock to settle a license fee obligation	$—	$—	$1,000
Fair value of warrants issued in connection with registered direct offering	$14,700	$3,678	$—

See accompanying notes to consolidated financial statements.

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ANTHERA PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. ORGANIZATION AND DESCRIPTION OF BUSINESS

Organization

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

Liquidity and Need for Additional Capital

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

Since inception in 2004, the Company has funded its operations through equity offerings, private placements of convertible debt, debt financing, equity investment and cost reimbursement from a former collaborative partner, and a research award from Cystic Fibrosis Foundation Therapeutics Incorporated ("CFFT"). On April 21, 2016, the Company entered into an At Market Issuance Sales Agreement with H.C. Wainwright & Co., LLC (“H.C. Wainwright ATM Agreement”) to create an at-the-market equity program under which the Company from time to time may offer and sell shares of its common stock, par value $0.001 per share, having an aggregate offering price of up to $25 million through H.C Wainwright, as agent., In June 2017, in connection with the execution of an equity purchase agreement (“the 2017 Equity Purchase Agreement “) (as defined below) with Lincoln Park Capital, LLC. (“LPC”), the Company filed a prospectus supplement suspending all offerings pursuant to the H.C. Wainwright ATM Agreement.

On June 19, 2017, the Company entered into the 2017 Equity Purchase Agreement LPC, pursuant to which the Company has the right, at its discretion, to sell up to an aggregate of $10.0 million in shares of the Company’s common stock and issue up to 181,708 shares of the Company’s common stock as a commitment fee to LPC. As of February 28, 2018, the Company has sold an aggregate of 1,870,411 shares of common stock for net proceeds of $3.1 million and issued an aggregate of 139,848 shares of common stock as commitment fee to LPC and maximized the number of shares of common stock it can sell to LPC pursuant to Nasdaq Rule 5635(d)(2).

On October 23, 2017, the Company entered into a definitive agreement with certain accredited investors in connection with a private placement of equity securities, (the “Private Placement”) for up to an aggregate of $15 million in gross proceeds. The Private Placement was structured with two closings. The first closing occurred on October 27, 2017 (“Initial Closing”) and resulted in net proceeds of approximately $2.7 million. The second closing (“Second Closing”) was conditioned upon and subject to the Company receiving the requisite shareholder approval pursuant to Nasdaq Rule 5635(d), which was obtained on January 5, 2018. The Second Closing subsequently occurred on January 9, 2018

and resulted in incremental net proceeds of $11.1 million.

The Company's cash balance of $2.2 million as of December 31, 2017, together with the net proceeds of $11.1 million from the Second Closing of the Private Placement and $3.1 million from warrant exercises and sale of common stock pursuant to an equity purchase agreement subsequent to December 31, 2017 is expected to fund the Company's operations through the first half of 2018. Therefore, there is substantial doubt about the Company's ability to continue as a going concern within one year after the date the financial statements are issued. The Company's current cash position is sufficient to enable it to complete its Phase 3 clinical study of Sollpura (the "RESULT" study) in patients with exocrine pancreatic insufficiency due to cystic fibrosis, which study's topline data is expected in March 2018. If the RESULT study meets its primary endpoint, the Company plans to raise sufficient capital following the study's readout and use the proceeds to fund the preparation of its Biologics License Application ("BLA") for Sollpura, continuation of its manufacturing of drug products and general corporate purpose.

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The Company cannot ascertain any future financing will be available on terms favorable to the Company, if at all. The financial statements do not include any adjustments that might result from the outcome of this uncertainty. If adequate funds are not available, the Company will be required to delay its development programs. This would include, amongst other things, eliminating or reducing the scope of one more of our clinical trials, delaying BLA submission for Sollpura, delaying manufacturing activities, and reducing headcount. The Company plans to meet its capital requirements for the next twelve months primarily through issuances of equity securities, potential partnerships and debt financing. Failure to raise additional capital would adversely affect the Company's ability to achieve its intended business objectives.

Basis of Presentation

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States, or GAAP.

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

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

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Revenue Recognition

During 2015, the Company had a collaboration with Zenyaku Kogyo Co., Ltd. ("Zenyaku") which provided for various types of payments from Zenyaku, including development milestones, sales milestone, royalty, and reimbursement for a portion of the Company's internal and external costs. All payments from Zenyaku are 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 the Financial Accounting Standards Board ("FASB") 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 the Company's control.

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

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

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Use of Estimates

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

Financial Instruments with Characteristics of Both Equity and Liabilities

The Company has issued certain financial instruments, including warrants to purchase common stock, which have characteristics of both liabilities and equity. Financial instruments such as warrants that are classified as liabilities are fair valued upon issuance and are re-measured at fair value at subsequent reporting periods with the resulting change in fair value recorded in other income/(expense). The fair value of warrants is estimated using valuation models that require the input of subjective assumptions including stock price volatility, expected life, and the probability of future equity issuances.

Cash and Cash Equivalents

The Company considers all highly liquid instruments purchased with an original maturity or remaining maturities of three months or less at the date of purchase to be cash equivalents. Cash equivalents consist primarily of cash currencies and money market funds, for which the carrying amounts are reasonable estimates of fair value. Cash equivalents are recognized at fair value.

Property and Equipment—Net

Property and equipment are stated at cost, less accumulated depreciation. Depreciation is computed over the estimated useful lives of the respective assets, which range from three to five years, using the straight-line method. Repairs and maintenance costs are expensed as incurred. Leasehold improvements are stated at cost and amortized using the straight-line method over the term of the lease or the life of the related asset, whichever is shorter.

Long-Lived Assets

The Company’s long-lived assets and other assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. Recoverability of an asset to be held and used is measured by a comparison of the carrying amount of an asset to the future undiscounted cash flows expected to be generated by the asset. If such asset is considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the asset exceeds its fair value. Through December 31, 2017, the Company had not experienced material impairment losses on its long-lived assets.

Accrued Clinical Studies

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 are generally accrued based on time and materials incurred by the service providers and in accordance with the contracts. This process involves reviewing open contracts and purchase orders, communicating with applicable personnel to identify services that have been performed on the Company's behalf and estimating the level of service performed and the associated cost incurred for the service when the Company has not yet been invoiced or otherwise notified of actual cost. The majority of service providers invoice at least monthly in arrears for services performed. The Company periodically confirms the accuracy of estimates with the service providers and makes adjustments if necessary. Examples of estimated accrued clinical expenses include:

·fees paid to Contract Research Organizations, or CROs, in connection with clinical studies;

·fees paid to investigative sites in connection with clinical studies; and

·fees paid to contract manufacturers in connection with the production of clinical study materials.

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Research and Development Costs

Research and development expenses consist of personnel costs, including salaries, benefits and stock-based compensation, clinical studies performed by CROs, materials and supplies, and overhead allocations consisting of various administrative and facilities related costs. Clinical study expenses are further separated into two main categories: clinical development and pharmaceutical development. Clinical development costs include costs for Phase 1, 2 and 3 clinical studies. Pharmaceutical development costs consist of expenses incurred in connection with manufacturing campaigns, product formulation and chemical analysis.

The Company charges research and development costs, including clinical study costs, to expense when incurred. Clinical study costs are a significant component of research and development expenses. All of the Company's clinical studies are performed by third-party CROs. The Company accrues costs for clinical expenses based on time and materials incurred by the service providers.

All material contracts are terminable by the Company upon written notice and the Company is generally only liable for actual effort expended by the service providers and certain noncancelable expenses incurred at any point of termination.

Income Taxes

The Company accounts for income taxes in accordance with the liability method whereby deferred tax asset and liability account balances are determined based on differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. The Company provides a valuation allowance, if necessary, to reduce deferred tax assets to their estimated realizable value.

Segments

The Company operates in only one segment. Management uses cash flow as the primary measure to manage its business and does not segment its business for internal reporting or decision-making. The Company's long-lived tangible assets consist of mainly machinery purchased by the Company and installed by its contract manufacturing vendors. The machinery is used for all of the Company's product manufacturing campaigns.

Stock-Based Compensation

The Company uses the Black-Scholes option pricing model as the method for determining the estimated fair value for all stock-based awards, including employee stock options, and rights to purchase shares under the Company's Employee Stock Purchase Plan, and recognizes the costs in its consolidated financial statements over the employees' requisite service period. The Black-Scholes option pricing model requires the use of highly subjective and complex assumptions which determine the fair value of share-based awards, including the option's expected term and the price volatility of the underlying stock. Additionally, the Company is required to include an estimate of the number of awards that will be forfeited in calculating compensation costs, which are recognized over the requisite service period of the awards on a straight-line basis.

Expected Term —The Company's expected term represents the period that the Company's stock-based awards are expected to be outstanding and is determined using the simplified method, which is computed as the arithmetic mean of weighted vesting period and contractual life.

Expected Volatility —Expected volatility is estimated using the Company's historical stock prices.

Expected Dividend —The Black-Scholes option pricing model calls for a single expected dividend yield as an input and the Company has never paid dividends and has no plans to pay dividends.

Risk-Free Interest Rate —The risk-free interest rate used in the Black-Scholes option pricing method is based on the U.S. Treasury zero-coupon issues in effect at the time of grant for periods corresponding with the expected term of option.

Estimated Forfeitures —The estimated forfeiture rate is determined based on the Company's historical forfeiture rates to date. The Company monitors actual forfeitures and periodically updates the estimate.

Equity instruments issued to nonemployees are recorded at their fair value as determined in accordance with guidance provided by the FASB and are periodically revalued as the equity instruments vest and recognized as expense over the related service period.

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Recent Accounting Pronouncements

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

In May 2014, the FASB issued Accounting Standards Update (“ASU”) No. 2014-09, Revenue from Contracts with Customers (ASC Topic 606). The standards update outlines a single comprehensive model for entities to utilize to recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration that will be received in exchange for the goods and services. Additional disclosures will also be required to enable users to understand the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. In 2016, the FASB issued accounting standards updates to address implementation issues and to clarify the guidance for identifying performance obligations, licenses and determining if a company is the principal or agent in a revenue arrangement. In August 2015, the FASB issued ASU 2015-14, Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date, which deferred the effective date of ASU 2014-09. The mandatory adoption date of ASC 606 for the Company is now January 1, 2018. There are two methods of adoption allowed, either a “full” retrospective adoption or a “modified” retrospective adoption. The Company plans to adopt the standard on a modified retrospective basis applying the new rules to all contracts existing at January 1, 2018. Given that the Company is not currently generating revenue and was not generating revenue at the date of adoption, the adoption of this guidance will not materially impact our consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842). ASU 2016-02 impacts any entity that enters into a lease with some specified scope exceptions. This new standard establishes a right-of-use (ROU) model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the statement of operations. The guidance updates and supersedes Topic 840, Leases. For public entities, ASU 2016-02 is effective for fiscal years, and interim periods with those years, beginning after December 15, 2018, and early adoption is permitted. A modified retrospective transition approach is required for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. The Company does not expect the adoption of this standard to have a material impact on its financial statements.

Effective January 1, 2017, the Company adopted ASU No. 2016-09, Compensation-Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting. Among other requirements, the new guidance requires all tax effects related to share-based payments at settlement (or expiration) to be recorded through the income

statement. Previously, tax benefits in excess of compensation cost ("windfalls") were recorded in equity, and tax deficiencies ("shortfalls") were recorded in equity to the extent of previous windfalls, and then to the income statement. As required, this change was applied prospectively to all excess tax benefits and tax deficiencies resulting from settlements. Under the new guidance, the windfall tax benefit is to be recorded when it arises, subject to normal valuation allowance considerations. As required, this change was applied on a modified retrospective basis. There was $0.3 million of unrecognized deferred tax assets attributable to excess tax benefits that were not previously recognized as the Company did not reduce income taxes payable. The cumulative adjustment for the adoption of ASU No. 2016-09 did not have an impact on net equity as the incremental deferred tax assets were fully offset by a corresponding increase in the deferred tax asset valuation allowance. ASU No. 2016-09 addressed the presentation of employee taxes paid on the statement of cash flows. The Company is now required to present the cost of shares withheld from the employee to satisfy the employees' income tax liability as a financing activity on the statement of cash flows rather than as an operating cash flow. This change is applied on a retrospective basis, as required, but did not impact the statement of cash flows for the year ended December 31, 2017. ASU No. 2016-09 also permits entities to make an accounting policy election related to how forfeitures will impact the recognition of compensation cost for stock-based compensation to either estimate the total number of awards for which the requisite service period will not be rendered, as currently required, or to account for forfeitures as they occur. Upon adoption, the Company elected to not make any changes to the current policy of accounting for forfeitures.

3. RESEARCH AWARD

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

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

As of December 31, 2017, the Company had fully recognized the research award.

4. FAIR VALUE OF INSTRUMENTS

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

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

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

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

- Level 3 —Valuations based on unobservable inputs in which there are little or no market data, which requires the Company to develop its 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 December 31, 2017 and 2016 (in thousands):

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

December 31, 2016

	Estimated Fair Value	Level 1	Level 2	Level 3
Assets:				
Money market funds	$19,416	$19,416	$ —	$ —

The Company used quoted market prices to determine the fair value of cash equivalents, which consist of money market funds and therefore these are classified in Level 1 of the fair value hierarchy. There were no transfers between Level 1, Level 2 or Level 3 for the year ended December 31, 2017.

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

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The following table summarizes the changes in the Company's Level 3 warrant liability during the years ended December 31, 2017 and 2016 (in thousands):

	December 31, 2017
Beginning balance	$ —
Addition to fair value of warrant liability upon the issuance of warrants in connection with a direct offering of common stock in March 2017	14,700
Decrease in fair value of warrant liability from April 1, 2017 to December 31, 2017	(10,235)
Balance reclassified to additional paid-in capital upon exercise of warrants	(8)
Ending balance	$ 4,457

	December 31, 2016
Beginning balance	$ —
Addition to fair value of warrant liability upon the issuance of warrants in connection with a direct offering of preferred stock in September 2016	3,678
Change in fair value upon fixation of exercise price and number of shares underlying the warrants	(1,744)
Balance reclassified to additional paid-in capital	(1,934)
Ending balance	$ —

There were no transfers between Level 1, Level 2 or Level 3 for the years ended December 31, 2017 and 2016.

5. WARRANT LIABILITY

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

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

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

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

2. The warrants permit the holder to require the Company to settle the warrants for cash in an amount equal to the Black-Scholes value of the warrants in the event of a fundamental transaction, including a sale of the business.

At the end of each reporting period, the changes in fair value during the period are recorded as a component of non-operating income (expense) in the consolidated statement of operations. The initial fair value of the liability associated with these warrants was $14.7 million. The Tranche 2 Warrants expired on October 28, 2017 on which date the warrants were out of the money and had a fair value of zero. As of December 31, 2017, the fair value of the liability associated with the Tranche 1 Warrants was $4.5 million. The decrease of $10.2 million in fair value of the warrant liability was recorded as non-operating income during the year ended December 31, 2017. The Company estimated the fair value of the warrants using the Monte Carlo simulation model, which combines expected cash outflows with market-based assumptions regarding risk-adjusted yields, stock price volatility, and the number of potential future Stock Combination Events. Inputs used in the valuation of each tranche on issuance date and December 31, 2017 were as follows:

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Issuance Date	Tranche 1		Tranche 2	
Common stock price	$ 3.44		$ 3.44	
Exercise price	$ 4.40		$ 4.00	
Expected volatility	112.5	%	112.5	%
Dividend yield	0	%	0	%
Risk-free interest rate	2.03	%	2.03	%
Expected term (years)	5.0		0.5	
Number of potential future Stock Combination Events	1.57		0.03	

December 31, 2017	Tranche 1	
Common stock price	$ 1.65	
Exercise price	$ 1.89	
Expected volatility	97.8	%
Dividend yield	0	%
Risk-free interest rate	2.13	%
Expected term (years)	4.33	
Number of potential future Stock Combination Events	1.43	

For the fair value determination, the Company computed the historical volatility based on daily pricing observations for a period that corresponds to the expected term of the warrants. The expected term for all valuation dates were based on the remaining contractual terms of the warrants. The risk-free interest rates were the U.S. Treasury bond rate as of the valuation months and years. The probability of future Stock Combination Events is based on the number of potential reverse stock splits that is determined on simulated stock price under a trigger price of $1.00 for 30 consecutive days. The number of potential future Stock Combination Event is the average of reverse splits from all the simulation trials.

6. COLLABORATIVE AGREEMENT

In December 2014, the Company entered into an exclusive license agreement with Zenyaku (“Zenyaku Agreement”) for the development and commercialization of blisibimod in Japan and potentially other countries throughout Asia, while the Company retained full development and commercialization rights of blisibimod for all other global territories including North America and the European Union. The Zenyaku Agreement was mutually terminated in January 2016. Consequently, the Company accelerated the amortization period of its deferred revenue and fully amortized it as of January 7, 2016.

7. PROPERTY AND EQUIPMENT

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

	December 31,	
	2017	2016
Laboratory equipment	$1,877	$2,013
Computer and software	115	115
Office furniture and fixtures	140	140
Leasehold improvements	206	206
Total property and equipment	2,338	2,474
Less accumulated depreciation and amortization	(1,856)	(1,711)
Property and equipment, net	$482	$763

For the years ended December 31, 2017, 2016, and 2015, the Company recorded $281,000, $266,000, and $285,000 respectively, in depreciation and amortization expense.

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8. COMMITMENTS AND CONTINGENCIES

Leases

The Company leases its main operating facility in Hayward, California. The lease was for approximately 14,000 square feet and the lease agreement was due to expire in September 2017. On July 20, 2017, the Company terminated the lease agreement and concurrently entered into a sublease agreement for approximately 8,000 square feet of the same facility. The sublease agreement will expire on August 31, 2019. In April 2016, the Company leased its second operating facility in Pleasanton, California. The lease is for approximately 1,200 square feet and the lease agreement was due to expire in May 2019.

For the years ended December 31, 2017, 2016, and 2015, the Company recognized $211,000, $195,000, and $222,000, respectively, in rental expense.

As of December 31, 2017, future minimum lease payments under non-cancellable operating leases were as follows (in thousands):

2018	$191
2019	106
Total	$297

In February 2018, the Company early terminated the lease agreement for its Pleasanton office and reduced its total future lease payments by approximately $42,000.

Other Commitments

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

On July 11, 2014, the Company and Eli Lilly and Company (“Eli Lilly”) entered into a worldwide, exclusive license agreement (the “Lilly Agreement”), to develop and commercialize Sollpura, a Phase 3 novel investigational Pancreatic Enzyme Replacement Therapy (“PERT”), for the treatment of patients with Exocrine Pancreatic Insufficiency, or EPI, often seen in patients with cystic fibrosis and other conditions. Under the terms of the Lilly Agreement, the Company was not required to make any up-front payment but is obligated to make milestone payments of up to 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 December 31, 2017. In addition, after sales of the licensed products exceed an aggregate of $100.0 million in the United States, the Company is obligated to pay tiered royalties on future net sales of products, ranging from the single digits to the mid-teens, that are developed and

approved as defined in the Lilly Agreement. The Company's royalty obligations as to a particular licensed product will be payable, on a licensed product-by-licensed product basis, for the longer of (a) the date of expiration of the last to expire valid claim within the licensed patents that covers the manufacture, use or sale, offer to sell, or import of such licensed product by the Company or a sublicense in such country, or (b) 12 years after the first commercial sale of the applicable licensed product in the applicable country.

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

9. STOCKHOLDERS' EQUITY (DEFICIT)

Preferred Stock

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

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In September 2016, the Company entered into a subscription agreement with certain institutional investors pursuant to which it sold 17,000 Series X units for a purchase price of $1,000 per unit in a registered direct offering (the "Subscription Agreement"). Each unit consists of one share of Series X Convertible Preferred Stock and a warrant to purchase 15.87 shares of common stock. The registered direct offering resulted in gross proceeds of $17.0 million. The holders of Series X Convertible Preferred Stock do not have any voting rights nor the right to elect any members to the board of directors. The Series X Convertible Preferred Stock has a contingent redemption clause. The Company is not required to issue any shares of common stock upon conversion of any shares of Series X Convertible Preferred Stock to the extent that (i) the aggregate issuance of common stock will be greater than 1,048,229 shares or 19.99% of the total outstanding shares of the Company (the "Threshold Amount") and (ii) the conversion has not been approved by the Company's stockholders in accordance with the stockholder approval requirements of Nasdaq Marketplace Rule 5635(d) (a "Blocked Conversion"). Due to the contingent redemption feature related to Nasdaq conversion limits that could result in a potential redemption for cash, the Company initially classified the 17,000 shares of Series X Convertible Preferred Stock in the mezzanine section (between equity and liabilities) on the date of issuance. On November 16, 2016, the conversion price became fixed at $15.7536 and therefore, the Series X Convertible Preferred Stock became convertible into 1,079,119 shares of common stock, which exceeded the aggregate number of common stock permitted for conversion by 30,890 shares of common stock, or 487 shares of Series X Convertible Preferred Stock. As such, the 487 shares of Series X Convertible Preferred Stock remained contingently redeemable until shareholder approval was obtained for the conversion of these shares; while the remaining 16,513 shares of Series X Convertible Preferred Stock ceased to be redeemable and were reclassified from the mezzanine section to equity as of December 31, 2016. On April 27, 2017, shareholder approval was obtained to convert the 487 shares of Series X Convertible Preferred Stock into common stock, and consequently the 487 shares of Series X Convertible Stock were no longer redeemable by the holder and were reclassified from temporary to permanent equity in the statement of stockholders' equity on the date hereof.

The conversion price of the shares of Series X Convertible Preferred Stock was less than the fair value of the Company's common stock at the date of issuance and therefore the in-the-money conversion feature (Beneficial Conversion Feature, or BCF) requires separate financial statement recognition and was measured at the intrinsic value (i.e., the amount of the increase in value that preferred stockholders would realize upon conversion based on the value of the conversion shares on the issuance date). A BCF of $8.8 million was recorded as a discount to the contingently redeemable Series X Convertible Preferred Stock in mezzanine and was immediately accreted as a deemed preferred stock dividend and, accordingly, an adjustment to net loss to arrive at net loss applicable to common stockholders. Furthermore, in December 2016, certain holders converted 7,501 shares of Series X Convertible Preferred Stock into 476,145 shares of common stock. The conversion was reflected as a reduction in Series X Convertible Preferred Stock in permanent equity. The unamortized discount was recognized as a deemed dividend of $2.1 million in connection with the conversion of the Series X Convertible Preferred Stock. For the year ended December 31, 2016, the Company recorded a total deemed dividend of $10.9 million. During the year ended December 31, 2017, 9,069 shares of Series X Convertible Preferred Stock were converted into 575,678 shares of common stock and concurrent with the conversion, the Company recorded $2.5 million in deemed dividend. As of December 31, 2017, an aggregate of 16,570 shares of Series X Convertible Preferred Stock have been converted into an aggregate of 1,051,823 shares of common stock, leaving a balance of 430 shares of Series X Convertible Preferred Stock issued, outstanding and convertible into 27,296 shares of common stock.

Common Stock

In March 2016, the Company filed a universal shelf registration statement with the SEC on Form S-3 for the proposed offering from time to time of up to $100.0 million of its securities, including common stock, preferred stock, debt securities and/or warrants. As of December 31, 2017, the Company has registered a total of $82.6 million under this registration statement, leaving a balance of $17.4 million available for future issuance under the registration statement.

The S-3 registration statement is subject to Instruction I.B.6. of Form S-3, which imposes a limitation on the maximum amount of securities that the Company may sell pursuant to the registration statement during any twelve-month period. When the Company sells securities pursuant to the registration statement, the amount of securities to be sold plus the amount of any securities the Company has sold during the prior twelve months in reliance on Instruction I.B.6. may not exceed one-third of the aggregate market value of its outstanding common stock held by non-affiliates as of a day during the 60 days immediately preceding such sale, as computed in accordance with Instruction I.B.6. Based on this calculation, the Company expects it will be significantly limited to sell securities pursuant to its effective registration statement on Form S-3 for a period of twelve months from March 16, 2017, unless and until the market value of the Company's outstanding common stock held by non-affiliates increases to above $75 million. If the Company cannot sell securities under its shelf registration, the Company may be required to utilize more costly and time-consuming means of accessing the capital markets, which could materially adversely affect its liquidity and cash position.

In March 2017, the Company entered into an underwriting agreement with H.C. Wainwright, pursuant to which the Company sold an aggregate of 3,750,000 shares of its common stock and issued warrants to purchase shares of the Company's common stock. The financing transaction resulted in proceeds of $14.1 million. The warrants were recorded as liabilities upon issuance due to price protection, as discussed in Note 5. The fair value of these warrants was estimated to be $14.7 million at issuance, which exceeded the proceeds of $14.1 million. The excess of $0.6 million between the fair value of the warrants and cash proceeds was expensed during the first quarter of 2017.

In June 2017, the Company executed an equity purchase agreement with Lincoln Park Capital, LLP. ("LPC") (the "2017 Equity Purchase Agreement") to sell to LPC up to an aggregate of $10.0 million in shares of common stock and issue up to 181,708 shares of our common stock valued at $0.3 million as a commitment fee to LPC over a period of thirty months. As of February 28, 2018, the Company has sold an aggregate of 1,870,411 shares of common stock for net proceeds of $3.1 million and issued an aggregate of 139,848 shares of common stock as commitment fee to LPC and maximized the number of shares of common stock it can sell to LPC pursuant to Nasdaq Rule 5635(d)(2).

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On October 23, 2017, the Company entered into a Securities Purchase Agreement ("SPA") for a Private Placement with a select group of accredited investors (the "Purchasers"). The Private Placement is structured with two closings. Pursuant to the SPA, at the Initial Closing on October 27, 2017, the Purchasers purchased 2,306,737 shares of the Company's common stock at $1.25 per share. Each share of common stock was issued with a warrant to purchase 3.0 additional shares of the Company's common stock at an exercise price of $1.55 per share. The Second Closing required shareholder approval pursuant to Nasdaq Rule 5635(d), which was obtained on January 5, 2018. At the Second Closing, the Purchasers purchased 7,625,741 shares of the Company's common stock at $1.25 per share and 2,067,522 shares of the Company's non-voting Class Y Convertible Preferred Stock (the "Class Y Preferred Stock") at $1.25 per share, convertible into 2,067,522 shares of Company common stock upon certain conditions. Each share of common stock or Class Y Preferred Stock were issued with a warrant that is immediately exercisable to purchase 1.0 additional share of the Company's common stock at an exercise price of $1.25 per share, resulting in net proceeds of $2.2 million, after deducting underwriter commission and legal expense. The financial instrument represented by the obligation to issue Class Y Preferred Stock and warrants in the event shareholder approval is received is equity classified. The Company accounted for the Initial Closing in October 2017. On the date of issuance, the fair value of the common stock and warrants was $3.9 million and $9.8 million, respectively. The Company allocated the net proceeds based on the relative fair value method, resulting in $0.6 million and $1.6 million being allocated to common stock and warrants, respectively. Conditions for completing the Second Closing were not met as of December 31, 2017 due to shareholder approval not being obtained until January 2018.

At December 31, 2017, the Company had reserved the following shares for future issuance, which did not include any securities issuable pursuant to the Second Closing of the Private Placement:

Convertible Series X preferred stock	27,296
Common stock options outstanding	1,066,121
Common stock warrants outstanding	10,940,206
Common stock options available for future grant under stock option plan	242,481
Common stock available for future grant under ESPP plan	449
Total	12,276,553

Warrants

In connection with a venture debt financing executed in March 2011, the Company issued a seven-year warrant to the lender for the purchase of 5,022 shares of the Company's common stock at an exercise price of $384.00 per share. The warrant was immediately exercisable and expires in March 2018. As of December 31, 2017, the warrants remained outstanding and exercisable. These warrants are classified in permanent equity on the Company's consolidated Balance Sheet.

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In connection with the issuance of Series X convertible preferred stock in September 2016, the Company issued warrants to certain institutional investors to purchase shares of the Company's common stock. On November 16, 2016, the exercise price and number of shares of common stock underlying the warrants became fixed at $18.90 and 269,779, respectively. The warrants are exercisable at any time and from time to time after March 13, 2017, and will expire on September 13, 2019. As of December 31, 2017, the warrants remained outstanding and exercisable. These warrants are classified in permanent equity on the Company's consolidated Balance Sheet.

Pursuant to the underwriting agreement for the sale of common stock and warrants in March 2017, the Company issued 30,000,000 warrants ("Tranche 1 Warrants") at an initial exercise price of $0.55 per share and 30,000,000 ("Tranche 2 Warrants") at an initial exercise price of $0.50 per share to the investors to purchase shares of the Company's common stock. The Company did not have sufficient authorized but unissued common stock to issue the warrants at the time the underwriting agreement was executed. On April 28, 2017, with shareholders' approval, the Company effectuated a one-for-eight reverse split of its outstanding common stock. Subsequent to the Reverse Stock Split, the Tranche 1 Warrant shares and exercise prices were adjusted to 3,750,007 and $4.40, respectively, and the Tranche 2 Warrants shares and exercise price were adjusted to 3,750,007 and $4.00, respectively. Effective as of May 22, 2017, the Tranche 1 and Tranche 2 Warrants' exercise price were further adjusted to $1.8918 pursuant to Section 2(c) of the warrant agreements, which was the average VWAP of the five (5) lowest trading days during the fifteen (15) consecutive trading days following the April 28, 2018 reverse stock split. A total of 96,021 Tranche 2 Warrants were exercised on October 5, 2017 and the remaining 3,653,986 Tranche 2 Warrants expired on October 28, 2017. A total of 4,813 Tranche 1 warrants were exercised on November 11, 2017, leaving a balance of 3,745,194 Tranche 1 Warrants outstanding and exercisable as of December 31, 2017 with an expiry date of April 28, 2022. These warrants are classified as liabilities on the Company's consolidated Balance Sheet until the warrants are exercised or expired, see Note 5.

Pursuant to the Private Placement for the sale of common stock and warrants in October 2017, the Company issued warrants to certain institutional investors to purchase shares of the Company's common stock. The Private Placement was structured with two closings. The Initial Closing occurred on October 27, 2017, which resulted in the Company issuing 6,920,211 warrants to the investors at an exercise price of $1.55 per share. The Tranche 1 Warrants will become exercisable on the six month and one day anniversary of the Initial Closing and have a term of five years and six months. The Tranche 1 Warrants were classified in equity pursuant to the accounting guidance prescribed under ASC Topic 815, ASC Topic 480 Distinguishing Liabilities from Equity and ASC 825 Financial Instruments – Registration Payment Arrangements. The Company measured the fair value of the Tranche 1 Warrants using the Black-Scholes option pricing model on issuance date based on the following assumptions:

Common stock price	$1.72
Exercise price	$1.55
Expected volatility	110 %
Dividend yield	0 %
Risk-free interest rate	1.98%
Expected term (years)	5.50

For the fair value determination, the Company computed the historical volatility based on daily pricing observations for a period that corresponds to the expected term of the Tranche 1 Warrants. The expected term was based on the contractual term of the Tranche 1 Warrants. The risk-free interest rate was the U.S. Treasury bond rate as of the valuation month and year. As of December 31, 2017, the Tranche 1 Warrants remained outstanding but not were not exercisable.

10. STOCK-BASED AWARDS

2013 Plan

On March 25, 2013, the Company's board of directors adopted the 2013 Stock Option and Incentive Plan (the "2013 Plan"), which was also approved by the Company's stockholders at its annual general meeting on May 16, 2013. The Company initially reserved 218,750 shares of its common stock for the issuance of awards under the 2013 Plan, plus all shares remaining available for grant under the Company's 2010 Stock Option and Incentive Plan (the "2010 Plan"), plus any additional shares returned under the 2010 Plan or 2013 Plan as a result of the cancellation, forfeiture or other termination (other than by exercise) of awards issued pursuant to the 2010 Plan or 2013 Plan, subject in all cases to adjustment including reorganization, recapitalization, reclassification, stock dividend, stock split, reverse stock split or other similar change in the Company's capital stock. In May 2015, the Company's shareholders approved an additional 223,852 shares of its common stock for issuance of awards under the 2013 Plan. Of the shares of common stock reserved for issuance under the 2013 Plan, no more than 93,750 shares will be issued to any individual participant as incentive options, non-qualified options or stock appreciation rights during any calendar year. The 2013 Plan permits the granting of incentive and non-statutory stock options, restricted and unrestricted stock awards, restricted stock units, stock appreciation rights, performance share awards, cash-based awards and dividend equivalent rights to eligible employees, directors and consultants. The option exercise price of an option granted under the 2013 Plan may not be less than 100% of the fair market value of a share of the Company's common stock on the date the stock option is granted. Options granted under the 2013 Plan have a maximum term of 10 years and generally vest over four years. In addition, in the case of certain large stockholders, the minimum exercise price of incentive options must equal 110% of fair market value on the date of grant and the maximum term is limited to five years. Subject to overall Plan limitations, the maximum aggregate number of shares of common stock that may be issued in the form of incentive options shall not exceed 781,250 shares of common stock. The 2013 Plan does not allow the option holders to exercise their options prior to vesting.

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The following table summarizes stock option activity for the years ended December 31, 2017, 2016 and 2015:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life in Years	Aggregate Intrinsic Value
Balance at December 31, 2014	380,073	$ 29.57	8.92	$ —
Options granted	174,065	$ 56.78		
Options exercised	(10,029)	$ 29.95		
Options forfeited	(7,327)	$ 31.63		
Options expired	(4,768)	$ 47.15		
Balance at December 31, 2015	532,014	$ 38.27	8.44	$ 4,330
Options granted	370,019	$ 26.14		
Options exercised	(14,599)	$ 17.61		
Options forfeited	(101,063)	$ 57.71		
Options expired	(36,854)	$ 43.17		
Balance at December 31, 2016	749,517	$ 29.82	8.19	$ —
Options granted	727,265	$ 1.68		
Options exercised	—	$ —		
Options forfeited	(350,638)	$ 31.18		
Options expired	(60,023)	$ 32.35		
Balance at December 31, 2017	1,066,121	$ 10.04	8.68	$ 18
Ending vested at December 31, 2017	501,337	$ 13.44	8.14	$ 8
Vested and expected to vest at December 31, 2017	993,495	$ 10.27	8.64	$ 17

As of December 31, 2017, there were 242,481 shares available for grant under the 2013 Plan. On January 5, 2018, the Company adopted the 2018 Stock Option and Incentive Plan (the “2018 Plan”). The 2018 Plan superseded the 2013 Plan. See note 14 for more details.

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

	Years Ended December 31,		
	2017	2016	2015
Expected Volatility	132 %	98 %	94 %
Dividend Yield	0 %	0 %	0 %
Risk-Free Interest Rate	1.90 %	1.51 %	1.70 %
Expected Term (years)	6.13	5.90	5.92
Weighted-average fair value per option	$ 1.51	$ 2.53	$ 5.40

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. Additional information related to our stock options is summarized below (in thousands except per share information):

	Years Ended December 31,		
	2017	2016	2015
Intrinsic value of options exercised	$ —	$ 177	$ 140

Proceeds received from the exercise of stock options	$ —	$ 257	$ 299

There was $2.6 million of total forfeiture adjusted compensation expense related to non-vested awards as of December 31, 2017 and is expected to be amortized on a straight-line basis over a weighted-average remaining period of 1.89 years.

Information about stock options outstanding, vested and exercisable as of December 31, 2017, was as follows:

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	Options Outstanding		Options Vested & Exercisable	
Range of Exercise Price	Number of Shares	Weighted-Average Remaining Contractual Life (In Years)	Number of Shares	Weighted-Average Remaining Contractual Life (In Years)
$ 1.00 - $10.00	694,509	9.38	264,636	9.32
$ 10.01 - $20.00	113,943	7.39	81,665	7.10
$ 20.01 – $30.00	180,790	7.91	80,711	7.32
$ 30.01 - $40.00	74,003	6.19	71,548	6.11
$ 40.01 - $600.00	2,876	2.26	2,777	2.07
Total	1,066,121	8.68	501,337	8.14

2010 Employee Stock Purchase Plan

Effective July 2010, under the terms of the ESPP, eligible employees of the Company may authorize the Company to deduct amounts from their compensation, which amounts are used to enable the employees to purchase shares of the Company's common stock. The Company initially reserved 1,562 shares of common stock for issuance thereunder on January 1, 2011, and on each January 1 thereafter, the number of shares of stock reserved and available for issuance under the Plan shall be cumulatively increased by the lesser of (i) one percent (1%) of the number of shares of common stock issued and outstanding on the immediately preceding December 31 or (ii) 3,906 shares of common stock. On January 1, 2017, in accordance with the ESPP's annual increase provisions, the authorized shares in the ESPP increased by 3,906. On April 27, 2017, the Company's shareholders approved a one-time increase to the ESPP pool by 27,344 shares and increase the number of shares available for issuance under the Plan by the lesser of (i) one percent (1%) of the number of shares of common stock issued and outstanding on the immediately preceding December 31 or (ii) 31,250 shares of common stock, starting on January 1, 2018.

Under the ESPP, eligible employees of the Company may authorize the Company to deduct amounts from their compensation, which amounts are used to enable the employees to purchase shares of the Company's common stock. The purchase price per share is 85% of the fair market value of the common stock as of the first date or the ending date of the applicable semi-annual purchase period, whichever is less (the "Look-Back Provision"). The 15% discount and the Look-Back Provision make the ESPP compensatory. The following table summarizes ESPP activity for the years ended December 31, 2017, 2016 and 2015 (in thousands except share and per share information):

	Number of Options	Weighted-Average Purchase Price
Shares available at December 31, 2014	10,642	—
Annual increase provision	3,906	—
Shares issued	(7,556)	$ 14.62
Balance at December 31, 2015	6,992	—
Annual increase provision	3,906	—
Shares issued	(2,313)	$ 21.01
Shares available at December 31, 2016	8,585	—
Annual increase provision	3,906	—
One-time increase	27,344	—
Shares issued	(39,386)	$ 2.04
Shares available at December 31, 2017	449	—

The Black-Scholes option pricing model was used to value the employee stock purchase rights. For the years ended December 31, 2017, 2016 and 2015, the following weighted-average assumptions were used in the valuation of the stock purchase rights:

	Years Ended December 31,		
	2017	2016	2015
Expected Volatility	147 %	97 %	82 %
Dividend Yield	0 %	0 %	0 %
Risk-Free Interest Rate	0.64 %	0.38 %	0.08 %
Expected Term (years)	0.50	0.50	0.50
Weighted-average grant date fair value per right	$ 0.57	$ 1.50	$ 1.04

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Stock-Based Compensation Expense

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

	Years Ended December 31,		
	2017	2016	2015
Research and development (1)	$ 2,234	$ 1,795	$ 1,453
General and administrative (2)	2,145	4,944	2,088
Total employee stock-based compensation	$ 4,379	$ 6,739	$ 3,541

(1) Included in 2017 research and development expense was approximately $944,000 in non-cash stock-based compensation associated with the cancellation of stock options.

(2) Included in 2017 and 2016 general and administrative expense was approximately $440,000 and $1.5 million in non-cash stock-based compensation associated with the cancellation of stock options .

11. NET LOSS PER SHARE

Basic net loss attributable to common stockholders per share is computed by dividing income available to common stockholders (the numerator) by the weighted-average number of common shares outstanding (the denominator) during the period. Shares issued during the period and shares reacquired during the period are weighted for the portion of the period that they were outstanding. The computation of diluted Earnings Per Share, or EPS, is similar to the computation of basic EPS except that the denominator is increased to include the number of additional common shares that would have been outstanding if the dilutive potential common shares had been issued. In addition, in computing the dilutive effect of convertible securities, the numerator is adjusted to add back any convertible preferred dividends. Diluted EPS is identical to basic EPS since common equivalent shares are excluded from the calculation, as their effect is anti-dilutive.

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

	Year Ended December 31,		
	2017	2016	2015
Net loss per share			
Numerator			
Net loss	$(26,874)	$(55,523)	$(35,220)
Deemed dividend attributable to preferred stock	(2,503)	(10,914)	—
Net loss applicable to common stockholders	$(29,377)	$(66,437)	$(35,220)
Denominator			
Weighted average common shares outstanding	10,278,391	5,163,784	4,453,905
Basic and diluted net loss per share	$(2.86)	$(12.87)	$(7.91)

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:

	Year Ended December 31,		
	2017	2016	2015
Total options to purchase common stock	1,066,121	749,517	532,014
Total warrants to purchase common stock	10,940,206	274,801	5,022

Series X convertible preferred stock	27,296	572,083	—
Total restricted stock units	—	—	117
Total	12,033,623	1,326,621	537,153

12. EMPLOYEE BENEFIT PLAN

The Company maintains a defined contribution 401(k) plan, or the 401(k) Plan. Employee contributions are voluntary and are determined on an individual basis, limited by the maximum amounts allowable under federal tax regulations. Prior to 2011, the Company had not made any contributions to the 401(k) Plan. In December 2012, the Company amended its 401(k) plan to provide for non-elective employer contribution at the Company's discretion. No non-elective employer contribution was made into the employees' 401(k) accounts during the year ended December 31, 2017. During the years ended December 31, 2016 and 2015, the Company contributed approximately $264,000 and $284,000, respectively, in non-elective employer contribution into the employees' 401(k) accounts.

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13. INCOME TAXES

The Company's loss before provision for income taxes during the years ended December 31, 2017, 2016 and 2015, was a domestic loss of $29.4 million, $66.4 million, and $35.2 million, respectively.

The Company has incurred net operating losses since inception. The Company has not reflected any benefit of such net operating loss carryforwards in the accompanying consolidated financial statements and has established a full valuation allowance against its deferred tax assets.

The components of the provision for income taxes (benefit) during the years ended December 31, 2017, 2016 and 2015 are as follows (in thousands):

	December 31,		
	2017	2016	2015
Current:			
Federal	$—	$—	$—
State	1	1	1
Foreign	—	—	—
Total current	1	1	1
Deferred:			
Federal	27,228	(20,942)	(11,080)
State	1,703	8,936	(3,250)
Foreign	—	—	—
Total deferred	28,931	(12,006)	(14,330)
Valuation allowance	(28,931)	12,006	14,330
Total provision for income taxes	$—	$—	$—

Deferred income taxes reflect the net tax effects of (a) temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes, and (b) operating losses and tax credit carryforwards.

The significant components of the Company's deferred tax assets as of December 31, 2017 and 2016 are as follows (in thousands):

	December 31,	
	2017	2016
Deferred tax assets:		
Net operating loss carryforwards	$31,086	$44,909
Tax credits	4,394	4,084
Intangible assets	745	1,470
Capitalized R&D	26,661	40,297
Other	729	1,677
Total deferred tax assets	63,615	92,437
Deferred tax liabilities	—	—
Valuation allowance	(63,615)	(92,437)
Net deferred tax asset	$—	$—

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The reconciliation between the Company's effective tax rate on income (loss) from continuing operations and the statutory tax rates for the years ended December 2017, 2016, and 2015 is as follows:

	2017	2016	2015
Statutory rate	34 %	34 %	34 %
State tax	(4)%	(9)%	6 %
Tax credit	3 %	1 %	2 %
Deemed dividend and warrant liability revaluation	8 %	(4)%	— %
Stock based compensation	(7)%	(4)%	(1)%
Valuation allowance	98 %	(18)%	(41)%
Expiration of tax attribute due to 382 limitation	(21)%	— %	— %
Re-measurement due to change in federal statutory rate	(111)%	0 %	0 %
Effective tax rates	0 %	0 %	0 %

On December 22, 2017, new U.S. income tax reform measures known as the Tax Cuts & Jobs Act (TCJA) were enacted. As a result of the TCJA, the federal income tax rate for all corporations was permanently changed to 21% from 34%. Consequently, the Company's deferred tax assets are required to be measured using the new enacted tax rate. As a result of the remeasurement, the Company's deferred tax assets have decreased by $32.7 million. The decrease in the deferred tax asset was offset by an equal decrease in the valuation allowance, such that there is no impact on income tax expense.

Tax benefits of net operating losses, temporary differences and credit carryforwards are recorded as an asset to the extent that management assesses that realization is "more likely than not." Realization of the future tax benefits is dependent on the Company's ability to generate sufficient taxable income within the carryforward period. Because of the Company's history of operating losses, management believes that the deferred tax assets arising from the above-mentioned future tax benefits are currently not likely to be realized and, accordingly, has provided a full valuation allowance. The net valuation allowance decreased by $28.9 million in 2017, increased by $12.0 million in 2016, and increased by $14.3 million in 2015.

Net operating losses and tax return credit carryforwards as of December 31, 2017, are as follows (in thousands):

	Amount	Expiration Years
Net operating losses—federal	$126,090	Beginning 2024
Net operating losses—state	$65,975	Beginning 2028
Tax return credits—federal	$2,028	Beginning 2032
Tax return credits—state	$2,995	Do not expire

Utilization of the domestic NOL and tax credit forwards may be subject to a substantial annual limitation due to ownership change limitations that may have occurred or that could occur in the future, as required by the Internal Revenue Code Section 382, as well as similar state provisions. In general, an "ownership change," as defined by the code, results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50 percentage points of the outstanding stock of a company by certain stockholders or public groups. Any limitation may result in expiration of all or a portion of the NOL or tax credit carryforwards before utilization. The Company incurred Section 382 ownership changes in 2012 and 2015 and as such, the Company's net operating loss carryforwards have been limited. Additionally, the pre-change R&D tax credits have also been limited for federal tax purposes. The 2012 and 2015 Section 382 limitations resulted in the write-off of $159.9 million of the Company's net operating loss and $12.6 million of the Company's R&D credits. As of December 31, 2017, the Company has federal net operating losses of $126.1 million, of which $57.0 million are not subject to limitation and the remaining $69.1 million are subject to annual limitations due to the aforementioned ownership change in 2012 and 2015. The state

R&D credits are not subject to limitation as they are carried forward indefinitely. Furthermore, on January 9, 2018, the Company incurred another Section 382 ownership change and as such, the Company's net operating loss carryforwards will be further limited in the future. As a result of the ownership change, federal and state net operating loss carryforwards as of December 31, 2017 that would be available subsequent to January 9, 2018 were reduced to $7.5 million and $6.4 million, respectively. Furthermore, all of the federal R&D credits will be written off on January 9, 2018.

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As of December 31, 2017, the Company had unrecognized tax benefits of $1.7 million, all of which would not currently affect the Company's effective tax rate if recognized due to the Company's deferred tax assets being fully offset by a valuation allowance. The Company did not anticipate any significant change to the unrecognized tax benefit balance due to the Section 382 limitation in January 2018 discussed above. A reconciliation of unrecognized tax benefits is as follows (in thousands):

	Amount
Balance as of December 31, 2014	999
Additions based on tax positions related to prior year	—
Additions based on tax positions related to current year	269
Balance as of December 31, 2015	$ 1,268
Additions based on tax positions related to prior year	(27)
Additions based on tax positions related to current year	420
Balance as of December 31, 2016	$ 1,661
Deductions based on tax positions related to prior year	(378)
Additions based on tax positions related to current year	392
Balance as of December 31, 2017	$ 1,675

For the year ended December 31, 2017, the $0.4 million reduction in the unrecognized tax benefit related to prior years' position is due to the Section 382 limitation discussed above.

The Company would classify interest and penalties related to uncertain tax positions in income tax expense, if applicable. There was no interest expense or penalties related to unrecognized tax benefits recorded through December 31, 2017. The tax years 2004 through 2017 remain open to examination by one or more major taxing jurisdictions to which the Company is subject.

The Company does not anticipate that total unrecognized net tax benefits will significantly change prior to the end of 2018.

14. SUBSEQUENT EVENTS

On January 5, 2018, the Company obtained stockholders' approval to complete the Second Closing of a private placement of securities transacted in October 2017. Pursuant to the Second Closing, the Company issued 7,625,741 shares of the Company's common stock, par value $0.001, at $1.25 per share and 2,067,522 shares of the Company's non-voting Class Y Convertible Preferred Stock, par value $0.001 (the "Class Y Preferred Stock"), at $1.25 per share, convertible into 2,067,522 shares of Company common stock upon certain conditions. Each share of common stock or Class Y Preferred Stock was issued with a warrant that is immediately exercisable to purchase 1.0 additional share of the Company's common stock at an exercise price of $1.25 per share. The warrants issued in the Second Closing have a term of five years from their date of issuance. The Second Closing was completed on January 9, 2018 and the Company received net proceeds of approximately $11.1 million, after deducting placement agent fees and professional fees. The Second Closing resulted in a Section 382 ownership change. Refer to Note 13 Income Taxes for discussion of the impact on the Company's federal and state net operating loss carryforward and federal R&D credits.

On November 16, 2017, the Company's board of directors adopted the 2018 Stock Option and Incentive Plan (the "2018 Plan"), which was approved by the Company's stockholders at a Special Stockholders meeting on January 5, 2018. Upon adoption of the 2018 Plan, the Company reserved 6,000,000 shares of its common stock for the issuance of awards, plus all shares remaining available for grant under the Company's 2013 Plan, plus any additional shares returned under all previous stock option plans, the 2013 Plan as a result of the cancellation, forfeiture or other

termination (other than by exercise) of awards issued pursuant to those plans, subject in all cases to adjustment including reorganization, recapitalization, reclassification, stock dividend, stock split, reverse stock split or other similar change in the Company's capital stock. Of the shares of common stock reserved for issuance under the 2018 Plan, no more than 2,000,000 shares will be issued to any individual participant as incentive options, non-qualified options or stock appreciation rights during any calendar year; no more than 10% of the total number of shares of authorized for issuance under the 2018 Plan may be granted in the form of unrestricted stock awards; and no more than 6,000,000 shares may be issued in the form of incentive stock options. The shares available for issuance under the 2018 Plan may be authorized but unissued shares of stock or shares reacquired by the Company.

On January 5, 2018, the Company's stockholders approved an amendment to the 2010 ESPP to (i) increase the maximum number of shares authorized for issuance thereunder by 500,000 shares and (ii) amend the maximum number of shares that may be purchased by any participant with respect to any purchase period to be the least of (a) the number of shares determined by dividing the participant's accumulated payroll deductions on the last day of the purchase period by the purchase price per share for the stock, (b) 12,500 shares or (c) such lesser maximum number of shares determined by the administrator.

Subsequent to December 31, 2017 and through the filing of this report, the Company received net proceeds of $3.1 million from the issuance of 1,308,180 shares of common stock pursuant to warrant exercises and the sale of 666,000 shares of common stock to LPC pursuant an equity purchase agreement.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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.

By: /s/ J. Craig Thompson
J. Craig Thompson

Chief Executive Officer
(Principal Executive Officer)

Dated: March 5, 2018

POWER OF ATTORNEY

We, the undersigned officers and directors of Anthera Pharmaceuticals, Inc., hereby severally constitute and appoint Craig Thompson and May Liu, and each of them singly (with full power to each of them to act alone), our true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution in each of them for him or her and in his or her name, place and stead, and in any and all capacities, to sign for us and in our names in the capacities indicated below any and all amendments to this report, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises, as full to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or any of them, or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/J. Craig Thompson J. Craig Thompson	Chief Executive Officer and Director (Principal Executive Officer)	March 5, 2018
/s/ May Liu May Liu	Senior Vice President, Finance and Administration (Principal Accounting Officer)	March 5, 2018
/s/ Paul F. Truex Paul F. Truex	Chairman of the Board of Directors	March 5, 2018
/s/ Christopher S. Henney Christopher S. Henney	Director	March 5, 2018
/s/ Brian R. Mueller	Director	March 5, 2018

Brian R. Mueller		
/s/ David E. Thompson David E. Thompson	Director	March 5, 2018
/s/ Brent V. Furse Brent V. Furse	Director	March 5, 2018
/s/ Philip T. Sager Philip T. Sager	Director	March 5, 2018

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Exhibit Index

Number	Description
3.1	Fifth Amended and Restated Certificate of Incorporation(1)
3.2	Certificate of Amendment to the Fifth Amended and Restated Certificate of Incorporation filed October 12, 2012(2)
3.3	Certificate of Amendment to the Fifth Amended and Restated Certificate of Incorporation filed July 12, 2013 and effective July 15, 2013(3)
3.4	Certificate of Amendment to the Fifth Amended and Restated Certificate of Incorporation filed April 28, 2017(4)
3.5	Amended and Restated Certificate of Designation of Preferences, Rights and Limitations of Series X Convertible Preferred Stock filed on September 15, 2016(5)
3.6	Form of Certificate of Designation of Preferences, Rights and Limitations of Series X-1 Convertible Preferred Stock filed on September 12, 2016(6)
3.7	Amended and Restated Bylaws, as amended on May 21, 2015(7)
3.8	Certificate of Designation of Preferences, Rights and Limitations of Class Y Convertible Preferred Stock, dated October 24, 2017(8)
4.1	Specimen certificate evidencing shares of common stock(9)
4.2	Specimen Series X Convertible Preferred Stock certificate(10)
4.3	Form of Warrant sold pursuant to that Securities Purchase Agreement, among the Company and the purchasers thereto, dated September 20, 2010(11)
4.4	Form of Warrant Agreement dated as of March 25, 2011(12)
4.5	Form of Warrant sold pursuant to that Subscription Agreement, among the Company and the purchasers thereto, dated September 6, 2016(13)
4.6	Form of Warrant sold pursuant to that Securities Purchase Agreement, among the Company and the purchasers thereto, dated October 23, 2017 (14)
4.7	Specimen Class Y Convertible Preferred Stock Certificate (15)
#10.1	2005 Equity Incentive Plan and form agreements thereunder(16)
#10.2	Amended and Restated 2010 Stock Option and Incentive Plan(17)
#10.3	Certificate of Amendment to Amended and Restated 2010 Stock Option and Incentive Plan(18)
#10.4	

	Form of Non-Qualified Stock Option Agreement for Company Employees Under the Anthera Pharmaceuticals, Inc. 2010 Stock Option and Incentive Plan(19)
#10.5	Form of Non-Qualified Stock Option Agreement for Non-Employee Directors Under the Anthera Pharmaceuticals, Inc. 2010 Stock Option and Incentive Plan(19)
#10.6	Form of Incentive Stock Option Agreement Under the Anthera Pharmaceuticals, Inc. 2010 Stock Option and Incentive Plan(19)
#10.7	Form of Restricted Stock Award Agreement Under the Anthera Pharmaceuticals, Inc. 2010 Stock Option and Incentive Plan(19)
#10.8	Restricted Stock Unit Award Agreement Under the Anthera Pharmaceuticals, Inc. 2010 Stock Option and Incentive Plan(20)

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Number	Description
#10.9	2010 Employee Stock Purchase Plan(21)
#10.10	Amendment No. 1 to 2010 Employee Stock Purchase Plan(22)
#10.11	Amendment No. 2 to 2010 Employee Stock Purchase Plan(23)
#10.12	Amendment No. 3 to 2010 Employee Stock Purchase Plan(24)
#10.13	2013 Stock Option and Incentive Plan(25)
#10.14	Form of Non-Qualified Stock Option Agreement for Company Employees Under the 2013 Stock Option and Incentive Plan(26)
#10.15	Form of Non-Qualified Stock Option Agreement for Non-Employees Directors Under the 2013 Stock Option and Incentive Plan(26)
#10.16	Form of Incentive Stock Option Agreement Under the 2013 Stock Option and Incentive Plan(26)
#10.17	Form of Restricted Stock Award Agreement Under the 2013 Stock Option and Incentive Plan(26)
#10.18	Form of Restricted Stock Unit Award Agreement Under the 2013 Stock Option and Incentive Plan(26)
#10.19	Form of Amended and Restated Indemnification Agreement(27)
+10.20	License Agreement between Amgen Inc. and the Company, dated as of December 18, 2007(28)
10.21	Amendment No. 1 to License Agreement between Amgen Inc. and the Company, dated as of October 16, 2009(29)
+10.22	Amendment No. 2 to License Agreement between Amgen Inc. and the Company, dated as of November 26, 2014(30)
10.23	Lease by and between the Company and MEPT Mount Eden LLC, dated as of May 4, 2011(31)
10.24	Lease Amendment by and between the Company and MEPT Mount Eden LLC, dated as of November 13, 2013(32)
+10.25	License Agreement between the Company and Eli Lilly, dated as of July 11, 2014(33)
#10.26	Deferred Compensation Election Form by and between the Company and Paul Truex, effective as of December 28, 2015 (34)
#10.27	Employment Agreement, by and between the Company and Mr. Paul Truex, dated as of January 25, 2016 (35)
#10.28	Employment Offer Letter, by and between the Company and Dr. James Pennington, dated as of April 1, 2016 (36)

10.29	Subscription Agreement between the Company and Anthera Pharmaceuticals, Inc. and purchasers affiliated with Biotechnology Value Fund, L.P. and Rock Springs Capital Master Fund LP, dated September 6, 2016 (37)
10.30	Amendment to At Market Issuance Sales Agreement between the Company and H.C. Wainwright & Co., LLC, dated March 14, 2017(38)
10.31	Purchase Agreement between the Company and Lincoln Park Capital Fund, LLC, dated June 19, 2017(39)
10.32	Sublease Agreement by and between the Company and NewRT, dated July 20, 2017(40)
10.33	Securities Purchase Agreement by and among the Company and the Purchasers party thereto, dated October 23, 2017(41)
10.34	Registration Rights Agreement, by and among the Company and the Purchasers party thereto, dated October 23, 2017(42)
#10.35	Amended and Restated Employment Agreement by and between the Company and Craig Thompson, dated January 5, 2018
#10.36	Amended and Restated Employment Agreement by and between the Company and May Liu, dated January 5, 2018
#10.37	Employment Agreement by and between the Company and William Shanahan, M.D., dated January 5, 2018.
#10.38	Employment Agreement by and between the Company and Renee Martin, Ph.D., dated January 5, 2018.
#10.39	Employment Agreement by and between the Company and Patrick Murphy, dated January 5, 2018.
#10.40	2018 Stock Option and Incentive Plan (43)
#10.41	Termination of Pleasanton Office lease, dated February 28, 2018
14.1	Code of Ethics(44)
21.1	Subsidiaries of Anthera Pharmaceuticals, Inc.(45)

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Number	Description
23.1	Consent of BDO USA LLP, independent registered public accounting firm
24.1	Power of Attorney (included on signature page hereto)
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

+Certain provisions of this Exhibit have been omitted pursuant to a request for confidential treatment.

#Indicates management contract or compensatory plan, contract or agreement.

(1) Filed as Exhibit 3.6 to the registrant's Registration Statement on Form S-1/A (File No. 333-161930), filed with the SEC on February 3, 2010 and incorporated herein by reference.

(2) Filed as the same numbered exhibit to the registrant's Annual Report on Form 10-K, filed with the SEC on March 26, 2013 and incorporated herein by reference.

(3) Filed as Exhibit 3.1 to the registrant Current Report on Form 8-K, filed with the SEC on July 16, 2013 and incorporated herein by reference.

(4) Filed as Exhibit 3.1 to the registrant Current Report on Form 8-K, filed with the SEC on April 28, 2017 and incorporated herein by reference.

(5) Filed as Exhibit 3.1 to the registrant's Form 8-K filed with the SEC on September 15, 2016 and incorporated herein by reference.

(6) Filed as Exhibit 3.2 to the registrant Current Report on Form 8-K, filed with the SEC on September 12, 2016 and incorporated herein by reference.

(7) Filed as Exhibit 3.4 to the registrant's Quarterly Report on Form 10-Q filed with the SEC on August 10, 2015 and incorporated herein by reference.

(8) Filed as Exhibit 3.1 to the registrant's Form 8-K filed with the SEC on October 25, 2017 and incorporated herein by reference.

(9)

Filed as the same numbered exhibit to the registrant's Amendment No. 3 to Registration Statement on Form S-1 (File No. 333-161930), filed with the SEC on January 29, 2010 and incorporated herein by reference.

(10) Filed as Exhibit 4.2 to the registrant's Current Report on Form 8-K, filed with the SEC on September 12, 2016 and incorporated herein by reference.

(11) Filed as Exhibit 4.1 to the registrant's Current Report on Form 8-K, filed with the SEC on September 22, 2010 and incorporated herein by reference.

(12) Filed as Exhibit 10.2 to the registrant's Current Report on Form 8-K, filed with the SEC on March 29, 2011 and incorporated herein by reference.

(13) Filed as Exhibit 4.1 to the registrant's Current Report on Form 8-K, filed with the SEC on September 6, 2016 and incorporated herein by reference.

(14) Filed as Exhibit 10.3 to the registrant's Form 8-K filed with the SEC on October 25, 2017 and incorporated herein by reference.

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(15) Filed as Exhibit 3.1 to the registrant's Current Report on Form 8-K, filed with the SEC on October 25, 2017 and incorporated herein by reference.

(16) Filed as the same numbered exhibit to the registrant's Registration Statement on Form S-1 (File No. 333-161930), filed with the SEC on September 15, 2009 and incorporated herein by reference.

(17) Filed as Appendix A to the registrant's Definitive Proxy Statement on Schedule 14A, filed with the SEC on June 8, 2010 and incorporated herein by reference.

(18) Filed as Exhibit 10.2 to registrant's Quarterly Report on Form 10-Q, filed with the SEC on August 12, 2011 and incorporated herein by reference.

(19) Filed as Exhibit 10.2 to the registrant's Amendment No. 4 to Registration Statement on Form S-1 (File No. 333-161930), filed with the SEC on February 3, 2010 and incorporated herein by reference.

(20) Filed as Exhibit 10.1 to the registrant's Quarterly Report on Form 10-Q, filed with the SEC on May 14, 2010 and incorporated herein by reference.

(21) Filed as Appendix B to the registrant's Definitive Proxy Statement on Schedule 14A, filed with the SEC on June 8, 2010 and incorporated herein by reference.

(22) Filed as Exhibit 10.42 to the registrant's Annual Report on Form 10-K, filed with the SEC on March 7, 2011 and incorporated herein by reference.

(23) Filed as Exhibit 10.34 to the registrant's Annual Report on Form 10-K, filed with the SEC on March 26, 2013 and incorporated herein by reference.

(24) Filed as Annex F to the registrant's Form 14A filed with the SEC on December 7, 2017 and incorporated herein by reference.

(25) Filed as Annex B to the registrants Definitive Proxy Statement on Schedule 14A, filed with the SEC on April 5, 2013 and incorporated herein by reference.

(26) Filed as the same numbered exhibit to the registrant's Annual Report on Form 10-K, filed with the SEC on March 28, 2014 and incorporated herein by reference.

(27) Filed as Exhibit 10.3 to the registrant's Registration Statement on Form S-1 (File No. 333-161930), filed with the SEC on September 15, 2009 and incorporated herein by reference.

(28) Filed as Exhibit 10.10 to the registrant's Registration Statement on Form S-1 (File No. 333-161930), filed with the SEC on September 15, 2009 and incorporated herein by reference.

(29) Filed as Exhibit 10.18 to the registrant's Amendment No. 1 to Registration Statement on Form S-1 (File No. 333-161930), filed with the SEC on October 19, 2009 and incorporated herein by reference.

(30) Filed as Exhibit 10.23 to the registrant's Annual Report on Form 10-K, filed with the SEC on March 16, 2015, and incorporated herein by reference.

(31)

Filed as Exhibit 10.4 to the registrant's Quarterly Report on Form 10-Q, filed with the SEC on May 13, 2011, and incorporated herein by reference.

(32) Filed as Exhibit 10.27 to the registrant's Annual Report on Form 10-K, filed with the SEC on March 28, 2014, and incorporated herein by reference.

(33) Filed as Exhibit 10.1 to the registrant's Quarterly Report on Form 10-Q/A, filed with the SEC on December 12, 2014 and incorporated herein by reference.

(34) Filed as Exhibit 10.33 to the registrant's Annual Report on Form 10-K, filed with the SEC on March 14, 2016 and incorporated herein by reference.

(35) Filed as Exhibit 10.35 to the registrant's Annual Report on Form 10-K, filed with the SEC on March 14, 2016 and incorporated herein by reference.

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(36) Filed as Exhibit 10.1 to the registrant's Quarterly Report on Form 10-Q, filed with the SEC on May 10, 2016 and incorporated herein by reference.

(37) Filed as Exhibit 10.1 to the registrant's Form 8-K filed with the SEC on September 12, 2016 and incorporated herein by reference.

(38) Filed as Exhibit 10.1 to the registrant's Form 8-K filed with the SEC on March 16, 2017 and incorporated herein by reference.

(39) Filed as Exhibit 1.1 to the registrant's Form 8-K filed with the SEC on June 19, 2017 and incorporated herein by reference.

(40) Filed as Exhibit 10.2 to the registrant's Form 10-Q filed with the SEC on August 9, 2017 and incorporated herein by reference.

(41) Filed as Exhibit 10.1 to the registrant's Form 8-K filed with the SEC on October 25, 2017 and incorporated herein by reference.

(42) Filed as Exhibit 10.2 to the registrant's Form 8-K filed with the SEC on October 25, 2017 and incorporated herein by reference.

(43) Filed as Annex E to the registrant's Form 14A filed with the SEC on December 4, 2017 and incorporated herein by reference.

(44) Filed as the same numbered exhibit to the registrant's Annual Report on Form 10-K, filed with the SEC on March 7, 2011 and incorporated herein by reference.

(45) Filed as the same numbered exhibit to the registrant's Annual Report on Form 10-K, filed with the SEC on March 14, 2012 and incorporated herein by reference.

ITEM 16. FORM 10-K SUMMARY

None.