Anthera Pharmaceuticals Inc
Form 10-K
March 26, 2013

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

FORM 10-K

(Mark One)

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2012

OR

o 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 (Address of Principal Executive Offices)	94545 (Zip Code)

(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 Global 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 o No x

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 o No x

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 x No o

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 x No o

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. o

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

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

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

The aggregate market value of the registrant's common stock held by non-affiliates as of June 30, 2012 was approximately $23,551,659 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 March 19, 2013, the number of outstanding shares of the registrant's common stock, par value $0.001 per share, was 148,900,254.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for the registrant's 2013 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, 2012 and are incorporated by reference in Part III of this report.

ANTHERA PHARMACEUTICALS, INC.

FORM 10-K FOR THE FISCAL YEAR ENDED DECEMBER 31, 2012

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SPECIAL NOTE 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 stateme
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.

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 statement is made, whether as a result of new information, future events or circumstances or otherwise.

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PART I

ITEM 1. BUSINESS

Unless the context otherwise requires, we use the terms “Anthera Pharmaceuticals,” “Anthera,” “we,” “us,” “the Company” a “our” in this report to 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.

Overview

Anthera Pharmaceuticals, Inc. is a biopharmaceutical company focused on developing and commercializing products to treat autoimmune diseases. We currently have one Phase 3 ready product candidate, blisibimod, which targets elevated levels of B-cell activating factor, or BAFF, which has been associated with a variety of B-cell mediated autoimmune diseases, including systemic lupus erythematosus (SLE), or lupus, Immunoglobin A nephropathy, or IgAN, lupus nephritis, vasculitis, rheumatoid arthritis, idiopathic thrombocytopenia purpura, and others.

Our BAFF Antagonism Portfolio

BAFF, also known as BLyS, is a tumor necrosis family member and is critical to the development, maintenance and survival of B-cells. B-cells are a vital part of the human immune system producing natural antibody responses to invading pathogens such as viruses. Abnormal elevations in BAFF and B-cells have been correlated with several autoimmune diseases. The potential role of BAFF inhibition and associated reductions in B-cell concentrations in lupus and rheumatoid arthritis has been validated in multiple clinical studies with blisibimod and other BAFF antagonists. We intend to advance the clinical development of our BAFF inhibitor, blisibimod, to exploit its broad potential clinical utility in a number of autoimmune diseases. Blisibimod, a peptibody directed against BAFF, was developed as an alternative to antibodies and is produced in Escherichia coli bacterial culture which contrasts with antibody therapeutics that are typically manufactured 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 and relatively small molecular weight. Blisibimod inhibits both soluble and membrane bound BAFF.

We have worldwide rights to blisibimod in all potential indications. In 2012, we completed a Phase 2b clinical study named PEARL-SC, to evaluate the efficacy and safety of subcutaneous blisibimod in patients with active and seropositive lupus. Lupus patients suffer from chronic autoimmune disease, where an inappropriate or abnormal immune response often leads to severe skin rash, fatigue, joint pain, major kidney complications and cardiovascular disease. Inhibition of BAFF is believed to reduce survival and subsequent elevations in B-cells leading to a reduction in severity of disease and resolution of Lupus symptoms.

Our product development programs are focused on blisibimod and its use as therapeutic treatments for lupus and other serious autoimmune diseases for which we believe current treatments are either inadequate or non-existent. Our current plan includes commencing the CHABLIS-SC and BRIGHT-SC clinical studies, continuing the ongoing blisibimod open label extension safety and efficacy study, or OLE study, and investigating the structure of future clinical studies and research and development activities. Anthera has successfully manufactured blisibimod at launch scale volumes and has sufficient inventory to support the CHABLIS-SC and BRIGHT-SC clinical studies in 2013. The blisibimod product is designed for at-home, self-administration and is presented as a pre-filled syringe for subcutaneous administration. We are actively pursuing various partnerships with major pharmaceutical and biotech companies to develop and commercialize blisibimod for both lupus and additional indications.

Our current development plans include the phase 3 development of blisibimod for lupus and a focus on orphan indications, which may provide an accelerated and cost-efficient path to regulatory approval and commercialization both in the United States and Asia. We believe that certain of these markets and product opportunities for blisibimod can be commercialized through utilization of a limited specialty sales force targeting a small set of clinical specialists. In addition, we believe blisibimod may address market opportunities in chronic indications such as lupus and to maximize these opportunities we may seek development and commercialization partners to address non-specialty and international markets.

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Product Candidate	Study Name	Development Stage	Indications	Next Milestone(s)
Blisibimod	PEARL-SC Open Label Extension (OLE)	Phase 2b (1)	Lupus	· Complete patient dosing in 1H 2013 · Data announcement in 2H 2013
Blisibimod	BRIGHT-SC	Phase 2b (2)	IgA Nephropathy	· Initiate patient dosing in 1H 2013 · Complete 48-patient enrollment H2 2013 · Induction interim biomarker analysis at end of 2013
Blisibimod	CHABLIS-SC1	Phase 3 (2)	Lupus	· Initiate patient enrollment in 1H 2013 · Complete enrollment of 100 patient in H2 2013

(1) ongoing
(2) planned for initiation in 2013

Summary of Primary Product Development Program

Blisibimod a Potent Inhibitor of B-Cell Activating Factor

Blisibimod (also referred to as A-623) is a peptibody antagonist of the BAFF cytokine that we are developing as a treatment for systemic lupus erythematosus, or lupus and IgAN. BAFF, also known as BLyS, is a tumor necrosis family member and is critical to the development, maintenance and survival of B-cells. B-cells represent a critical component of a human immune response to infection and other pathogens. However abnormal elevations of B-cells, often accompanied by elevations in BAFF, may lead to an over active immune response which may damage normal healthy tissues and organ systems. Although the cause of lupus is still not completely understood, B-cell activation and autoantibody production are known to be central to the process. Evidence has emerged that over-expression of BAFF plays an important role in these disease processes. In preclinical studies, transgenic mice created to over-express BAFF begin to exhibit symptoms similar to lupus. In preclinical studies in mice that develop lupus-like disease, BAFF is known to be elevated, and treatment with blisibimod improves outcomes and survival. Similarly, in IgAN, mice that over-express BAFF develop a fatal nephropathy associated with IgA.

According to the Journal of Arthritis and Rheumatism the prevalence of lupus is estimated to be between 50 and 150 per 100,000 in the United States. The Journal of Arthritis and Rheumatism estimates similar prevalence rates for Europe and Asia. IgAN is the most common form of primary glomerulonephritis throughout the world, although the U.S. prevalence is estimated at approximately 130,000 patients. The prevalence of IgAN varies throughout the world,

with the highest prevalence in Asia (Singapore, Japan, and Hong Kong), Australia, Finland, and southern Europe (20 to 40% of all glomerulnephritis).

Blisibimod Development History

In April of 2012 we completed a Phase 2b clinical study, called PEARL-SC, with blisibimod for the treatment of patients with seropositive markers of lupus and active disease defined as SELENA-SLEDAI score of greater than 6. The primary endpoint of the PEARL-SC study was a clinical improvement in the Systemic Lupus Erythematosus responder index, or SRI-5, at week 24 for the pooled blisibimod dose groups versus pooled placebo groups. SRI-5 is defined as a five-point improvement in the SELENA-SLEDAI score, no new BILAG A or two B scores, and no increase in a physician's global assessment of more than 0.3 points.

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In June and July of 2012 we announced results from the Phase 2b PEARL-SC study which we believe support the initiation of a differentiated Phase 3 registration plan utilizing the 200mg weekly dose of blisibimod in patients with active lupus, despite the concomitant use of corticosteroids. While the pre-specified primary efficacy endpoint in the PEARL-SC clinical study was not met due to an apparent lack of clinical efficacy in the two lowest dose groups, additional prospective data from the PEARL-SC study suggest consistent treatment benefits in the 200mg weekly dose group when utilizing higher thresholds of disease improvement, as measured by larger point reductions in SELENA-SLEDAI scoring index.

In addition, in a subgroup population of severely ill, seropositive lupus patients, defined as those patients having a SELENA-SLEDAI score of greater or equal to ten who were also receiving background corticosteroid medication at the time of randomization, a more pronounced treatment benefit was seen with the blisibimod 200mg weekly dose compared to other doses.

Using a higher treatment threshold of an eight point reduction in the SELENA-SLEDAI, or an SRI-8 endpoint, in this enhanced subgroup population, the 200mg blisibimod treatment group demonstrated a 15.6% treatment difference compared to pooled placebo (41.7% versus 26.1%, $p \leq 0.05$) and 31.1% treatment difference compare to treatment matched placebo (41.7% versus 10.6%, $p < 0.001$) at 24 weeks. In this subgroup, which we plan to enroll in our Phase 3 CHABLIS-SC studies, separation of clinical response occurred as early as week eight and numerical differences were observed beyond week 24. All doses of blisibimod demonstrated consistent serological response including reductions of B-cells, double-stranded-DNA antibodies and improvement in complement levels. Blisibimod was safe and well-tolerated at all dose levels with no meaningful imbalances in serious adverse events.

Systemic Lupus Erythematosus Responder Index (SRI) at Various SELENA-SLEDAI Disease Improvement Levels
In Subjects Enrolled in the Pearl-SC Study (MITT Population)

An SRI-5 responder achieved all of the following: ≥5 point improvement in SELENA-SLEDAI, AND no new BILAG A or ≥2B organ domain scores, AND no worsening (<0.3 increase) in Physician's Global Assessment. Across all subjects enrolled in the PEARL-SC study, the percent of subjects achieving the SRI-5 at 24 weeks was higher in subjects receiving the highest dose of blisibimod (200mg QW) compared with placebo. SRI improvements compared with placebo were generally higher in subjects who attained SELENA–SLEDAI improvements of ≥6, ≥7, ≥8 (SRI-6, SRI-7, and SRI-8, respectively). Graphs show data for blisibimod (200mg once-weekly) and treatment matched or pooled placebo administered subcutaneously for 24 weeks.

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Systemic Lupus Erythematosus Responder Index (SRI) in Subjects with Baseline SELENA-SLEDAI ≥10 and Receiving Steroids

An SRI-5 responder achieved all of the following: ≥5 point improvement in SELENA-SLEDAI, AND no new BILAG A or ≥2B organ domain scores, AND no worsening (<0.3 increase) in Physician's Global Assessment. In a subgroup analysis of patients with severe lupus disease (SELENA–SLEDAI≥10 and receiving steroid at baseline, n=278), the percent of subjects achieving the SRI-5 was higher in subjects receiving the highest dose of blisibimod (200mg QW) compared with placebo. SRI improvements compared with placebo were higher still in subjects who attained SELENA–SLEDAI improvements of ≥6, ≥7, ≥8 (SRI-6, SRI-7, and SRI-8, respectively). Graph shows data for blisibimod (200mg once-weekly) and regimen matched placebo administered subcutaneously for 24 weeks.

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The following table shows the N values at the different time points in the graph above.

	Pooled Placebo	200 mg QW Placebo	200 mg QW blisibimod	Real Difference versus Pooled Placebo	Real Difference versus 200mg QW Placebo
Total Study N	N=269	N=92	N=92		
Subgroup N	N=138	N=47	N=48		
SRI-5	47.1% N=65	40.4% N=19	54.2% N=26	+7.1% p=0.48	+13.8% p=0.18
SRI-5 + No Increase in Steroid dose	43.5% N=60	38.3% N=18	52.1% N=25	+8.6% p=0.48	+13.8% p=0.18
SRI-6	46.4% N=64	38.3% N=18	54.2% N=26	+7.8% p=0.43	+15.9% p=0.12
SRI-7	28.3% N=39	12.8% N=6	41.7% N=20	+13.4% p=0.11	+28.9% p=0.002
SRI-8	26.1% N=36	10.6% N=5	41.7% N=20	+15.6% p=0.05	+31.1% p < 0.001

*SRI is defined as patients who respond to treatment and achieve a reduction in SELENA-SLEDAI equal to or greater than the number indicated, no new BILAG A or two B organ domain scores, and no increase in Physician's Global Assessment (PGA) of greater than 0.3 on a three point scale.

To date, three (3) randomized, placebo-controlled clinical studies have been conducted with blisibimod in patients with lupus: two (2) Phase 1 dose-ranging studies in which a total of 104 patients were randomized, and a Phase 2b dose-ranging clinical outcomes study in which 547 subjects were enrolled. In all three (3) studies, statistically significant reductions in total B-cells were observed in patients treated with blisibimod versus those treated with placebo due to its mechanism of BAFF inhibition. In addition, treatment with blisibimod was associated with significant improvements in lupus disease activity and lupus biomarkers, including anti-double-stranded DNA antibodies, urine protein content, or proteinuria, and complement components C3 and C4. Details of the findings of these trials are provided in the Historical Clinical Studies section.

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Effect of Blisibimod on Proteinuria
Subgroup: Baseline Proteinuria = 1-6g/24hour (N=49)

In subjects with baseline urinary protein excretion equivalent to 1-6 g/24hrs, treatment with blisibimod resulted in significantly greater reductions in proteinuria compared to placebo from Week 8 through Week 24. Furthermore, the observed treatment-related decreases in proteinuria resulted in near normalization of the proteinuria to ≤1g/24hrs in those subjects receiving blisibimod. Graphs show data for blisibimod (all pooled dose levels as well as 200mg once-weekly) and placebo administered subcutaneously for 24 weeks.

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BioMarker Changes Associated With Blisibimod in Subjects Enrolled in the PEARL-SC Study

With its mechanism of BAFF inhibition, blisibimod treatment was associated with significant reductions in the numbers of total B cells, anti-dsDNA antibodies, as well as significant increases in complement components C3 and C4. Graphs show data for blisibimod (average of all dose levels) and placebo administered subcutaneously for 24 weeks.

In addition, we believe blisibimod may offer a number of potential opportunities for differentiation versus the currently marketed BAFF antagonist, belimumab, as well as other novel B-cell directed therapies including:

- Clinical differentiation:
  - a superior Phase 3 clinical design which utilizes more stringent restrictions to background medication;
  - a requirement that patients are receiving steroid therapy at time of randomization;
  - restricting background medications sooner and therefore demonstrating an earlier clinical benefit, and
  - requiring larger disease reduction in the SELENA-SLEDAI clinical efficacy measurement tool as part of the primary endpoint;
- Patient convenience: A convenient, at-home, patient-administered subcutaneous product;
- Mechanism of Action: Blisibimod is able to inhibit the activity of both membrane-bound and soluble BAFF;

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- Manufacturing and peptibody design: Blisibimod represents a novel molecular structure, which confers manufacturing benefits and lower cost of goods based on a bacterial fermentation manufacturing process; and utilizes multiple binding sites to achieve highest reported affinity for inhibition of BAFF.

On-going Blisibimod PEARL-SC Open Label Extension Study

As part of the PEARL-SC clinical study program, patients who completed the study were eligible to enroll in an open label extension study. In the OLE study all patients, including those from the placebo arm of the PEARL-SC clinical study receive active therapy for a minimum of 12 months following their final dose in the PEARL-SC study. We expect to complete dosing in this open label extension study during the first half of 2013. Safety and efficacy will be evaluated using key disease biomarkers such as double-stranded DNA, C3, C4 and proteinuria. Data from this study will be presented during the second half of 2013.

Phase 3 Development of Blisibimod in Lupus

During the third quarter of 2012 we met with the U.S. Food and Drug Administration, or FDA, at an end of phase 2 meeting. At the meeting we presented the results of the PEARL-SC clinical study and our plans for Phase 3 registration studies in patients with active lupus who are receiving steroids. As a result of this meeting we plan to initiate patient enrollment in our initial Phase 3 CHABLIS-SC1 clinical study in 2013.

The Phase 3 studies (CHABLIS-SC1 and CHABLIS-SC2) are currently planned to be multicenter, placebo-controlled, randomized, double-blind studies designed to evaluate the efficacy, safety, tolerability and immunogenicity of blisibimod in patients with clinically active SLE (SELENA-SLEDAI > 10) who require corticosteroid therapy in addition to standard-of-care for treatment of their disease. Each study will randomize approximately 400 patients to receive either 200mg of blisibimod or placebo for 52 weeks. As agreed with the FDA, the primary endpoint of the Phase 3 studies will be clinical improvement in the SRI-8 response at 52 weeks. We plan to conduct periodic interim analyses during the course of the CHABLIS-SC1 study to ensure the accuracy of our estimates. Following an interim analysis of clinical data from the CHABLIS-SC1 study we plan to initiate patient enrollment in our second Phase 3 clinical study, CHABLIS-SC2. Based on significant improvements in renal disease biomarkers such as proteinuria, C3 and C4 observed with blisibimod, in 2013 we plan to meet with the FDA to discuss and finalize the enrollment criteria of the CHABLIS-SC2 clinical study in an effort to include patients diagnosed with or without glomerulonephritis. This revised study design could allow for the incremental inclusion of patients with more significant kidney manifestations of lupus including proteinuria and evidence of renal damage.

Development of Blisibimod for Orphan Indications

BRIGHT-SC Phase 2b Clinical Study in Patients with IgA Nephropathy

In 2013 we will begin to study blisibimod in patients with B-cell mediated autoimmune diseases such as IgA nephropathy (Berger's disease). According to the National Organization for Rare Disorders (NORD) IgA nephropathy, an orphan indication is believed to affect approximately 130,000 people annually in the United States. In Asia, a similar prevalence to the U.S. would be estimated to affect over 500,000 people annually. In Asia, routine urinalyses are often performed for school children, and renal biopsies are performed for any patients with asymptomatic hematuria, thus raising the reported prevalence of the disease. According to the National Kidney and Urologic Diseases Information Clearinghouse, 25% of adults with IgA nephropathy eventually develop total kidney failure. Immunoglobulin A, or IgA, is a human antibody that helps the body fight infections. IgA nephropathy may occur when excessive plasma B-cells express excessive amounts of abnormal IgA and this immunogenic protein is deposited in the kidneys. These IgA deposits build up inside the small blood vessels of the kidney and as a result kidney

glomeruli become inflamed and damaged leading to leakage of blood and protein into urine. According to the New England Journal of Medicine, 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.

Similar to patients with other autoimmune diseases such as lupus, in IgA Nephropathy, elevated levels of BAFF are associated with the proliferation of B-cells and plasma B-cells which may contribute to the disease. In patients with IgAN, levels of BAFF are significantly higher than in healthy patients. In IgAN, increased plasma B-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 plasma B-cells were observed in previous clinical studies of SLE patients with another BAFF inhibitor antibody, belimumab. In our PEARL-SC Phase 2b study, significant reductions in total B-cells as well as significant improvements in proteinuria and increases in complement C3 were observed with blisibimod in lupus patients. We believe inhibition of BAFF may reduce proliferative B-cells and plasma B-cells, reduce serum levels of IgA and therefore reduce progressive renal damage in patients with IgAN.

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We plan to initiate patient enrollment in a Phase 2 proof-of-concept study for the treatment of IgA Nephropathy in 2013. The BRIGHT-SC study will enroll approximately 48 patients with biopsy-proven IgAN who have proteinuria greater than 1 gram per 24 hours and are receiving standard of care. Patients will receive high dose, 300mg weekly, blisibimod or placebo for 8 weeks, during the induction phase, followed by 24 weeks of 200mg weekly blisibimod or placebo, the maintenance phase. The primary endpoint of the BRIGHT-SC study will be improvements in proteinuria versus placebo after 32 weeks. We plan to conduct an interim analysis after the eight-week induction phase to determine effects of blisibimod on proteinuria. In 2013, we will submit an orphan designation application to the FDA for the use of blisibimod as a treatment for IgA nephropathy. We believe data from the BRIGHT-SC clinical study may provide information for other B-cell mediated kidney orphan diseases such as idiopathic membranous glomerulonephritis and lupus nephritis.

Market Opportunity

Lupus

Lupus is an autoimmune disorder that involves inflammation that causes swelling, pain and tissue damage throughout the body. Lupus can affect any part of the body, but especially the skin, heart, brain, lungs, joints and the kidneys. The course of the disease is unpredictable, with periods of illness, called flares alternating with remission. According to the Journal of Arthritis and Rheumatism, the prevalence of lupus is estimated to be between 50-150 per 100,000 in the United States. The journal of Arthritis and Rheumatism estimates similar prevalence rates for Europe and Asia. Although lupus may affect people of either sex, women are 10 times more likely to suffer from the disease than men, according to the Lupus Foundation.

Patients with active lupus may have a broad range of symptoms related to the inflammation. Inflammation of the brain may cause seizures and other neurologic abnormalities. Inflammation of the heart may cause heart failure or sudden death. Lung inflammation causes shortness of breath. Lupus may also cause swollen joints, proteinuria and severe rash. In addition, patients with lupus nephritis may require kidney dialysis or eventual transplantation.

Although the cause of lupus is still not completely understood, B-cell activation and autoantibody production are known to be central to the process. Evidence has emerged that over-expression of BAFF plays an important role in this disease process. In preclinical studies, transgenic mice created to over-express BAFF begin to exhibit symptoms similar to lupus. In addition, treatment of lupus-prone mice with blisibimod ameliorates the disease.

IgA Nephropathy

Immunoglobulin A (IgA) is an antibody that plays a critical role in mucosal immunity. IgA Nephropathy (also known as IgA nephritis or Berger's disease) is a form of glomerulonephritis (inflammation of the glomeruli of the kidney) and leading cause of end stage renal disease. IgA is a human antibody that helps the body fight infections. IgA nephropathy occurs when too much of this protein, especially aberrant and immunogenic forms of IgA, is deposited in the kidneys. These immunogenic IgA immune complexes deposit inside the small blood vessels of the kidney and as a result kidney glomeruli become inflamed and damaged leading to leakage of blood and protein into urine. The classic presentation (in 40-50% of the cases) of signs and symptoms in patients with IgAN is episodic frank hematuria which usually starts within a day or two of a non-specific upper respiratory tract infection or (less commonly) gastrointestinal or urinary infection. All of these infections have in common the activation of mucosal defenses and hence IgA antibody production.

According to the New England Journal of Medicine, 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. Men are affected three times as often as women. There is also a striking geographic variation in the

prevalence of IgAN throughout the world. According to the National Organization for Rare Disorders (NORD) IgA nephropathy, an orphan disease is believed to affect approximately 130,000 people annually in the United States. In Asia, assuming similar prevalence rates as the United States, IgAN is estimated to affect over 500,000 people annually. In Asia, routine urinalyses are performed for school children, and renal biopsies are performed for patients with asymptomatic hematuria, thus raising the reported prevalence of the disease. According to the National Kidney and Urologic Diseases Information Clearinghouse, 25% of adults with IgA nephropathy eventually develop total kidney failure.

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PEARL-SC Phase 2b Clinical Study in Patients with Lupus

Based on positive results among 104 patients in our Phase 1a and 1b clinical studies, we initiated a Phase 2b clinical study in lupus patients called PEARL-SC in 2010, exploring three doses of blisibimod for the treatment of patients with seropositive markers of lupus and active disease defined as SELENA-SLEDAI score of greater than 6. PEARL-SC was a randomized, placebo-controlled, Phase 2b study which enrolled 547 patients in 11 countries at 72 clinical sites. Subjects were randomized into three active subcutaneous treatment arms and one placebo treatment arm for a minimum of 24 weeks and a maximum of 52 weeks. All patients completed the PEARL-SC study when the final enrolled patient completed six months of therapy.

The primary endpoint of the PEARL-SC study was a clinical improvement at the SLE responder index, or SRI-5, at week 24 for the pooled bisibimod dose groups versus placebo groups. SRI-5 is defined as a five-point improvement in the SELENA-SLEDAI score, no new BILAG A or two BILAG B scores, and no new increase in physician's global assessment of more than 0.3 points. Secondary endpoints included safety, improvement in other clinical assessment scores, and clinical response in patients with various baseline disease severities, resolution of fatigue, steroid utilization and time to flare.

In June and July 2012 we announced results from the Phase 2b PEARL-SC study which we believe support the initiation of a differentiated Phase 3 registration plan utilizing the 200mg weekly dose of blisibimod in patients with active lupus, despite the concomitant use of corticosteroids. While the pre-specified primary efficacy endpoint in the PEARL-SC clinical study was not met due to a lack of clinical efficacy in the two lower dose groups, additional prospective data from the PEARL-SC study suggest consistent treatment benefits in the 200mg weekly dose group when utilizing higher thresholds of disease improvement, as measured by larger point reductions in the SELENA-SLEDAI scoring index. In addition, in a subgroup population of severely ill, seropositive lupus patients, defined as those patients having a SELENA-SLEDAI score of > 10 who were also receiving background corticosteroid medication at the time of randomization, a more pronounced treatment benefit was seen with the blisibimod 200mg weekly dose compared to other doses.

Using a higher treatment threshold of an eight point reduction in the SELENA-SLEDAI, or an SRI-8 endpoint, in this enhanced subgroup population, the 200mg blisibimod treatment group demonstrated a 15.6% treatment difference compared to pooled placebo (41.7% versus 26.1%, $p<0.05$) and 31.1% treatment difference compare to treatment matched placebo (41.7% versus 10.6%, $p<0.001$) at 24 weeks. In this subgroup, which we plan to enroll in our Phase 3 CHABLIS-SC studies, separation of clinical response occurred as early as week eight and numerical differences were observed beyond week 24. All doses of blisibimod demonstrated consistent serological response including reductions of B-cells, ds-DNA antibodies and improvement in complement levels. Blisibimod was safe and well-tolerated at all dose levels with no meaningful imbalances in serious adverse events. Additional information and publications from the PEARL-SC clinical study can be found at www.anthera.com/studies_pearl-sc.asp.

Open Label Extension Clinical Study in Patients Enrolled in PEARL-SC

Upon completion of PEARL-SC, patients were invited to enroll in an open-label extension study in which patients receive active study drug (blisibimod) for the primary objective of monitoring long-term safety. The open-label extension study completed enrollment in 2012 and we anticipate completing patient dosing in this safety and efficacy study in 2013. Additional information about the OLE clinical study can be found at www.anthera.com/studies_open-label-extension-study.asp.

Phase 3 Development of Blisibimod in lupus

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

The Phase 3 studies (CHABLIS-SC1 and CHABLIS-SC2) are planned to be multicenter, placebo-controlled, randomized, double-blind studies designed to evaluate the efficacy, safety, tolerability and immunogenicity of blisibimod in patients with clinically active SLE (SELENA-SLEDAI > 10) who require corticosteroid therapy in addition to standard of care for treatment of their disease. Each study will randomize approximately 400 patients to receive either 200mg of blisibimod or placebo weekly for 52 weeks. As agreed with the FDA, the primary endpoint of the Phase 3 studies will be clinical improvement in the SRI-8 response at 52 weeks. We plan to conduct periodic interim analyses during the course of the CHABLIS-SC1 study to ensure the accuracy of our estimates. Following our initial interim analysis of clinical data from the CHABLIS-SC1 study we plan to initiate patient enrollment in our second Phase 3 clinical study, CHABLIS-SC2. Additional information for the CHABLIS-SC1 clinical studies can be found at www.anthera.com/studies_chablis-sc1.asp

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Development of Blisibimod for Orphan Indications

BRIGHT-SC Phase 2b Clinical Study in Patients with IgA Nephropathy

Similar to patients with other autoimmune diseases such as lupus, in IgA Nephropathy, elevated levels of BAFF are associated with the proliferation of B-cells and plasma B-cells which may contribute to disease. In patients with IgAN, levels of BAFF are significantly higher than in healthy patients. In IgAN, increased plasma B-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 plasma B-cells were observed in previous clinical studies of SLE patients with another BAFF inhibitor antibody, belimumab. In our PEARL-SC Phase 2b study, significant reductions in total B-cells as well as significant improvements in proteinuria and increases in complement C3, biomarkers known to be correlated with severity of kidney injury, were observed with blisibimod in SLE patients. We believe inhibition of BAFF may reduce proliferative B-cells and plasma B-cells, reduce serum levels of IgA and therefore reduce progressive renal damage in patients with IgAN.

In 2013 we plan to initiate patient enrollment in BRIGHT-SC, a Phase 2 proof-of-concept study for the treatment of IgA nephropathy, our first clinical study addressing an orphan indication for the treatment of renal disease. BRIGHT-SC will serve as our initial proof of concept study for an eventual Phase 3 path in renal diseases with blisibimod. The BRIGHT-SC study will enroll approximately 48 patients with biopsy-proven IgAN who have proteinuria greater than one gram per 24 hours and are receiving standard of care. Patients will receive high dose, 300mg weekly, blisibimod or placebo for 8 weeks the induction phase, followed by 24 weeks of 200mg weekly blisibimod or placebo in the maintenance phase. The primary endpoint of the BRIGHT-SC study will be improvements in proteinuria versus placebo after completion of the maintenance phase of the study, or 32 weeks. We plan to conduct an interim analysis of the BRIGHT-SC clinical results after the eight-week induction phase to determine effects of blisibimod as an induction therapy on proteinuria. Additional information about the BRIGHT-SC clinical study can be found at www.anthera.com/studies_bright-sc.asp.

Blisibimod Manufacturing Strategy

In December 2011, we completed the technology transfer from Amgen Inc., or Amgen and manufacturing scale up to 3,000 liters at our contract manufacturing organization, or CMO (Fujifilm Diosynth Bioservices or “Fujifilm”). Two batches of blisibimod produced under U.S. and EU good manufacturing procedures, or GMPs, at the 3,000 liter scale passed all physical quality specifications and comparability assessments. Data from our first 3,000 liter manufacturing campaign was submitted to the FDA, and product from this batch was released for use in the PEARL-SC and OLE studies.

We have successfully manufactured blisibimod at launch scale volumes and currently have sufficient inventory to support the CHABLIS-SC1 and BRIGHT-SC studies in 2013. The product is designed for patient at-home administration and is presented in pre-filled syringes for subcutaneous administration. We are actively pursuing various partnerships with major pharmaceutical and biotech companies to develop and commercialize blisibimod for both lupus and additional indications.

The following chart outlines the basic manufacturing steps required for the production of blisibimod.

Blisibimod Regulatory Strategy

The Phase 3 program for blisibimod was presented to the European Medicines Agency (EMA, Scientific Advice) in the second quarter of 2012 and to the FDA in the third quarter of 2012 (End-of-Phase 2 meeting). The Phase 3

CHABLIS-SC program incorporates feedback and advice obtained from both regulatory agencies. The Phase 3 studies (CHABLIS-SC1 and CHABLIS-SC2) are planned to be multicenter, placebo-controlled, randomized, double-blind studies designed to evaluate the efficacy, safety, tolerability and immunogenicity of blisibimod in patients with clinically active SLE (SELENA-SLEDAI > 10) who require corticosteroid therapy in addition to standard of care for treatment of their disease. Each study will randomize approximately 400 patients to receive either 200mg of blisibimod or placebo for 52 weeks.

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We submitted an application to the FDA in January 2013 requesting orphan designation for the use of blisibimod as a treatment for IgAN. We believe data from the BRIGHT-SC clinical study may provide information for other B-cell mediated kidney orphan diseases such as lupus nephritis and idiopathic membranous glomerulonephritis.

In 2014, we anticipate submitting an application to designate blisibimod as a breakthrough therapy in the treatment of IgAN. The recent Food and Drug Administration and Innovation Act (FDASIA) provide a number of mechanisms intended to expedite the review and development of drugs for serious or life-threatening conditions.

Historical Clinical Studies

Prior to our in-licensing of blisibimod, Amgen completed two Phase 1 clinical studies of blisibimod in lupus patients to evaluate the safety and pharmacokinetics of single and multiple doses of the drug using intravenous and subcutaneous formulations. The randomized, placebo-controlled, dose-escalation Phase 1a clinical study evaluated blisibimod as a single intravenous or subcutaneous therapy among 56 lupus patients. Intravenous doses included 1, 3 and 6 mg/kg, and subcutaneous doses included 0.1, 0.3, 1 and 3 mg/kg. The primary endpoint was to assess the safety and tolerability of single dose administrations of blisibimod. Secondary endpoints were designed to assess the plasma pharmacokinetic profile and immunogenicity of blisibimod. Results from this clinical study indicated the safety and tolerability of blisibimod administered as a single intravenous or subcutaneous dose was comparable to placebo. Single doses of blisibimod exhibited linear pharmacokinetics after both intravenous and subcutaneous administration. There were comparable adverse events between the blisibimod and placebo groups with no deaths reported. In addition, no neutralization antibodies were seen across all doses. The most common adverse events were nausea (15%), headache (10%), upper respiratory tract infection (10%) and diarrhea (8%).

Blisibimod was evaluated in a randomized, placebo-controlled, multi-dose Phase 1b clinical study as an intravenous or subcutaneous therapy among 63 lupus patients. The intravenous dose was 6 mg/kg, and subcutaneous doses included 0.3, 1 and 3 mg/kg. Patients received their doses of blisibimod or placebo once-weekly for four weeks. The primary endpoint was to assess the safety and tolerability of multiple dose administrations of blisibimod. Secondary endpoints were designed to assess the plasma pharmacokinetic profile and immunogenicity of blisibimod after multiple doses. Results showed that multiple doses of blisibimod exhibited dose-proportional pharmacokinetics after both intravenous and subcutaneous administration. Further, results demonstrated a significant decrease in total B-cells as early as 15 days of treatment, and total B-cell reduction (up to approximately 60-70% of baseline) reached its nadir after about 160 days of therapy. By six months after treatment, the B-cell populations had returned to baseline levels. Further analyses of B cell subsets found that naïve B cells and activated B cells were significantly decreased while memory B cells were transiently significantly increased following treatment with blisibimod, consistent with a correction of the B cell abnormalities reported in lupus patients.

There were no deaths reported between the blisibimod and placebo groups. Few neutralization antibodies were seen, and all resolved in subsequent visits. Based on these results and published data from competitor studies, we conducted a Phase 2b clinical study evaluating blisibimod in lupus patients from the second half of 2010 to the third quarter of 2012.

Terminated Products

Two of our former product candidates, varespladib and varespladib sodium, were designed to inhibit a novel enzyme target known as secretory phospholipase A2, or sPLA2. Elevated levels of sPLA2 have been implicated in a variety of acute inflammatory conditions, including acute coronary syndrome and acute chest syndrome associated with sickle cell disease, as well as in chronic diseases, including stable coronary artery disease, or CAD.

In March 2012, an independent data safety monitoring board (DSMB) recommended stopping the VISTA-16 clinical study for varespladib due to a lack of efficacy that could not be reasonably overcome in the remainder of the trial. The study was prematurely terminated by the DSMB because of the inability of VISTA-16 to detect a statistically significant benefit of the drug on the prespecified primary and secondary endpoints even if the trial continued to its scheduled termination with the proposed expanded sample size.

The same data reviewed by the DSMB were subsequently brought in-house and examined by a committee of medical and drug safety professionals. In addition to reviewing the primary endpoint data, this review included an unblinded review of demographics, baseline characteristics, laboratory results, concomitant medications, treatment emergent adverse events (AEs), and serious adverse events (SAEs). No obvious clinical or scientific reason has been found for the increased hazard for non-fatal myocardial infarction amongst subjects treated with varespladib despite positive treatment-related changes in LDL-C and CRP. At the time of study termination the hazard ratio for the primary endpoint (time to first occurrence of the combined endpoint of cardiovascular death, non-fatal myocardial infarction, non-fatal stroke, or documented unstable angina with objective evidence of ischemia requiring hospitalization) was 1.244 (p=0.155). This is primarily driven by the increased occurrence of non-fatal myocardial infarction, a single component of the composite primary endpoint: HR 1.686 p=0.009. Additional details about the VISTA-16 study can be found at www.anthera.com/studies_vista-16.asp.

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In connection with the termination of varespladib and varespladib sodium, we implemented an organizational restructuring plan in 2012 that lowered operating expenses through headcount reductions and the elimination of certain vendor activities. We modified work orders with key vendors to ensure efficient wind-down activities, while still maintaining patient safety as a top priority. We have reallocated our remaining resources to other potential development programs and product portfolio efforts. Based on the recommendation of the DSMB, we do not expect to engage in any further development activities of varespladib and varespladib sodium. Therefore, we provided notice of termination to the collaborators in August 2012 to terminate the license agreement. The license agreement was effectively terminated in November 2012.

Our Strategy

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

Advancing Clinical Development of Blisibimod

We are advancing the development of blisibimod to exploit the broad potential clinical utility of BAFF antagonism. We have completed Phase 1 and Phase 2b clinical studies with blisibimod in lupus patients and plan to advance blisibimod into a Phase 3 registration program in 2013. We may opportunistically enter into collaborations with third parties for development of this compound in lupus or in other B-cell mediated diseases, such as IgA nephropathy, lupus nephritis, vasculitis, rheumatoid arthritis, idiopathic thrombocytopenia purpura, and others that may benefit from BAFF antagonism, including securing corporate partners whose capabilities complement ours.

Obtaining Orphan Indications with Blisibimod

Orphan indications in renal diseases represent a substantial untapped opportunity. We intend to build an orphan path upon the secondary data we collected from our Phase 2b PEARL-SC study and recently published renal effects of Benlysta. The data will help us select an appropriate orphan path to supplement our approach in lupus. We believe that this orphan approach will further differentiate blisibimod from other anti-BAFF molecules in a capital-efficient manner.

The progression of patients with IgA nephropathy and lupus nephritis to end stage renal disease poses a considerable cost and societal burden. We believe improvement in patient outcomes will allow for premium orphan pricing for blisibimod. In addition, we believe successful outcomes in the BRIGHT-SC study will support future lifecycle expansion for blisibimod. Furthermore, disease-specific dosing regimens may enable product commercialization at substantially different price points.

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

Our primary product candidate is focused on highly-specialized physician segments, such as rheumatologists 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. In other chronic indications, we intend to seek commercial collaborations with companies that have a large, dedicated sales force focused on general practitioners and we plan to seek commercialization partners for products in non-specialty and international markets.

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. 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.

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Many of our potential competitors, including many of the organizations named below, have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of products and the commercialization of those products. Accordingly, our competitors may be more successful than we may be in obtaining FDA approval for drugs and achieving widespread market acceptance. Our competitors' drugs may be more effective, or more effectively marketed and sold, than any drug we may commercialize and may render our product candidate obsolete or non-competitive before we can recover the expenses of developing and commercializing our product candidate. We anticipate that we will face intense and increasing competition as new drugs enter the market and advanced technologies become available. Finally, the development of new treatment methods for the diseases we are targeting could render our drugs non-competitive or obsolete.

Approved Categories of Drugs

Lupus

Human Genome Sciences, Inc.'s and partner GlaxoSmithKline plc's Benlysta (belimumab) was approved in 2011 by the FDA for the treatment of lupus. It is the first novel therapy approved in the last 50 years. Current therapies such as non-steroidal anti-inflammatory drugs, or NSAIDs, corticosteroids and immunosuppressants generally act to hold back broadly the proliferation of many types of cells, including white blood cells. However, use of these agents is associated with significant adverse events and broad immune suppression.

Several new biological agents under development have targeted BAFF (or BLyS) and other B-cell related pathways for the treatment of lupus. These product candidates include Benlysta (belimumab) from Human Genome Sciences, Inc., tabalumab (LY2127399) from Eli Lilly and Company, atacicept, or TACI-Ig, from ZymoGenetics Inc. and epratuzumab from Immunomedics, Inc., as well as others acting via non B-cell mechanisms, such as Lupuzor from Cephalon. We believe that blisibimod may offer potential differentiation from these agents, including demonstrated dosing flexibility with both subcutaneous and intravenous delivery; selective modulation and reduction of relevant B-cell types in lupus patients; the ability to inhibit the activity of both membrane-bound and soluble BAFF; the use of a bacterial expression platform which is expected to translate to lower manufacturing costs compared with therapeutic antibodies; and distinct patent protection based on a novel and proprietary technology developed and commercialized by Amgen.

Compound	Stage	Company	Indications	Notes
Benlysta (belimumab) (intravenous and subcutaneous)	Approved	GlaxoSmithKline plc	Lupus, Lupus Nephritis, Idiopathic Membranous Nephropathy	• Monoclonal antibody against soluble BAFF • Positive results reported in two Phase 3 clinical studies • Phase 3 trials in lupus (evaluating subcutaneous administration) and lupus nephritis ongoing • Phase 2 trial in membranous nephropathy ongoing
LY2127399 (subcutaneous)	Phase 3	Eli Lilly and Company	Lupus, Rheumatoid Arthritis,	• Monoclonal antibody against BAFF inhibits soluble and membrane-bound BAFF

			Multiple Myelomas	• Phase 3 rheumatoid arthritis trial recently halted
Atacicept (intravenous)	Phase 3	ZymoGenetics Inc./Merck Serono S.A.	Lupus	• TACI receptor fused to human Fc which targets BAFF and APRIL; Phase 2/3 clinical study in lupus ongoing
Epratuzumab (intravenous)	Phase 3	Immunomedics, Inc./UCB S.A.	Lupus, Non-Hodgkin's Lymphoma	• Humanized antibody against CD-22, an agent that specifically targets B-cells and leads to partial depletion of peripheral B-cells • Initiating Phase 3 clinical studies in severe lupus ongoing
Lupuzor (subcutaneous)	Phase 3	Cephalon, Inc./ImmuPharma PLC	Lupus	• Modulates CD 4 T cells • Positive Phase 2b clinical study results

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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.

Blisibimod

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

- Two U.S. patents;
- One pending U.S. non-provisional patent application;
- Two European Patents or 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;
- Fifteen non-EP foreign patents in Australia, Canada, China, Estonia, Eurasia (validated in all nine Eurasian countries), Hong Kong, Japan, New Zealand, Norway, the Philippines, Poland, Singapore, South Korea and South Africa; and
- Eleven pending non-EP foreign patent applications in Brazil, Bulgaria, China, the Czech Republic, Hong Kong, Hungary, Israel, Mexico, Norway, Poland, Serbia, Montenegro and Slovakia.

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 pending U.S. non-provisional patent application, one EP patent, one pending EP patent application, 14 non-EP foreign patents, and over 40 pending non-EP foreign patent applications relating to general peptibody compositions and formulations.

The exclusively licensed U.S. patents are currently scheduled to expire in May 2022 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 May 2027 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 European 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.

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The U.S. patent system permits the filing of provisional and non-provisional patent applications. A non-provisional patent application is examined by the U.S. Patent 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.

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

Licenses

Amgen

In December 2007, we entered into a license agreement with Amgen, which was amended in October 2009, 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.

Under the agreement, we obtained exclusive rights under the licensed patents and know-how to research, develop, make, have made, use, sell, offer for sale and import pharmaceutical products containing blisibimod, as well as the right to grant sublicenses. 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.

During the seven-year period after execution of the agreement, Amgen is prohibited from clinically developing or commercializing any BAFF peptibody. Similarly, we are prohibited during the term of the agreement from clinically developing or commercializing any molecule other than blisibimod that modulates BAFF as the primary intended therapeutic mechanism of action.

We paid a first installment fee of $3.0 million and a second installment fee of $3.0 million. 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, European Union or Japan. 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 license 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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Terminated Licenses

Eli Lilly and Shionogi & Co., Ltd.

In July 2006, we entered into a license agreement with Eli Lilly and Company or Eli Lilly and Shionogi & Co., Ltd., pursuant to which we obtained an exclusive license in all countries except for Japan to certain technology and compounds relating to sPLA2 inhibitors. The licensed technology was largely developed under a research and development agreement between Eli Lilly and Shionogi & Co., Ltd., which was entered into between the parties in August 1992 and terminated in December 2004.

Under the agreement, we obtained exclusive rights to (i) use licensed patent rights and know-how to identify and develop sPLA2 inhibitors, (ii) develop, make, have made, use, import, offer for sale and sell licensed compounds and pharmaceutical formulations thereof, including varespladib, varespladib sodium, A-003 and other sPLA2 inhibitors and (iii) grant sublicenses. The licensed patent rights include a specific set of previously filed U.S. and foreign patents and applications, as well as any applications filed after the execution date by Eli Lilly or Shionogi & Co., Ltd. that relate to licensed know-how. Certain patents and applications within the licensed patent rights are defined as "core patents." Although the agreement does not allow us to sell or offer for sale licensed products in Japan, it does allow us to conduct preclinical and clinical studies in Japan in support of applications for marketing authorization outside of Japan, and to make and have made licensed products in Japan for use or sale outside of Japan. Eli Lilly and Shionogi & Co., Ltd. retain the right to use licensed products for research purposes only. Eli Lilly also retains the right to conduct studies of specific compounds in animals for research purposes, but only with our prior written approval. In addition, Shionogi & Co., Ltd. retains the non-exclusive right to make and have made licensed products for supply to us, as well as its rights to continue research, development and marketing of licensed technology in Japan.

Upon entering into the license agreement, we assumed control of all prosecution and maintenance of core patents prosecuted and maintained by Eli Lilly prior to the agreement. All core patents prosecuted and maintained by Shionogi & Co., Ltd. prior to the agreement remained under the control of Shionogi & Co., Ltd. Licensed patent rights that were not classified as core remained under the control of Eli Lilly and Shionogi & Co., Ltd. However, control of certain of these patents and applications has since been transferred to us following the decision by Eli Lilly or Shionogi & Co., Ltd. to discontinue prosecution and maintenance.

Upon entering into the license agreement, we made one-time payments of cash in the amount of $250,000 and issued shares of convertible preferred stock with a total aggregate value of $2.3 million to Eli Lilly and Shionogi & Co., Ltd. Based on the recommendation of the DSMB in March 2012 to terminate the VISTA-16 study of varespladib, we do not expect to engage in any further development activities of our sPLA2 portfolio, including varespladib and varespladib sodium. Therefore, we do not expect to incur further payments to our collaborators. In August 2012, we provided notice of termination to Eli Lilly to terminate the license agreement. The license agreement was effectively terminated in November 2012 and U.S. Investigational New Drug application, or IND was withdrawn in January 2013.

Manufacturing and Supply

We currently rely on contract manufacturers to produce drug substances and drug products required for our clinical studies under current Good Manufacturing Practice ("cGMP") 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 candidate if and when approved for marketing by the FDA. Should a supplier or a manufacturer on which we have relied to produce a product candidate provide us with a faulty product or such product is later recalled, we would likely experience significant delays and material additional costs.

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 candidate. In order to commercialize our product candidate, we must 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 candidate alone. In therapeutic areas that require a large sales force selling to a large and diverse prescribing population, we currently plan to partner with third parties to commercialize our product candidate while retaining rights to co-promote our products to a select audience of high prescribing physicians in the United States, thereby supplementing or enhancing the efforts of a commercial partner. We also plan to seek commercialization partners for products in non-specialty and international markets.

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We intend to build the commercial infrastructure necessary to bring our product candidate to market alone or in collaboration with a co-development or co-promotion partner. 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 the product.

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 candidate must be approved by the FDA through the new drug application, or NDA, process, and our biological product candidate, blisibimod, must be approved by the FDA through the biologics license application, or BLA, process before they may legally be marketed in the United States.

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, a clinical hold, 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:

- 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 candidate 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. Preclinical 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 will also include a protocol detailing, among other things, the objectives of the initial clinical study, 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 preclinical 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.

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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. Protocols detail, among other things, the objectives of the clinical study, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety.

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 and safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse events. Phase 1, Phase 2 and Phase 3 testing may not be completed successfully within any specified period, if at all. The FDA 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.

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 candidate 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 candidate does not undergo unacceptable deterioration over its 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, which was reauthorized under the Food and Drug Administration Amendments Act of 2007, 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. 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.

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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

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 candidate, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term 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 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.

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. HR 3590 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.

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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. The current pediatric exclusivity provision was reauthorized in September 2007.

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 United States 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, 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 our product candidate 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.

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 meet certain criteria. Specifically, new drugs and biological products are eligible for fast track designation if they 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.

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The Food and Drug Administration Safety and Innovation Act (FDASIA) includes a provision that allows sponsors to 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 1 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 1 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.

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.

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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.

Failure to comply with any requirements under the new law may result in significant penalties. The new law also authorizes significant civil money penalties for the dissemination of false or misleading direct-to-consumer advertisements and allows the FDA to require companies to submit direct-to-consumer television drug advertisements for FDA review prior to public dissemination. Additionally, the new law expands the clinical study registry so that sponsors of all clinical studies, except for Phase 1 clinical studies, are required to submit certain clinical study information for inclusion in the clinical study registry data bank. 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.

Reimbursement

Sales of pharmaceutical products depend significantly on the availability 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. However, these 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 candidate 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.

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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, in March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, and the associated reconciliation bill, which we refer to collectively as the Health Care Reform Law, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Effective October 1, 2010, the Health Care Reform Law revises the definition of "average manufacturer price" for reporting purposes, which could increase the amount of Medicaid drug rebates to states once the provision is effective. Further, beginning in 2011, the new law imposes a significant annual fee on companies that manufacture or import certain branded prescription drug products and biologic agents. Substantial new provisions affecting compliance also have been enacted, which may require us to modify our business practices with healthcare practitioners. We will not know the full effects of the Health Care Reform Law until applicable federal and state agencies issue regulations or guidance under the new law. Although it is too early to determine the effect of the Health Care Reform Law, the new law appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and also may increase our regulatory burdens and operating costs.

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. Medicare Part D went into effect on January 1, 2006. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities which will provide coverage of outpatient prescription drugs. Part D 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. 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.

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.

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 candidate and operate profitably.

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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 candidate 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.

Employees

As of December 31, 2012, we had 23 employees. All of our employees are engaged in administration, finance, clinical, 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 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.

The mailing address of our headquarters is 25801 Industrial Blvd, 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.

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ITEM 1A. RISK FACTORS

Before you decide to invest in our common stock, you should carefully consider the risks described below, together with the other information contained in this Annual Report on Form 10-K, including the financial statements and the related notes that appear at the end of this report. We believe the risks described below are the risks that are material to us as of the date 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. In these circumstances, the market price of our common stock could 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 development stage company with only eight years of operating history. We have focused primarily on developing our three product candidates, blisibimod, varespladib and varespladib sodium. The two latter product candidates were terminated in March 2012. We have financed our operations exclusively through equity offerings, private placements of convertible debt, and debt financings and we have incurred losses in each year since our inception in September 2004. As of December 31, 2012, we had an accumulated deficit of approximately $260.4 million. Substantially all of our losses resulted from costs incurred in connection with our product development programs and from general and administrative costs associated with our operations.

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

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

Our ability to generate revenue and achieve profitability depends on our ability, alone or with collaborators, to successfully complete the development of our product candidates, conduct preclinical tests in animals and clinical studies in human beings, obtain the necessary regulatory approvals for our product candidate and commercialize any approved products. We have not generated any revenue from our development-stage product candidate, and we do not know when, or if, we will generate any revenue. The commercial success of our development-stage product candidate will depend on a number of factors, including, but not limited to, our ability to:

- obtain favorable results for and advance the development of our product candidate blisibimod for the treatment of B-cell mediated autoimmune diseases, including successfully launching and completing clinical studies in patients with systemic lupus erythematosus, or lupus, IgA nephropathy, or other indications related to the development of blisibimod;
- obtain regulatory approval for blisibimod;
- if regulatory approvals are obtained, begin the commercial manufacturing of our product candidate with third-party manufacturers;
-

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

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

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

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Our drug discovery efforts may not produce any other viable or marketable product candidates.

Even if our product candidate is approved for commercial sale, the approved product candidate may not gain market acceptance or achieve commercial success. Physicians, patients, payors or the medical community in general may be unwilling to accept, utilize or recommend our product. We would anticipate incurring significant costs associated with commercializing any approved product. Even if we are able to generate product sales, which we cannot guarantee, we may not achieve profitability soon thereafter, if ever. If we are unable to generate product revenues, we will not become profitable and may be unable to continue operations without additional funding.

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

We will need to raise substantial additional capital to fund our operations and to develop our product candidate. Our future capital requirements could be substantial and 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 candidate;
- manufacturing campaign for blisibimod clinical matters, including formulation development and product enhancement;
- non-clinical activities that we may pursue parallel to our clinical studies;
- the cost, timing and outcomes of regulatory proceedings;
- payments received under any strategic collaborations;
- the filing, prosecution and enforcement of patent claims;
- the costs associated with commercializing our product candidate 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 candidate; and
- revenues received from approved products, if any, in the future.

As of the date of this report, we anticipate that our existing cash, cash equivalents and short-term investments, will enable us to meet our obligations and sustain our operations through at least the next 12 months. Changing circumstances may cause us to consume capital significantly faster than we currently anticipate. Additional financing may not be available when we need it or may not be available on terms that are favorable to us. If adequate funds are not available to us on a timely basis, or at all, we may be required to:

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

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

In December 2007, we entered into a license agreement with Amgen Inc., or Amgen, pursuant to which we obtained an exclusive worldwide license to certain technology and compounds relating to blisibimod. Pursuant to our license agreement with Amgen, 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 double digits as net sales increase. The timing of our achievement of these events and corresponding milestone payments becoming due to Amgen is subject to factors relating to the clinical and regulatory development and commercialization of blisibimod, 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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Our limited operating history makes it difficult to evaluate our business and prospects.

We were incorporated in September 2004. Our operations to date have been limited to organizing and staffing our company, acquiring product and technology rights, conducting product development activities for our primary product candidates, blisibimod, varespladib and varespladib sodium (the two latter product candidates were terminated in March 2012), and performing research and development. We have not yet demonstrated an ability to obtain regulatory approval for or commercialize a product candidate. Consequently, any predictions about our future performance may not be as accurate as they could be if we had a history of successfully developing and commercializing pharmaceutical products.

Risks Associated with Development and Commercialization of Our Product Candidate

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

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

Our lead product candidate blisibimod has completed several Phase 1 and Phase 2 clinical studies. In July 2010, we received clearance from the FDA to begin recruitment of lupus patients into the PEARL-SC Phase 2b clinical study. In November 2010, we placed a voluntary hold on the PEARL-SC study due to problems found with vials. Patient enrollment in the study was temporarily suspended and dosing was discontinued in patients who were enrolled in the study while we conducted an analysis of the problem. We resolved the issues found with the vials in December 2010. After analysis, simulation and consultation with industry experts, we determined that shipping on dry ice was the root cause of the issue. Shipping logistics were modified and we reinitiated enrollment in PEARL-SC and dosing in January 2011. We have received no reports of patient-related side effects or problems with drug administration that could be attributed to the vial problem. On October 24, 2011 we filed an amendment with the FDA for the PEARL-SC clinical study to modify the primary efficacy SLE response index and to include an option for an interim efficacy analysis. The trial was completed and results were announced during 2012.

Our product candidate is prone to the risks of failure inherent in drug development. Before obtaining regulatory approvals for the commercial sale of any product candidate 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 candidate is safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate. Despite our efforts, our product candidate 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 blisibimod our product candidate in the United States until we receive approval of a biologics license application, or BLA, from the FDA, or in any foreign countries until we receive the requisite approval from such countries. We have not submitted a BLA or received marketing approval for our product candidate.

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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.

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

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 a product candidate or other materials for use in clinical studies;
- obtaining institutional review board, or IRB, approval or the approval of other reviewing entities to conduct a clinical study at a prospective site;
- 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. For example, while an independent statistician had completed an analysis of various biomarkers of cardiovascular risk and determined that treatment with once-daily varespladib met the pre-specified criteria for the VISTA-16 study to proceed, an independent DSMB reviewing the clinical data from the VISTA-16 study recommended the clinical study be discontinued due to a lack of efficacy that could not be overcome in the remainder of the trial. In addition, a clinical study may be suspended or terminated by us, the FDA, the IRB or other reviewing entity overseeing the clinical study at issue, any of our clinical study sites with respect to that site, or other regulatory authorities due to a number of factors, including:

- failure to conduct the clinical study in accordance with regulatory requirements or our clinical protocols;

- inspection of the clinical study operations or study sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;

- unforeseen safety issues or any determination that a clinical study presents unacceptable health risks; and

- lack of adequate funding to continue the clinical study, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional clinical studies and increased expenses associated with the services of our CROs and other third parties.

Product development costs to us and our collaborators will increase if we have delays in testing or approval of our product candidate 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 delaying factors outside our control.

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Additionally, changes in regulatory requirements and policies may occur and we may need to amend clinical study protocols to reflect these changes. Amendments may require us to resubmit our clinical study protocols to IRBs for reexamination, 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 candidate 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 a product candidate. 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, blisibimod or any other 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 candidate, 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 candidate. If later stage clinical studies do not produce favorable results, our ability to achieve regulatory approval for our product candidate may be adversely impacted. Even if we believe that our product candidate has performed satisfactorily in preclinical testing and clinical studies, we may nonetheless fail to obtain FDA approval for our product candidate.

If we breach the license agreement for our primary product candidate, we could lose the ability to continue the development and commercialization of our primary product candidate.

We are party to an agreement with Amgen containing exclusive, worldwide licenses of the composition of matter and methods of use for blisibimod. The agreement requires us to make timely milestone and royalty payments, provide regular information, maintain the confidentiality of and indemnify Amgen under the terms of the agreement.

If we fail to meet these obligations, our licensor may terminate our exclusive license and may be able to re-obtain licensed technology and aspects of any intellectual property controlled by us that relate to the licensed technology that originated from the licensor. Our licensor could effectively take control of the development and commercialization of blisibimod after an uncured, material breach of our license agreement by us or if we voluntarily terminate the agreement. 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 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 could result in our loss of exclusive rights and may lead to a complete termination of our product development and any commercialization efforts for blisibimod.

Our industry is subject to intense competition. If we are unable to compete effectively, our product candidate 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 candidate obsolete or non-competitive, which could adversely affect our revenue potential. Key competitive factors affecting the commercial success of our product candidate is likely to be efficacy, safety profile, reliability, convenience of dosing, price and reimbursement.

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The market for inflammatory disease therapeutics is especially large and competitive. For lupus, Human Genome Sciences, Inc.'s and GlaxoSmithKline plc's BAFF antagonist monoclonal antibody, Benlysta, was recently approved by the FDA for treatment of lupus. Further, we are aware of companies with other products in development that are being tested for potential treatment of lupus, Bristol-Myers Squibb Company and Merck Serono S.A., whose dual BAFF/APRIL antagonist fusion protein, Atacicept, is in a Phase 3 clinical study for lupus; and Immunomedics, Inc. and UCB S.A., who recently reported favorable results for their CD-22 antagonist humanized antibody, epratuzumab, which completed a Phase 2b clinical study in lupus and has begun a Phase 3 study, and Eli Lilly's anti-BLYS monoclonal antibody, LY2127399, which has begun two Phase 3 studies.

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, obtaining FDA and other regulatory approvals of products and the commercialization of those products. Accordingly, our competitors may be more successful than we may be in obtaining FDA approval for drugs and achieving widespread market acceptance. Our competitors' drugs may be more effective, have fewer adverse effects, be less expensive to develop and manufacture or be more effectively marketed and sold than any product candidate we may commercialize and may render our product candidate obsolete or non-competitive before we can recover the expenses of developing and commercializing our product candidate. 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 candidate 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 candidate 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. Phase 2 clinical studies conducted by us with our product candidate have generated differences in adverse effects and serious adverse events. The most common adverse effects seen with any of our product candidates versus placebo include diarrhea, headache, nausea and increases in alanine aminotransferase, which is an enzyme that indicates liver cell injury. The most common serious adverse events seen with any of our product candidates include death, VOC and congestive heart failure. A Phase 3 clinical study conducted by us with our terminated product candidate varespladib has generated differences in adverse effects and serious adverse events. In the VISTA-16 clinical study the most common adverse effects seen included cardiac disorders, gastrointestinal disorders, general disorders and other nervous system and respiratory disorders. There were more cardiovascular events in the varespladib arm of this study versus the placebo (117 versus 95, p=0.113). This finding was driven by a significantly higher occurrence of non-fatal myocardial infarction in those patients treated with varespladib compared to those treated with placebo. While none of these serious adverse events were considered related to the administration of our product candidates by the clinical investigators, if serious adverse events that are considered related to our product candidate is observed in any Phase 3 clinical studies, our ability to obtain regulatory approval for our product candidate may be adversely impacted. Further, if our product candidate receives marketing approval and we or others later discover, after approval and use in an increasing number of patients, that our product could have adverse effect profiles that limit their usefulness or require their withdrawal (whether or not the therapies showed the adverse effect profile in Phase 1 through Phase 3 clinical studies), a number of potentially significant negative consequences could result, including:

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

- we may be required to change the way the product is administered, conduct additional clinical studies or change the labeling of the product;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

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

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

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Even if we project positive clinical results and file for regulatory approval, we cannot commercialize our product candidate until the appropriate regulatory authorities have reviewed and approved the applications for such product candidate. We cannot assure you that the regulatory agencies will complete their review processes in a timely manner or that we will obtain regulatory approval for any product candidate 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 candidate 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. Our product candidate 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 a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. If we, our product candidate or the manufacturing facilities for our product candidate fail to comply with applicable regulatory requirements, a regulatory agency may:

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

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

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

New federal legislation or regulatory requirements could affect the requirements for obtaining regulatory approvals of our product candidate or otherwise limit our ability to commercialize any approved products or subject our products to more rigorous post-approval requirements. For example, the FDA Amendments Act of 2007, or FDAAA, granted the FDA new authority to impose post-approval clinical study requirements, require safety-related changes to product

labeling and require the adoption of risk management plans, referred to in the legislation as risk evaluation and mitigation strategies, or REMS. The REMS may include requirements for special labeling or medication guides for patients, special communication plans to health care professionals, and restrictions on distribution and use. Pursuant to the FDAAA, if the FDA makes the requisite findings, it might require that a new product be used only by physicians with specified specialized training, only in specified designated health care settings, or only in conjunction with special patient testing and monitoring. The legislation also included the following: requirements for providing the public information on ongoing clinical studies through a clinical study registry and for disclosing clinical study results to the public through such registry; renewed requirements for conducting clinical studies to generate information on the use of products in pediatric patients; and substantial new penalties, for example, for false or misleading consumer advertisements. Other proposals have been made to impose additional requirements on drug approvals, further expand post-approval requirements, and restrict sales and promotional activities. The new legislation, and the additional proposals if enacted, may make it more difficult or burdensome for us to obtain approval of our product candidate, 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.

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

The commercial success of our product candidate for which we obtain marketing approval from the FDA or other regulatory authorities will depend upon the acceptance of the product by the medical community, including physicians, patients and health care payors. The degree of market acceptance of any 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 blisibimod in the treatment of lupus;
- 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 candidate is approved but do not achieve an adequate level of acceptance by physicians, health care payors and patients, we may not generate sufficient revenue from the product, 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 candidate may require significant resources and may never be successful.

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

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

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

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

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

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

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

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

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

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

The use of our product candidate 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;

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- substantial monetary awards to patients or other claimants;
- the inability to commercialize our product candidate; and
- decreased demand for our product candidate, if approved for commercial sale.

Our product liability insurance coverage for our clinical studies may not be sufficient to reimburse us for all expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If and when we obtain marketing approval for our 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 candidate 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 clinical drug supplies and on which we intend to rely to produce commercial supplies of our approved product candidate may delay or impair our ability to commercialize our product candidate.

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 candidate 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 candidate or market them.

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Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured our product candidate 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 candidate 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 candidate 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 of our product candidate in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of our product candidate. In addition, such failure could be the basis for action by the FDA to withdraw approvals for product candidates previously granted to us and for other regulatory action, including recall or seizure, total or partial suspension of production or injunction.

In December 2011, we completed the technology transfer from Amgen and manufacturing scale up to 3,000 liters at our contract manufacturing organization, or CRO (Fujifilm Diosynth Bioservices or “Fujifilm”). Two (2) batches of blisibimod produced under FDA good manufacturing procedures, or GMP, at the 3,000 liter scale passed all physical quality specifications and comparability assessments. We submitted plans to the FDA on March 4, 2011 and September 9, 2011 establishing criteria to demonstrate comparability of blisibimod manufactured by Fujifilm to that manufactured by Amgen. Data confirming comparability to Phase 1 material (Amgen) was filed with the FDA on August 8, 2011 and September 8, 2011. In September 2012, we received comments from the FDA on the submissions listed above. The FDA agreed that the material manufactured by Fujifilm was comparable to that previous manufactured by Amgen.

We rely on our manufacturers to purchase from third-party suppliers the materials necessary to produce our product candidate for our clinical studies. There are a small number of suppliers for certain capital equipment and raw materials that we use to manufacture our drugs. Such suppliers may not sell these raw materials 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 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 a product candidate to complete the clinical study, any significant delay in the supply of a product candidate 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 of our product candidate. If our manufacturers or we are unable to purchase these raw materials after regulatory approval has been obtained for our product candidate, the commercial launch of our product candidate would be delayed or there would be a shortage in supply of such product candidate, which would impair our ability to generate revenues from the sale of our product candidate.

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 any of our drugs, 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, the satisfaction of which on a timely basis may not be met.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidate, 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 we may receive regulatory approval.

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Government agencies issue regulations and guidelines directly applicable to us and to our product candidate. 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. For example, organizations like the American Heart Association have made recommendations about therapies in the cardiovascular therapeutics market. Changes to these recommendations or other guidelines advocating alternative therapies could result in decreased use of any products for which we may receive regulatory approval, which may adversely affect our results of operations.

Risks Related to Our Intellectual Property

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

As of the date of this report, we hold license rights to numerous U.S. EP, and non-EP foreign patents and patent applications for blisibimod. Our blisibimod portfolio includes exclusively and non-exclusively licensed patents and patent applications from Amgen, Inc.

We also own several U.S. and non-U.S. patents and patent applications relating to our terminated varespladib sodium/varespladib programs. These patents and patent applications include both patents and patent applications originally filed by Anthera and patents assigned to Anthera by Eli Lilly or Shionogi & Co., Ltd. Our varespladib sodium/varespladib portfolio previously included a larger set of patents and patent applications relating to sPLA2 inhibiting compounds and exclusively licensed from Eli Lilly Shionogi & Co., Ltd. In August 2012, we provided notice of termination to our collaborators to terminate the license agreement. The license agreement was effectively terminated in November 2012. Due to termination of the varespladib programs, we do not expect to incur further payments to our collaborators under the license agreement.

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 candidate 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 candidate 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 candidate and any future products are covered by valid and enforceable patents or are effectively maintained as trade secrets.

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

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

- we or our licensors were the first to file patent applications for these inventions;
- others will not independently develop similar or alternative technologies or duplicate any of our technologies;
- any of our or our licensors' pending patent applications will result in issued patents;
- any of our or our licensors' patents will be valid or enforceable;
- any patents issued to us or our licensors and collaborators will provide a basis for commercially viable products, will provide us with any competitive advantages or will not be challenged by third parties;
- we will develop additional proprietary technologies or product candidates that are patentable; or
- the patents of others will not have an adverse effect on our business.

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

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

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

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

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 previously had obtained exclusive, worldwide licenses, except for Japan, of the composition of matter, methods of making and methods of use for certain sPLA2 compounds from Eli Lilly and Shionogi & Co., Ltd. In August 2012, we provided notice of termination to our collaborators to terminate the license agreement. The license agreement was effectively terminated in November 2012. Due to termination of the varespladib programs, we do not expect to incur further payments to our collaborators under the license agreement. We may enter into additional licenses to third- party intellectual property in the future.

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

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

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

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The United States Drug Price Competition and Patent Term Restoration Act of 1984, more commonly known as the "Hatch-Waxman Act," provides for an extension of patent term for drug compounds for a period of up to five years to compensate for time spent in the regulatory approval process. Assuming we gain a five-year patent term extension for blisibimod and that we continue to have rights under our license agreement with respect to blisibimod, we would have exclusive rights to blisibimod's U.S. new chemical entity patent 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. Assuming we gain such a five-year extension for blisibimod and that we continue to have rights under our license agreement with respect blisibimod, we would have exclusive rights to blisibimod's European new chemical entity patents until 2027. Further, since blisibimod has not been previously approved, blisibimod could be eligible for 12 years of data exclusivity from the FDA. During the 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 molecule compound or biologic will have a 10-year period of data exclusivity for that compound or 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 new chemical entity patent covering such compound expires. A generic version of the approved drug may not be marketed or sold during such market exclusivity period. However, there is no assurance that we will receive the extensions of our patents or other exclusive rights available under the Hatch-Waxman Act or similar foreign legislation. If we fail to receive such Hatch-Waxman extensions or marketing exclusivity rights or if we receive extensions that are materially shorter than expected, our ability to prevent competitors from manufacturing, marketing and selling generic versions of our products will be materially harmed.

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

We typically develop our 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 these product candidates, we may file additional patent applications for these new inventions or we may need to ask our licensors to file them. We may also need to license additional patent rights or other rights on compounds, treatment methods or manufacturing processes because we learn that we need such rights during the continuing development of our product candidates.

Although our in-licensed and original patents may prevent others from making, using or selling similar products, they do not ensure that we will not infringe the patent rights of third parties. We may not be aware of all patents or patent applications that may impact our ability to make, use or sell any of our product candidate or proposed 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 candidate. 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 drug 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 our product candidate 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 candidate 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 candidate, 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.

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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 candidate or the enforceability, validity or scope of protection offered by our patents relating to our product candidate.

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 candidate to market; or be precluded from participating in the manufacture, use or sale of our product candidate or methods of treatment requiring licenses.

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

Our common stock is currently at risk for delisting from NASDAQ in June 2013. Delisting could adversely affect the liquidity of our common stock and the market price of our common stock could decrease.

Our common stock is currently listed on The NASDAQ Global Market, or NASDAQ. NASDAQ has minimum requirements that a company must meet in order to remain listed on NASDAQ. These requirements include maintaining a minimum closing bid price of $1.00 per share.

On December 20, 2012, we received a letter from The Nasdaq Global Stock Market informing us that for the last 30 consecutive business days the bid price of our common stock has closed below the minimum $1.00 per share requirement for continued inclusion under Listing Rule 5450(a)(1). The letter stated that Nasdaq will provide the Company a grace period of 180 calendar days, or until June 18, 2013, to regain compliance. To regain compliance, any time before June 18, 2013, the bid price of our common stock must close at $1.00 per share or more for a minimum of 10 consecutive business days.

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

If our common stock is not listed on NASDAQ or another national exchange, the trading price of our common stock is below $5.00 per share and we have net tangible assets of $6,000,000 or less, the open-market trading of our common stock will be subject to the "penny stock" rules promulgated under the Securities Exchange Act of 1934, as amended. If our shares become subject to the "penny stock" rules, broker-dealers may find it difficult to effectuate customer transactions and trading activity in our securities may be adversely affected. Under these rules, broker-dealers who recommend such securities to persons other than institutional accredited investors must:

- make a special written suitability determination for the purchaser;
- receive the purchaser's written agreement to the transaction prior to sale;
- provide the purchaser with risk disclosure documents which identify certain risks associated with investing in "penny stocks" and which describe the market for these "penny stocks" as well as a purchaser's legal remedies; and

- obtain a signed and dated acknowledgement from the purchaser demonstrating that the purchaser has actually received the required risk disclosure document before a transaction in a “penny stock” can be completed.

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

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

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

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

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

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

Our executive officers, directors and greater than 5% stockholders, in the aggregate, own approximately 30% of our outstanding common stock. As a result, such persons, acting together, will have the ability to control our management and affairs and substantially all matters submitted to our stockholders for approval, including the election and removal

of directors and approval of any significant transaction. These persons will also have the ability to control our management and business affairs. This concentration of ownership may have the effect of delaying, deferring or preventing a change in control, impeding a merger, consolidation, takeover or other business combination involving us, or discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of our business, even if such a transaction would benefit other stockholders.

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

As of December 31 2011 and December 2012, there were 40,933,354 and 79,151,592, shares respectively, of our common stock outstanding. In January 2013, we issued 60,606,061 shares at an initial closing of a public offering, followed by a second closing of 9,090,909 shares in February 2013. In addition, as of December 31, 2012, we had outstanding options to purchase shares of our common stock, restricted stock units and warrants of 7,440,521 that, if exercised or released, will result in these additional shares becoming available for sale. A large portion of these shares and outstanding equity awards are held by a small number of persons and investment funds. Sales by these stockholders or option holders of a substantial number of shares could significantly reduce the market price of our common stock. Moreover, certain holders of shares of common stock will have rights, subject to some conditions, to require us to file registration statements covering the shares they currently hold, or to include these shares in registration statements that we may file for ourselves or other stockholders.

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We have registered all common stock that we may issue under our Amended and Restated 2010 Stock Option and Incentive Plan (the "2010 Plan") and our Employee Stock Purchase Plan (the "ESPP"). As of December 31, 2012, an aggregate of 3,386,379 shares of our common stock has been reserved for future issuance under the 2010 Plan, plus any shares reserved and unissued or cancelled under our 2005 Equity Incentive Plan, and an aggregate of 600,000 shares has been reserved for future issuance under our ESPP. These shares can be freely sold in the public market upon issuance. If a large number of these shares are sold in the public market, the sales could reduce the trading price of our common stock.

We filed a universal shelf registration statement with the SEC on Form S-3 (File No. 333-179043) on January 17, 2012, which was declared effective on January 24, 2012, 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. In July 2012, we issued 37,950,000 shares at $1.00 per share pursuant to the shelf registration, raising net proceeds of approximately $35.6 million. In January 2013, we issued 60,606,061 shares at $0.66 per share pursuant to the shelf registration at an initial closing of a public offering, followed by 9,090,909 at a second closing in February 2013, raising net proceeds of approximately $43.0 million.

On November 8, 2012, we entered into an At Market Issuance Sales Agreement (the "Agreement") with MLV & Co. LLC ("MLV"), 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 (the "Shares") through MLV, as agent. We have not sold any shares of our common stock pursuant to the Agreement, which was terminated effective January 24, 2013. This facility is no longer available for use.

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

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

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

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, our administrative staff will be required to perform additional tasks. For example, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, as well as rules subsequently implemented by the SEC and The NASDAQ Global Market, impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. We must also bear all 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. In 2012, our independent registered public accounting firm was not required to report on the effectiveness of internal control over

financial reports due to the exemptions allowed to small companies as part of the Investor Protection 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, our stock price could decline, and we could face sanctions, delisting or investigations by The NASDAQ Global Market, or other material adverse effects on our business, reputation, results of operations, financial condition or liquidity.

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

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

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

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

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

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

Our ability to use our net operating loss carryforwards will 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 incurred an ownership change within the meaning of Section 382 ownership of the Internal Revenue Code during 2012 and as such, our net operating loss carryforward 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.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

We lease our main operating facility in Hayward, California. We occupied 7,800 square feet under a sublease that commenced in the fourth quarter of 2008 and was then amended in April 2011. The new lease commenced on August 1, 2011 and includes approximately $245,000 in tenant improvement reimbursements from the landlord. Pursuant to the amendment, the lease increased the Company's square footage from 7,800 square feet to approximately 14,000 square feet. The new lease expires on September 30, 2014. We believe our existing facilities are 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.

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 has been listed on The NASDAQ Global Market under the symbol "ANTH" since our initial public offering ("IPO"). Prior to that offering, 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 2011	$ 6.99	$ 3.65
Second Quarter 2011	$ 9.08	$ 5.25
Third Quarter 2011	$ 8.63	$ 4.42
Fourth Quarter 2011	$ 7.45	$ 4.60
First Quarter 2012	$ 8.42	$ 2.20
Second Quarter 2012	$ 3.21	$ 0.68
Third Quarter 2012	$ 1.79	$ 0.60
Fourth Quarter 2012	$ 1.17	$ 0.58

Holders of our Common Stock

As of December 31, 2012, an aggregate of 79,151,592 shares of our common stock were issued and outstanding and were held by approximately 53 holders of record and beneficial holders, based on information provided by the Company's transfer agent. In January 2013, we issued 60,606,061 shares of our common stock at an initial closing of a public offering, followed by a second closing of 9,090,909 shares in February 2013. 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.

Performance Graph

The following graph shows a comparison of cumulative total return of our common stock, the NASDAQ Composite Index and the Nasdaq Biotech Index from March 1, 2010 (the first day our stock began trading on the NASDAQ Global Market through December 31, 2012. The graph and table assume that $100 was invested on March 1, 2010 in each of our common stock, the NASDAQ Composite Index and the NASDAQ Biotech Index, and that all dividends were reinvested. The past performance of our common stock is no indication of future performance.

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	3/1/2010	3/31/2010	6/30/2010	9/30/2010	12/31/2010	3/31/2011	6/30/2011	9/30/2011	12/31/2011
Anthera Pharmaceuticals, Inc.	$ 100.00	$ 99.71	$ 76.46	$ 59.77	$ 69.61	$ 96.29	$ 116.55	$ 68.05	$ 87.59
Nasdaq Composite	$ 100.00	$ 105.47	$ 92.77	$ 104.18	$ 116.68	$ 122.32	$ 121.99	$ 106.24	$ 114.58
Nasdaq Biotech	$ 100.00	$ 104.08	$ 88.66	$ 99.24	$ 107.53	$ 115.36	$ 122.85	$ 107.47	$ 120.23

	3/31/2012	6/30/2012	9/30/2012	12/31/2012
Anthera Pharmaceuticals, Inc.	$31.53	$9.70	$14.12	$8.84
Nasdaq Composite	$135.98	$129.09	$137.06	$132.81
Nasdaq Biotech	$142.00	$149.81	$164.72	$158.59

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 of this report.

Recent Sales of Unregistered Securities

All information under this Item has been previously reported on our Current Reports on Form 8-K, filed with the Securities and Exchange Commission (the “SEC”).

Issuer Purchases of Equity Securities

We did not repurchase any securities during the quarter ended December 31, 2012.

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

	Year Ended December 31,					Cumulative Period from September 9 2004 (Date of Inception) to December 31,
	2012	2011	2010	2009	2008	2012
Statement of Operations Data:						
Operating expenses						
Research and development	$49,219	$85,281	$29,457	$8,415	$10,882	$ 215,281

General and administrative	6,715	7,857	6,301	3,426	2,980	30,790
Total operating expenses	55,934	93,138	35,758	11,841	13,862	246,071
Loss from operations	(55,934)	(93,138)	(35,758)	(11,841)	(13,862)	(246,071)
Other Income (Expense)						
Other income (expense)	(111)	606	(15)	(192)	178	1,500
Interest expense	(3,354)	(2,803)	(845)	(170)	(296)	(7,702)
Mark-to-market adjustment of warrant liability	—	—	(3,796)	—	—	(3,796)
Beneficial conversion feature	—	—	—	—	(4,119)	(4,309)
Total other income (expense)	(3,465)	(2,197)	(4,656)	(362)	(4,237)	(14,307)
Net loss	$(59,399)	$(95,335)	$(40,414)	$(12,203)	$(18,099)	$ (260,378)
Net loss per share—basic and diluted(1)	$(1.03)	$(2.55)	$(1.76)	$(8.06)	$(13.47)	
Weighted-average number of shares used in per share calculation—basic and diluted(2)	57,803,491	37,417,775	22,909,802	1,513,598	1,343,420	

(1) 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.

(2) Issued and outstanding shares do not include weighted-average shares of unvested stock for 2008 of 230,028, for 2009 of 110,079, for 2010 of 47,654, for 2011 of 13,374 and for 2012 of 1,098. These shares were subject to a risk of repurchase by us until such shares are vested.

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	As of December 31,				
	2012	2011	2010	2009	2008
Balance Sheet Data:					
Cash and cash equivalents	$19,431	$65,624	$40,030	$3,803	$7,895
Short-term investments	5,322	1,746	23,351	—	—
Working capital	6,429	37,742	57,241	(14,344)	(496)
Total assets	26,445	69,493	65,263	5,889	8,034
Notes Payable	20,550	24,331	—	—	—
Total liabilities	29,971	50,409	8,005	18,168	8,494
Convertible preferred stock	—	—	—	52,124	52,124
Deficit accumulated during the development stage	(260,378)	(200,979)	(105,644)	(65,230)	(53,026)
Total stockholders' (deficit) equity	(3,526)	19,084	57,258	(12,279)	(460)

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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 financial statements and the related notes set forth under "Item 8. 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

We are a biopharmaceutical company focused on developing and commercializing products to treat serious diseases associated with inflammation and autoimmune diseases. Our Phase 3 ready product candidate, blisibimod, targets elevated levels of B-cell activating factor, or BAFF, which has been associated with a variety of B-cell mediated autoimmune diseases, including system lupus erythematosus (SLE), or lupus, IgA nephropathy, lupus nephritis, vasculitis, rheumatoid arthritis, idiopathic thrombocytopenia purpura, and others.

Blisibimod is a peptibody antagonist of the BAFF cytokine that is initially being developed as a treatment for lupus. BLyS, also known as B-cell activating factor, or BAFF, is a tumor necrosis family member and is critical to the development, maintenance and survival of B-cells. It is primarily expressed by macrophages, monocytes and dendritic cells and interacts with three different receptors on B-cells including BAFF receptor, or BAFF-R, B-cell maturation, or BCMA, and transmembrane activator and cyclophilin ligand interactor, or TACI. The BAFF-R receptor is expressed primarily on peripheral B-cells.

We intend to advance the clinical development of our BAFF inhibitor, blisibimod, to exploit its broad potential clinical utility in a number of autoimmune diseases. Blisibimod, a peptibody directed against BAFF, was developed as an alternative to antibodies and is produced in Escherichia coli bacterial culture versus antibodies that are 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 and relatively small molecular weight. We have worldwide rights to blisibimod in all potential indications.

In June and July 2012, we announced results from our Phase 2b PEARL-SC clinical study in patients with SLE. In September 2012, we completed the End of Phase 2 discussions with the FDA and announced our intention to advance blisibimod into Phase 3 clinical trials for patients with SLE. The Phase 3 studies (CHABLIS-SC1 and CHABLIS-SC2) are planned to be multicenter, placebo-controlled, randomized, double-blind studies designed to evaluate the efficacy, safety, tolerability and immunogenicity of blisibimod in patients with clinically active SLE (SELENA-SLEDAI > 10) who require corticosteroid therapy in addition to standard-of-care for treatment of their disease. Each study will randomize approximately 400 patients to receive either 200mg of blisibimod or placebo for 52 weeks. As agreed with the FDA, the primary endpoint of the Phase 3 studies will be clinical improvement in the SRI-8 response at 52 weeks. We plan to conduct periodic interim analyses during the course of the CHABLIS-SC1 study to ensure the accuracy of our estimates. Following our initial interim analysis of clinical data from the CHABLIS-SC1 study we plan to initiate patient enrollment in our second Phase 3 clinical study, CHABLIS-SC2.

Results from the Phase 2b PEARL-SC study that was completed in 2012 showed a statistically significant treatment reduction in proteinuria in both the pooled blisibimod treatment group and the 200mg weekly blisibimod treatment group. Following the encouraging results from the Phase 2b PEARL-SC study, we plan to initiate patient enrollment in a Phase 2 proof-of-concept study for the treatment of IgA nephropathy (BRIGHT-SC) in 2013, our first orphan indication for the treatment renal disease and will serve as our initial catalyst for a Phase 3 path in renal diseases with

blisibimod. The BRIGHT-SC study will enroll approximately 48 patients with biopsy-proven IgAN who have proteinuria greater than one gram per 24 hours and are receiving standard of care. Patients will receive high dose blisibimod or placebo for 8 weeks, the induction phase, followed by 24 weeks, the maintenance phase, of 200mg weekly blisibimod or placebo. The primary endpoint of the BRIGHT-SC study will be improvements in proteinuria versus placebo after 32 weeks. We plan to conduct an interim analysis after the eight-week induction phase to determine effects of blisibimod on proteinuria.

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Two of our former product candidates, varespladib and varespladib sodium, were designed to inhibit a novel enzyme target known as secretory phospholipase A2, or sPLA2. Elevated levels of sPLA2 have been implicated in a variety of acute inflammatory conditions, including acute coronary syndrome and acute chest syndrome associated with sickle cell disease, as well as in chronic diseases, including stable coronary artery disease.

In March 2012, an independent data safety monitoring board (DSMB) recommended stopping our VISTA-16 clinical study for varespladib due to a lack of efficacy that could not be reasonably overcome in the remainder of the trial. The study was prematurely terminated by the DSMB because of the inability of VISTA-16 to detect a statistically significant benefit of the drug on the prespecified primary and secondary endpoints even if the trial continued to its scheduled termination with the proposed expanded sample size.

The same data reviewed by the DSMB were subsequently brought in-house and examined by a committee of medical and drug safety professionals. In addition to reviewing the primary endpoint data, this review included unblinded review of demographics, baseline characteristics, laboratory results, concomitant medications, treatment emergent adverse events (AEs), and serious adverse events (SAEs). No obvious clinical or scientific reason has been found for the increased hazard for non-fatal myocardial infarction amongst subjects treated with varespladib despite positive treatment-related changes in LDL-C and CRP. At the time of study termination the hazard ratio for the primary endpoint (time to first occurrence of the combined endpoint of cardiovascular death, non-fatal myocardial infarction, non-fatal stroke, or documented unstable angina with objective evidence of ischemia requiring hospitalization) was 1.244 (p=0.155). This is primarily driven by the increased occurrence of non-fatal myocardial infarction, a single component of the composite primary endpoint: HR 1.686 p=0.009.

In connection with the termination of varespladib and varespladib sodium, we implemented an organizational restructuring plan in 2012 that lowered operating expenses through headcount reductions and the elimination of certain vendor activities. We modified work orders with key vendors to ensure wind-down activities were efficient, while still maintaining patient safety as a top priority. We have reallocated our remaining resources to other potential development programs and product portfolio efforts. Based on the recommendation of the DSMB, we do not expect to engage in any further development activities of varespladib and varespladib sodium. Therefore, we provided notice of termination to the collaborators in August 2012 to terminate the license agreement. The license agreement was effectively terminated in November 2012.

We were incorporated and commenced operations in September 2004. Since our inception, we have generated significant losses. As of December 31, 2012, we had an accumulated deficit of approximately $260.4 million. In January 2012, Anthera Pharmaceuticals, Limited, a wholly-owned subsidiary, was incorporated in Ireland. The establishment of this subsidiary was part of the Company’s ongoing growth activities and strategic plan. As of the date of this filing, we have never generated any revenue and have generated only interest income from cash and cash equivalents and short-term investments. We expect to incur substantial and increasing losses for at least the next several years as we pursue the development and commercialization of our product candidates.

As of December 31, 2012, we have funded our operations through equity offerings, private placements of convertible debt and debt financings, raising net proceeds of approximately $260.0 million. 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 development-stage companies, we may never successfully complete development of any 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 any of our product candidates.

Revenue

To date, we have not generated any revenue. We do not expect to generate revenue unless or until we obtain regulatory approval of, and commercialize our product candidate or in-license additional products that generate revenue. We intend to seek to generate revenue from a combination of product sales, up-front fees and milestone payments in connection with collaborative or strategic relationships and royalties resulting from the licensing of the commercial rights to our intellectual property. We expect that any revenue we generate will fluctuate from quarter to quarter as a result of the nature, timing and amount of milestone payments we may receive upon the sale of our products, to the extent any are successfully commercialized, as well as any revenue we may receive from our collaborative or strategic relationships.

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Research and Development Expenses

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

We expense both internal and external research and development costs as incurred. 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, but rather are allocated across our clinical stage programs. 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 2012, 2011, and 2010, and for the period from September 9, 2004 (Date of Inception) through December 31, 2012 (in thousands):

	Years Ended December 31,			For the Period September 9, 2004 (Date of Inception) to December 31,
	2012	2011	2010	2012
Allocated costs:				
Varespladib	$ 20,468	$ 46,139	$ 19,230(1)	$ 113,699(1)(2)
Blisibimod	24,151	32,300	5,827	68,421(3)
Varespladib sodium	51	118	(12)	6,676
Unallocated costs	4,549	6,724	4,412	26,485
Total development	$ 49,219	$ 85,281	$ 29,457	$ 215,281

(1) Includes milestone payments of $3.5 million pursuant to amendments to the license agreements with each of Eli Lilly and Shionogi & Co. Ltd., which were paid in the form of shares of common stock.

(2) Includes license fees of $4.0 million pursuant to a license agreement with each of Eli Lilly and Shionogi & Co. Ltd., which were paid in cash and shares of preferred stock in 2006.

(3) Includes a one-time license initiation fee of $6.0 million pursuant to a license agreement with Amgen.

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

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

- the number of sites included in the studies;
- the length of time required to enroll suitable patient subjects;
- the number of patients that participate in the studies;
- the number of doses that patients receive;

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- the drop-out or discontinuation rates of patients; and
- the duration of patient follow-up.

Our expenses related to clinical studies are based on estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and clinical research organizations 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 depend on factors such as the successful enrollment of patients or the completion of clinical study milestones. Expenses related to clinical studies generally are accrued based on contracted amounts and the achievement of milestones such as number of patients enrolled. If timelines or contracts are modified based upon changes to the clinical study design or scope of work to be performed, we modify our estimates of accrued expenses accordingly on a prospective basis.

None of our product candidates have 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 executive and operational functions, including clinical, chemical manufacturing, regulatory, finance and business development. Other significant costs include professional fees for legal services, including legal services associated with obtaining and maintaining patents. We will continue to incur significant general and administrative expenses as a public company, including costs for insurance, costs related to the hiring of additional personnel, payment to outside consultants, lawyers and accountants and complying with the corporate governance, internal controls and similar requirements applicable to public companies.

Critical Accounting Policies and Estimates

Our management’s discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. Generally Accepted Accounting Principles, or GAAP. The preparation of these 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 financial statements included in this Annual Report on Form 10-K for the year ended December 31, 2012, 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 financial

statements.

Accrued Clinical Expenses

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

- fees paid to CROs in connection with clinical studies;
- fees paid to investigative sites in connection with clinical studies;

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

We base our accruals related to clinical studies on our estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that conduct and manage clinical studies on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical study milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual accordingly. If we do not identify costs that we have begun to incur or if we underestimate or overestimate the level of services performed or the costs of these services, our actual expenses could differ from our estimates.

Results of Operations

Comparison of Years Ended December 31, 2012 and 2011

Research and Development Expenses

	2012	2011	$ Change	% Change
Research and development expense ($ in millions)	$ 49.2	$ 85.3	$ (36.1)	(42)%

Research and development expenses decreased in 2012 from 2011 primarily due to decreased clinical trial costs of approximately $24.6 million associated with our Phase 3 clinical study of varespladib as a direct result of the termination of the VISTA-16 study in March 2012. Furthermore, manufacturing activities for our Phase 2 clinical study of blisibimod was substantially completed by December 2011 and all patients completed dosing by June 2012, which also contributed to the decrease in research and development expenses by approximately $10.8 million.

General and Administrative Expenses

	2012	2011	$ Change	% Change
General and administrative expenses ($ in millions)	$ 6.7	$ 7.9	$ (1.2)	(15)%

General and administrative expenses decreased in 2012 to 2011 primarily due to lower legal cost associated with patent prosecution of varespladib as a result of the termination of the VISTA-16 study in March 2012. Furthermore, we reduced our spending on consulting and professional services in line with the termination of the varespladib program.

Other Income (Expense)

	2012	2011	$ Change	% Change
Other income (expense) ($ in millions)	$ (0.1)	$ 0.6	$ (0.7)	(117)%
Interest expense	(3.4)	(2.8)	0.6	21 %

Other expense recorded in 2012 is a result of net loss realized from foreign currency exchange fluctuations. Other income recorded in 2011 was primarily due to realized gain on our short-term investments. Interest expense in 2012 included 12 months of interest recognized on our notes payable to Hercules Technology II, L.P and Hercules Growth Capital (together, "Hercules") as compared to only 9 months of interest recognized in 2011 because notes were issued in March 2011.

Comparison of Years Ended December 31, 2011 and 2010

Research and Development Expenses

	2011	2010	$ Change	% Change
Research and development expenses ($ in millions)	$ 85.3	$ 29.5	$ 55.8	189 %

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Research and development expenses increased from 2010 to 2011 primarily due to increased clinical trial costs associated with our Phase 3 clinical study of varespladib and Phase 2 clinical study of blisibimod of approximately $41.2 million. The trial costs increased as a result of continued enrollment and the addition of clinical sites for the VISTA-16 and PEARL-SC clinical studies. Manufacturing development activities also increased by approximately $13.9 million as compared to the prior period. We also increased headcount to support our clinical development activities in 2011, which resulted in increased salaries and benefits of $2.0 million.

	2011	2010	$ Change	% Change
General and administrative expense ($ in millions)	$ 7.9	$ 6.3	$ 1.6	25 %

General and administrative expenses increased from 2010 to 2011 primarily due to increased headcount and professional services incurred in connection with our financial audit and other costs associated with operating as a public company.

Other Income (Expense)

	2011	2010	$ Change	% Change
Other income (expense) ($ in millions)	$ 0.6	$ (0.0)	$ 0.6	100 %
Interest expense	(2.8)	(0.9)	1.9	211 %
Warrant mark to market adjustment	—	(3.8)	3.8	(100)%

Other income increased in 2011 from 2010 primarily as a result of higher cash and investment balances in 2011 as compared to the prior year due to proceeds received from the issuance of notes payable and equity offering. Further included in 2011 were realized foreign currency gains of approximately $0.4 million on short-term investments. Interest expense increased in 2011 from 2010 was primarily due to 9 months of interest recognized on our notes payable to Hercules. Interest expense for 2010 consisted of primarily non-cash charges related to the amortization of discounts associated with our convertible promissory notes issued in July and September of 2009, which were converted into shares of our common stock upon the closing of our IPO in March 2010.

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 our IPO raising net proceeds of approximately $303.0 million. As of December 31, 2012, we had cash, cash equivalents and short-term investments of approximately $24.7 million.

Cash, cash equivalents and investments consist of the following (in millions):

	2012	2011
Cash and cash equivalents	$ 19.4	$ 65.6
Short-term investments	5.3	1.7
Total	$ 24.7	$ 67.3

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

We filed a universal shelf registration statement with the SEC on Form S-3 (File No. 333-179043) on January 17, 2012, which was declared effective on January 24, 2012, 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. In July 2012, we issued 37,950,000 shares at $1.00 per share pursuant to the shelf registration, raising net proceeds of approximately $35.6 million. In January 2013, we issued 60,606,061 shares at $0.66 per share in an initial closing of a public offering, followed by 9,090,909 shares in a second closing in February 2013, raising net proceeds of approximately $43.0 million. We may issue securities in the future based on market conditions or other circumstances.

On November 8, 2012, we entered into an At Market Issuance Sales Agreement (the "Agreement") with MLV & Co. LLC ("MLV"), 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 $25,000,000 (the "Shares") through MLV, as agent. We have not sold any shares of our common stock pursuant to the Agreement, which was terminated January 24, 2013. This facility is no longer available for use.

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Cash Flows

Comparison of Years Ended December 31, 2012 and 2011

Cash flow from continued operations during the years ended December 21, 2012 and 2011 consist of the following (in millions):

	2012	2011
Net cash used in operating activities	$ (73.6)	$ (73.1)
Net cash (used in) provided by investing activities	(3.8)	20.2
Net cash provided by financing activities	31.3	78.4
Effect of exchange rate on cash	(0.1)	—
Total	$ (46.2)	$ 25.5

During the years ended 2012 and 2011, our operating activities used cash of $73.6 million and $73.1 million, respectively, primarily resulting from our net losses and changes in our working capital accounts. The increase in cash used in 2012 compared to 2011 was primarily due to payments made in the current year against the prior year's payable balances.

During the year ended 2012, cash used in investing activities was $3.8 million. During the year ended 2011, cash provided by investing activities was $20.2 million. Our investing activities consisted primarily of purchases and maturities of short term investments.

During the year ended 2012, financing activities provided cash of $31.3 million, which was primarily derived from proceeds received from our public offering of common stock in July 2012 from which we raised a total of $35.6 million in net proceeds after deducting underwriting discounts, commissions and offering expenses, offset by principal payment of $4.5 million against Hercules' notes payable. Cash provided by financing activities during the year ended 2011 was $78.4 million, derived from a public offering of common stock in June 2011 from which we received net proceeds of $54.0 million and issuance of notes payable to Hercules in March 2011 from which we received net proceeds of $24.7 million.

Comparison of Years Ended December 31, 2011 and 2010

Cash flow from continued operations during the years ended December 21, 2011 and 2010 consist of the following (in millions):

	2011	2010
Net cash used in operating activities	$ (73.1)	$ (27.8)
Net cash provided by (used in) investing activities	20.2	(23.4)
Net cash provided by financing activities	78.4	87.5
Effect of exchange rate on cash	—	(0.1)
Total	$ 25.5	$ 36.2

During the years ended 2011 and 2010, our operating activities used cash of $73.1 million and $27.8 million, respectively, primarily resulting from our net losses and changes in our working capital accounts. The increase in cash used in 2011 compared to 2010 was primarily due increased clinical trial costs associated with our Phase 3 clinical study of varespladib and Phase 2 clinical study of blisibimod.

During the year ended 2011, our investing activities provided cash of $20.2 million. During the year ended 2010, cash used in investing activities was $23.4 million. Our investing activities are consisted of primarily purchases and maturities of short term investments.

During the year ended 2011, financing activities provided cash of 78.4 million, derived from a public offering of common stock in June 2011 from which we received net proceeds of $54.0 million and issuance of notes payable to Hercules in March 2011 from which we received net proceeds of $24.7 million. Cash provided by financing activities during the year ended 2010 was $87.5 million, derived from our IPO of common stock in March 2010 from which we received proceeds of $61.2 million and $29.6 million from the issuance of common stock and warrants in connection with the private placement offering in September, and proceeds of approximately $0.2 million received from the exercise of stock options and issuance of common stock through our ESPP, offset by approximately $3.5 million of issuance cost paid during 2010.

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Contractual Obligations and Commitments

We have lease obligations consisting of an operating lease our operating facility that expires September 2014, for office space, and office equipment lease that expires in June 2013.

On March 25, 2011, we entered into a Loan and Security Agreement ("Loan Agreement") with Hercules. Under the terms of the Loan Agreement, we borrowed $25.0 million at an interest rate of the higher of (i) 10.55% or (ii) 7.30% plus the prime rate as reported in the Wall Street Journal, and issued to Hercules a secured term promissory note evidencing the loan. The loan is secured by our assets, excluding intellectual property. We made interest only payments for the initial 15 months from April 2011 to June 2012. Thereafter, the loan is being repaid in 30 equal monthly installments of approximately $1.0 million, at the initial interest rate. We will be obligated to pay an end of the term charge of $0.9 million, which is being expensed over the term of the Loan Agreement using the effective interest rate.

The following table summarizes our estimated scheduled future minimum contractual obligations and commitments as of December 31, 2012 (in millions):

Payments Due by Period	Less than 1 year	1 - 3 years	3-5 years	More than 5 years	Total
Notes Payable	$ 9.7	$ 10.8	$ —	$ —	$ 20.5
Interest on Notes Payable(1)	1.7	1.6	—	—	3.3
Facility Lease	0.2	0.2	—	—	0.4
Total	$ 11.6	$ 12.6	—	—	$ 24.2

(1) Interest payments reflected are estimated based on an interest rate of 10.55% throughout the term of the note, plus an additional end of term charge of $937,500.

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 our license agreement with Amgen to develop and commercialize blisibimod, 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.

Funding Requirements

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

- continue clinical development of blisibimod;
- hire additional clinical, scientific and management personnel; and
- implement new operational, financial and management information systems.

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

- the progress of clinical studies of our product candidate;
- 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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As of the date of this report, we believe our existing cash, cash equivalents and short-term investments will enable us to meet our obligations and sustain our operations through at least the next 12 months. However, we may require significant additional funds earlier than we currently expect to conduct additional or extended clinical studies and seek regulatory approval of our product candidate. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidate, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical studies.

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

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

Off-Balance Sheet Arrangements

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

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. We are exposed to market risk related to fluctuations in interest rates, market prices, and foreign currency exchange rates. However, since a majority of our investments are in short-term certificates of deposit, FDIC-insured corporate bonds and money market funds, we do not believe we are subject to any material market risk exposure. As of December 31, 2012, we did not have any material derivative financial instruments. The fair value of our marketable securities, including those included in cash equivalents and short-term investments, was $24.7 million as of December 31, 2012.

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

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The 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

As of December 31, 2012, the end of the period covered by this Annual Report on Form 10-K, management performed, under the supervision and with the participation of the Company's chief executive officer and chief financial officer, an evaluation of the effectiveness of the Company's disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act. The Company's disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports the Company files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to management, including the Company's chief executive officer and chief financial officer, to allow timely decisions regarding required disclosures. Based on this evaluation, the Company's chief executive officer and chief financial officer have concluded that, as of December 31, 2012, the Company's disclosure controls and procedures were effective to provide reasonable assurance that information required to be disclosed was accumulated and communicated to management as appropriate to allow timely decisions regarding required disclosure.

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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 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 assessed the effectiveness of our internal control over financial reporting as of December 31, 2012, using the criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). Based on our assessment, management has concluded that we maintained effective internal control over financial reporting as of December 31, 2012, based on the COSO criteria.

Changes in Internal Control Over Financial Reporting

During the quarter ended December 31, 2012, there were no changes in the Company's internal control over financial reporting that materially affected, or are reasonably likely to materially affect, the Company's 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 information required by this Item 10 is incorporated by reference from our definitive Proxy Statement for our 2013 Annual Meeting of Stockholders ("Proxy Statement"), where it appears under the headings "Election of Directors", "Executive Officers" and "Section 16(a) Beneficial Ownership Reporting Compliance."

We have adopted a Code of Ethics that applies to all directors, officers and employees of the Company. We publicize the Code of Business Conduct and Ethics through posting the policy on our website, http://www.anthera.com.

ITEM 11. Executive Compensation

The information required by this Item 11 is incorporated by reference from our Proxy Statement where it appears under the headings "Compensation Discussion and Analysis", "Compensation of Executive Officers", "Election of Directors" and "Compensation Committee Report."

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

The information required by this Item 12 is incorporated by reference from our Proxy Statement where it appears under the headings "Security Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information."

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

The information required by this Item 13 is incorporated by reference from our Proxy Statement where it appears under the headings "Certain Relationships and Related Transactions" and "Election of Directors."

ITEM 14. Principal Accountant Fees and Services

The information required by this Item 14 is incorporated by reference from our Proxy Statement where it appears under the heading "Ratification of Auditors."

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PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) The following documents are filed as part of this report:

(1) Index list to Financial Statements:

(2) Financial Statement Schedules

All other schedules are omitted because they are not required or the required information is included in the 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.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of Anthera Pharmaceuticals, Inc.:

We have audited the accompanying balance sheets of Anthera Pharmaceuticals, Inc. (a development stage company) (the “Company”) as of December 31, 2012 and 2011, and the related statements of operations, comprehensive loss, stockholders’ equity (deficit), and cash flows for each of the three years in the period ended December 31, 2012, and for the period from September 9, 2004 (Date of Inception) to December 31, 2012. These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, 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. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2012 and 2011, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2012, and for the period from September 9, 2004 (Date of Inception) to December 31, 2012, in conformity with accounting principles generally accepted in the United States of America.

The Company is in the development stage as of December 31, 2012. The Company is engaged in developing therapeutics to treat diseases associated with inflammation and autoimmune diseases. As discussed in Note 1 to the financial statements, successful completion of the Company’s development program and, ultimately, the attainment of profitable operations is dependent upon future events, including obtaining adequate financing to fulfill its development activities, obtaining regulatory approval, and achieving a level of sales adequate to support the Company’s cost structure.

/s/ Deloitte & Touche LLP

San Francisco, California
March 26, 2013

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ANTHERA PHARMACEUTICALS, INC
(A Development Stage Company)

BALANCE SHEETS

(in thousands except share amounts)

	December 31, 2012	December 31, 2011
ASSETS		
Current assets:		
Cash and cash equivalents	$ 19,431	$ 65,624
Short-term investments	5,322	1,746
Prepaid expenses and other current assets	426	607
Total current assets	25,179	67,977
Property and equipment—net	1,150	1,276
Debt issuance costs	116	240
TOTAL	$ 26,445	$ 69,493
LIABILITIES AND STOCKHOLDERS' EQUITY(DEFICIT)		
Current liabilities:		
Accounts payable	$ 5,206	$ 17,432
Accrued clinical studies	3,374	7,715
Accrued liabilities	497	559
Accrued payroll and related costs	344	372
Short term portion of notes payable, net of discount	9,329	4,157
Total current liabilities	18,750	30,235
Notes payable, net of discount	11,221	20,174
Total liabilities	29,971	50,409
Commitments and contingencies (Note 7)		
Stockholders' equity (deficit)		
Common stock, $0.001 par value, 195,000,000 shares authorized; 79,151,592 and 40,933,354 shares issued and outstanding as of December 31, 2012 and 2011, respectively	79	41
Additional paid-in capital	256,790	220,051
Accumulated comprehensive loss	(17)	(29)
Deficit accumulated during the development stage	(260,378)	(200,979)
Total stockholders' (deficit) equity	(3,526)	19,084
TOTAL	$ 26,445	$ 69,493

See accompanying notes to financial statements.

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ANTHERA PHARMACEUTICALS, INC.
(A Development Stage Company)

STATEMENTS OF OPERATIONS

(in thousands except share and per share amounts)

	Years Ended December 31,			Cumulative Period from September 9, 2004 (Date of Inception) to December 31,
	2012	2011	2010	2012
OPERATING EXPENSES:				
Research and development	$49,219	$85,281	$29,457	$ 215,281
General and administrative	6,715	7,857	6,301	30,790
Total operating expenses	55,934	93,138	35,758	246,071
LOSS FROM OPERATIONS	(55,934)	(93,138)	(35,758)	(246,071)
OTHER INCOME (EXPENSE):				
Other income (expense)	(111)	606	(15)	1,500
Interest expense	(3,354)	(2,803)	(845)	(7,702)
Mark-to-market adjustment of warrant liability	—	—	(3,796)	(3,796)
Beneficial conversion features	—	—	—	(4,309)
Total other income (expense)	(3,465)	(2,197)	(4,656)	(14,307)
NET LOSS	$(59,399)	$(95,335)	$(40,414)	$ (260,378)
Net loss per share—basic and diluted	$(1.03)	$(2.55)	$(1.76)	
Weighted-average number of shares used in per share calculation—basic and diluted	57,803,491	37,417,775	22,909,802	

See accompanying notes to financial statements.

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ANTHERA PHARMACEUTICALS, INC.
(A Development Stage Company)

STATEMENTS OF COMPREHENSIVE LOSS

(in thousands except share and per share amounts)

	Years Ended December 31,		
	2012	2011	2010
Net loss	$(59,399)	$(95,335)	$(40,414)
Unrealized gain (loss) on short term investments and foreign currency translation net	12	21	(50)
Comprehensive loss	$(59,387)	$(95,314)	$(40,464)

See accompanying notes to financial statements.

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Anthera Pharmaceuticals, Inc.
(A Development Stage Company)

STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
(in thousands except share and per share amounts)

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Deficit Accumulated During Development Stage	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
DATE OF INCEPTION—September 9, 2004								
Issuance of common stock to founders for cash	—	$ —	140,186	$ —	$ —	$ —	$ —	$ —
Issuance of common stock to founders for service	—	—	735,981	1	1	—	—	2
Repurchase of common stock from founder	—	—	(73,014)	—	—	—	—	—
Issuance of Series A convertible preferred stock for cash at $1.47 per share, net of issuance cost of $8,555	526,955	1	—	—	767	—	—	768
Issuance of Series A convertible preferred stock in exchange for service at $1.47 per share	25,575	—	—	—	38	—	—	38
Issuance of common stock upon exercise of stock options	—	—	33,292		5	—	—	5
Reclass of early exercise of stock options to liability	—	—	(29,204)	—	(4)	—	—	(4)
Share-based compensation related to equity awards	—	—	—	—	1	—	—	1
Net loss	—	—	—	—	—	—	(554)	(554)
BALANCE—December 31, 2005	552,530	1	807,241	1	808	—	(554)	256
Conversion of Series A convertible preferred stock to Series A-1 convertible preferred stock at a ratio of 1:1	—	—	—	—	—	—	—	—
Issuance of Series A-2 convertible preferred stock for cash at $5.14 per share—net of issuance cost of $202,019	1,138,677	1	—	—	5,645	—	—	5,646
Issuance of Series A-2 convertible preferred stock	224,248	—	—	—	962	—	—	962

upon conversion of convertible promissory notes at $3.85 and $5.14 per share								
Issuance of Series A-2 convertible preferred stock in exchange for licensed technology at $5.14 per share	257,744	—	—	—	1,324	—	—	1,324
Beneficial conversion feature related to conversion of convertible promissory notes into Series A-1 convertible preferred stock	—	—	—	—	190	—	—	190
Issuance of Series B convertible preferred stock for cash at $7.28 per share—net of issuance cost of $20,930	2,619,568	3	—	—	19,036	—	—	19,039
Issuance of Series B convertible preferred stock in exchange for licensed technology at $7.28 per share	127,297	—	—	—	926	—	—	926
Issuance of common stock upon exercise of stock options	—	—	125,581	—	17	—	—	17
Reclass of early exercise of stock options to liability	—	—	(36,810)	—	(5)	—	—	(5)
Share-based compensation related to equity awards	—	—	—	—	9	—	—	9
Net loss	—	—	—	—	—	—	(8,679)	(8,679)
BALANCE—December 31, 2006	4,920,064	5	896,012	1	28,912	—	(9,233)	19,685
Issuance of common stock upon exercise of stock options	—	—	493,605	—	118	—	—	118
Reclass of early exercise of stock options liability	—	—	(240,165)	—	(60)	—	—	(60)
Issuance of common stock for service	—	—	16,355	—	2	—	—	2
Share-based compensation related to equity awards	—	—	—	—	87	—	—	87
Unrealized loss on investments	—	—	—	—	—	(2)	—	(2)
Net loss	—	—	—	—	—	—	(25,695)	(25,695)
BALANCE—December 31, 2007	4,920,064	5	1,165,807	1	29,059	(2)	(34,928)	(5,865)
Conversion of Series B convertible preferred stock to Series B-1 convertible preferred stock at a ratio of 1:1	—	—	—	—	—	—	—	—
Issuance of Series B-2 convertible preferred stock	962,066	1	—	—	6,512	—	—	6,513

for cash at $7.28 per share—net of issuance cost of $242,327								
Issuance of Series B-2 convertible preferred stock upon conversion of convertible promissory notes at $5.46 per share	2,235,661	2	—	—	12,198	—	—	12,200
Issuance of Series B-2 convertible preferred stock in lieu of interest payment at $5.46 per share	28,517	—	—	—	156	—	—	156
Issuance of warrants in connection with issuance of Series B-2 convertible preferred stock	—	—	—	—	244	—	—	244
Beneficial conversion feature related to conversion of convertible promissory notes into Series B-2 convertible preferred stock	—	—	—	—	4,119	—	—	4,119
Issuance of common stock upon exercise of stock options	—	—	179,886	—	68	—	—	68
Release of early exercise of stock options liability	—	—	128,180	—	13	—	—	13
Repurchase of common stock upon employee termination	—	—	(18,983)	—	(5)	—	—	(5)
Share-based compensation related to equity awards	—	—	—	—	195	—	—	195
Unrealized gain on investments	—	—	—	—	—	1	—	1
Net loss	—	—	—	—	—	—	(18,099)	(18,099)
BALANCE—December 31, 2008	8,146,308	8	1,454,890	1	52,559	(1)	(53,027)	(460)

See accompanying notes to financial statements.

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Anthera Pharmaceuticals, Inc.
(A Development Stage Company)

STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
(in thousands except share and per share amounts)

	Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Deficit Accumulated During Development
	Shares	Amount	Shares	Amount	Capital	Loss	Stage
BALANCE—December 31, 2008	8,146,308	$8	1,454,890	$1	$52,559	$(1)	$(53,02
Issuance of common stock upon exercise of stock options	—	—	19,089	—	15	—	—
Release of early exercise of stock options liability	—	—	92,220	—	26	—	—
Share-based compensation related to equity awards	—	—	—	—	342	—	—
Unrealized gain on investments	—	—	—	—	—	1	—
Net loss	—	—	—	—	—	—	(12,20
Balance—December 31, 2009	8,146,308	8	1,566,199	1	$52,942	—	(65,23
Conversion of convertible preferred stock to common stock at a ratio of 1:1	(8,146,308)	(8)	8,146,308	8	—	—	—
Issuance of common stock for cash at $7.00 per share—net of issuance cost of $3,039,257	—	—	6,000,000	6	37,075	—	—
Issuance of common stock upon conversion of convertible promissory notes and accrued interest at $5.25 and $6.28 per share	—	—	2,511,235	2	13,882	—	—
Issuance of common stock upon release of escrow funds	—	—	2,598,780	3	17,097	—	—
Issuance of common stock upon cashless exercise of warrants	—	—	194,474	—	—	—	—
Issuance of common stock to collaborator in lieu of milestone payment	—	—	531,914	1	3,499	—	—
Issuance of common stock upon exercise of overallotment by underwriters net of issuance cost of $17,291	—	—	604,492	1	3,960	—	—
Issuance of common stock upon exercise of stock options	—	—	138,878	—	116	—	—
Issuance of common stock pursuant to employee stock purchase plan	—	—	24,916	—	81		
Issuance of common stock upon private placement transaction, net of issuance cost of $508,384	—	—	10,500,000	11	23,767	—	—
Issuance of warrants in conjunction with private placement transaction	—	—	—	—	5,324	—	—
Net change of early exercise of stock options and liability	—	—	35,836	—	1	—	—
Reclass of warrant and derivative liability to equity in conjunction with conversion of convertible promissory notes into common stock	—	—	—	—	4,473	—	—
Share-based compensation related to equity awards	—	—	—	—	702	—	—
Unrealized loss on investments and foreign currency translation	—	—	—	—	—	(50)	—

Net loss	—	—	—	—	—	—	(40,41
BALANCE—December 31, 2010	—	—	32,853,032	33	162,919	(50)	(105,6
Issuance of common stock upon exercise of stock options	—	—	264,726	—	241	—	—
Issuance of common stock for cash at $7.50 per share—net of issuance cost of $197,681	—	—	7,666,667	8	53,845	—	—
Issuance of common stock upon exercise of warrants	—	—	66,667	—	220	—	—
Issuance of common stock upon release of restricted stock units	—	—	31,345	—	102	—	—
Issuance of common stock pursuant to employee stock purchase plan	—	—	28,283	—	134	—	—
Net change of early exercise of stock options and liability	—	—	22,634	—	21	—	—
Issuance of warrants in conjunction with debt financing	—	—	—	—	1,276	—	—
Share-based compensation related to equity awards	—	—	—	—	1,293	—	—
Unrealized loss on investments and foreign currency translation	—	—	—	—	—	21	—
Net loss	—	—	—	—	—	—	(95,33
BALANCE—December 31, 2011	—	$—	40,933,354	$41	$220,051	$(29)	$(200,9

See accompanying notes to financial statements.

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Anthera Pharmaceuticals, Inc.
(A Development Stage Company)

STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
(in thousands except share and per share amounts)

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Deficit Accumulated During Development Stage	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
BALANCE—December 31, 2011	—	$ —	40,933,354	$ 41	$ 220,051	$ (29)	$ (200,979)	$ 19,084
Issuance of common stock upon exercise of stock options	—	—	154,529	—	157	—	—	157
Issuance of common stock for cash at $1.00 per share—net of issuance cost of $98,035	—	—	37,950,000	38	35,537	—	—	35,575
Issuance of common stock upon release of restricted stock units	—	—	54,896	—	65	—	—	65
Issuance of common stock pursuant to employee stock purchase plan	—	—	54,126	—	29	—	—	29
Net change of early exercise of stock options and liability	—	—	4,687	—	7	—	—	7
Share-based compensation related to equity awards	—	—	—	—	944	—	—	944
Unrealized loss on investments and foreign currency translation	—	—	—	—	—	12	—	12
Net loss	—	—	—	—	—	—	(59,399)	(59,399)
BALANCE—December 31, 2012	—	$ —	79,151,592	$ 79	$ 256,790	$ (17)	$ (260,378)	$ (3,526)

See accompanying notes to financial statements.

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ANTHERA PHARMACEUTICALS, INC.
(A Development Stage Company)

STATEMENTS OF CASH FLOWS

(in thousands)

	Years Ended December 31,			September 9, 2004 (Date of Inception) to December 31,
	2012	2011	2010	2012
CASH FLOW FROM OPERATING ACTIVITIES:				
Net loss	$(59,399)	$(95,335)	$(40,414)	$ (260,378)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation	331	80	17	501
Amortization of premium on short-term investments	—	84	102	56
Realized loss/(gain) on short-term investments and foreign currency exchange rates fluctuation	46	(8)	—	(118)
Stock-based compensation expense	960	2,423	702	4,720
Issuance of preferred and common stock for license fee, interest and service	—	—	3,673	6,122
Beneficial conversion feature	—	—	—	4,309
Amortization of discount and deferred interest on convertible notes and notes payable	749	364	541	2,054
Amortization of debt issuance cost	123	374	228	540
Mark-to-market adjustment on warrant liability	—	—	3,796	3,796
Changes in assets and liabilities:				
Prepaid expenses and other assets	184	1,253	(1,845)	(427)
Accounts payable	(12,226)	13,574	2,664	5,397
Accrued clinical study	(4,340)	4,579	2,572	3,376
Accrued liabilities	(35)	(191)	(270)	235
Accrued payroll and related costs	(28)	(264)	456	317
Net cash used in operating activities	(73,635)	(73,067)	(27,778)	(229,500)
INVESTING ACTIVITIES:				
Property and equipment purchases	(207)	(1,346)	(22)	(1,660)
Purchase of short-term investments	(10,671)	(4,735)	(24,948)	(55,155)
Proceeds from maturities of short-term investments	7,095	26,313	1,610	49,940
Net cash provided by (used in) investing activities	(3,783)	20,232	(23,360)	(6,875)
FINANCING ACTIVITIES:				
Proceeds from issuance of convertible notes and notes payable, net of issuance costs	—	24,700	(210)	50,952
Principal payment against note payable	(4,468)	—	—	(4,468)
Proceeds from issuance of preferred stock, net	—	—	—	32,210
Proceeds from issuance of common stock, net of offering costs	35,575	54,012	87,543	176,856
	186	376	197	983

Proceeds from issuance of common stock pursuant to employee stock purchase plan and exercise of stock options				
Proceeds from issuance of common stock pursuant to exercise of warrant	—	220	—	220
Withholding taxes paid on vested restricted stock units	(37)	(879)	—	(916)
Net cash provided by financing activities	31,256	78,429	87,530	255,837
Effect of exchange rate changes on cash	(31)	—	(165)	(31)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(46,193)	25,594	36,227	—
CASH AND CASH EQUIVALENTS—Beginning of period	65,624	40,030	3,803	19,431
CASH AND CASH EQUIVALENTS—End of period	$19,431	$65,624	$40,030	$ 19,431
SUPPLEMENTAL CASH DISCLOSURES OF CASH FLOW INFORMATION:				
Interest paid	$2,583	$1,838	$—	$ 4,436
NONCASH INVESTING AND FINANCING ACTIVITIES:				
Conversion of convertible promissory notes and accrued interest into common stock, Series A-2 convertible preferred stock and Series B-2 convertible preferred stock, including unamortized debt discount	$—	$—	$13,883	$ 27,386
Beneficial conversion feature	$—	$—	$—	$ 4,309
Reclassification of issuance costs charged to equity	$—	$—	$3,565	$ 3,565

See accompanying notes to financial statements.

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ANTHERA PHARMACEUTICALS, INC.
(A Development Stage Company)

NOTES TO FINANCIAL STATEMENTS

1. ORGANIZATION AND DESCRIPTION OF BUSINESS

Anthera Pharmaceuticals, Inc. (the "Company" or "Anthera") was incorporated on September 9, 2004 in the state of Delaware. Anthera is a biopharmaceutical company focused on developing and commercializing therapeutics to treat serious diseases associated with inflammation and autoimmune diseases. The Company's primary product candidate, blisibimod, targets elevated levels of B-cell activating factor, or BAFF, which has been associated with a variety of B-cell mediated autoimmune diseases, including systemic lupus erythematosus, or lupus, IgA nephropathy, lupus nephritis, vasculitis, rheumatoid arthritis, idiopathic thrombocytopenia purpura, and others. In January 2012, Anthera Pharmaceuticals, Limited, a wholly-owned subsidiary, was incorporated in Ireland.

The Company's activities since inception have consisted principally of acquiring product and technology rights, raising capital, and performing research and development. Accordingly, the Company is considered to be in the development stage as of December 31, 2012, as defined by guidance issued by the Financial Accounting Standards Board ("FASB"). 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. To date, we have funded our operations through equity offerings, private placements of convertible debt and debt financings, raising net proceeds of approximately $303 million.

The accompanying financial statements have been prepared in conformity with accounting principles generally accepted in the United States, or GAAP. From September 9, 2004 (Date of Inception) through December 31, 2012, the Company had an accumulated a deficit of $260.4 million. During 2012, the Company incurred a net loss of $59.4 million and had negative cash flows from operations of $73.6 million. The Company expects to continue to incur substantial losses and negative cash flows from operations over the next several years during its clinical development phase. To fully execute its business plan, the Company will need to complete certain research and development activities and clinical studies. Further, the Company's product candidate will require regulatory approval prior to commercialization. These activities may span many years and require substantial expenditures to complete and may ultimately be unsuccessful. Any delays in completing these activities could adversely impact the Company. The Company plans to meet its capital requirements primarily through issuances of equity securities (see Note 16 for discussion of the January 2013 issuance of common stock for net proceeds of approximately $43.0 million), debt financing, and in the longer term, revenue from product sales. Failure to generate revenue or raise additional capital would adversely affect the Company's ability to achieve its intended business objectives.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Use of Estimates

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

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, for which the carrying amounts are reasonable estimates of fair value. Cash equivalents are recognized at fair value.

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Short-Term Investments

The Company has designated its investments as available for sale and the investment are carried at fair value. The Company determines the appropriate classification of securities at the time of purchase and reevaluates such classification as of each balance sheet date. Securities with maturity exceeding three months but less than one year are classified as short-term investments. Realized gains and losses and declines in value judged to be other-than-temporary are determined based on specific identification method and are reported in the statements of operations. The Company includes any unrealized gains and losses on short-term investments in stockholders' equity as a component of accumulated other comprehensive income (loss).

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash, cash equivalents and short-term investments. The Company's cash equivalents consist of certificates of deposit with maturities less than three months and treasury money market funds. The Company's short-term investments consist of certificates of deposit with maturities exceeding three months but less than one year. The Company has not experienced any losses in such accounts. The Company believes it is not exposed to significant credit risk related to cash, cash equivalents and short-term investments.

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, 2012, the Company had not experienced impairment losses on its long-lived assets.

Accrued Clinical Studies

The Company makes estimates of its accrued clinical expenses as of each balance sheet date based on facts and circumstances known at that time. 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 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.

Accruals related to clinical studies are based on estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that conduct and manage clinical studies on the Company's behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical study milestones. In accruing service fees, the Company estimates the time period over which services will be performed and the level of effort to be expensed in each period. If the actual timing of the performance of services or the level of effort varies from estimates, the accrual is adjusted accordingly. If costs are not identified or if the Company underestimates or overestimates the level of services performed or the costs of these services, actual expenses could differ from estimates.

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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 contract research organizations, or CROs, materials and supplies, licenses and fees, and overhead allocations consisting of various administrative and facilities related costs. Research and development activities are also separated into three main categories: research, clinical development, and pharmaceutical development. Research costs typically consist of preclinical and toxicology costs. Clinical development costs include costs for Phase 1, 2 and 3 clinical studies. Pharmaceutical development costs consist of expenses incurred in connection with 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 studies performed by CROs based on patient enrollment activities and adjusts the estimates, if required, based upon the Company's ongoing review of the level of effort and costs actually incurred by the CROs. The Company monitors levels of performance under each significant contract, including the extent of patient enrollment and other activities through communications with the CROs, and adjusts the estimates, if required, on a monthly basis so that clinical expenses reflect the actual effort expended by each CRO.

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

Amounts paid in advance related to incomplete services will be refunded if a contract is terminated. Some contracts include additional termination payments that become due and payable if the Company terminates the contract. Such additional termination payments are only recorded if a contract is terminated.

In 2010, research and development costs were offset by $1 million of grant monies received for certain research and development costs as provided by Section 48D of the Internal Revenue Code.

Comprehensive Loss

Comprehensive loss consists of certain changes in equity that is excluded from net loss. Specifically, the Company includes unrealized losses on available for sale securities and the effect of exchange rate changes on cash equivalents and short-term investments in other comprehensive loss. Comprehensive loss for each period presented is set forth in the Statement of Comprehensive Loss.

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.

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 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 and the after-tax amount of interest recognized in the period associated with any convertible debt. The numerator also is adjusted for any other changes in income or loss that would result from the assumed conversion of those potential common shares, such as profit-sharing expenses. Diluted EPS is identical to basic EPS since common equivalent shares are excluded from the calculation, as their effect is anti-dilutive.

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

	Years Ended December 31,		
	2012	2011	2010
Net loss per share			
Numerator			
Net loss	$(59,399)	$(95,335)	$(40,414)
Denominator			
Weighted-average common shares outstanding	57,804,589	37,431,149	22,957,456
Less: Weighted-average shares subject to repurchase	(1,098)	(13,374)	(47,654)
Denominator for basic and diluted net loss per share	57,803,491	37,417,775	22,909,802
Basic and diluted net loss per share	$(1.03)	$(2.55)	$(1.76)

The following table shows weighted-average historical dilutive common share equivalents outstanding, which are not included in the above calculation, as the effect of their inclusion is anti-dilutive during each period.

	Years Ended December 31,		
	2012	2011	2010
Options to purchase common stock	504,114	807,301	978,231
Common stock subject to repurchase	1,098	13,374	47,654
Warrants to purchase common stock	97,830	1,675,050	1,496,314
Restricted stock units	274,040	232,114	153,658
	877,082	2,727,839	2,675,857

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 our Employee Stock Purchase Plan based on their estimated fair value, and recognize the costs in our 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. Compensation costs related to all equity instruments granted after January 1, 2006 are recognized at the grant-date fair value of the awards. 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.

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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.

Expected Volatility—Expected volatility is estimated using comparable public company volatility for similar terms.

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 expenses 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.

3. CASH EQUIVALENTS AND INVESTMENTS

The Company's cash equivalents and short-term investments as of December 31, 2012 are as follows (in thousands):

	Amortized Cost	Gross Unrealized Gains	Fair Value
Cash	$ 3,811	$ —	$ 3,811
Money market funds	15,620	—	15,620
Certificates of deposit	5,325	(3)	5,322
Total	24,756	(3)	24,753
Less amounts classified as cash and cash equivalents	(19,431)	—	(19,431)
Total	$ 5,325	$ (3)	$ 5,322

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The Company's cash equivalents and short-term investments as of December 31, 2011 were as follows (in thousands):

	Amortized Cost	Gross Unrealized Gains	Fair Value
Cash	$ 65,624	$ —	$ 65,624
Certificates of deposit	1,745	1	1,746
Total	67,369	1	67,370
Less amounts classified as cash and cash equivalents	(65,624)	—	(65,624)
Total short-term investments	$ 1,745	$ 1	$ 1,746

Realized losses recorded for the years ended December 31, 2012 and 2011 were immaterial.

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 is little or no market data, which require us to develop our own assumptions. Examples of assets and liabilities utilizing Level 3 inputs are cost method investments, auction rate securities (ARS) and the Primary Fund.

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, 2012 and 2011 (in thousands):

	December 31, 2012			
	Estimated Fair Value	Level 1	Level 2	Level 3
Money market funds	$ 15,620	$ 15,620	$ —	$ —
Certificates of deposit	5,322	—	5,322	—
Total	$ 20,942	$ 15,620	$ 5,322	$ —

	December 31, 2011			
	Estimated Fair Value	Level 1	Level 2	Level 3
Certificates of deposit	$ 1,746	$ —	$ 1,746	$ —
Total	$ 1,746	$ —	$ 1,746	$ —

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5. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets are comprised of the following (in thousands):

	December 31,	
	2012	2011
Prepaid insurance	$ 376	$ 425
Other current assets	50	182
Prepaid expense and other current assets	$ 426	$ 607

6. PROPERTY AND EQUIPMENT

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

	December 31,	
	2012	2011
Lab equipment	$ 1,312	$ 1,312
Computers and software	50	50
Office equipment and furniture	45	7
Leasehold improvements	206	39
Total property and equipment	$ 1,613	$ 1,408
Less accumulated depreciation and amortization	(463)	(132)
Property and equipment, net	$ 1,150	$ 1,276

The Company recorded the following depreciation expense in the respective periods (in thousands):

	Years Ended December 31,			Period from September 9, 2004 (Date of Inception) to December 31,
	2012	2011	2010	2012
Depreciation expense	$ 331	$ 80	$ 17	$ 501

7. COMMITMENTS AND CONTINGENCIES

Leases

The Company leases its main operating facility in Hayward, California. The lease is for approximately 14,000 square feet and expires on September 30, 2014. The Company recognizes rental expense on the facility on a straight line basis over the term of the lease. Differences between the straight-line net expense on rent payments is classified as deferred rent liability and included in the accrued liabilities on the balance sheet.

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Rent expense was as follows (in thousands):

	Years Ended December 31,			Period from September 9, 2004 (Date of Inception) to December 31,
	2012	2011	2010	2012
Rent expense	$ 217	$ 184	$ 158	$ 1,092

As of December 31, 2012, future minimum lease payments under noncancellable operating leases were as follows (in thousands):

	2012
Less than 1 year	$ 226
1 to 3 years	173
Total	$ 399

Other Commitments

In December 2007, the Company with Amgen, Inc. (“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 is 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. As of December 31, 2012, there were no outstanding obligations due to Amgen.

In July 2006, the Company with Shionogi & Co., Ltd. and Eli Lilly entered into a license agreement (the “Eli Lilly Agreement”) to develop and commercialize certain sPLA2 inhibitors for any indications, including for the treatment of inflammatory diseases. The Eli Lilly Agreement granted the Company commercialization rights to Shionogi & Co., Ltd.’s and Eli Lilly’s sPLA2 inhibitors, including varespladib and varespladib sodium. The Company paid Shionogi & Co., Ltd. and Eli Lilly a one-time license initiation fee of $250,000 and issued an aggregate of 257,744 shares of Series A-2 convertible preferred stock at $5.14 per share and an aggregate of 127,297 shares of Series B-1 convertible preferred stock at $7.28 per share with a total aggregate value of $2.3 million to Shionogi & Co., Ltd. and Eli Lilly. The Company recorded the initiation and license fees in research and development expenses during 2006. In March 2010, the Company paid $1.75 million each to Eli Lilly and Shionogi & Co., Ltd. in the form of the Company’s common stock upon the commencement of the Company’s Phase 3 VISTA-16 study of varespladib. Based on the recommendation of the DSMB in March 2012 to terminate the VISTA-16 study of

varespladib, the Company does not expect it will engage in any further development activities of its sPLA2 portfolio, including varespladib and varespladib sodium. Therefore, the Company does not expect to incur further payments to its collaborators. In August 2012, the Company provided notice of termination to Eli Lilly to terminate the license agreement. The license agreement was effectively terminated in November 2012.

8. NOTES PAYABLE

In March 2011, the Company entered into the Loan Agreement with Hercules. Under the terms of the Loan Agreement, the Company borrowed $25.0 million at an interest rate of the higher of (i) 10.55% or (ii) 7.30% plus the prime rate as reported in the Wall Street Journal, and issued to Hercules a secured term promissory note evidencing the loan. The loan is secured by the Company's assets, excluding intellectual property. The Company made interest only payments for the initial 15 months. Thereafter, the loan is being repaid in 30 equal monthly installments of approximately $952,000, at the initial interest rate. The Company is also obligated to pay an end of the term charge of $937,500, which is being expensed over the term of the Loan Agreement using the effective interest method.

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The Loan Agreement limits both the seniority and amount of future debt the Company may incur. The Company may be required to prepay the loan in the event of a change in control. In conjunction with the loan, the Company issued a seven-year warrant to purchase 321,429 shares of the Company's common stock at an exercise price of $6.00 per share. The warrant is immediately exercisable and expires March 2018. The Company estimated the fair value of this warrant using the Black-Scholes option valuation model with the following assumptions: expected term of seven years, a risk-free interest rate of 2.87%, expected volatility of 63% and 0% expected dividend yield.

The Company applied the relative fair value method to allocate the $25.0 million proceeds received under the Loan Agreement between the loan and warrant. The initial carrying amount assigned to the loan was $23.7 million and was recorded as Notes payable—net of discount on the Company's balance sheet. We believe the carrying amount at December 31, 2012 approximates fair value. The fair value allocated to the warrant of $1.3 million was recorded as an increase to additional paid-in capital in the Company's balance sheet. The resulting $1.3 million discount from the $25.0 million par value of the loan is being amortized as an additional interest expense over the term of the loan using the effective interest rate method.

In connection with the Loan Agreement, the Company incurred note issuance costs of approximately $370,200, which are recorded as long-term assets on the Company's balance sheet. The note issuance costs are being amortized to interest expense over the term of the Loan Agreement using the effective interest rate method.

Notes payable as of December 31, 2012 consists of (in thousands):

	2012
Notes payable, net of discount	$ 20,550
Less current maturities, net of discount	9,329
	$ 11,221

Annual maturities of long-term debt as of December 31, 2012 are as follows (in thousands):

2013	$9,691
2014	11,392
Total	$21,083

9. STOCKHOLDERS EQUITY

Common Stock

Prior to the IPO, the Company funded its operations through private equity offerings and placements of convertible debt, raising net proceeds of approximately $47.6 million. In connection with the completion of the IPO in March 2010, all of the Company's outstanding convertible debt and outstanding shares of preferred were converted into common stock and no liquidation preference remained.

On February 26, 2010, the Company's Registration Statement on Form S-1 was declared effective for its IPO, pursuant to which the Company sold 6,000,000 shares of its common stock at a public offering price of $7.00 per share. The Company received net proceeds of approximately $37.1 million from this transaction. Concurrent with the closing of the IPO, the Company received an aggregate of $17.1 million from the issuance of 2,598,780 shares of its common stock to certain of its investors pursuant to a common stock purchase agreement.

On April 6, 2010, the Company sold 604,492 shares of common stock pursuant to the exercise of the underwriters' over-allotment option in connection with the Company's IPO and received net proceeds of approximately $4.0 million.

On September 24, 2010, the Company completed a private placement transaction with certain accredited investors pursuant to which the Company sold an aggregate of 10,500,000 units at a purchase price of $3.00 per unit, with each unit consisting of one share of common stock and a warrant to purchase an additional 0.40 shares of common stock. Each warrant is exercisable in whole or in part at any time until September 24, 2015 at a per share exercise price of $3.30, subject to certain adjustments as specified in the warrant. The Company received net proceeds of approximately $29.1 million.

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On June 8, 2011, the Company utilized its shelf registration statement to sell 7,666,667 shares of its common stock at $7.50 per share. The Company received net proceeds of approximately $54.0 million, which is being used for general corporate purposes.

In January 2012, the Company filed a universal shelf registration statement with the SEC for the proposed offering from time to time of up to $100.0 million of its securities, including common stock, preferred stock, debt securities and/or warrants. In July 2012 the Company issued 37,950,000 shares at $1.00 per share pursuant to the shelf registration, raising net proceeds of approximately $35.6 million. In January 2013, the Company issued 60,606,061 shares at $0.66 per share in an initial closing of a public offering, followed by 9,090,901 shares in a second closing in February 2013, raising net proceeds of approximately $43.0 million; see Note 16 of our financial statements for more information.

On November 8, 2012, the Company entered into an At Market Issuance Sales Agreement (the “Agreement”) with MLV & Co. LLC (“MLV”), 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 $25,000,000 (the “Shares”) through MLV, as agent. The Company has not sold any shares of its common stock pursuant to the Agreement which was terminated as of January 24, 2013. This facility is no longer available for use.

At December 31, 2012, the Company is authorized to issue 200,000,000 shares of capital stock, of which 195,000,000 shares are designated as common stock, par value $0.001 per share. Holders of common stock are entitled to one vote per share on all matters to be voted upon by the stockholders of the Company. Holders of common stock are entitled to receive ratably dividends, if any, as may be declared by the Board of Directors. No dividends have been declared to date.

At December 31, 2012, the Company had reserved the following shares for future issuance:

Common stock warrants outstanding	4,811,898
Common stock options outstanding	2,403,711
Restricted stock units outstanding	224,912
Common stock available for future grant under ESPP plan	492,675
Common stock options available for future grant under stock option plan	1,461,053
Total	9,394,249

The Company’s Fifth Amended and Restated Certificate of Incorporation designates 5,000,000 shares of the Company’s capital stock as undesignated preferred stock.

Warrants

On September 24, 2010, the Company closed a private placement transaction with certain accredited investors pursuant to which the Company sold an aggregate of 10,500,000 units at a purchase price of $3.00 per unit, with each unit consisting of one share of common stock and a warrant to purchase an additional 0.40 shares of common stock. Each warrant is exercisable in whole or in part at any time until September 24, 2015 at a per share exercise price of $3.30, subject to certain adjustments as specified in the warrant. The Company valued the warrant using the Black-Scholes option pricing model with the following assumptions: expected volatility of 64%, risk-free interest rate of 1.37% and expected term of five years. The fair value of the warrants was calculated to be $5.3 million and has been recorded in additional paid-in capital. As of December 31, 2012, 4,133,333 warrants remain outstanding. Each of the warrants contains a net issuance feature, which allows the warrant holder to pay the exercise price of the warrant by forfeiting a portion of the exercised warrant shares with a value equal to the aggregate exercise.

In conjunction with the Loan Agreement with Hercules, the Company issued a seven-year warrant to purchase 321,429 shares of the Company's common stock at an exercise price of $6.00 per share. The warrant is immediately exercisable and expires March 2018. At December 31, 2012, this warrant remained outstanding and exercisable.

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10. STOCK-BASED AWARDS

Option Plan

The Company's 2005 Equity Incentive Plan (the "2005 Plan") was adopted by the board of directors in January 2005. The 2005 Plan allows the option holders to exercise their options prior to vesting. Unvested shares are subject to repurchase by the Company at the option of the Company. As of December 31, 2012, there are no unvested shares subject to repurchase by the Company.

On February 1, 2010, the Company's board of directors adopted the 2010 Stock Option and Incentive Plan (the "2010 Plan") effective upon consummation of the IPO, which was also approved by the Company's stockholders. Upon adoption of the 2010 Plan, all shares remaining available for grant under the Company's 2005 Plan, plus any additional shares returned under the 2005 Plan as a result of the cancellation of options or the repurchase of shares issued pursuant to the 2005 Plan were added to the 2010 Plan. The 2010 Plan provides for annual increases in the number of shares available for issuance thereunder on the first day of each fiscal year, beginning with the 2011 fiscal year, equal to four percent (4%) of the outstanding shares of the Company's common stock on the last day of the immediately preceding fiscal year. The maximum aggregate number of shares of stock that may be issued in the form of incentive stock options shall not exceed the lesser of (i) the number of shares reserved and available for issuance under the Plan or (ii) 1,460,280 shares of stock, 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. The 2010 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 2010 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 2010 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.

The 2010 Plan does not allow the option holders to exercise their options prior to vesting.

The following table summarizes stock option activity for 2010, 2011 and 2012 (in thousands except share and per share information):

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life in Years	Aggregate Intrinsic Value
Balance at December 31, 2009	1,323,776	$0.92	7.94	
Options granted	112,000	$4.82		
Options exercised	(138,878)	$0.84		
Options cancelled	(20,907)	$1.50		
Balance at December 31, 2010	1,275,991	$1.26	7.07	
Options granted	1,413,000	$5.77		
Options exercised	(270,334)	$1.04		
Options cancelled	(134,886)	$6.53		
Balance at December 31, 2011	2,283,771	$3.77	7.88	$6,063
Options granted	814,644	$2.05		

Options exercised	(154,529)	$1.02		
Options cancelled	(540,175)	$5.31		
Balance at December 31, 2012	2,403,711	$3.02	6.84	$126
Ending vested at December 31, 2012	1,410,661	$2.80	6.20	$126
Ending vested and expected to vest at December 31, 2012	2,403,711	$3.02	6.84	$126

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

	Years Ended December 31,			Period from September 9, 2004 (Date of Inception) to December 31,
	2012	2011	2010	2012
Expected Volatility	68%	63%	69%	73%
Dividend Yield	0%	0%	0%	0%
Risk-Free Interest Rate	1.26%	2.25%	1.91%	2.92%
Expected Term (years)	6.25	6.25	6.25	6.25

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,			Period from September 9, 2004 (Date of Inception) to December 31,
	2012	2011	2010	2012
Weighted-average fair value per share granted	$1.25	$3.47	$3.10	$ 1.52
Intrinsic value of options exercised	$683	$1,579	$699	$ 3,090
Proceeds received from the exercise of stock options	$157	$280	$116	$ 782
Grant date fair value of options vested	$1,102	$1,929	$235	$ 3,675

There was $2.8 million of total unrecognized compensation expense as of December 31, 2012 related to options. The unrecognized compensation expense will be amortized on a straight-line basis over a weighted-average remaining period of 2.59 years.

Information about stock options outstanding, vested and expected to vest as of December 31, 2012, is as follows:

	Outstanding, Vested and Expected to Vest			Options Vested
Range of Exercise Price	Number of Shares	Weighted-Average Remaining Contractual Life (In Years)	Weighted Average Exercise Price	Number of Shares
$0.26 - $1.34	536,018	5.01	$ 0.54	473,018

$1.51 - $1.79	298,276	6.72	$ 1.56	267,026
$2.21 - $2.21	653,644	7.88	$ 2.21	144,816
$4.19 - $4.77	56,625	7.97	$ 4.27	45,645
$4.88 - $8.17	859,148	7.16	$ 5.78	480,156
	2,403,711	6.84	$ 2.80	1,410,661

As of December 31, 2012, there are 1,461,053 shares available for grant under the 2010 Plan.

Restricted Stock Units

The Company grants restricted stock unit awards (“RSUs”) under its 2010 Plan, as determined by the Company’s compensation committee. The restricted stock units granted represent a right to receive shares of common stock at a future date determined in accordance with the participant’s award agreement. An exercise price and monetary payment are not required for receipt of restricted stock units or the shares issued in settlement of the award. Instead, consideration is furnished in the form of the participant’s services to the Company. Substantially all of the RSUs vest over four years.

In June 2011, the Company amended the 2010 Plan to allow individuals who had received RSUs to net share settle in excess of the minimum statutory withholding amount for taxes. In accordance with guidance issued by the FASB, this modification resulted in the RSUs being classified as a liability, and the subsequent change in fair value to be recorded as expense. The unsettled RSUs are remeasured at each reporting date and will continue to be remeasured until they are fully vested in approximately 1.13 years. Any changes in valuation are recorded as compensation expense for the period. As of December 31, 2012, the liability related to the unsettled awards was not significant.

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The following table summarizes activity related to our restricted stock units:

	Shares	Weighted-Average Grant Date Fair Value
Outstanding at December 31, 2010	302,500	$ 5.13
Restricted stock units granted	54,000	$ 5.65
Restricted stock units released	(140,000)	$ 5.20
Restricted stock units forfeitures and cancellations	(10,125)	$ 4.48
Outstanding at December 31, 2011	206,375	$ 5.24
Restricted stock units granted	152,850	$ 4.71
Restricted stock units released	(74,023)	$ 5.16
Restricted stock units forfeitures and cancellations	(60,290)	$ 3.49
Outstanding at December 31, 2012	224,912	$ 5.38

2010 Employee Stock Purchase Plan

In July 2010, the Company's stockholders approved the ESPP. The Company reserved 100,000 shares of common stock for issuance thereunder plus on January 1, 2011 and 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) 250,000 shares of common stock.

Under the ESPP, eligible employees of the Company and certain designated subsidiaries of the Company may authorize the Company to deduct amounts from their compensation, which amounts are used to enable the employees to purchase shares of the Company's common stock. The purchase price per share is 85% of the fair market value of the common stock as of the first date or the ending date of the applicable semi-annual purchase period, whichever is less (the "Look-Back Provision"). The 15% discount and the Look-Back Provision make the ESPP compensatory. The Black-Scholes option pricing model was used to value the employee stock purchase rights. For the years ended December 31, 2012, December 31, 2011, December 31, 2010 and the period from September 9, 2004 (Inception Date) through December 31, 2012, the following weighted-average assumptions were used in the valuation of the stock purchase rights:

	Year Ended December 31, 2012	Year Ended December 31, 2011	Year Ended December 31, 2010	Period from September 9, 2004 (Date of Inception) to December 31, 2012
Expected Volatility	129%	62%	67%	93%
Dividend Yield	0%	0%	0%	0%
Risk-Free Interest Rate	0.18%	0.08%	0.16%	0.14%
Expected Term (years)	0.50	0.50	0.33	0.47

Stock-Based Compensation Expense

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

	Years Ended December 31,			Period from September 9, 2004 (Date of Inception) to December 31,
	2012	2011	2010	2012
Research and development	$ 460	$ 1,014	$ 231	$ 2,057
General and administrative	500	1,409	471	2,663
Total employee stock-based compensation	$ 960	$ 2,423	$ 702	$ 4,720

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11. 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, effective in plan year 2012. There was no contribution made to the 401(k) plan by the Company as of the date of this report.

12. INCOME TAXES

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 financial statements and has established a full valuation allowance against its deferred tax assets.

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 for the years ended December 31, 2012 and 2011 are as follows (in thousands):

	December 31,	
	2012	2011
Deferred tax assets:		
Net operating loss carryforwards	$ 19,375	$ 69,300
Tax credits	1,080	4,813
Intangible assets	2,483	2,749
Accrued bonus	137	148
Accrued liabilities	1,344	3,165
Stock-based compensation	511	657
Capitalized R&D	17,646	—
Other	(19)	44
Total deferred tax assets	42,557	80,876
Deferred tax liabilities	—	—
Valuation allowance	(42,557)	(80,876)
Net deferred tax asset	$ —	$ —

A reconciliation of the statutory tax rates and the effective tax rate for the years ended December 2012, 2011, and 2010 is as follows:

	2012	2011	2010
Statutory rate	34%	34%	34%
State tax	(8)%	6%	7%
Tax credit	0%	1%	2%
Expiration of tax attributes due to section 382 limitations	(90)%	—	—
Other	0%	0%	(4)%
Valuation allowance	64%	(41)%	(38)%
Effective tax rates	0%	0%	0%

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 recent 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 $38.3 million in 2012, increased by $39.2 million and $15.5 million in 2011 and 2010 respectively, and $42.6 million for the period from September 9, 2004 (Date of Inception) to December 31, 2012.

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Net operating losses and tax return credit carryforwards as of December 31, 2012, are as follows (in thousands):

		Amount	Expiration Years
Net operating losses—federal	$	48,653	Beginning 2024
Net operating losses—state	$	48,653	Beginning 2014
Tax return credits—federal	$	—	Not applicable
Tax return credits—state	$	1,636	Do not expire

Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change," generally defined as a greater than 50% change (by value) in its equity ownership over a three year period, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes, such as research tax credits, to offset its post-change income may be limited.

The Company incurred a Section 382 ownership change in 2012 and as such, the Company's net operating loss carryforwards have been limited. In addition, the pre-change R&D tax credits have also been limited for federal tax purposes. As a result of the Section 382 limitation, a significant portion of the Company’s net operating losses and R&D credits (deferred tax assets) have been written off.

As of December 31, 2012, the Company had unrecognized tax benefits of $0.5 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 as of December 31, 2012. A reconciliation of unrecognized tax benefits is as follows (in thousands):

		Amount
Balance as of December 31, 2009	$	892
Additions based on tax positions related to current year		469
Balance as of December 31, 2010		1,361
Additions based on tax positions related to current year		404
Balance as of December 31, 2011		1,765
Reductions based on tax positions related to prior years		(1,300)
Additions based on tax positions related to current year		80
Balance as of December 31, 2012	$	545

For the year end December 31, 2012, the $1.3 million reduction in the unrecognized tax benefit related to prior years’ positions 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, 2012. The tax years 2004 through 2012 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 2013.

13. SELECTED QUARTERLY DATA (unaudited)

Quarterly results were as follows (in thousands, except per share data):

	Quarters Ended			
	March 31,	June 30,	September 30,	December 31,
2012				
OPERATING EXPENSES:				
Research and development	$17,738	$14,865	$ 9,527	$ 7,089
General and administrative	2,322	1,799	1,594	1,000
LOSS FROM OPERATIONS	(20,060)	(16,664)	(11,121)	(8,089)
Interest expense	(843)	(908)	(806)	(797)
Other income (expense)	(10)	(28)	(46)	(27)
NET LOSS	$(20,913)	$(17,600)	$ (11,973)	$ (8,913)
Net loss per share—basic and diluted	$(0.51)	$(0.43)	$ (0.17)	$ (0.11)
Shares used in computing basic and diluted net loss per share	41,000,421	41,097,882	69,630,496	79,120,940

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	Quarters Ended			
2011	March 31,	June 30,	September 30,	December 31,
OPERATING EXPENSES:				
Research and development	$16,317	$20,586	$ 21,546	$ 26,832
General and administrative	2,340	2,096	1,824	1,597
LOSS FROM OPERATIONS	(18,657)	(22,682)	(23,370)	(28,429)
Interest expense	(69)	(902)	(920)	(912)
Other income (expense)	160	414	(153)	185
NET LOSS	$(18,566)	$(23,170)	$ (24,443)	$ (29,156)
Net loss per share—basic and diluted	$(0.56)	$(0.66)	$ (0.60)	$ (0.71)
Shares used in computing basic and diluted net loss per share	32,895,152	34,900,225	40,833,495	40,916,666

15. RELATED PARTY TRANSACTIONS

The Company engaged an outside service provider whose chief executive officer is a founder of the Company and spouse of an officer of the Company, for clinical management services. In consideration for the services rendered, the Company paid the following fees (in thousands):

	Years Ended December 31,			Period from September 9, 2004 (Date of Inception) to December 31,
	2012	2011	2010	2012
Project management fees	$ 2,431	$ 3,326	$ 534	$ 6,422

As of December 31, 2012, the Company had no amounts payable to this organization for services performed during the period compared to approximately $1.1 million payable as of December 31, 2011. The scope of the services performed by this entity was limited to close out activities for the VISTA-16 study during 2012, which resulted in a significant reduction in service compared to 2011.

16. SUBSEQUENT EVENTS

In January 2013, the Company completed an initial closing of underwritten public offering of 60,606,061 shares of its common stock at a price of $0.66 per share followed by a second closing of 9,090,909 shares in February 2013. The net proceeds to the Company from the sale of shares in this offering were approximately $43.0 million. The Company intends to use the net proceeds for advancing its clinical development program.

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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/ Paul F. Truex
Paul F. Truex
President and Chief Executive Officer (Principal Executive Officer)

Dated: March 26, 2013

POWER OF ATTORNEY

We, the undersigned officers and directors of Anthera Pharmaceuticals, Inc., hereby severally constitute and appoint Paul F. Truex and Christopher P. Lowe, 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 and in his 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 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/ Paul F. Truex Paul F. Truex	President, Chief Executive Officer and Director (Principal Executive Officer)	March 26, 2013
/s/ Christopher P. Lowe Christopher P. Lowe	Chief Financial Officer (Principal Financial and Accounting Officer)	March 26, 2013
/s/ Christopher S. Henney Christopher S. Henney	Chairman of the Board of Directors	March 26, 2013
/s/ Bogdan Dziurzynski Bogdan Dziurzynski	Director	March 26, 2013

/s/ James I. Healy James I. Healy	Director	March 26, 2013
/s/ Daniel K. Spiegelman Daniel K. Spiegelman	Director	March 26, 2013
/s/ David E. Thompson David E. Thompson	Director	March 26, 2013
/s/ Peter A. Thompson Peter A. Thompson	Director	March 26, 2013
/s/ Sanford S. Zweifach Sanford S. Zweifach	Director	March 26, 2013

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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
3.3	Amended and Restated Bylaws(2)
4.1	Specimen certificate evidencing shares of common stock(3)
4.2	Second Amended and Restated Investor Rights Agreement by and among the Company and the other persons and entities party thereto, dated as of July 17, 2009(3)
#10.1	2005 Equity Incentive Plan and form agreements thereunder(4)
#10.2	Amended and Restated 2010 Stock Option and Incentive Plan(5)
#10.3	Form of Amended and Restated Indemnification Agreement(4)
#10.4	Form of Amended and Restated Change in Control Agreement(6)
#10.5	Form of Amended and Restated Severance Benefits Agreement(6)
+10.6	Amended and Restated Technology Transfer Letter Agreement between Eli Lilly and Company and the Company, dated as of July 12, 2006(4)
+10.7	License Agreement between Amgen Inc. and the Company, dated as of December 18, 2007(4)
10.8	Consent to Sublease, by and among the Company, NewTower Trust Company Multi-Employer Property Trust and Guava Technologies, dated as of September 12, 2008(4)
10.9	Sublease by and between the Company and Guava Technologies, dated as of August 1, 2008(4)
10.10	Note and Warrant Purchase Agreement by and among the Company and the other persons and entities party thereto, dated as of July 17, 2009(4)
10.11	Form of Stock Purchase Warrant sold pursuant to that Note and Warrant Purchase Agreement, dated as of July 17, 2009(7)
10.12	Amendment No. 1 to License Agreement between Amgen Inc. and the Company, dated as of October 16, 2009(8)
10.13	Amendment No. 3 to Stock Purchase Agreement and Escrow Agreement by and among the Company and the other persons and entities party thereto, dated as of February 24, 2010(9)

10.14	Amendment No. 1 to Note Purchase Agreement by and between the Company and the other persons and entities party thereto, dated as of February 24, 2010(10)
#10.15	2010 Employee Stock Purchase Plan(11)
#10.16	Employment Agreement by and between the Company and James Pennington, effective as of May 1, 2010(12)
#10.17	Form of Non-Qualified Stock Option Agreement for Company Employees Under the Anthera Pharmaceuticals, Inc. 2010 Stock Option and Incentive Plan(13)
#10.18	Form of Non-Qualified Stock Option Agreement for Non-Employee Directors Under the Anthera Pharmaceuticals, Inc. 2010 Stock Option and Incentive Plan(13)

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Number	Description
#10.19	Form of Incentive Stock Option Agreement Under the Anthera Pharmaceuticals, Inc. 2010 Stock Option and Incentive Plan(13)
#10.20	Form of Restricted Stock Award Agreement Under the Anthera Pharmaceuticals, Inc. 2010 Stock Option and Incentive Plan(13)
#10.21	Restricted Stock Unit Award Agreement Under the Anthera Pharmaceuticals, Inc. 2010 Stock Option and Incentive Plan(14)
10.22	Form of Securities Purchase Agreement, among the Company and the purchasers thereto, dated September 20, 2010(15)
10.23	Form of Registration Rights Agreement, between the Company and the Holders thereto, dated September 20, 2010(16)
10.24	Form of Warrant sold pursuant to that Securities Purchase Agreement, among the Company and the purchasers thereto, dated September 20, 2010(17)
10.25	First Addendum to Sublease by and between the Company and Millipore Corporation, as successor in interest to Guava Technologies, dated as of September 24, 2010(18)
10.26	Second Addendum to Sublease by and between the Company and Millipore Corporation, as a successor in interest to Guava Technologies, dated as of January 12, 2011(19)
10.27	Amendment No. 1 to 2010 Employee Stock Purchase Plan(20)
10.28	Loan and Security Agreement by and between the Company, Hercules Technology II, L.P. and Hercules Technology Growth Capital, Inc., dated as of March 25, 2011(21)
10.29	Form of Warrant Agreement dated as of March 25, 2011(22)
10.30	Lease by and between the Company and MEPT Mount Eden LLC, dated as of May 4, 2011(23)
10.31	Certificate of Amendment to Amended and Restated 2010 Stock Option and Incentive Plan(24)
10.32	Second Amended and Restated Change in Control Agreement, by and between the Company and Dr. Colin Hislop, dated as of August 5, 2011(25)
10.33	Second Amended and Restated Change in Control Agreement, by and between the Company and Dr. Debra Odink, dated as of August 5, 2011(26)
10.34	Amendment No.2 to Employee Stock Purchase Plan
10.35	Deferred Compensation Agreement by and between the Company and Paul Truex, effective as of December 27, 2012

14.1	Code of Business Conduct and Ethics(27)
21.1	Subsidiaries of Anthera Pharmaceuticals, Inc. (28)
23.1	Consent of Deloitte &Touche 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.

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Number	Description
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.
32.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as adopted pursuant Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	XBRL Instance Document.
101.SCH*	XBRL Taxonomy Extension Schema Document.
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document.

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

# Indicates management contract or compensatory plan, contract or agreement

*In accordance with Rule 406T of Regulation S-T, the XBRL related information in Exhibit 101 to this Quarterly Report on Form 10-Q is furnished and shall not be deemed to be “filed” for purposes of Section 18 of the Exchange Act, or otherwise subject to the liability of the section, and shall not be part of any registration statement or other document filed under the Securities Act or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

(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 Exhibit 3.7 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.

(3) 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 January 29, 2010 and incorporated herein by reference.

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

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

(6) Filed as the same numbered exhibit to the registrant's Amendment No. 1 to Registration Statement on Form S-1 (File No. 333-161930), filed October 19, 2009 and incorporated herein by reference.

(7) Filed as Exhibit 10.15 to the registrant's Registration Statement on Form S-1 (File No. 333-161930), filed September 15, 2009 and incorporated herein by reference.

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

(9) Filed as Exhibit 10.27 to the registrant's Post-Effective Amendment No. 1 to Registration Statement on Form S-1 (File No. 333-161930), filed February 26, 2010 and incorporated herein by reference.

(10) Filed as Exhibit 10.28 to the registrant's Post-Effective Amendment No. 1 to Registration Statement on Form S-1 (File No. 333-161930), filed February 26, 2010 and incorporated herein by reference.

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

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(12) Filed as Exhibit 10.1 to the registrant's Current Report on Form 8-K filed June 4, 2010 and incorporated herein by reference

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

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

(15) Filed as Exhibit 10.1 to the registrant's Current Report on Form 8-K filed September 22, 2010 and incorporated herein by reference.

(16) Filed as Exhibit 10.2 to the registrant's Current Report on Form 8-K filed September 22, 2010 and incorporated herein by reference.

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

(18) Filed as Exhibit 10.40 to the registrant's Registration Statement on Form S-1 (File No. 333-170099), filed October 22, 2010 and incorporated herein by reference.

(19) Filed as Exhibit 10.41 to the registrant's Annual Report on Form 10-K filed March 7, 2011 and incorporated herein by reference.

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

(21) Filed as Exhibit 10.1 to the registrant's Current Report on Form 8-K filed March 29, 2011 and incorporated herein by reference.

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

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

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

(25) Filed as Exhibit 10.1 to the registrant's current Report on Form 8-K filed with the SEC on August 9, 2011, and incorporated herein by reference.

(26) Filed as Exhibit 10.2 to the registrant's current Report on Form 8-K filed with the SEC on August 9, 2011, and incorporated herein by reference.

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

(28)

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