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

FORM 10-K

(Mark One)

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

For the Fiscal Year Ended December 31, 2012

or

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

Commission File Number: 001-35798

KALOBIOS PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**2834**	**77-0557236**
(State or other jurisdiction of incorporation or organization)	**(Primary Standard Industrial Classification Code Number)**	**(I.R.S. Employer Identification No.)**

260 East Grand Avenue
South San Francisco, CA 94080
(Address of Principal Executive Offices) (Zip Code)

(650) 243-3100
(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 check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

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

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

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

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

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 definitions of "large accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

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

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

As of March 15, 2013, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was approximately $113.5 million, based on the closing price of the registrant's common stock on the NASDAQ Global Select Market of $6.36 per share. The registrant has elected to use March 15, 2013 as the calculation date, as on June 30, 2012 (the last business day of the registrant's most recently completed second fiscal quarter) the registrant was a privately-held concern.

The number of outstanding shares of the registrant's common stock on March 15, 2013 was 24,147,815.

DOCUMENTS INCORPORATED BY REFERENCE

Part III incorporates information by reference to the definitive proxy statement for the Company's Annual Meeting of Stockholders to be held in 2013, to be filed within 120 days of the registrant's fiscal year ended December 31, 2012.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report includes forward-looking statements. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends affecting the financial condition of our business. Forward-looking statements should not be read as a guarantee of future performance or results, and will not necessarily be accurate indications of the times at, or by, which such performance or results will be achieved. Forward-looking statements are based on information available at the time those statements are made and/or management's good faith belief as of that time with respect to future events, and are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in or suggested by the forward-looking statements.

Forward-looking statements include all statements that are not historical facts. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "could," "would," "expects," "plans," "anticipates," "believes," "estimates," "projects," "predicts," "potential," or the negative of those terms, and similar expressions and comparable terminology intended to identify forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- our expectations regarding our expenses and revenue, the sufficiency of our cash resources and needs for additional financing;
- our anticipated growth strategies;
- our expectations regarding competition;
- the anticipated trends and challenges in our business and the market in which we operate;
- the timing and success of preclinical studies and clinical trials conducted by us and our development partners, including the timing of Sanofi's initiation of a Phase 2b clinical trial of our KB001-A product candidate for ventilator associated pneumonia (VAP) caused by *Pseudomonas aeruginosa* (*Pa*) (*Pa* VAP), and our expectations as to the timing of enrollment and availability of clinical data;
- the ability to obtain and maintain regulatory approval of our product candidates, and the labeling for any approved products;
- the scope, progress, expansion, and costs of developing and commercializing our product candidates;
- the size and growth of the potential markets for our product candidates and the ability to serve those markets;
- the rate and degree of market acceptance of any of our product candidates;
- our ability to establish and maintain development partnerships;
- our ability to attract or retain key personnel;
- our expectations regarding federal, state and foreign regulatory requirements;
- regulatory developments in the United States and foreign countries; and
- our ability to obtain and maintain intellectual property protection for our product candidates.

These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties, including those set forth below in Item 1A, "Risk Factors," and in our other reports filed with the U.S. Securities Exchange Commission. Given these uncertainties, you should not place undue reliance on these forward-looking statements. These forward-looking statements represent our estimates and assumptions only as of the date of this Annual Report on Form 10-K and, except as required by law, we undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise after the date of this Annual Report on Form 10-K.

PART I

ITEM 1. BUSINESS

Initial Public Offering

On February 5, 2013, we closed our initial public offering of 8,750,000 shares of common stock at an offering price of $8.00 per share, resulting in net proceeds of approximately $61.5 million, after deducting underwriting discounts, commissions and offering expenses.

Overview

We are a biopharmaceutical company focused on the development of monoclonal antibody therapeutics for diseases that represent a significant burden to society and to patients and their families. Using our proprietary and patented Humaneered® antibody technology, we have produced a portfolio of patient-targeted, first-in-class, antibodies to treat serious medical conditions with a primary clinical focus on respiratory diseases and cancer. By focusing on disease-specific targets and patient selection criteria in developing these drugs, we aim to provide patients with medicines that are safe and effective and offer innovative approaches compared to current treatments. We believe that antibodies produced with our Humaneered® technology offer important clinical and economic advantages over antibodies generated by other methods, including enhanced binding activity to target epitopes and minimal immunogenicity (undesired immune response), making our antibodies potentially more suitable for chronic treatment. We seek to identify and develop products that may treat multiple indications through proof-of-concept studies, and then secure development partnerships with large pharmaceutical and biotechnology companies who will further develop and commercialize our products while we retain rights in specialty or orphan indications. We have partnered with Sanofi, the vaccines division of the Sanofi Group, to develop, manufacture, and commercialize one of our lead antibodies, KB001-A, for all human diseases and conditions caused by *Pa.*

We currently have three monoclonal antibodies at the clinical development stage (Figure 1). For each program, we have created a Humaneered® antibody from a mouse or chimeric (mouse-human) antibody, and customized the development candidate for specific applications:

- Our first antibody, KB001-A (a Humaneered®, recombinant, PEGylated, anti-PcrV of Pseudomonas Fab' antibody), is in a Phase 2 clinical trial, conducted by us, in cystic fibrosis (CF) patients with chronic *Pa* lung colonization. Clinical data are expected by mid-2014. Our partner, Sanofi, has an option to assume primary responsibility for developing and promoting KB001-A for *Pa* in CF or bronchiectasis patients after the completion of this Phase 2 clinical trial. As part of Sanofi's clinical development plan for *Pa* VAP, Sanofi is conducting a Phase 1 clinical study in healthy volunteers to evaluate higher doses than those that we previously tested. We understand that the Phase 1 study will be followed, after completion of manufacturing process development and scale-up, by a Phase 2b intravenous study in late 2014 to determine the safety and efficacy of KB001-A in preventing *Pa* VAP and then Sanofi plans a subsequent Phase 3 study. We also understand that the Phase 2b and Phase 3 trials are being designed as pivotal studies and are intended to serve as a basis for registration of KB001-A in the prevention of *Pa* VAP.
- Our second antibody, KB003 (a Humaneered®, recombinant, anti-granulocyte macrophage colony- stimulating factor (anti-GM-CSF) monoclonal antibody), is in a Phase 2 clinical trial in severe asthma patients inadequately controlled by corticosteroids. We plan to report data from this trial by early 2014.
- Our third antibody, KB004 (a Humaneered®, recombinant anti-EphA3 receptor tyrosine kinase monoclonal antibody), is in the dose escalation portion of a Phase 1 clinical trial in patients with hematologic malignancies.

Clinical trials in *Pa* VAP and CF patients infected with *Pa* were completed with a precursor molecule, KB001, that showed activity in Phase 1/2 clinical studies with a single dose for both indications. KB001-A differs from KB001 by a single amino acid substitution per chain. This amino acid change is not within the

antigen binding site and does not affect antigen binding. The change has been made to facilitate the PEGylation step of the production process. Similarly, KB002, the chimeric precursor molecule to KB003, showed activity with a single dose in a Phase 1/2 clinical study in persistent asthma and in a Phase 1 clinical study in rheumatoid arthritis (RA). KB003 targets the same binding site as KB002 and has been shown to be functionally similar and generally safe in our early clinical trials.

We take a patient-targeted approach with each of our antibody programs by developing a new or utilizing an existing screen or diagnostic method that we believe may identify those individuals most likely to benefit from our therapies. We believe this targeted approach could result in an enhanced treatment benefit, reduce the overall risk associated with clinical development, enable our trials to be conducted with a smaller number of patients, and ultimately provide therapies that are more effective than current treatments. Collectively, our Humaneered® antibodies have been tested clinically in over 90 patients with no evidence of immunogenicity.

Figure 1
KaloBios Patient-Targeted Product Candidates

Program	Status	Expected Next Step(s)	Screen	Responsible Party
KB001-A (Anti-PcrV of *Pa*)				
Prevention of *Pa* VAP	Phase 1/2 complete with KB001; high dose Phase 1 with KB001-A ongoing	Sanofi to initiate Phase 2b post-CMC development in late 2014	*Pa* colonization	Sanofi
CF Patients Infected with *Pa*	Phase 1/2 complete with KB001; Phase 2 with KB001-A ongoing	Phase 2 data expected by mid-2014	*Pa* infection	KaloBios subject to Sanofi option
KB003 (Anti-GM-CSF)				
Severe Asthma	Phase 1/2 complete with KB002; Phase 2 with KB003 ongoing	Phase 2 data expected by early 2014	Reversibility	KaloBios
KB004 (Anti-EphA3)				
Hematologic Malignancies	Phase 1 ongoing	Initiate expansion phase in third quarter of 2013	EphA3 expression	KaloBios

The growth of recombinant biologic therapeutic drugs over the last 20 years has had a dramatic impact on many areas of medicine, including infectious, inflammatory, autoimmune, and respiratory diseases, as well as hematology and oncology. The efficacy and safety of such biologic drugs have driven impressive market growth, with worldwide sales in 2011 of $140 billion according to data from the IMS Institute for Healthcare Informatics. Data from EvaluatePharma, an industry research firm, indicate that therapeutic monoclonal antibody products represent approximately 35% of the biopharmaceuticals market with 2011 global sales of greater than $48 billion

and expected 2018 global sales approaching $75 billion. At least 30 antibody products have been approved by the U.S. Food and Drug Administration (FDA) and international regulatory authorities, and more than 300 monoclonal antibodies are in various stages of clinical development. According to a 2010 statistical analysis by Tufts University, antibody products have shown a 2.5 times higher probability of successful clinical development as compared to small-molecule drugs.

While antibody therapeutics have been highly successful, current approaches to developing antibodies have faced challenges. The challenges include immunogenicity and potency based on target epitope selection. These can affect the antibody product's safety and efficacy, particularly in treating chronic illnesses. Our Humaneered® technology platform is designed to produce optimized antibodies by selecting targets specific to diseased cells, improving antibody affinity for such targets, reducing immunogenicity of such antibodies, and addressing downstream processing issues such as antibody solubility, expression, stability, and aggregation.

We have a management team with extensive antibody development experience at leading biopharmaceutical companies. Members of our management team have individual track records of successfully developing monoclonal antibodies, as well as successfully launching respiratory and cancer products, including Rituxan®, Tysabri®, Nexavar®, Xolair®, Betaseron®, Fludarabine®, Cimzia®, Mylotarg®, and Bexxar®. In February 2013, we raised net proceeds of approximately $61.5 million in our initial public offering, after deducting underwriting discounts, commissions and offering expenses. Prior to our initial public offering and since our inception, we have raised approximately $102 million in equity capital from well-respected venture capital and strategic investors. We have also generated over $70 million in non-dilutive capital from our collaborations.

Corporate Information

We were incorporated on March 15, 2000 in California and reincorporated as a Delaware corporation in September 2001. Our principal offices are located at 260 East Grand Avenue, South San Francisco, CA, 94080, and our telephone number is (650) 243-3100. Our website address is www.kalobios.com. Our website and the information contained on, or that can be accessed through, the website will not be deemed to be incorporated by reference in, and are not considered part of, this Annual Report on Form 10-K. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to reports filed or furnished pursuant to Sections 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended, are available free of charge on the Investor Relations portion of our web site at www.kalobios.com as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

We have a single operating segment and substantially all of our revenues are generated and operating assets are located in the United States. For information regarding our research and development expenses for the last three fiscal years, see Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations."

Our Product Candidates

KB001-A in Development for the Prevention and Treatment of Pa VAP and Pa Infection in CF Patients

KB001-A is in development for the prevention and treatment of infections caused by *Pa*, a gram-negative bacterium. *Pa* can cause pneumonia in mechanically ventilated patients and chronic respiratory infections in individuals with CF. Both of these indications represent a significant market opportunity for KB001-A. Mechanical ventilation is the fifth most common procedure in the United States and patients with *Pa* VAP have a high mortality rate, with greater hospital utilization costs than mechanically ventilated patients without pneumonia. In individuals with CF, chronic pulmonary infection by *Pa* is a leading contributor to respiratory deterioration that ultimately leads to respiratory failure and death.

The only currently approved treatments for *Pa* infections are antibiotics, and, while antibiotics may be effective, mortality and morbidity remain high due to *Pa* antibiotic resistance. Unlike antibiotics that attack and

kill *Pa,* KB001-A is designed to neutralize *Pa* pathogenicity allowing the body's natural immune system to kill and clear the bacteria. As a result, we believe this novel approach to preventing and treating *Pa* infections is not subject to the drug resistance mechanisms that affect antibiotics. KB001-A is being developed for hospitalized patients on mechanical ventilation susceptible to *Pa* (>48 hours on mechanical ventilation) as a single intravenous dose of KB001-A to prevent *Pa* VAP, as well as for CF patients infected with *Pa* as a subcutaneous dose of KB001-A suitable for chronic use.

In January 2010, we entered into an agreement with Sanofi pursuant to which we granted to Sanofi an exclusive worldwide license to develop and commercialize antibodies directed against the PcrV protein of *Pa* (including KB001-A) for all indications. As part of this agreement, we have retained responsibility for developing and promoting the product for the diagnosis, treatment and/or prevention of *Pa* in patients with CF or bronchiectasis. Sanofi has an option to assume primary responsibility for developing and promoting KB001-A for *Pa* infection in CF or bronchiectasis patients upon the completion of our Phase 2 clinical trial.

As part of Sanofi's clinical development plan for *Pa* VAP, Sanofi is conducting a Phase 1 clinical study in healthy volunteers to evaluate higher doses than those that we previously tested. We understand that the Phase 1 study will be followed, after completion of manufacturing process development and scale-up, by a Phase 2b intravenous study starting in late 2014 to determine the safety and efficacy of KB001-A in preventing *Pa* VAP and then Sanofi plans a subsequent Phase 3 study. We also understand that the Phase 2b and Phase 3 trials are being designed as pivotal studies and are intended to serve as a basis for registration of KB001-A in the prevention of *Pa* VAP. Because Sanofi has exclusive rights for the development of KB001-A for the prevention of *Pa* VAP, we do not have control over the conduct or timing of the studies for this indication.

In January 2013 we launched a 180 patient, 16-week, randomized, placebo-controlled, repeat-dose, Phase 2 clinical trial for the treatment of *Pa* in CF patients with chronic *Pa* infections, to investigate the efficacy and safety of intravenously administered KB001-A. Data from this study is expected by mid-2014. The primary endpoint is time to need for antibiotics for worsening of respiratory tract signs and symptoms, with secondary endpoints of changes in inflammatory markers, respiratory symptoms, subject-reported outcomes, changes in Forced Expiratory Volume in 1 second (FEV1, a measure of lung function), pharmacokinetics (PK), safety, and tolerability. We plan to use this trial to support pivotal trials of a subcutaneous formulation of KB001-A. We believe that a subcutaneous formulation will be commercially more attractive and convenient for the patient in the chronic setting. We anticipate that two Phase 3 trials as well as a subcutaneous bridging study will be required for registration of KB001-A in *Pa*-infected CF patients. We expect that the pivotal program would be dose ranging in nature and designed to support the approval of subcutaneous KB001-A for the management of respiratory *Pa* infection, either as a monotherapy or in combination with inhaled antibiotics. We anticipate that exacerbation will be the primary endpoint for these studies; however, the design of these studies is dependent on discussions with the FDA and other regulatory authorities.

KB003 in Development for the Treatment of Severe Asthma

We are developing our second antibody, KB003, for the treatment of severe asthma inadequately controlled by corticosteroids, an indication that currently has limited treatment options. KB003 may provide a clinical and commercial advantage by treating the two forms of asthma: allergic and non-allergic. We are targeting the severe asthma population, which represents approximately 5% to 10% of the total asthma population of approximately 300 million people worldwide. Severe asthma is associated with more frequent exacerbations than mild to moderate asthma and is responsible for approximately 50% of the economic costs associated with asthma.

In August 2012, we initiated a 150 patient, randomized, double-blind, placebo-controlled, monthly-dose, intravenous Phase 2 clinical trial in adults with severe asthma inadequately controlled by corticosteroids. Subjects are being pre-screened for "reversibility", or a demonstrated FEV1 bronchodilator response of ³12% from baseline, as this patient segment showed a positive trend in responding to our precursor antibody in our Phase 1/2 clinical study in persistent asthma. The primary endpoint in our study is change in FEV1. Secondary

endpoints include exacerbation, effect on asthma control, asthma symptoms, use of rescue therapy, and safety. We anticipate fully enrolling subjects in this trial in the third quarter of 2013 and reporting data by early 2014. We plan to conduct a bridging study to switch from an intravenous formulation to a subcutaneous formulation in 2014. We believe that a subcutaneous formulation will be commercially more attractive and convenient for the patient. After successful completion of these studies, we plan to conduct two Phase 2/3 trials with the subcutaneous formulation of KB003 that will be designed to support regulatory approval for the treatment of severe asthma inadequately controlled by corticosteroids. We expect these studies to be dose- ranging in design. We anticipate that exacerbation will be the primary endpoint for these studies; however, the design of these studies is dependent upon future discussions with the FDA and other regulatory authorities.

KB004 in Development for the Treatment of Hematologic Malignancies

Our third antibody, KB004, is directed against EphA3 receptor tyrosine kinase, an oncofetal antigen involved in the positioning of cells during fetal development and re-expressed on the surface of hematologic and solid tumor cells and the stem cell microenvironment, but not on normal cells. As a result, KB004 may have the potential to kill cancer cells and disrupt the stem cell microenvironment, providing for long-term responses while sparing normal cells. Thus, we believe KB004 represents a novel approach to treating both hematologic malignancies and solid tumors. Cancer is among the leading causes of death worldwide and the second leading cause of death in the United States. The National Institutes of Health estimates that the annual cost of medical treatment for cancer will be over $155 billion in the year 2020.

We are currently conducting the dose escalation portion of a Phase 1 clinical trial in hematologic malignancies for KB004. The study is designed to be composed of subjects with hematologic malignancies, including subjects with acute myelogenous leukemia (AML), chronic myelogenous leukemia (CML), myelodysplastic syndromes (MDS), myeloproliferative neoplasms (MPN), multiple myeloma (MM), chronic lymphocytic leukemia (CLL) or acute lymphoblastic leukemia (ALL) unresponsive to standard of care or unsuitable for such treatment, and is designed as a dose-escalation study to determine a maximum tolerated dose (MTD), and the safety and PK profile for KB004. Doses will be escalated until a MTD is determined, defined as a dose level with < 33% of subjects experiencing a dose limiting toxicity (DLT). We are currently in the fourth dose-level cohort, and an MTD has not yet been reached. We continue to enroll patients in our dose escalation study and intend to initiate the expansion portion of this trial, which will pre-screen subjects for EphA3 expression and assess the activity of KB004, in the third quarter of 2013.

Strategy

Our goal is to become a leading biopharmaceutical company focused on the development and commercialization of first-in-class, patient-targeted, monoclonal antibody therapeutics that address serious medical needs. Key elements of our strategy are to:

- Advance the clinical development of our lead product candidates, KB001-A for the treatment of *Pa*-infected patients with CF, KB003 for the treatment of severe asthma, and KB004 for the treatment of cancer;
- Focus on indications where patient selection is guided by tests, such as clinical measures or a companion diagnostic, that we believe will prospectively indicate which patient segments are likely to respond positively to our drug, thereby potentially reducing clinical trial costs and increasing the likelihood of regulatory approval and reimbursement;
- Enter into partnership arrangements with leading pharmaceutical and biotechnology companies while retaining rights to specialty or orphan indications, which can be addressed by a focused sales force; and
- Collaborate with Sanofi on the clinical development and commercialization of KB001-A.

Product Development Program: KB001-A

Overview

Our first antibody, KB001-A, is a Humaneered®, recombinant, PEGylated, anti-Pseudomonas PcrV high- affinity Fab' antibody that is being developed for the prevention and treatment of infections by *Pa*, a gram- negative bacteria that causes pneumonia in mechanically ventilated patients and chronic respiratory infections in individuals with CF. The only currently approved treatments for *Pa* are antibiotics, and while there is a broad array of available antibiotics, mortality and morbidity in this disease remains high due to bacterial antibiotic resistance. KB001-A is designed to bind to and neutralize the pathogenicity of *Pa* thereby allowing the body's natural immune system to kill and clear the bacteria. As a result, we believe our novel approach to treating *Pa* infections will not be subject to the drug resistance mechanisms that affect antibiotic therapy. KB001-A is being targeted for the treatment of both hospitalized patients on mechanical ventilation susceptible to *Pa* (>48 hours on mechanical ventilation) to prevent *Pa* VAP, and CF patients infected with *Pa*.. Identification of the pathogen to determine patient eligibility will be conducted using standard laboratory culture tests or another diagnostic method.

In January 2010, we entered into an agreement with Sanofi pursuant to which we granted to Sanofi an exclusive worldwide license to develop and commercialize KB001 (the precursor molecule to KB001-A), KB001-A and other antibodies directed against the PcrV protein of *Pa* for all indications. Under this agreement, Sanofi is solely responsible for conducting, at its cost, the research, development, manufacture, and commercialization of the licensed products for the diagnosis, treatment, and/or prevention of all human diseases and conditions caused by or associated with *Pa.* As part of this agreement, we have retained the right to develop and promote (such as marketing, advertising, branding, and sales detailing) the product for the diagnosis, treatment, and/or prevention of *Pa* in patients with CF or bronchiectasis. Subject to the terms of the agreement, Sanofi has an option to obtain rights to participate in the development and promotion of licensed products for the CF or bronchiectasis indications on pre-negotiated terms, either outside of the United States or worldwide, at any time up to 90 days after the delivery by us to Sanofi of the final clinical study report from our Phase 2 clinical trial. Sanofi is solely responsible for the development, promotion, and commercialization of KB001-A for pneumonia prevention and other hospital indications such as *Pa* VAP. As part of Sanofi's clinical development plan for *Pa* VAP, Sanofi is conducting a Phase 1 clinical study in healthy volunteers to evaluate higher doses than those that we previously tested. We understand that the Phase 1 study will be followed, after completion of manufacturing process development and scale-up, by a Phase 2b intravenous study in 2014 to determine the safety and efficacy of KB001-A in preventing *Pa* VAP and then Sanofi plans a subsequent Phase 3 study. We also understand that the Phase 2b and Phase 3 trials are being designed as pivotal studies and are intended to serve as a basis for registration of KB001-A in the prevention of *Pa* VAP. We initiated a Phase 2 clinical trial of KB001-A in *Pa*-infected CF patients in January 2013, with data expected by mid-2014.

We have an exclusive license under certain intellectual property rights related to the target to which KB001 and KB001-A are directed, and methods of preventing and treating *Pa*, from University of California at San Francisco (UCSF) and the Medical College of Wisconsin.

Market Opportunities

Pa VAP

Pa is an opportunistic gram negative bacteria that predominantly infects critically ill patients or individuals whose immune systems have been weakened by disease and/or treatment including patients on mechanical ventilation. It is the most common cause of hospital-acquired pneumonia due to gram negative bacteria. According to Decision Resources, in 2005, there were approximately 250,000 acute *Pa* hospital infections in the United States and 410,000 such infections in Europe. Patients on mechanical ventilation for longer than 48 hours are at increased risk for endotracheal tube *Pa* colonization and subsequent development of *Pa* VAP. VAP is estimated to occur in 8-28% of mechanically ventilated patients (of which there were estimated to be approximately 790,000 in the U.S. in 2005), with *Pa* estimated to be the cause of approximately 25% of VAP

infections each year in the United States. Based on these data, we estimate the annual average number of *Pa* VAP patients in the United States to be between 15,000 and 55,000. The mortality of VAP is estimated at 25% despite treatment with antibiotics. In the United States, VAP patients spend an average of 5-7 additional days in the intensive care unit (ICU), at an additional cost of approximately $50,000 per admission. U.S. hospitals, under pressure to reduce government reimbursement and faced with increased requirements for public disclosure, have a strong incentive to reduce the incidence of VAP. We believe the worldwide market for KB001-A for the prevention and treatment of *Pa* VAP could be significant given the lack of currently approved treatments to control *Pa* beyond antibiotics.

Chronic Pa Infections in CF Patients

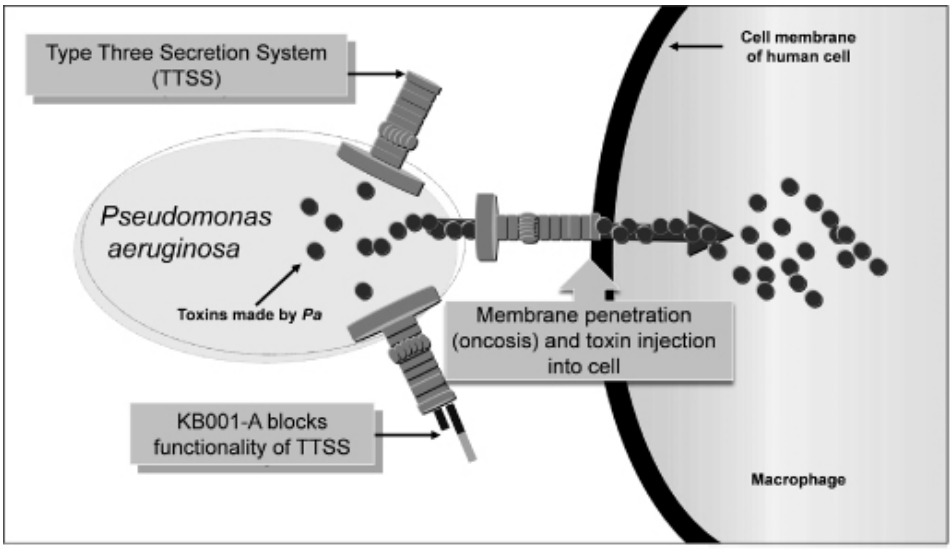
CF, among the most common genetic diseases, is characterized by a thick, sticky mucus buildup, most critically in the lungs. According to the Cystic Fibrosis Foundation, in 2010 the median life expectancy for those with CF in the United States is only 38.3 years. The most common causes of death are related to CF lung deterioration, believed to be caused predominantly by chronic infection with *Pa*, the most prevalent pathogen found in the lungs of individuals with CF. The prevalence of chronic *Pa* infection in the CF population increases with age, with positive respiratory tract cultures in 20% to 30% of infants, 30% to 40% of children aged 2 to 10 years, 60% of adolescents, and approximately 80% of adults. Once individuals with CF are chronically infected with *Pa,* typically as teenagers, their lung function slowly deteriorates over time at a rate of 2% to 4% per year, with a gradual loss of lung function leading to death. Chronic *Pa* infection is associated with greater morbidity and mortality, with earlier onset associated with a more severe loss of lung function and shorter life expectancy. There are approximately 1,000 new cases of CF each year in the United States, with a prevalence of approximately 30,000 individuals in the United States and 70,000 worldwide. In the second quarter of 2013, we plan to seek orphan drug designation for KB001-A for the treatment of *Pa*-infected CF patients in the United States.

Background and Mechanism of Action

CF is a disease with a vicious cycle of mucus buildup and obstruction of the airways, that leads to infection, and then inflammation, which further exacerbates obstruction of the airways. We believe KB001-A has a novel dual anti-infective and anti-inflammatory mechanism of action that could potentially mitigate this cycle. Unlike with antibiotics, bacteria are not likely to develop the resistance mechanisms to KB001-A that eventually make antibiotics ineffective. Moreover, because it has a different mechanism of action, KB001-A may be complementary to antibiotics. Based on our studies with KB001, we believe that KB001-A directly blocks the means by which *Pa* causes serious lung infection but, unlike antibiotics, does not directly kill the bacteria. Instead, based on our studies with KB001, we believe that KB001-A binds only to and blocks the function of the PcrV protein of *Pa*. The PcrV protein is an extracellular component of the type III secretion system (TTSS) which enables the bacteria to kill epithelial and immune cells either by direct puncture (oncosis) or injection of protein toxins. Free toxins also promote the release of pro-inflammatory cytokines leading to more tissue damage. By blocking PcrV function, KB001-A is designed to prevent immune cell killing by *Pa* and is also intended to reduce inflammatory cytokine release. The mechanism of action of KB001-A is illustrated in Figure 2. The KB001-A molecule has been optimized as a Fab' antibody rather than as a full antibody so that it does not

activate immune cells and exacerbate inflammation. To extend its time in the bloodstream and protect against breakdown by *Pa*, polyethylene glycol (PEG) is added to the Fab' fragment to generate the KB001-A molecule, which is a process called PEGylation.

Figure 2
KB001-A Mechanism of Action against *Pa* Infection



Source: KaloBios Pharmaceuticals, Inc.

We believe the possibility for *Pa* to develop resistance to KB001-A in a pathogenic strain of *Pa* is low because, unlike current antibiotics to which the bacteria may develop resistance, KB001-A is designed to neutralize or detoxify Pa rather than killing it directly. Thus, KB001-A is not subject to "selective pressure" drug resistance mechanisms that affect antibiotics. KB001-A is designed to protect the host immune cells from *Pa*, thereby enabling the natural clearance mechanism to fight disease. In animal experiments, anti-PcrV antibodies such as KB001-A demonstrated an ability to protect the immune system and allow it to remove or kill the bacteria. Because this mechanism is different from existing treatments for CF, KB001-A may also work in conjunction with existing CF therapies such as inhaled antibiotics and mucolytics, as well as newer CF transmembrane conductance regulator (CFTR) modulators.

Anti-PcrV Preclinical Activity Summary

In preclinical studies, anti-PcrV antibodies protected rats, mice, and rabbits from a lethal challenge of live *Pa* delivered directly into the airways. Bacteria were cleared from the lungs of infected animals within 48 hours of dosing with antibodies. Tobramycin, ciprofloxacin, and ceftazidime, representing three different classes of antibiotics that directly kill bacteria, have been shown to work in combination with anti-PcrV antibodies in acute *Pa* infection models in mice, which we believe supports their use with anti-PcrV antibodies in clinical trials. Anti-PcrV antibodies have also been shown to enhance the activity of the antibiotic imipenem against imipenem-resistant *Pa* lung infection in neutropenic mice. This suggests that some antibiotics that are ineffective due to drug resistance mechanisms could be effective when dosed in combination with KB001-A. It is also encouraging that neutrophils, a type of white blood cell, may not be essential for the protective effect of the antibody because some patients with *Pa* infections may be neutropenic or immunocompromised due to their underlying disease or other treatments.

In a chronic *Pa* lung infection animal model, anti-PcrV antibodies reduced the level of inflammatory cytokines in the lungs compared to untreated control animals. This model demonstrated the anti-inflammatory action of anti-PcrV antibodies during chronic *Pa* lung infection and the potential of this approach in the treatment of chronic *Pa* lung infection in diseases such as CF.

KB001-A Clinical Development Program

We have completed three clinical trials with KB001, which is the predecessor molecule to KB001-A, as described in more detail below. A Phase 1 trial in 15 healthy adult volunteers showed that KB001 was well tolerated in humans, with no immunogenicity, DLTs, or drug-related serious adverse events (SAEs) observed. We subsequently completed two Phase 1/2 trials of KB001, one in France in *Pa*-colonized, ventilator-supported patients hospitalized in ICUs, and the other in the United States in individuals with CF who were infected with *Pa*.

Table 1 summarizes the clinical development of KB001 and KB001-A.

Table 1
KB001/KB001-A Clinical Development Summary

Clinical Trial Phase	No. of Subjects	Indication	Trial Design	Status/Results
KB001				
Phase 1	15	Healthy volunteers	Placebo-controlled, single-dose, dose escalation, intravenous	• No immunogenicity, DLTs, or SAEs observed • Serum half-life 12 to 14 days
Phase 1/2	39	Pneumonia prevention in mechanically ventilated patients	Randomized, double-blind, placebo-controlled, single-dose, intravenous	• No safety issues and nonimmunogenic • Trend toward improved clinical outcomes
Phase 1/2	27	CF patients infected with *Pa*	Randomized, double-blind, placebo-controlled, single-dose, intravenous	• No safety issues and nonimmunogenic • Reductions in inflammatory markers • Trend in reducing mucoid *Pa* burden in sputum
KB001-A				
Phase 2	180	CF patients infected with *Pa*	Randomized, double-blind, placebo-controlled, repeat dose, intravenous	• Ongoing

We are developing KB001-A, also a PEGylated Fab' antibody, as the successor antibody to KB001. KB001-A and KB001 bind to the same target site on PcrV protein and we believe have been shown to be functionally comparable. KB001-A differs from KB001 by a single amino acid substitution per chain. This amino acid change is not within the antigen binding site and does not affect antigen binding. The change has been made to facilitate the PEGylation step of the production process. We have conducted animal toxicity studies necessary to demonstrate the safety of KB001-A for our planned CF study. Sanofi held a pre- investigational new drug

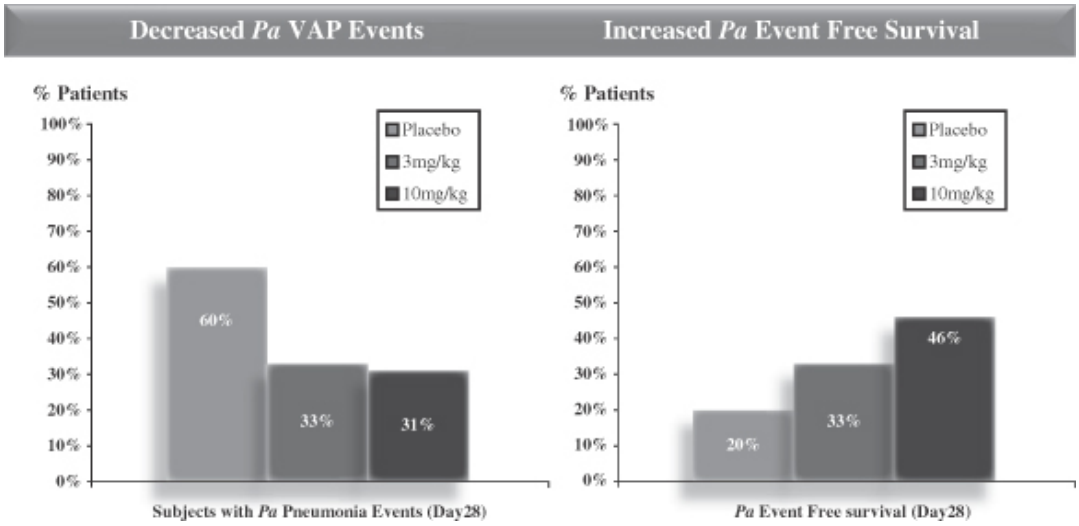
(IND) discussion with the FDA that included discussion of the comparability and safety of KB001-A and KB001. The FDA noted that our proposed nonclinical pharmacodynamic and pharmacology evaluation program, which includes the analytical bridging of KB001 to KB001-A, appeared adequately designed to support KB001-A clinical development. If bridging of the structural and functional characteristics are adequately demonstrated, then KB001 safety pharmacology studies will apply to KB001-A. We initiated our Phase 2 clinical trial in the CF indication in January 2013 and expect data by mid-2014. As part of Sanofi's clinical development plan for *Pa* VAP, Sanofi is conducting a Phase 1 safety study to evaluate KB001-A at higher doses than we had tested for KB001. All future clinical and preclinical studies for this program will be conducted using KB001-A.

Pa VAP Treatment and Prevention Clinical Development Program

Our Phase 1/2 study of KB001 in 39 subjects for the treatment and prevention of *Pa* pneumonia was designed to assess safety and tolerability. The trial design required laboratory culture screens of over 500 subjects to determine if they were colonized with *Pa*. These colonized subjects were then randomized into three treatment groups: standard of care medications only (control group), standard of care co-administered with low-dose KB001, and standard of care co-administered with high-dose KB001.

KB001 was well tolerated in this study, with no drug-related SAEs. While the study was not designed to evaluate efficacy and not powered for statistical significance, there was a greater trend toward fewer *Pa* pneumonia adverse events versus standard of care, with a reduction in the occurrence of *Pa* pneumonia by nearly 50% 28 days following a single dose of KB001 of 10 mg/kg. There was also a trend towards an increase in *Pa* event-free survival. (Figure 3).

Figure 3
KB001 Was Effective in Preventing *Pa* VAP in a Single-Dose Study



Source: KaloBios Pharmaceuticals, Inc. Clinical Study Report.

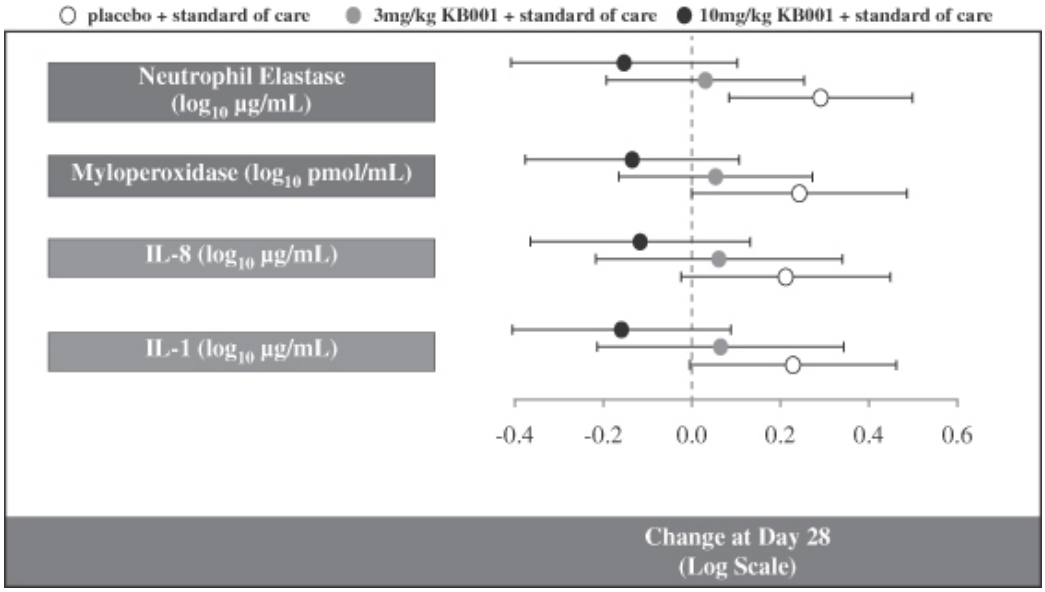
Sanofi is continuing the development of KB001-A in *Pa* VAP with a Phase 1 intravenous pharmacokinetic and safety clinical trial in healthy volunteers to evaluate dose levels higher than previously studied in KB001 and higher than planned in our CF development program. The FDA has indicated that the design of the study appears adequate, and if the bridging of structural and functional characteristics of KB001 and KB001-A is adequately demonstrated, then the safety pharmacology studies for KB001 will be applicable to KB001-A. We understand that the Phase 1 study will be followed, after completion of manufacturing process development and scale-up, by

a Phase 2b intravenous study in late 2014 to determine the safety and efficacy of KB001-A in preventing *Pa* VAP and then Sanofi plans a subsequent Phase 3 study. We also understand that the Phase 2b and Phase 3 trials are being designed as pivotal studies and are intended to serve as a basis for registration of KB001-A in the prevention of *Pa* VAP. Because Sanofi has exclusive rights for the development of *Pa* VAP, we do not have control over the conduct and timing of the studies, nor the regulatory strategy, for this indication. For additional information, see "Licensing and Collaborations—Sanofi Pasteur."

Pa Infection in CF Clinical Development Program

We have conducted a Phase 1/2 trial in CF patients with chronic *Pa* respiratory infection to assess the safety and tolerability of KB001. In this single-dose study, KB001 was not associated with any drug-related SAEs. While median baseline total *Pa* burdens in sputum, measured by bacterial culture *ex vivo*, were similar across the groups, the largest mean change from baseline in total *Pa* burden was observed for the 10mg/kg KB001 treatment group. In addition, when sputum samples were assessed, groups treated with KB001 at 10 mg/kg showed a trend toward reduction in four out of eight inflammation biomarkers tested, with a statistically significant, short-term reduction in neutrophil elastase and IL-1 (Table 2). Neutrophil elastase is of particular clinical interest because not only is it a marker of inflammation, it is also believed to be the cause of some of the irreversible lung damage in CF. For the 10mg/kg treatment group, a significant reduction in neutrophil elastase in sputum of 64% versus placebo was noted at day 28. This trend toward reduction in inflammatory biomarkers is consistent with the activity of anti-PcrV treatment in a chronic disease model of *Pa* lung infection in mice, which caused a reduction in lung neutrophils and inflammatory cytokines.

Table 2
KB001 Showed a Statistically Significant
Reduction in Neutrophil Elastase at 10mg/kg in a Single-Dose Study of
27 Subjects with CF and Chronic *Pa* Respiratory Infection



Source: KaloBios Pharmaceuticals, Inc. Clinical Study Report.

We plan to build on our KB001 CF clinical study experience by developing KB001-A as a treatment to reduce lung inflammation in CF patients with chronic *Pa* infection. We plan to enroll 180 such subjects in a

16-week, double-blind, placebo-controlled, repeat-dose, Phase 2 trial of KB001-A administered monthly by intravenous infusion. We initiated the Phase 2 trial in January 2013. The primary endpoint will be time to need for antibiotics to treat worsening of respiratory tract signs and symptoms over 16 weeks, with secondary endpoints to include changes in inflammatory markers (including neutrophil elastase), respiratory symptoms, subject-reported outcomes, changes in FEV1, PK, safety, and tolerability. All subjects will receive standard inhaled antibiotic therapy concurrent with doses of KB001-A or placebo for the first four study weeks, followed by KB001-A or placebo without antibiotics for an additional 12 weeks. The trial will be conducted primarily in North America, in conjunction with the Cystic Fibrosis Foundation Therapeutic Development Network. We expect to fully enroll subjects in the trial by the end of 2013 with data expected by mid-2014. Our KB001-A Phase 2 CF trial is designed to detect a statistically significant difference on the primary endpoint of time-to-need for antibiotics between the KB001-A and placebo arms. The study protocol allows for a sample size re-estimation after 60 subjects have completed the study in order to assess the possibility of achieving a statistically significant difference on the primary endpoint. This analysis compares the placebo group's actual treatment effect at the time of analysis to the original study design's predicted treatment effect to determine the number of additional patients needed, if any, to achieve the power of the original study design. If the re-estimation results in a larger subject sample size than we currently plan and we decide to increase the number of subjects in our study, the time period for our trial will be longer than we currently plan.

Data from this trial, if positive, will be used to support pivotal trials of a subcutaneous formulation of KB001-A. We anticipate that two Phase 3 trials, as well as a subcutaneous bridging study, will be required for approval of KB001-A in *Pa*-infected CF patients. We believe that a subcutaneous formulation will be commercially more attractive and convenient for the patient and, as such, we have commenced development efforts for such a formulation. We expect that the pivotal program would be dose ranging in nature and designed to support the approval of subcutaneous KB001-A for the management of respiratory *Pa* infection, either as a monotherapy or in combination with inhaled antibiotics. Because we will be testing different dose levels as part of our pivotal trials, the trials will be larger than the standard pivotal trial. In addition, testing different dose levels at a later stage in development increases the risk that we will not successfully identify a dose with an acceptable safety and efficacy profile.

KB001-A has been designed to have a novel mechanism of action not only as an anti-infective, but also with anti-inflammatory characteristics. The CF scientific community has considered the concept of using an anti- inflammatory drug as a disease-modifying therapy in CF to reduce the overall rate of lung function deterioration (the leading cause of death for patients with CF) although demonstrating such a benefit would likely require infeasible long-term mortality studies. Inhaled antibiotics, the current standard of care for CF, acutely improve FEV1. However, this standard of care is not believed to be effective in reducing the overall rate of lung function deterioration in the long term. Clinical trials of an anti-inflammatory drug (ibuprofen) have indicated that using chronic, high doses of ibuprofen given over several years may reduce the long-term deterioration of lung function. We believe KB001-A may have the potential of being disease-modifying because it may act as an anti- inflammatory agent to reduce the overall rate of lung function deterioration. However, we plan to only seek approval on the basis of short-term clinical benefits (such as reduction in exacerbations) and have no plans to conduct clinical trials for a disease-modifying indication.

Product Development Program: KB003

Overview

KB003 is a Humaneered®, recombinant monoclonal antibody that is designed to target and neutralize human granulocyte macrophage colony-stimulating factor (GM-CSF), with potential for use in inflammatory and autoimmune indications. GM-CSF is an important part of an inflammatory cascade that stimulates white blood cells (granulocytes, including eosinophils, neutrophils, and macrophages) and maintains them in an active state during infection. However, as described in a number of scientific publications, excessive GM-CSF may be involved in tissue damage associated with inflammatory diseases including asthma and RA. The results of anti-GM-CSF in ex vivo studies suggest KB003 has potential in treating asthma, chronic obstructive pulmonary

disease (COPD), RA, multiple sclerosis (MS), and certain oncology conditions. We initially plan to focus on treating severe asthma with a monthly, subcutaneous formulation of KB003, and could also pursue other inflammatory indications in the future. Asthma subjects will be prescreened based on lung function according to a "reversibility" criterion defined as having a ≥12% improvement in FEV1 from baseline after a beta agonist, as this patient segment showed a positive trend in responding to our precursor antibody in our Phase 1/2 clinical study.

Data from our single-dose, Phase 1 and Phase 1/2 clinical trials with monoclonal antibody KB002, the chimeric predecessor to the Humaneered® KB003, support our clinical trials with KB003. In these studies, KB002 was well tolerated. KB003 targets the same binding site as KB002 and has been shown to be functionally similar and generally safe in our early clinical trials. We then took the next step and held a discussion with the FDA regarding initiating a trial with KB003. During this telephone conference, the FDA accepted our proposed repeat- dose, Phase 2 clinical trial with the inclusion of a safety run-in portion. On completing the run-in safety portion of this trial, which showed KB003 to be well tolerated with no clinically significant adverse events, we reassessed the increasingly competitive and crowded RA market and chose to redirect our study of KB003 to severe asthma inadequately controlled by corticosteroids. We initiated a randomized, double-blinded, placebo-controlled, repeat dose, intravenous Phase 2 clinical trial of asthma inadequately controlled by corticosteroids in August 2012.

We licensed KB002, a low picomolar affinity, novel chimeric antibody, from Ludwig Institute for Cancer Research (LICR) in 2004. KB003 is a Humaneered® version of the KB002 antibody, with the same epitope target and therefore the same mechanism of action. We plan to use KB003 for all future clinical studies in this program.

Market Opportunity for GM-CSF Inhibitors

Severe Asthma

KB003 is for the treatment of adults with severe asthma who are clinically nonresponsive to standard of care inhaled corticosteroids and beta agonists as the first indication for KB003 because of the high unmet medical need. Asthma is a respiratory condition in which pulmonary airways become inflamed and constricted, usually in response to one or more environmental triggers. Although serious and potentially fatal if left untreated, asthma usually can be managed with standard drug therapies and by avoiding disease triggers. The severe asthma population represents approximately 5% to 10% of the total asthma population of approximately 300 million people worldwide. Severe asthma is responsible for approximately 50% of asthma's economic costs.

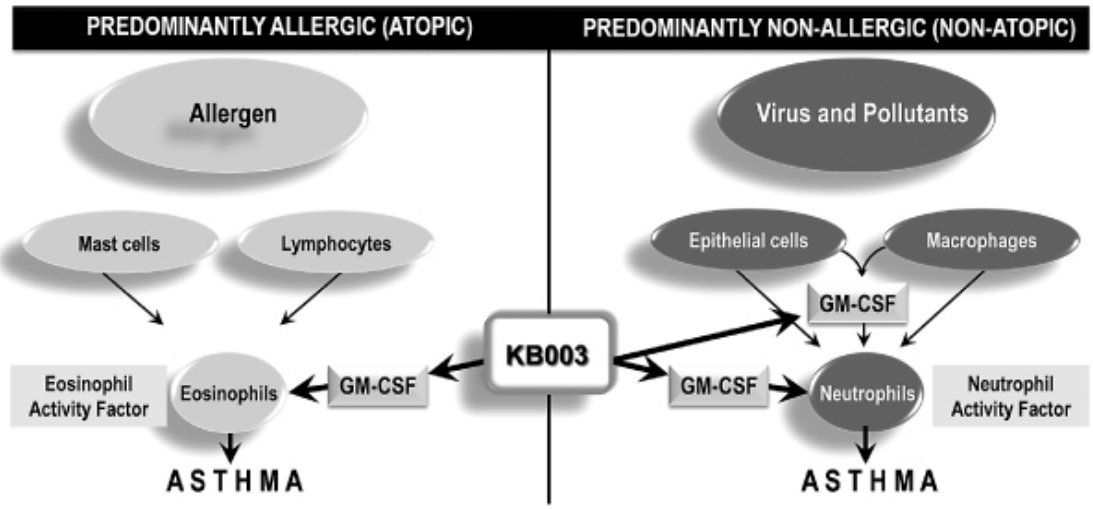
Asthma treatments currently available on the market, such as long-acting beta agonists (LABAs), inhaled corticosteroids, and omalizumab (anti-igE), may be ineffective for more severe cases of asthma. The monoclonal antibody, omalizumab, is limited to treatment of moderate to severe, allergic asthma in patients with positive immunoglobulin E (IgE). Other monoclonal antibodies in clinical development predominantly target allergic rather than non-allergic asthma. Because anti-GM-CSF treatment reduces the activity of the eosinophils or neutrophils that predominate in both types of asthma, KB003 has the potential to treat both allergic and non-allergic severe asthma.

Background and Mechanism of Action

Two main forms of asthma exist: allergic or atopic asthma, characterized by the presence of large numbers of eosinophils in pulmonary airways, and non-allergic or non-atopic asthma, in which neutrophils predominate. As GM-CSF plays an important role in the differentiation, proliferation, and enhanced survival of both inflammatory cell types (Figure 4), we believe reduction of excess GM-CSF is a potentially effective treatment for severe asthma. We believe KB003 is unique among antibodies being developed to treat asthma because it reduces inflammation caused by both eosinophils and neutrophils, thus acting on both the allergic and non-allergic forms of asthma. Diagnosed cases of asthma are believed to be divided approximately equally between both types, and many severe asthma patients have a mixed form that has eosinophilic and neutrophilic

components. Since currently available therapies for severe asthma treat predominantly allergic asthma, we believe KB003 may provide a clinical and commercial advantage by treating both allergic and non-allergic severe asthma.

Figure 4
KB003 Acts on Both Allergic and Non-Allergic Asthma



Source: Douwes J, Gibson P, Pekkanen J, Pearce N. Non-eosinophilic asthma: importance and possible mechanisms. Thorax. 2002;57(7):643-648. Adapted to show role of KB003.

Anti-GM-CSF Preclinical Activity Summary

Data from animal studies support the neutralization of GM-CSF for the treatment of allergic and non-allergic asthma. Mice sensitized to allergens respond to allergen challenge with a large increase in eosinophils in their lungs. Mutant mice lacking the GM-CSF gene are unable to mount an eosinophilic response, suggesting that GM-CSF is essential for increasing eosinophils in allergic asthma. Similarly, allergen-sensitized mice treated with anti-GM-CSF antibody show a reduction in eosinophils in the lungs following allergen challenge. In regard to non-allergic asthma, mice challenged with intranasal bacterial extract experience neutrophilic cell infiltration into their lungs. Treatment with an anti-GM-CSF antibody prevents this neutrophil infiltration. These data demonstrate the importance of GM-CSF in eosinophil and neutrophil recruitment into the lungs in allergic and non-allergic asthma.

In humans, GM-CSF levels are elevated in sputum taken from individuals with severe asthma but not mild asthma. A source of this GM-CSF appears to be lung epithelial cells. Lung epithelial cells isolated from individuals with asthma make and secrete more GM-CSF than those isolated from non-asthmatics. One function of lung GM-CSF in severe asthma may be to prevent the death (apoptosis) of activated eosinophils and neutrophils, which typically die off in a few days. In vitro studies have demonstrated that GM-CSF is effective at preventing cell death of human neutrophils and eosinophils for prolonged periods of time.

KB003 Clinical Development Program

We have conducted a combined total of seven early-stage clinical trials with intravenous KB002, the predecessor chimeric anti-GM-CSF antibody, and intravenous KB003, our Humaneered® antibody (Table 3). Our Phase 1 and Phase 1/2 clinical trials in RA and persistent asthma with KB002 showed the antibody to be well tolerated, and generated activity data to support continued development in both indications. We plan to use

information from those clinical trials to guide the development of KB003 in severe asthma. KB003, a Humaneered® antibody designed to be less immunogenic than KB002, will be used for all future clinical trials. KB003 was tested in a Phase 1, single-dose study in healthy adult volunteers and in the repeat-dose, safety run-in portion of a planned Phase 2 study in subjects with RA. The adverse events reported in this study were predominantly mild-to-moderate in severity. The main portion of the KB003 RA study was not initiated because we made the decision not to pursue the RA market as it was becoming increasingly competitive in an already crowded market. Instead, we are continuing the development of KB003 with a randomized, double-blind, placebo-controlled, monthly dose, intravenous Phase 2 clinical trial in patients with severe asthma inadequately controlled by corticosteroids.

Table 3 summarizes clinical development of KB002 and KB003.

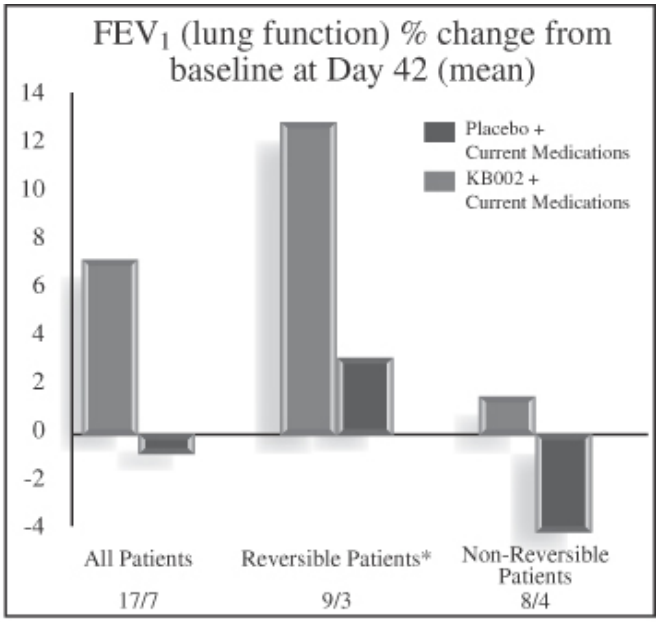
Table 3
KB002/KB003 Clinical Development Summary

Clinical Trial Phase	No. of Subjects	Indication	Trial Design	Status/Results
KB002				
Phase 1	12	Healthy adult volunteers	Double-blind, placebo-controlled, single-dose, dose escalation, intravenous	• No safety issues and well tolerated • No dose-limiting toxicity
Phase 1/2	24	Persistent asthma despite treatment with glucocorticoids	Randomized, double-blind, placebo-controlled, single-dose, intravenous	• No safety issues and well tolerated • Improvement in disease measures of activity
Phase 1	32	RA uncontrolled despite stable treatment with methotrexate	Randomized, double-blind, placebo-controlled, single-dose, dose escalation, intravenous	• No safety issues and well tolerated • Improvement in disease measures of activity
Phase 1/2 and Phase 1 Studies	24	Pharmacodynamic studies	Randomized, double-blind, placebo-controlled, single-dose, intravenous	• No safety issues and well tolerated
KB003				
Phase 1	12	Healthy adult volunteers	Placebo-controlled, single-dose, dose escalation, intravenous	• Generally safe • Nonimmunogenic • No dose-limiting toxicity
Phase 2 (Safety run-in)	9	RA inadequately treated with biologics	Randomized, double-blind, placebo-controlled, monthly dose, intravenous	• Generally safe and well tolerated over approximately 3 months of repeat dosing • Nonimmunogenic
Phase 2	150	Severe asthma inadequately controlled by inhaled corticosteroids	Randomized, double-blind, placebo-controlled, monthly dose, intravenous	• Ongoing

In the KB002 Phase 1 RA study, which randomized 32 subjects (3:1, active vs. placebo) to four escalating dose groups, a single dose of KB002 was found to be well tolerated, with no drug-related SAEs. KB002 dose groups demonstrated an early, durable, and clinically meaningful reduction in swollen and tender joints (Disease Activity Score at Day 28 (DAS28), a measure of swollen and tender joints), an effect that persisted for more than 90 days. While we have decided not to pursue additional trials in RA at this time, these data add support to the safety and activity of anti-GM-CSF therapy and the development of KB003.

The KB002 Phase 1/2 asthma study, which screened over 50 patients to enroll both allergic (eosinophilic) and non-allergic (neutrophilic) asthma subjects, randomized 24 subjects (2:1, active versus placebo). The objectives of the study were to primarily evaluate safety and tolerability, effects on sputum inflammatory markers and lung function after a single dose of KB002. KB002 was found to be generally safe and well tolerated. Mean FEV1 value for the active group increased 120ml from baseline to Day 42 and decreased 40ml for the placebo group. Of the 24 subjects enrolled in this small study (17 on KB002 and 7 on placebo), 59% on KB002 versus 29% on placebo had a >100 mL FEV1 increase at day 42. In addition, when patients were segmented retrospectively by the criteria of "reversibility," with reversible patients defined as having a ≥12% improvement in FEV1 from baseline after a beta agonist, reversible patients on KB002 experienced a greater increase in FEV1 from baseline at day 42 versus those on placebo. A majority of responders showed an FEV1 improvement of more than 10%, which is a level that is generally accepted as clinically meaningful). At day 42, 78% of KB002-treated reversible subjects had at least a 100-mL increase in FEV1 compared with 38% of KB002-treated nonreversible subjects, 33% of placebo-treated reversible subjects, and 25% of placebo-treated nonreversible subjects. A majority of KB002-treated patients who had an improvement in FEV1 also had measureable antibody in the sputum in addition to a decrease in eosinophils or neutrophils at day 28.

Figure 5
A Single Dose of Anti-GM-CSF Improved FEV_1 in Reversible Patients



* Defined by improving ≥12% from baseline in FEV_1 after beta agonist
Note: Effect seen in both cosinophillic and neutrophilic disease

Source: KaloBios Pharmaceuticals, Inc. Clinical Study Report.

Based on this data, we decided to proceed with a repeat-dose, Phase 2 clinical trial of KB003 in severe asthma. We initiated a randomized, double-blinded, placebo-controlled, Phase 2 clinical trial in asthma inadequately controlled with corticosteroids, in which we plan to enroll 150 subjects randomized equally between KB003 and placebo. Eligible subjects are being screened for a history of asthma inadequately controlled by high-dose inhaled corticosteroids, FEV1 function, and Asthma Control Questionnaire (ACQ) scores. Subjects are also pre-screened for reversibility, a demonstrated FEV1 bronchodilator response of $\geq$12% from baseline. Subjects will receive intravenous fixed doses of KB003 or placebo at multiple time points through week 20. The primary endpoint will be change in FEV1 through week 24. Secondary endpoints include exacerbation, effect on asthma control, asthma symptoms, use of rescue therapies, and safety. We anticipate fully enrolling subjects in this trial in the third quarter of 2013 and reporting data from this trial by early 2014. Our KB003 Phase 2 asthma trial is designed, and sized based on prior studies, to detect a statistically significant difference on the primary endpoint of FEV1 between the KB003 and placebo arms. The study protocol also provides for an optional re-estimation of the subject sample size after 60 subjects have completed the study in order to assess the possibility of achieving a statistically significant difference on the key secondary endpoint of exacerbation. This analysis compares the placebo group's actual exacerbation rate at the time of analysis to the original study design's predicted exacerbation rate to determine the number of additional patients needed, if any, to achieve the power of the original study design. Based on this re-estimation, we will evaluate whether to add the additional patients indicated by the sample size re-estimation. If the re-estimation results in a larger subject sample size than we currently plan and we decide to increase the number of subjects in our study, the time period for our trial will be longer than we currently plan.

In addition, we plan to conduct a bridging study to switch from an intravenous to a subcutaneous formulation. If we successfully complete the bridging program, we plan to conduct two Phase 2/3 trials with the subcutaneous formulation of KB003 that will be designed to support regulatory approval for the treatment of adults with severe asthma inadequately controlled by corticosteroids. These studies will be dose-ranging in design. Because we will be testing different dose levels as part of our pivotal trials, the trials will be larger than the standard pivotal trial. In addition, testing different dose levels at a later stage in development increases the risk that we will not successfully identify a dose with an acceptable safety and efficacy profile. We anticipate that exacerbation will be the primary endpoint for these studies; however the design of these studies is dependent upon future discussions with the FDA and other regulatory authorities. We believe that a subcutaneous formulation will be commercially more attractive and convenient for the patient and, as such, we have commenced development efforts for such a formulation.

Product Development Program: KB004

Overview

KB004 is a Humaneered®, recombinant monoclonal antibody that binds to EphA3 receptor and is being developed for the treatment of cancer. EphA3 plays an important role in cell positioning and tissue organization during fetal development but is not thought to play a significant role in healthy adults. However, EphA3 is aberrantly expressed on the tumor cell surface in a number of hematologic malignancies and solid tumors, and is also expressed on the stem cell compartment. This compartment includes malignant stem cells, the vasculature that feeds them, and the stromal cells that protect them. Given this differential expression pattern, KB004 may have the potential to kill cancer cells and the stem cell microenvironment, providing for long-term responses while sparing normal cells. As KB004 is designed to target and kill tumor cells and/or disrupt tumor blood vessels that express EphA3, we intend to pre-screen patients whose tumors express EphA3 using a companion diagnostic utilizing standard techniques such as flow cytometry or immunohistochemistry. We are currently conducting the dose escalation portion of a Phase 1 clinical trial of KB004 in multiple hematologic malignancies, and plan to follow that study with an expansion phase, which will assess activity in subjects pre-screened for EphA3 expression. We plan to select and validate an assay and amend the protocol to include EphA3 positive status as an inclusion criterion prior to conducting the expansion study. Once we select the assay format, we intend to initiate discussions with the FDA's Office of In Vitro Diagnostics and Radiological Health (OIR) regarding the use of the assay in our trials of the molecule.

KB004 is a Humaneered®, monoclonal antibody in which the carbohydrate chains lack fucose, thereby enhancing the targeted cell-killing activity of the antibody. In 2006, we entered into a license agreement with LICR pursuant to which LICR granted to us certain exclusive rights to the KB004 prototype and EphA3 intellectual property.

Market Opportunity for Hematologic Malignancies and Solid Tumors

Cancer is one of the leading causes of death worldwide and the second leading cause of death in the United States. The American Cancer Society (ACS) estimates that in 2012 more than 1.5 million people in the United States will be newly diagnosed with cancer and more than 560,000 will die from the disease. The ACS also estimates that nearly one in every four deaths in the United States is due to cancer. Five common solid cancer types (non–small cell lung, breast, ovarian, prostate and colorectal) together represent more than 50% of all new cases of cancer in the United States each year and account for more than 50% of all cancer deaths in the United States. The ACS also estimated that more than 100,000 people were diagnosed with a hematologic malignancy in 2012 in the United States.

The increasing number of cancer diagnoses and the approval of new cancer treatments are expected to continue to fuel the growth of the worldwide market for cancer drugs. Products targeting specific cancer-related molecules are the fastest-growing market segment in the pharmaceutical industry and are driving much of the cancer market growth. Data Monitor forecasts estimated aggregate annual sales in seven major markets (the United States, Japan, France, Germany, Italy, Spain and the United Kingdom) of approximately $34.5 billion by 2017.

Background and Mechanism of Action

KB004 is a high-affinity, non-fucosylated antibody that can potentially kill tumor cells in three ways: (1) direct induction of programmed cell death (apoptosis); (2) enhanced (via non-fucosylation) antibody- dependent cell-mediated cytotoxicity (ADCC) activity; or (3) disruption of the tumor vasculature by binding to EphA3 on the endothelial cells that line the vasculature.

EphA3 is expressed in some hematologic malignancies including AML, CML, MDS, MPN, MM, CLL, and ALL. It is also expressed on some tumor stromal cells and endothelial cells in the vascular compartment in the majority of solid tumors. We believe that the expression of EphA3 in a wide variety of tumors and tumor vasculature and on stem cells, with restricted expression in normal tissue, as well as the multiple mechanisms to kill tumors, makes this protein a promising target for anticancer therapy.

Anti-EphA3 Preclinical Activity Summary

In ex vivo testing, we found EphA3 expressed in approximately half of early-stage leukemia patient samples. Cancer cells are killed by KB004 binding to EphA3 through apoptosis, or ADCC, at relatively low concentrations. KB004 ex vivo selectively targets and kills leukemic stem cells, but not normal hematopoietic stem cells. In ex vivo assays of these cells, KB004 appears to kill all cells expressing EphA3. Whenever AML stem cells were detected, killing of these stem cells by KB004 was observed. This is significant because killing stem cells may lead to durable responses in cancers and may potentially prove effective in delaying or preventing relapses in the post-transplant setting, an area of high unmet medical need.

EphA3 expression has been documented in multiple solid tumor types of cancer, including melanoma, breast, non-small cell lung, colon, renal, glioblastoma and prostate cancers. EphA3 expression in colorectal cancer is a marker of poor prognosis.

To date, anti-EphA3 has shown encouraging preclinical proof-of-concept results in multiple tumor models. The xenograft studies we conducted show that the anti-EphA3 antibody causes growth inhibition in EphA3- positive tumors, as well as in tumors that do not express EphA3 (the latter presumably through the effect on tumor vasculature).

We completed a 13-week, multiple-dose, preclinical monkey toxicology study of KB004 and found no DLTs in doses up to 100 mg/kg/week.

KB004 Clinical Development Program

We are currently conducting the dose escalation portion of a Phase 1 clinical trial in hematologic malignancies for KB004. The study is designed to be composed of subjects with hematologic malignancies, including AML, CML, MDS, MPN, MM, CLL, or ALL unresponsive to standard of care or unsuitable for such treatment, and is designed as a dose-escalation study to determine a MTD, safety and the PK profile for KB004. Doses will be escalated until a MTD is determined, defined as a dose level with < 33% of subjects experiencing a DLT. Subjects are dosed weekly for three weeks to constitute one 21-day cycle for the MTD evaluation, and may continue to be treated for up to approximately one year. Subjects may continue dosing until disease progression or safety finding precludes further safe dosing. Blood, bone marrow aspirate and bone marrow biopsy specimens are evaluated throughout the study for disease status and biomarker assessment.

We are currently in the fourth level dose cohort and the MTD has not yet been reached. To date, the most common adverse event attributed to KB004 has been infusion reactions (chills and shivering), an expected safety finding based on its mechanism of action. Such reactions are observed with other monoclonal antibodies targeting destruction/lysis of leukemic cells (e.g., rituximab). Of the first six subjects treated, infusion reactions were observed in four subjects. All reactions were resolved with standard treatment. Of these first six subjects, three experienced fatal intracranial hemorrhages, two of which were deemed possibly related to the study drug by the study investigator. Bleeding is typical in late-stage AML patients and intracranial hemorrhages are the second leading cause of death in these patients. The rate of fatal bleeding events observed in the trial was higher than expected but because of confounding factors such as the fact that little to no drug was present in the blood at the time of the SAEs in most cases, it is inconclusive whether the events were related to the drug. In accordance with FDA regulations, we informed the FDA of these SAEs. After discussing the status of the trial with the FDA, we amended the protocol to enroll only lower-risk subjects less likely to have disease-related bleeding complications and instituted a coagulation monitoring plan as recommended by the FDA. Following those changes in 2011, there have been no additional events of intracranial hemorrhage, including at doses higher than those tested prior to the amendment. We are continuing to enroll patients in our dose escalation study and anticipate selecting a recommended dose in the first half of 2013 for the expansion portion of this trial, which will pre-screen subjects for EphA3 expression and assess the activity of KB004. We plan to select and validate the assay and amend the protocol to include EphA3 positive status as an inclusion criterion prior to conducting the expansion. Once we select the assay format, we intend to initiate discussions with OIR regarding the use of the assay in our trials of the molecule. We anticipate completing enrollment of the expansion phase for a primary indication by the end of 2014. If the expansion phase of the study is highly successful in demonstrating activity in a particular hematologic malignancy, it is possible that the next clinical trial we will conduct will be a pivotal trial.

For further discussion regarding risks related to our product development efforts, see Item 1A, “Risk Factors.”

Technology Platform

Our Humaneered® technology platform addresses issues of therapeutic antibody engineering (e.g., specificity, affinity, immunogenicity) and equally important down stream processing issues (e.g., antibody solubility, expression, stability, aggregation). Our Humaneered® technology is a method for converting antibodies (typically mouse) into engineered, high-affinity human antibodies designed for therapeutic use, particularly for chronic conditions. The technology is designed to produce optimized antibodies that have high specificity and high affinity for their target antigen, low propensity for aggregation, and excellent long-term stability. Because their sequences are very close to those of human germ-line antibody gene sequences, we believe Humaneered® antibodies will produce fewer immunological adverse side effects in patients than chimeric or conventionally humanized antibodies. The selection process for Humaneered® antibodies is also designed to provide high-expressing variable region (v-region) portions of the antibody and high-affinity antibodies.

We develop or in-license targets or research (mouse) antibodies, typically from academic institutions, and then apply our Humaneered® technology to them. KB001-A, KB003, and KB004 are all Humaneered® antibodies or antibody fragments. Thus far, together our Humaneered® antibodies have been tested clinically in over 90 patients with no evidence of serious immunogenicity. As we are focused on progressing our current portfolio of antibodies through clinical development, we are currently not dedicating additional resources to the research of additional Humaneered® antibodies.

In April 2007, we granted Novartis a nonexclusive license to our proprietary Humaneered® technology after applying our Humaneered® technology to several antibodies for them. Under the license agreement, Novartis is now able to develop Humaneered® antibodies to create its own therapeutics. We have also completed Humaneered® projects for five U.S. and Japanese biotechnology and pharmaceutical companies: Biogen Idec, Inc.; Daogen Inc.; Novartis Pharma AG; Otsuka Pharmaceutical Co., Ltd.; and Taligen Therapeutics, Inc. For each of these companies, we Humaneered® antibodies to certain targets under predefined criteria. In each case, we demonstrated the robustness and versatility of the technology by creating Humaneered® antibodies with increased affinity.

Capabilities of Humaneered® Technology

Our proprietary and patented Humaneered® technology generates Humaneered® antibodies from an existing antibody with the required specificity as a starting point and provides the following:

- retention of identical target epitope specificity of the starting antibody and frequent generation of higher affinity antibodies;
- very near to human germ-line sequence, which means it is less likely to induce an inappropriate immune response in broad patient populations when used chronically;
- antibodies with physiochemical properties that facilitate process development and formulation (lack of aggregation at high concentration);
- high solubility;
- high antibody expression yields; and
- an optimized antibody processing time of three to six months.

Licensing and Collaborations

Our strategy is to partner our programs while retaining rights to orphan or targeted indications. We currently have a collaboration with Sanofi for the development of KB001-A and have licensed our proprietary Humaneered® technology non-exclusively to Novartis. We have also in-licensed certain rights from, among others, UCSF and LICR. For further discussion regarding risks related to our licensing and collaboration efforts, see Item 1A, “Risk Factors.”

Sanofi Pasteur

In January 2010, we entered into an agreement with Sanofi pursuant to which we granted to Sanofi an exclusive worldwide license to develop and commercialize KB001 (the precursor to KB001-A), KB001-A and other antibodies directed against the PcrV protein of *Pa* for all indications. Under this agreement, Sanofi is solely responsible for conducting the research, development, manufacture, and commercialization of licensed products for the diagnosis, treatment and/or prevention of all human diseases and conditions caused by *Pa.* As part of this agreement, we retain the right to develop and promote (such as marketing, advertising, branding, and sales detailing) the product for the diagnosis, treatment and/or prevention of *Pa* in patients with CF or bronchiectasis. Sanofi is solely responsible for the development, promotion, and commercialization of KB001-A for pneumonia prevention and other hospital indications such as *Pa* VAP. Under the agreement, we received an initial upfront

payment of $35 million and an additional $5 million payment in August 2011. We have the potential to receive contingent payments aggregating up to $250 million upon achievement by Sanofi of certain clinical, regulatory, and commercial events, including $5 million upon initiation of a Phase 2 clinical trial for licensed products and $20 million upon successful completion of a Phase 2 clinical trial. We will also receive tiered royalties from 12% to 17% of net sales of licensed products, except that we receive other payments based on sales of licensed products for the diagnosis, treatment and/or prevention of *Pa* in patients with CF or bronchiectasis.

We are conducting a Phase 2 trial of KB001-A in *Pa*-infected patients with CF, the design of which has been agreed to by Sanofi. For a period of up to 90 days following the delivery of our study report for such Phase 2 clinical trial to Sanofi, Sanofi has the right to exercise an option with respect to the CF or bronchiectasis indications either (i) solely outside the United States or (ii) worldwide subject to an arrangement in which we could co-develop, jointly market, and share profits with Sanofi on licensed product sales in the United States. In the event that Sanofi exercises its option to obtain exclusive rights in these indications only outside the United States, Sanofi would be solely responsible for the development, regulatory approval, and commercialization of licensed products in countries outside the United States. Sanofi would also pay 50% of costs incurred by either Sanofi or us with respect to the development of licensed products for these indications where the data from such development activities are contemplated to be used in regulatory filings both within and outside the United States, and we would be entitled to royalties of 18% of net sales of licensed products for these indications outside the United States. If Sanofi exercises its option to obtain worldwide rights in these indications, we and Sanofi would jointly develop and promote licensed products for such indications within the United States, with such joint efforts to be coordinated through joint committees and to be conducted in accordance with mutually agreed plans. In addition, in such case, Sanofi would be solely responsible for the development, regulatory approval and commercialization of the product outside the United States. Sanofi would also pay for 75% of the costs incurred with respect to the development of licensed products for such indications where the data from such development activities are contemplated to be used in regulatory filings both within and outside of the United States, and we would be entitled to royalties of 18% of net sales of licensed product for such indications, except in the United States where we would split profits equally on licensed product sales for these indications. In order to exercise its option, Sanofi would make certain pre-negotiated payments to us related to the actual costs incurred by us in developing licensed products for *Pa* in patients with CF or bronchiectasis. If Sanofi exercises its option, we estimate that the pre-negotiated payments to us will be in the range of $25 million to $50 million based on projected estimated costs. If Sanofi elects to exercise its option worldwide, we can elect to cease participating in the development and promotion of licensed products for CF and bronchiectasis and instead receive a royalty on worldwide net sales of licensed products for these indications. If Sanofi does not exercise its option for the CF or bronchiectasis indications, Sanofi will nevertheless retain the exclusive right to perform certain necessary commercial activities (including the exclusive right to sell and distribute KB001-A) with respect to such indications but will have no obligation to perform such activities. In such event, if Sanofi were to decide not to commercialize KB001-A for the CF or bronchiectasis indications, and we nevertheless wished to commercialize KB001-A for either of these indications if approved, we would need to renegotiate with Sanofi certain terms of our agreement but may be unable to do so on reasonable terms, in a timely manner, or at all.

If we are acquired by a top 25 pharmaceutical company based on market capitalization at the time of such acquisition, Sanofi also has the option to exclusively assume all aspects of development and commercialization of licensed products in *Pa*-infected CF or bronchiectasis patients worldwide. If Sanofi exercises this option prior to regulatory approval of KB001-A for these indications, Sanofi would pay us an amount equal to 2.5 times our development costs for these indications from the time of entering into our agreement with Sanofi through the completion of our Phase 2 trial in CF patients plus additional amounts which will depend on whether or not Sanofi has exercised its option to develop and promote CF and bronchiectasis and, if exercised, whether the option exercise was for worldwide rights or just outside the United States, or if licensed products have already been approved by regulatory authorities for commercial use when Sanofi exercises this option, an amount equal to the greater of the amount owed us had the option been exercised prior to regulatory approval of KB001-A for

these indications or the amount based on the projected net present value of profits of licensed products in such indications for the following five years. Thereafter, Sanofi will pay us a royalty of 18% of worldwide product net sales of licensed product for these indications.

Sanofi is responsible for the manufacture of licensed products for its own use and for the manufacture of drug substance for our development and promotion activities in our retained indications. If Sanofi is unable or unwilling to supply drug substance to us, we have the right to have drug substance manufactured by a third party. We and Sanofi both have an obligation to use commercially reasonable efforts to perform our respective development, promotion (and, in the case of Sanofi, commercialization) obligations in our respective indications with respect to licensed products, although we can terminate our rights and obligations with respect to our retained indications if Sanofi exercises its option to obtain worldwide rights in the treatment of *Pa*-infected patients with CF or bronchiectasis, at any time after Sanofi exercises such option under the terms of the agreement. In addition, we can terminate our rights with respect to our retained indications upon 180 days' notice. While our agreement with Sanofi remains in effect, neither we nor our affiliates may develop or commercialize any other anti-*Pa* antibody. This would apply to a future acquiror, except with respect to any anti-*Pa* antibody of the acquiror existing on the date of acquisition and developed thereafter.

Sanofi's royalty obligation to us applies on a country-by-country and licensed product-by-licensed product basis, beginning upon the first commercial sale of such licensed product in a country and ending on the latest to occur of (i) 10 years from first commercial sale of such licensed product in such country or (ii) expiration of the last to expire patent covering licensed product in such country, which is expected to expire in 2028 in the United States. The agreement will remain in effect until all payment obligations under the agreement end. Sanofi may terminate the agreement for convenience, and either Sanofi or we may terminate the agreement for material breach of the agreement by the other party. In the event Sanofi terminates the agreement for convenience or we terminate due to Sanofi's material breach, worldwide rights to develop, manufacture and commercialize licensed products revert back to us, and we are granted a license from Sanofi to allow us to develop, manufacture, and commercialize licensed products worldwide, subject to commercially reasonable financial terms to be negotiated by the parties after such termination. In the event that we materially breach the agreement, Sanofi may, rather than terminate the agreement, opt to deduct any damages awarded for our breach against future contingent payments and royalties otherwise payable by Sanofi under the agreement.

Novartis

In April 2007, we entered into an agreement with Novartis granting a nonexclusive license to our proprietary Humaneered® technology for use at Novartis' research sites to develop human antibodies for therapeutic indications. Under the agreement, Novartis was excluded from using the technology against certain targets until March 2012. In accordance with the terms of the agreement, Novartis paid us $30 million and we transferred the know-how related to making Humaneered® antibodies to enable Novartis to internally make its own antibodies.

This agreement will remain in effect until the expiration of the last to expire licensed patent, which is currently expected to expire in 2025. However, either party may terminate the agreement for material breach by the other party.

University of California at San Francisco

In April 2004, we exclusively licensed rights from UCSF and the Medical College of Wisconsin to intellectual property that relate to KB001-A. These intellectual property rights include a method of treatment of *Pa* infection using isolated antibodies and an antibody that specifically binds to a key target epitope, as well as diagnostic methods useful in the detection of infection by *Pa*. Under our agreement with UCSF, we were granted rights to practice the invention as well as further develop antibodies to treat *Pa*. As a result, we developed and own a composition of matter patent for KB001-A which provides patent protection through 2028 in the United States. We are responsible for researching, developing and selling products covered by such intellectual

property and must use commercially reasonable efforts to market such products. Under our agreement with UCSF, we paid an upfront license fee of $25,000 and we are responsible for paying an annual license fee of $10,000, aggregate contingent milestone payments of less than $2 million, and royalties on net sales of 3%. We must also pay to UCSF a percentage of certain consideration we receive from our sublicensees. Aggregate payments made to UCSF under this license through December 31, 2012 amounted to $1.2 million. Our royalty obligation applies on a country-by-country and licensed product-by-licensed product basis, and will begin on the first commercial sale of a licensed product in a given country and will end on the later of the expiration of the last to expire patent covering such licensed product in such country, which in the United States is currently expected in 2019, or 10 years from first commercial sale of such licensed product in such country. We are obligated to diligently develop, manufacture and sell licensed products and market the products using commercially reasonable efforts to meet market demands. We may terminate our agreement with UCSF for convenience, and UCSF may terminate the agreement in the event of our material breach, in which cases our rights to use the intellectual property will also terminate.

The Ludwig Institute for Cancer Research

In May 2004, we entered into a license agreement with LICR, pursuant to which LICR granted to us an exclusive license under intellectual property rights and materials related to chimeric anti-GM-CSF antibodies which formed the basis for the KB003 development program. Under the agreement, we were granted an exclusive license to develop antibodies related to LICR's antibodies against GM-CSF. Using our Humaneered® technology, we developed and own a composition of matter patent covering KB003 and related Humaneered® anti-GM-CSF antibodies which provides patent protection through April 2029. We are responsible for using commercially reasonable efforts to research, develop, and sell KB003. We pay LICR a quarterly license fee and are obligated to pay to LICR a royalty from 1.5% to 3% of net sales of licensed products, subject to certain potential offsets and deductions. Our royalty obligation applies on a country-by-country and licensed product-by-licensed product basis, and will begin on the first commercial sale of a licensed product in a given country, and end on the later of the expiration of the last to expire patent covering a licensed product in a given country, which in the United States, is currently expected in 2023, or 10 years from first commercial sale of such licensed product in such country. We must also pay to LICR a certain percentage of sublicensing revenue received by us. Aggregate payments made to LICR under this license through December 31, 2012 amounted to $1.0 million. We may terminate our license for convenience, and LICR may terminate the agreement in the event of our material breach, in which cases our rights to use the intellectual property will also terminate.

In 2006, we entered into a license agreement with LICR pursuant to which LICR granted to us certain exclusive rights to the KB004 prototype and EphA3-related intellectual property. Under the agreement, we have rights to develop and commercialize products made through use of licensed patents and any improvements thereto, including human or Humaneered® antibodies that bind to or modulate EphA3. We paid LICR an upfront option fee of $50,000 and a further $50,000 upon our exercise of the option for the exclusive license outlined above. We are responsible for contingent milestone payments of less than $2.5 million and royalties of 3% of net sales subject to certain potential offsets and deductions. In addition, we are obligated to pay to LICR a percentage of certain payments we receive from a sublicensee in consideration for a sublicense. Our royalty obligation exists on a country-by-country and licensed product-by-licensed product basis, which will begin on the first commercial sale and end on the later of the expiration of the last to expire patent covering such licensed product in such country, which in the United States is currently expected in 2030, or 10 years from first commercial sale of such licensed product in such country. Aggregate payments made to LICR under this license through December 31, 2012 amounted to $334,000. We have current and pending patent applications for anti-EphA3 antibodies and their use, and have composition of matter patent applications that, if issued, are currently expected to expire in 2030. We may terminate our license for convenience, while both LICR and we may terminate the agreement in the event of the other party's material breach. In the event that the agreement is terminated for any reason other than our termination for LICR's material breach, our rights to use the licensed intellectual property will also terminate.

Intellectual Property

Patent and trade secret protection is critical to our business. Our success will depend in large part on our ability to obtain, maintain, defend and enforce patents and other intellectual property for our Humaneered® technology and our product candidates, to extend the life of patents covering our product candidates, to preserve trade secrets and proprietary know-how, and to operate without infringing the patents and proprietary rights of third parties. We actively seek patent protection in the United States and select foreign countries.

We solely own nine issued U.S. patents, own one issued U.S. patent jointly with a third party, and have an exclusive license to six U.S. patents and we own 16 issued foreign patents. We have 113 patent applications pending globally, including 19 non-provisional patent applications in the United States, which include 16 that are solely-owned by us and three that we own jointly with others. The patents to our Humaneered® technology cover methods of producing very specific human antibodies using only a small region from mouse antibodies.

We exclusively licensed rights from UCSF and the Medical College of Wisconsin to intellectual property that relate to KB001-A. These intellectual property rights include a method of treatment of *Pa* using isolated antibodies and an antibody that specifically binds to a key target epitope, as well as diagnostic methods useful in the detection of infection by *Pa*. This portfolio also includes issued patents covering compositions and methods of treatment of *Pa* infection that expire in 2019. Under our agreement with UCSF, we were granted rights to practice the invention as well as further develop antibodies to treat *Pa*. As a result, we developed and own a composition of matter patent for KB001-A which provides patent protection through 2028 in the United States. We also have filed counterparts in a number of foreign countries where our patents are pending.

We entered into a license agreement with LICR, pursuant to which LICR granted to us an exclusive license under certain intellectual property rights and technology related to chimeric anti-GM-CSF antibodies, which formed the basis of the intellectual property for the KB003 development program. Under the agreement, we were granted rights to issued U.S. and select foreign country patents covering chimeric anti-GM-CSF antibodies, as well as the right to develop antibodies related to LICR's antibodies against GM-CSF. Using our Humaneered® technology, we developed and own a composition of matter patent covering KB003 and related Humaneered® anti-GM-CSF antibodies which provides patent protection through April 2029 and have additional pending patents in the United States and a number of foreign countries covering various methods of treatment.

We entered into a license agreement with LICR, pursuant to which LICR granted to us an exclusive license under certain intellectual property rights related to the KB004 prototype and EphA3. Under the agreement, we have rights to develop human antibodies that bind to or modulate EphA3. We have current and pending patent applications in the United States and selected foreign countries for anti-EphA3 antibodies and their use, and have composition of matter patent applications that, if issued, are currently expected to expire in 2030.

We have a license from BioWa, Inc. and Lonza Sales AG to their Potelligent® CHOK1SV technology, a technology that is used to enhance the cell killing capabilities of antibodies.

See Item 1A, "Risk Factors," for further discussion of risks related to protecting our intellectual property.

Competition

We compete in an industry that is characterized by rapidly advancing technologies, intense competition, and a strong emphasis on proprietary products. Our competitors include pharmaceutical companies, biotechnology companies, academic institutions, and other research organizations. We compete with these parties for promising targets for antibody-based therapeutics and in recruiting highly qualified personnel. Many competitors and potential competitors have substantially greater scientific, research, and product development capabilities as well as greater financial, marketing and sales, and human resources than we do. In addition, many specialized biotechnology firms have formed collaborations with large, established companies to support the research,

development and commercialization of products that may be competitive with ours. Accordingly, our competitors may be more successful than we may be in developing, commercializing, and achieving widespread market acceptance. In addition, our competitors' products may be more effective or more effectively marketed and sold than any treatment we or our development partners may commercialize and may render our product candidates obsolete or noncompetitive before we can recover the expenses related to developing and commercializing any of our product candidates.

There are several companies treating *Pa* using antibiotics or alternative approaches. For example, Intercell has a fusion protein vaccine program in Phase 2/3 for the prevention of *Pa* in mechanically ventilated ICU patients and Kenta Biotech Ltd. is conducting a Phase 2 trial for KBPA101, a monoclonal antibody against a specific *Pa* serotype. There are two inhaled antibiotics (Tobi® and Cayston®) that have been approved for *Pa* to treat CF. However, like traditional antibiotics, data reported on both drugs show patients often become less responsive over time to these inhaled antibiotics. We are aware of only one biologic drug (Pulmozyme®) that is approved in the United States to treat respiratory problems in CF patients. However, Pulmozyme does not directly target *Pa*. KALYDECO®, a small-molecule transmenbrane conductance regulator potentiator that treats a form of the defective protein that causes CF, was recently approved by the FDA. KALYDECO is a drug that targets only the CF population having at least one copy of the G551D mutation in the CFTR gene (approximately 4% of the CF population). VX-809 is a compound being developed by Vertex in Phase 2 clinical trials for CF and potentially complementary to KB001-A.

Several companies are also working on anti-GM-CSF antibodies: Morphosys has announced the results of a Phase 1/2 trial in RA and is conducting a Phase 1 trial in MS; Micromet (now part of Amgen) has partnered with Nycomed (now part of Takeda) in a Phase 1 trial in RA; and MedImmune is conducting a Phase 2 trial in RA with an antibody against the GM-CSF receptor. Although we are no longer pursing the RA indication, these competitors could nonetheless affect our market for an anti-GM-CSF antibody for severe asthma. Many companies are developing drugs for asthma. Monoclonal antibody drug development has primarily focused on allergic asthma. Xolair®, which is co-developed by Genentech and Novartis, is currently the only monoclonal antibody that we are aware of that is approved for the treatment of severe asthma. However, Xolair only targets IgE-positive individuals, which represents only 50% of the population, but generated worldwide sales of $1 billion in 2011. Genentech (Roche), MedImmune, Novartis and Pfizer each has an anti-IL-13 antibody program in Phase 2 or Phase 3 testing for asthma. Other monoclonal antibodies in development target cytokines such as IL-4, IL-5, and IL-9 or their receptors. Although these drugs function differently, if successfully developed, these drugs will compete in the asthma market. Finally, although several companies are developing anti-GM-CSF antibodies, we are not aware that they are developing antibodies to treat asthma.

Competition in cancer drug development is intense, with more than 250 compounds in clinical trials by large pharmaceutical and biotechnology companies. Many of these companies are focused on targeted therapies. We anticipate that we will face intense and increasing competition as new treatments enter the market and advanced technologies become available. See Item 1A, "Risk Factors," for further discussion of risks regarding competition.

Manufacturing

We perform our own basic development activities, develop formulation prototypes, and have adopted a manufacturing strategy of contracting with third parties for the manufacture of drug substance and product. Additional contract manufacturers are used to fill, label, package, and distribute investigational drug products. This allows us to maintain a more flexible infrastructure while focusing our expertise on developing our products.

Sanofi is responsible for the manufacture of KB001-A drug substance for our development and promotion activities in our retained indications and has sub-contracted with a contract manufacturer for the production of drug substance for Sanofi's Phase 1 trial and our Phase 2 trial. Sanofi is also responsible for filling product for

our Phase 2 clinical trial. We will have to identify another drug product manufacturer for the further development of a subcutaneous formulation of KB001-A.

We have an agreement with a contract manufacturer for the manufacture of drug substance and drug product of KB003 for our early clinical trials. A new contract manufacturer may need to be identified to manufacture KB003 for our Phase 3 clinical trial. We also contract the production of the KB004 drug substance and drug product for our clinical trials. We have contracted with additional contract manufacturers for the filling, labeling, packaging, and distribution of investigational drug products.

FDA Approval Process

All of our current product candidates are subject to regulation in the United States by the FDA as biological products, or biologics. The FDA subjects biologics to extensive pre- and post-market regulations. The Public Health Service Act (PHSA), the FDC Act and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of biologics. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending Biologic Licensing Application (BLA), withdrawal of approvals, clinical holds, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, or criminal penalties.

To help reduce the increased risk of the introduction of adventitious agents, the PHSA emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The PHSA also provides authority to the FDA to immediately suspend licenses in situations where there exists a danger to public health, to prepare or procure products in the event of shortages and critical public health needs, and to authorize the creation and enforcement of regulations to prevent the introduction, or spread, of communicable diseases in the United States and between states.

The process required by the FDA before a new biologic may be marketed in the United States is long, expensive, and inherently uncertain. Biologics development in the United States typically involves preclinical laboratory and animal tests, the submission to the FDA of either a notice of claimed investigational exemption or an IND, which must become effective before clinical testing may commence, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the biologic for each indication for which FDA approval is sought. Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity, and novelty of the product or disease.

Preclinical tests include laboratory evaluation of product chemistry, formulation, and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements, including good laboratory practices. The results of preclinical testing are submitted to the FDA as part of an IND along with other information, including information about product chemistry, manufacturing and controls, and a proposed clinical trial protocol. Long term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

An IND must become effective before United States clinical trials may begin. A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has neither commented on nor questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin.

Clinical trials involve the administration of the investigational new drug or biologic to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with good clinical practice, or GCP, an international standard meant

to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators, and monitors; as well as (iii) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The study protocol and informed consent information for patients in clinical trials must also be submitted to an institutional review board (IRB) for approval. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions. The study sponsor may also suspend a clinical trial at any time on various grounds, including a determination that the subjects or patients are being exposed to an unacceptable health risk.

Clinical trials to support BLAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap or be combined. In Phase 1, the biologic is initially introduced into healthy human subjects or patients, and the biologic is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses, and, if possible, early evidence on effectiveness. In the case of some products for severe or life-threatening diseases, such as cancer treatments, initial human testing may be conducted in the intended patient population. Phase 2 usually involves trials in a limited patient population to determine the effectiveness of the biologic for a particular indication, dosage tolerance, and optimum dosage, and to identify common adverse effects and safety risks. If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites. These Phase 3 clinical trials are intended to establish data sufficient to demonstrate substantial evidence of the efficacy and safety of the product to permit the FDA to evaluate the overall benefit-risk relationship of the biologic and to provide adequate information for the labeling of the biologic. Sponsors of clinical trials for investigational drugs must publicly disclose certain clinical trial information, including detailed trial design and trial results in FDA public databases. These requirements are subject to specific timelines and apply to most controlled clinical trials of FDA-regulated products.

After completion of the required clinical testing, a BLA is prepared and submitted to the FDA. FDA review and approval of the BLA is required before marketing of the product may begin in the United States. The BLA must include the results of all preclinical, clinical, and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture, and controls and must demonstrate the safety and efficacy of the product based on these results. The BLA must also contain extensive manufacturing information. The cost of preparing and submitting a BLA is substantial. Under federal law, the submission of most BLAs is additionally subject to a substantial application user fee, currently exceeding $1,958,500, and the manufacturer and/or sponsor under an approved BLA are also subject to annual product and establishment user fees, currently exceeding $98,000 per product and $526,000 per establishment. These fees are typically increased annually.

The FDA has 60 days from its receipt of a BLA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of BLAs. Most such applications for standard review biologics are reviewed within ten to twelve months. The FDA can extend these timelines by three months and FDA review may not occur in a timely basis at all. The standard review process for both standard and priority review may be extended by the FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission. The FDA may also refer applications for novel biologics, or biologics which present difficult questions of safety or efficacy, to an advisory committee—typically a panel that includes clinicians and other experts—for review, evaluation, and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it

generally follows such recommendations. Before approving a BLA, the FDA will typically inspect one, or more, clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the biologic is manufactured. The FDA will not approve the product unless compliance with current good manufacturing practice, or GMP—a quality system regulating manufacturing—is satisfactory and the BLA contains data that provide substantial evidence that the biologic is safe and effective in the indication studied.

After the FDA evaluates the BLA and the manufacturing facilities, it issues either an approval letter, a complete response letter, or denies approval of the license. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the BLA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. The FDA approval is never guaranteed, and the FDA may refuse to approve a BLA if applicable regulatory criteria are not satisfied.

An approval letter authorizes commercial marketing of the biologic with specific prescribing information for specific indications. The approval for a biologic may be significantly more limited than requested in the application, including limitations on the specific diseases and dosages or the indications for use, which could restrict the commercial value of the product. The FDA may also require that certain contraindications, warnings, or precautions be included in the product labeling. In addition, as a condition of BLA approval, the FDA may require a risk evaluation and mitigation strategy (REMS) to help ensure that the benefits of the biologic outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use (ETASU). ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the biologic. Moreover, product approval may require, as a condition of approval, substantial post-approval testing and surveillance to monitor the biologic's safety or efficacy. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

After a BLA is approved, the product may also be subject to official lot release. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official lot release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA may also perform certain confirmatory tests on lots of some products, such as viral vaccines, before releasing the lots for distribution by the manufacturer. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency, and effectiveness of biological products. After approval of biologics, manufacturers must address any safety issues that arise, are subject to recalls or a halt in manufacturing, and are subject to periodic inspection after approval.

Because biologically sourced raw materials are subject to unique contamination risks, their use may be restricted in some countries.

FDA Pre-Market Approval Pathway—Devices

In the United States, medical devices, including *in vitro* diagnostics (IVDs), are subject to extensive regulation by the FDA, pursuant to the FDC Act, and its implementing regulations, and other federal and state statutes and regulations. These regulations govern, among other things, medical device design and development, preclinical and clinical testing, premarket clearance or approval, registration and listing, manufacturing, labeling, storage, advertising, and promotion, sales and distribution, export and import, and post-market surveillance.

The FDC Act classifies medical devices based on the risks associated with the device. Devices are classified into one of three categories—Class I, Class II, and Class III. Class I devices are deemed to be low risk and are therefore subject to the least regulatory controls. Class II devices are subject to the FDA's general controls and

any other special controls as deemed necessary by the FDA to provide reasonable assurance of the safety and effectiveness of the device. Pre-market review and clearance by the FDA for Class II devices are generally accomplished through the 510(k) pre-market notification procedure. Class III devices are generally the highest risk devices and are therefore subject to the highest level of regulatory control to provide reasonable assurance of the device's safety and effectiveness. Class III devices are generally required to undergo the premarket approval (PMA) process in which the manufacturer must demonstrate reasonable assurance of the safety and effectiveness of the device to the FDA's satisfaction.

A medical device can be legally marketed and sold within the United States if the FDA has: (i) approved a PMA application prior to marketing, generally applicable to Class III devices, or (ii) cleared the device in response to a premarket notification, or 510(k) submission, generally applicable to Class II devices, or the device is otherwise exempt from premarket clearance and approval requirements.

The PMA process involves a rigorous premarket review during which the applicant must prepare and provide the FDA with reasonable assurance of the device's safety and effectiveness and information about the device and its components regarding, among other things, device design, manufacturing and labeling. PMA applications are subject to an application fee. In addition, a PMA for a Class III device must generally include the results from extensive preclinical and adequate and well-controlled clinical trials to establish the safety and effectiveness of the device for each indication for which FDA approval is sought. In particular, for a diagnostic, the company must demonstrate that the diagnostic is reproducible when the same sample is tested multiple times by multiple users at multiple laboratories. For significant risk devices and Class III devices regulated pursuant to the PMA requirements, the FDA regulations require that human clinical investigations conducted in the United States be the subject of an investigational device exemption, or IDE, which must become effective before clinical testing may commence. In addition, to approve a PMA for an IVD, the FDA must be convinced that a device has clinical utility, meaning that an IVD provides information that is clinically meaningful. A biomarker's clinical significance may be obvious, or the applicant may be able to rely upon published literature or submit data to show clinical utility. As part of the PMA review, the FDA will typically inspect the manufacturer's facilities for compliance with Quality System Regulation, or QSR, requirements, which impose elaborate testing, control, documentation and other quality assurance procedures. The PMA process, including the gathering of clinical and nonclinical data and the submission to and review by the FDA can take several years or longer. In addition, approval is not guaranteed and the FDA may ultimately respond to a PMA submission with a not approvable determination based on deficiencies in the application and require additional clinical trial or other data that may be expensive and time-consuming to generate and that can substantially delay approval.

If the FDA's evaluation of the PMA application is favorable, the FDA typically issues an approvable letter requiring the applicant's agreement to specific conditions, such as changes in labeling, or specific additional information, such as submission of final labeling, in order to secure final approval of the PMA. If the FDA concludes that the applicable criteria have been met, the FDA will issue a PMA for the approved indications, which can be more limited than those originally sought by the manufacturer. The PMA can include post-approval conditions that the FDA believes necessary to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution.

After a device is placed on the market, regardless of the classification or pre-market pathway, it remains subject to significant regulatory requirements. Even if regulatory approval or clearance of a medical device is granted, the FDA may impose limitations or restrictions on the uses and indications for which the device may be labeled and promoted. Medical devices may be marketed only for the uses and indications for which they are cleared or approved. Device manufacturers must also establish registration and device listings with the FDA. A medical device manufacturer's manufacturing processes and those of its suppliers are required to comply with the applicable portions of the Quality Systems Regulations, which cover the methods and documentation of the design, testing, production, processes, controls, quality assurance, labeling, packaging and shipping of medical devices. Domestic facility records and manufacturing processes are subject to periodic unscheduled inspections by the FDA. The FDA also may inspect foreign facilities that export products to the United States.

Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions: warning letters, fines, injunctions, civil or criminal penalties, recall or seizure of current or future products, operating restrictions, partial suspension or total shutdown of production, denial of 510(k) clearance or PMA approval of new products, or rescissions to existing 510(k) clearances or withdrawals of PMA approvals.

Biosimilars

The Patient Protection and Affordable Care Act (Affordable Care Act) signed into law on March 23, 2010, included a subtitle called the Biologics Price Competition and Innovation Act of 2009 (BPCIA), which created an abbreviated approval pathway for biological products shown to be highly similar to or interchangeable with an FDA-licensed reference biological product. Biosimilarity, which requires that there be no differences between the biological product and the reference product in conditions of use, route of administration, dosage form, and strength, and no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, is required to be shown through analytical studies, animal studies, and at least one clinical study, absent a waiver by the Secretary. Interchangeability requires that a product meet the higher hurdle of demonstrating that it can be expected to produce the same clinical results as the reference product and, for products administered multiple times, the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. No biosimilar or interchangeable products have been approved under the BPCIA to date. Complexities associated with the larger, and often more complex, structures of biological products, as well as the process by which such products are manufactured, pose significant hurdles to implementation which are still being worked out by the FDA.

A reference biologic is granted 12 years of exclusivity from the time of first licensure of the reference product, and no application for a biosimilar can be submitted for four years from the date of licensure of the reference product. The first biologic product submitted under the abbreviated approval pathway that is determined to be interchangeable with the reference product has exclusivity against a finding of interchangeability for other biologics for the same condition of use for the lesser of (i) one year after first commercial marketing of the first interchangeable biosimilar, (ii) 18 months after the first interchangeable biosimilar is approved if there is no patent lawsuit, (iii) 18 months after resolution of a lawsuit over the patents of the reference biologic in favor of the first interchangeable biosimilar applicant, or (iv) 42 months after the first interchangeable biosimilar's application has been approved if a patent lawsuit is ongoing within the 42-month period.

Advertising and Promotion

Once a BLA is approved, a product will be subject to continuing post-approval regulatory requirements. For instance, FDA closely regulates the post-approval marketing and promotion of biologics, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet. Failure to comply with these regulations can result in significant penalties, including the issuance of warning letters directing a company to correct deviations from FDA standards, a requirement that future advertising and promotional materials be precleared by the FDA, and federal and state civil and criminal investigations and prosecutions.

Biologics may be marketed only for the approved indications and in accordance with the provisions of the approved labeling. Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new BLA or BLA supplement before the change can be implemented. A BLA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing BLA supplements as it does in reviewing BLAs.

Adverse Event Reporting and GMP Compliance

Adverse event reporting and submission of periodic reports are required following FDA approval of a BLA. The FDA also may require post-marketing testing, known as Phase 4 testing, risk minimization action plans, and surveillance to monitor the effects of an approved product, or the FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, quality-control, biologic manufacture, packaging, and labeling procedures must continue to conform to current Good Manufacturing Practice (cGMP) after approval. Biologics manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the agency inspects manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money, and effort in the areas of production and quality-control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals, request product recalls, or impose marketing restrictions through labeling changes or product removals if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

Companion Diagnostics

The FDA regulates the sale or distribution, in interstate commerce, of medical devices, including IVDs. IVDs are a type of medical device that are intended to detect diseases, conditions, or infections, or the presence of certain genetic or other biomarkers. If safe and effective use of a therapeutic depends on an IVD, the FDA generally will require approval or clearance of the companion diagnostic, at the same time that the FDA approves the therapeutic.

The FDA previously has required *in vitro* companion diagnostics intended to identify the patients most likely to respond to a cancer treatment to obtain PMA simultaneously with approval of the biologic.

Orphan Drug

Under the Orphan Drug Act, the FDA may grant orphan drug designation to biologics intended to treat a rare disease or condition—generally a disease or condition that affects fewer than 200,000 individuals in the United States. Orphan drug designation must be requested before submitting a BLA. After the FDA grants orphan drug designation, the generic identity of the biologic and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. The first BLA applicant to receive FDA approval for a particular active ingredient to treat a particular disease with FDA orphan drug designation is entitled to a seven-year exclusive marketing period in the United States for that product, for that indication. During the seven-year exclusivity period, the FDA may not approve any other applications to market the same drug for the same disease, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. Orphan drug exclusivity does not prevent the FDA from approving a different biologic for the same disease or condition, or the same biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the BLA application user fee.

Other Healthcare Laws and Compliance Requirements

In the United States, our activities are potentially subject to regulation by federal, state, and local authorities in addition to the FDA, including the Centers for Medicare and Medicaid Services, other divisions of the U.S. Department of Health and Human Services (e.g., the Office of Inspector General), the U.S. Department of Justice and individual U.S. Attorney offices within the Department of Justice, and state and local governments.

International Regulation

In addition to regulations in the United States, a variety of foreign regulations govern clinical trials, commercial sales, and distribution of product candidates. The approval process varies from country to country and the time to approval may be longer or shorter than that required for FDA approval.

Pharmaceutical Coverage, Pricing, and Reimbursement

In the United States and other countries, sales of any products for which we receive regulatory approval for commercial sale will depend in part on the availability of reimbursement from third-party payors, including government health administrative authorities, managed care providers, private health insurers, and other organizations. Third-party payors are increasingly examining the medical necessity and cost effectiveness of medical products and services in addition to safety and efficacy and, accordingly, significant uncertainty exists as to the reimbursement status of newly approved therapeutics. Third-party reimbursement adequate to enable us to realize an appropriate return on our investment in research and product development may not be available for our product candidates.

Employees

As of December 31, 2012, we had 22 employees, 20 of whom were full-time. None of our employees are represented by any collective bargaining unit. We believe that we maintain good relations with our employees.

ITEM 1A. RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the following risk factors, as well as the other information in this Annual Report on Form 10-K, before deciding whether to invest in shares of our common stock. The occurrence of any of the following adverse developments described in the following risk factors could harm our business, financial condition, results of operations or prospects. In that case, the trading price of our common stock could decline, and you may lose all or part of your investment.

RISK FACTORS

Risk Related to Our Business and the Development, Regulatory Approval, and Commercialization of Our Product Candidates

We have a history of operating losses, we expect to continue to incur losses, and we may never become profitable.

As of December 31, 2012, we had an accumulated deficit of $98.3 million, and for the year ended December 31, 2012, we incurred a net loss of $23.5 million. We have incurred net losses each year since our inception except for the year ended December 31, 2007, including net losses of $2.2 million for the year ended December 31, 2011, and $5.1 million for the year ended December 31, 2010. To date, we have only recognized revenue from payments for funded research and development and for license or collaboration fees. We expect to make substantial expenditures and incur additional operating losses in the future to further develop and commercialize our product candidates. Our accumulated deficit is expected to increase significantly as we expand our development and clinical trial efforts. Our ability to achieve and sustain profitability depends on obtaining regulatory approvals for and successfully commercializing our lead product candidates, either alone or with third parties. We do not currently have the required approvals to market any of our product candidates and we may never receive them. We may not be profitable even if we, Sanofi, or any of our future development partners succeed in commercializing any of our product candidates. Because of the numerous risks and uncertainties associated with developing and commercializing our product candidates, we are unable to predict the extent of any future losses or when we will become profitable, if at all.

We have limited sources of revenue, and we will need substantial additional capital to develop and commercialize our product candidates, and we may be unable to raise additional capital when needed, or at all, which would force us to reduce or discontinue operations.

As of December 31, 2012, we had $20.3 million in cash, cash equivalents, and marketable securities. Our contract revenue for the year ended December 31, 2012 were $6.1 million. We consumed a net $23.9 million of cash in operating activities during the year ended December 31, 2012. We expect our spending levels to increase in connection with our Phase 2 clinical trials for KB001-A and KB003, as well as other corporate activities.

Our spending levels vary based on new and ongoing development and corporate activities. As a result, our cash used in operating activities will also fluctuate from period to period. We have not sold any product candidates, and we do not expect to sell any product candidates or derive royalty revenue from product candidate sales for the foreseeable future, if ever. In order to develop and bring product candidates through clinical trials, we must commit substantial resources to costly and time-consuming clinical trials. As such, we anticipate that we will need to raise substantial additional capital, the requirements of which will depend on many factors, including:

- the type, number, costs, and results of the product candidate development programs which we are pursuing or may choose to pursue in the future;
- the scope, progress, expansion, costs, and results of our clinical trials;
- the timing of and costs involved in obtaining regulatory approvals;

- our ability to establish and maintain development partnering arrangements;
- the timing, receipt and amount of contingent, royalty, and other payments from Sanofi or any of our future development partners;
- the emergence of competing technologies and other adverse market developments;
- the costs of maintaining, expanding, and protecting our intellectual property portfolio, including potential litigation costs and liabilities;
- the resources we devote to marketing, and, if approved, commercializing our product candidates;
- the scope, progress, expansion, and costs of manufacturing our product candidates;
- our ability to draw funds from our loan and security agreement; and
- the costs associated with being a public company.

Since our inception, we have been financing our operations primarily through private placements of our equity securities, interest income earned on cash, cash equivalents, and marketable securities, lines of credit, and payments under agreements with Sanofi and Novartis International Pharmaceutical Ltd. (together with its affiliates, Novartis), a licensee of our Humaneered® technology. Our future capital requirements are substantial and in order to fund our future needs, we may seek additional funding through equity or debt financings, development partnering arrangements, lines of credit, or other sources. We believe our cash on hand, together with the net proceeds received from our recently completed initial public offering and our access to funds through our existing credit facility, will be sufficient to fund our operations for the next 12 months. Our expectations are based on management's current assumptions and clinical development plans, which may prove to be wrong, and we could spend our available financial resources much faster than we currently expect. We will require substantial additional capital to support clinical trials, regulatory approvals, and, if approved, the potential commercialization of our product candidates. Additional funding may not be available to us on a timely basis or at acceptable terms, or at all.

If we are unable to raise additional funds when needed, we may be required to delay, reduce, or terminate some or all of our development programs and clinical trials. We may also be required to sell or license to others our technologies, product candidates, or development programs that we would have preferred to develop and commercialize ourselves.

Because we have a short operating history developing clinical-stage antibodies, there is a limited amount of information about us upon which you can evaluate our product candidates and business prospects.

We commenced our first clinical trial in 2006, and we have a limited operating history developing clinical- stage antibodies upon which you can evaluate our business and prospects. In addition, as an early-stage clinical development company, we have limited experience in conducting clinical trials, and we have never conducted clinical trials of a size required for regulatory approvals. Further, we have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical area. For example, to execute our business plan we will need to successfully:

- execute our product candidate development activities, including successfully completing our clinical trial programs;
- obtain required regulatory approvals for the development and commercialization of our product candidates;
- manage our spending as costs and expenses increase due to clinical trials, regulatory approvals, manufacturing and commercialization;

- secure substantial additional funding;
- develop and maintain successful strategic relationships;
- build and maintain a strong intellectual property portfolio;
- build and maintain appropriate clinical, sales, distribution, and marketing capabilities on our own or through third parties; and
- gain broad market acceptance for our product candidates.

If we are unsuccessful in accomplishing these objectives, we may not be able to develop product candidates, raise capital, expand our business, or continue our operations.

Our product candidates are at an early stage of development and may not be successfully developed or commercialized.

Our product candidates are in the early stage of development and will require substantial clinical development, testing, and regulatory approval prior to commercialization. We currently only have two product candidates in Phase 2 clinical trials and one product candidate in Phase 1 clinical trials. None of our product candidates have advanced into a pivotal study and it may be years before such study is initiated, if at all. Of the large number of drugs in development, only a small percentage successfully complete the FDA regulatory approval process and are commercialized. Accordingly, even if we are able to obtain the requisite financing to continue to fund our development programs, we cannot assure you that our product candidates will be successfully developed or commercialized. If we, Sanofi, or any of our future development partners are unable to develop, or obtain regulatory approval for or, if approved, successfully commercialize, one or more of our product candidates, we may not be able to generate sufficient revenue to continue our business.

Our product candidates are subject to extensive regulation, compliance with which is costly and time consuming, may cause unanticipated delays, or prevent the receipt of the required approvals to commercialize our product candidates.

The clinical development, manufacturing, labeling, storage, record-keeping, advertising, promotion, import, export, marketing, and distribution of our product candidates are subject to extensive regulation by the FDA in the United States and by comparable authorities in foreign markets. In the United States, we are not permitted to market our product candidates until we receive regulatory approval from the FDA. The process of obtaining regulatory approval is expensive, often takes many years, and can vary substantially based upon the type, complexity, and novelty of the products involved, as well as the target indications. Approval policies or regulations may change and the FDA has substantial discretion in the drug approval process, including the ability to delay, limit, or deny approval of a product candidate for many reasons. Despite the time and expense invested in clinical development of product candidates, regulatory approval is never guaranteed.

The FDA or other comparable foreign regulatory authorities can delay, limit, or deny approval of a product candidate for many reasons, including:

- such authorities may disagree with the design or implementation of our, Sanofi's, or any of our future development partners' clinical trials;
- we, Sanofi, or any of our future development partners may be unable to demonstrate to the satisfaction of the FDA or other regulatory authorities that a product candidate is safe and effective for any indication;
- such authorities may not accept clinical data from trials which are conducted at clinical facilities or in countries where the standard of care is potentially different from the United States;
- the results of clinical trials may not demonstrate the safety or efficacy required by such authorities for approval;

- we, Sanofi, or any of our future development partners may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- such authorities may disagree with our interpretation of data from preclinical studies or clinical trials or the use of results from antibody studies that served as precursors to our current drug candidates;
- such authorities may find deficiencies in the manufacturing processes or facilities of third-party manufacturers with which we, Sanofi, or any of our future development partners contract for clinical and commercial supplies;
- we may not be successful in developing any companion diagnostic necessary to demonstrate efficacy in our desired target populations for KB004;
- such authorities may delay approval or clearance of any companion diagnostic for KB004; or
- the approval policies or regulations of such authorities may significantly change in a manner rendering our, Sanofi's, or any of our future development partners' clinical data insufficient for approval.

With respect to foreign markets, approval procedures vary among countries and, in addition to the aforementioned risks, can involve additional product testing, administrative review periods, and agreements with pricing authorities. In addition, events raising questions about the safety of certain marketed pharmaceuticals may result in increased cautiousness by the FDA and comparable foreign regulatory authorities in reviewing new drugs based on safety, efficacy or other regulatory considerations and may result in significant delays in obtaining regulatory approvals. Any delay in obtaining, or inability to obtain, applicable regulatory approvals would prevent us, Sanofi, or any of our future development partners from commercializing our product candidates.

The results of preclinical studies and early clinical trials are not always predictive of future results. Any product candidate we, Sanofi, or any of our future development partners advance into clinical trials may not have favorable results in later clinical trials, if any, or receive regulatory approval.

Drug development has inherent risk. We, Sanofi, or any of our future development partners will be required to demonstrate through adequate and well-controlled clinical trials that our product candidates are effective, with a favorable benefit-risk profile, for use in their target indications before we can seek regulatory approvals for their commercial sale. Drug development is a long, expensive and uncertain process, and delay or failure can occur at any stage of development, including after commencement of any of our clinical trials. In addition, success in early clinical trials does not mean that later clinical trials will be successful because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety or efficacy despite having progressed through initial clinical testing. Furthermore, our future trials will need to demonstrate sufficient safety and efficacy for approval by regulatory authorities in larger patient populations. Companies frequently suffer significant setbacks in advanced clinical trials, even after earlier clinical trials have shown promising results. In addition, only a small percentage of drugs under development result in the submission of a New Drug Application (NDA) or BLA to the FDA and even fewer are approved for commercialization.

Although we have completed two Phase 1/2 clinical studies of KB001, the precursor molecule to KB001-A, Sanofi has commenced a Phase 1 clinical study of KB001-A in healthy volunteers to evaluate higher doses than those that we previously tested and planned for in our Phase 2 CF development program. The results of Sanofi's Phase 1 clinical study could delay or adversely impact our KB001-A development program.

Furthermore, the efficacy or safety data demonstrated with KB001 and KB002, the precursor molecules to KB001-A and KB003, respectively, and intravenous formulation of KB001-A and KB003 may not be reproduced in KB001-A and KB003. Similarly, the subcutaneous formulations of KB001-A and KB003 may not produce any efficacy observed with intravenous formulations. We may need to conduct additional preclinical and clinical testing to confirm such data in the successor molecules and reformulations. We are still developing a subcutaneous formulation for KB001-A and need to further evaluate the subcutaneous formulation for KB003.

We have yet to reach the stage at which we will inform the FDA that we intend to switch dosage forms from intravenous to subcutaneous formulations. Also, our current development timelines for KB001-A are based on demonstrating to the FDA that KB001-A is comparable to KB001 and that data obtained with intravenous KB001-A and KB003 can be bridged to the development of subcutaneous formulations of these product candidates. There can be no assurance that we will be successful in demonstrating this comparability to the FDA on our current timelines, or at all. In addition, we do not currently plan to test different dose levels of drug until we conduct our pivotal trials. Because we will be testing different dose levels as part of our pivotal trials, the trials will be larger than the standard pivotal trial. In addition, testing dose levels at a later stage in development increases the risk that we will not successfully identify a dose with an acceptable safety and efficacy profile.

Any product candidate we, Sanofi, or any of our future development partners advance into clinical trials may cause unacceptable adverse events or have other properties that may delay or prevent its regulatory approval or commercialization or limit its commercial potential.

Unacceptable adverse events caused by any of our product candidates that we advance into clinical trials could cause us or regulatory authorities to interrupt, delay, or halt clinical trials and could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications and markets. This in turn could prevent us from completing development or commercializing the affected product candidate and generating revenue from its sale. For example, we observed fatal intracranial hemorrhages in two subjects deemed possibly related to the study drug by the study investigator in our KB004 Phase 1 clinical trial and, as a result, we amended our clinical protocol, which caused a delay in our program.

We and Sanofi have not yet completed testing of any of our product candidates for the treatment of the indications for which we intend to seek approval in humans, and we currently do not know the extent of adverse events, if any, that will be observed in individuals who receive any of our product candidates. If any of our product candidates cause unacceptable adverse events in clinical trials, we and Sanofi, as applicable, may not be able to obtain regulatory approval or commercialize such product candidate.

Anti-GM-CSF antibodies, including KB003, may contribute to the development of pulmonary alveolar proteinosis (PAP), in which case we may need to delay, redesign or terminate our clinical trials of KB003.

PAP is a very uncommon lung disease which is associated with the presence of high concentrations of anti-GM-CSF antibody, but such antibodies alone may not be sufficient to cause disease. PAP is characterized by excessive accumulation of the normal alveolar lining fluid (surfactant) within the lung. The clinical course of PAP is variable, ranging from spontaneous remission to respiratory failure. The estimated incidence of the disorder is 0.36 per 1 million people per year. Although PAP is associated with anti-GM-CSF antibodies, it is unclear if these antibodies are the sole cause of surfactant accumulation. For example, blood donors and cancer patients who have measurable anti-GM-CSF antibodies do not develop signs or symptoms of PAP. Natural neutralizing anti-GM-CSF antibodies have been reported in 0.3% of healthy populations. While we believe the risk for development of PAP with KB003 is low, in the event that KB003 is linked to the development of PAP, we may need to delay, redesign, or terminate our clinical trials of KB003.

We may experience delays in commencing or conducting our clinical trials or in receiving data from third parties or in the completion of clinical testing, which could result in increased costs to us and delay our ability to generate product candidate revenue.

Before we can initiate clinical trials in the United States for our product candidates, we need to submit the results of preclinical testing to the FDA as part of an IND application, along with other information including information about product candidate chemistry, manufacturing, and controls and our proposed clinical trial protocol. We rely in part on preclinical, clinical, and quality data generated by Sanofi and other third parties for regulatory submissions for KB001-A. If Sanofi does not make timely regulatory submissions for KB001-A, it

will delay our plans for our clinical trials for CF. If those third parties do not make this data available to us, we will likely have to develop all necessary preclinical and clinical data on our own, which will lead to significant delays and increase development costs of the product candidate. In addition, the FDA may require us to conduct additional preclinical testing for any product candidate before it allows us to initiate clinical testing under any IND, which may lead to additional delays and increase the costs of our preclinical development. Despite the presence of an active IND for a product candidate, clinical trials can be delayed for a variety of reasons including delays in:

- identifying, recruiting, and training suitable clinical investigators;
- reaching agreement on acceptable terms with prospective contract research organizations (CROs) and trial sites, the terms of which can be subject to extensive negotiation, may be subject to modification from time to time, and may vary significantly among different CROs and trial sites;
- obtaining sufficient quantities of a product candidate for use in clinical trials, including as a result of transferring the manufacturing of a product candidate to another site or manufacturer;
- obtaining and maintaining institutional review board (IRB) or ethics committee approval to conduct a clinical trial at an existing or prospective site;
- identifying, recruiting, and enrolling subjects to participate in a clinical trial;
- retaining or replacing participants who have initiated a clinical trial but may withdraw due to adverse events from the therapy, insufficient efficacy, fatigue with the clinical trial process, or personal issues; and
- readiness of any companion diagnostic necessary to ensure that the study enrolls the target population.

The FDA may also put a clinical trial on clinical hold at any time during product candidate development.

Once a clinical trial has begun, recruitment and enrollment of subjects may be slower than we anticipate. In addition, clinical trials will take longer than we anticipate if we are required, or believe it is necessary, to enroll additional subjects. Clinical trials may also be delayed as a result of ambiguous or negative interim results. Further, a clinical trial may be suspended or terminated by us, an IRB, an ethics committee, or a data safety monitoring committee overseeing the clinical trial, any of our clinical trial sites with respect to that site or the FDA or other regulatory authorities due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- inspection of the clinical trial operations or clinical trial site by the FDA or other regulatory authorities;
- unforeseen safety issues, known safety issues that occur at a greater frequency or severity than we anticipate, or any determination that the clinical trial presents unacceptable health risks; or
- lack of adequate funding to continue the clinical trial.

Additionally, under the terms of our license and collaboration agreement with Sanofi, Sanofi has the exclusive right to develop and commercialize KB001, KB001-A and other antibodies directed against the PcrV protein or *Pa* for all indications. Although this agreement requires Sanofi to use commercially reasonable efforts to engage in certain product development activities, Sanofi may decide to amend, suspend or terminate the clinical trials related to these licensed product candidates. Further, if Sanofi or any of our future development partners do not develop the licensed product candidates in the manner that we expect, or at all, the clinical development efforts related to these licensed product candidates could be delayed or terminated.

Any delays in the commencement of our clinical trials, including any delays by Sanofi attributed to terminating or switching any subcontractors for the manufacture of the KB001-A drug substance, will delay our ability to pursue regulatory approval for our product candidates. Changes in U.S. and foreign regulatory

requirements and guidance also may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for re-examination, which may affect the costs, timing, and likelihood of a successful completion of a clinical trial. If we, Sanofi, or any of our future development partners experience delays in the completion of, or if we, Sanofi, or any of our future development partners must terminate, any clinical trial of any product candidate our ability to obtain regulatory approval for that product candidate will be delayed and the commercial prospects, if any, for the product candidate may suffer as a result. In addition, many of these factors may also ultimately lead to the denial of regulatory approval of a product candidate.

If we pursue development of a companion diagnostic intended to identify patients who are likely to benefit from KB004, failure to obtain approval for the diagnostic may prevent or delay approval of KB004.

We are in the initial phases of developing a companion diagnostic which is intended to identify patients who are likely to derive the most benefit from KB004. If we are able to develop this companion diagnostic, we intend to amend our Phase 1 protocol prior to initiating the expansion phase to include EphA3 positive status as an inclusion criterion.

The FDA regulates companion diagnostics, or *in-vitro* diagnostics, such as the one we are developing, as medical devices. FDA regulations pertaining to medical devices govern, among other things, the research, design, development, pre-clinical and clinical testing, manufacture, safety, efficacy, storage, record-keeping, packaging, labeling, adverse event reporting, advertising, promotion, marketing, distribution, and import and export of medical devices. Pursuant to the Federal Food, Drug, and Cosmetic Act (FDC Act), medical devices are subject to varying degrees of regulatory control and are classified in one of three classes depending on the controls the FDA determines necessary to reasonably ensure their safety and efficacy. In July 2011, the FDA issued draft guidance that stated that if safe and effective use of a therapeutic depends on an *in vitro* diagnostic, then the FDA generally will not approve the therapeutic until it is ready to approve or clear this *in vitro* companion diagnostic device. While this guidance is still in draft form, we believe that it states the FDA's current position and that KB004 may not be approved until the FDA has sufficient information to also approve or clear our companion device. Moreover, the FDA's expectations for *in vitro* companion diagnostics are evolving and some aspects of the FDA's regulatory approach remain unclear. The FDA's developing expectations will affect, among other things, the development, testing and review of our *in vitro* companion diagnostics.

Because our companion diagnostic candidate is at an early stage of development, we have yet to seek a meeting with the FDA to discuss our companion diagnostic test in development and therefore cannot yet know what the FDA will require for this test. We may not be able to develop or obtain approval or clearance for the companion diagnostic, and any failure to obtain regulatory approval or clearance could delay development or prevent approval of KB004.

If our competitors develop treatments for the target indications of our product candidates that are approved more quickly, marketed more successfully or demonstrated to be safer or more effective than our product candidates, our commercial opportunity will be reduced or eliminated.

We operate in highly competitive segments of the biotechnology and biopharmaceutical markets. We face competition from many different sources, including commercial pharmaceutical and biotechnology enterprises, academic institutions, government agencies, and private and public research institutions. Our product candidates, if successfully developed and approved, will compete with established therapies as well as with new treatments that may be introduced by our competitors. Many of our competitors have significantly greater financial, product candidate development, manufacturing, and marketing resources than we do. Large pharmaceutical and biotechnology companies have extensive experience in clinical testing and obtaining regulatory approval for drugs. In addition, many universities and private and public research institutes are active in cancer research, some in direct competition with us. We also may compete with these organizations to recruit management, scientists,

and clinical development personnel. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. New developments, including the development of other pharmaceutical technologies and methods of treating disease, occur in the pharmaceutical and life sciences industries at a rapid pace. Developments by competitors may render our product candidates obsolete or noncompetitive. We will also face competition from these third parties in recruiting and retaining qualified personnel, establishing clinical trial sites, and registering subjects for clinical trials, and in identifying and in-licensing new product candidates.

There are several companies treating *Pa* using antibiotics or alternative approaches. For example, Intercell AG has a fusion protein vaccine program in Phase 2/3 for the prevention of *Pa* in mechanically ventilated intensive care unit patients and Kenta Biotech Ltd. is conducting a Phase 2 trial for KBPA101, a monoclonal antibody against a specific *Pa* serotype. There are two inhaled antibiotics (Tobi® and Cayston®) that have been approved for *Pa* to treat CF. We are also aware of one biologic drug (Pulmozyme®) that is approved in the United States to treat respiratory problems in CF patients. KALYDECO®, a small-molecule drug that potentiates the form of the defective protein that causes CF, was recently approved by the FDA. VX-809 is a compound being developed by Vertex Pharmaceuticals, Inc. in Phase 2 clinical trials for CF.

Several companies are also working on anti-GM-CSF antibodies: Morphosys recently announced results of a Phase 1/2 trial in RA and is conducting a Phase 1 trial in multiple sclerosis (MS); Micromet (now part of Amgen) has partnered with Nycomed (now part of Takeda) in a Phase 1 trial in RA; and MedImmune is conducting a Phase 2 trial in RA with an antibody against the GM-CSF receptor. Although we are no longer pursuing the RA indication, these competitors could nonetheless affect our market for an anti-GM-CSF antibody for severe asthma. Many companies are developing drugs for asthma. Monoclonal antibody drug development has primarily focused on allergic asthma. Xolair®, which is co-developed by Genentech and Novartis, is currently the only monoclonal antibody that we are aware of that is approved for the treatment of severe asthma. Genentech (Roche), MedImmune, Novartis and Pfizer each has an anti-IL-13 antibody program in Phase 2 or Phase 3 testing for asthma. Other monoclonal antibodies in development target cytokines such as IL-4, IL-5, and IL-9 or their receptors. Although these drugs function differently, if successfully developed these drugs will compete in the asthma market.

Competition in cancer drug development is intense, with more than 250 compounds in clinical trials by large pharmaceutical and biotechnology companies. Many of these companies are focused on targeted therapies. We anticipate that we will face intense and increasing competition as new treatments enter the market and advanced technologies become available.

We are subject to a multitude of manufacturing risks, any of which could substantially increase our costs and limit supply of our products.

The process of manufacturing our products is complex, highly regulated and subject to several risks, including:

- The process of manufacturing biologics, such as KB001-A, KB003, and KB004, is extremely susceptible to product loss due to contamination, equipment failure or improper installation or operation of equipment, or vendor or operator error. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our products or in the manufacturing facilities in which our products are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination.
- The manufacturing facilities in which our products are made could be adversely affected by equipment failures, labor shortages, natural disasters, power failures and numerous other factors.
- We and our contract manufacturers must comply with the FDA's current Good Manufacturing Practice (cGMP) regulations and guidelines. We and our contract manufacturers may encounter difficulties in

achieving quality control and quality assurance and may experience shortages in qualified personnel. We and our contract manufacturers are subject to inspections by the FDA and comparable agencies in other jurisdictions to confirm compliance with applicable regulatory requirements. Any failure to follow cGMP or other regulatory requirements or delay, interruption or other issues that arise in the manufacture, fill- finish, packaging, or storage of our products as a result of a failure of our facilities or the facilities or operations of third parties to comply with regulatory requirements or pass any regulatory authority inspection could significantly impair our ability to develop and commercialize our products, including leading to significant delays in the availability of products for our clinical studies or the termination or hold on a clinical study, or the delay or prevention of a filing or approval of marketing applications for our product candidates. Significant noncompliance could also result in the imposition of sanctions, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approvals for our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could damage our reputation. If we are not able to maintain regulatory compliance, we may not be permitted to market our products and/or may be subject to product recalls, seizures, injunctions, or criminal prosecution.

- Any adverse developments affecting manufacturing operations for our products may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of our products. We may also have to take inventory write-offs and incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives.

We may not be able to successfully develop and manufacture a subcutaneous formulation of KB001-A or KB003.

We believe that we must develop a subcutaneous formulation of KB001-A for the treatment of *Pa* in CF patients and a subcutaneous formulation of KB003 in order for such products to be commercially viable, if such products are approved. We are currently in the very early stages of developing subcutaneous formulations and any pivotal study that we intend to rely on for purposes of seeking regulatory approval must be conducted using the formulation that we intend to commercialize. In addition, we will need to demonstrate to the FDA's satisfaction that any subcutaneous formulation we develop may rely upon data derived from preclinical and clinical trials using our current intravenous formulations, and the FDA may require us to conduct additional testing or even repeat some of our earlier testing. There are no assurances that we will be able to successfully develop and manufacture a subcutaneous formulation for KB001-A or KB003, and even if we can, there is no guarantee that the FDA will accept these formulations. If we fail to develop and successfully manufacture subcutaneous formulations for either of these product candidates, we may not be able to successfully commercialize such products.

We currently rely on Sanofi and other manufacturers for the supply of KB001-A and KB003. However, we will need to identify a new drug product manufacturer for the further development of subcutaneous formulations of KB001-A and KB003. Transitioning to a new manufacturer may result in significant expenses and devotion of our resources, and there is no guarantee that such manufacturer will be secured, or if secured, will be able to address our ongoing manufacturing needs for the subcutaneous formulation of KB001-A or KB003.

If we are unable to identify a contract manufacturer for the drug substance for KB003 and enter into an agreement on a timely basis, any Phase 3 clinical trial of KB003 would be delayed.

We currently have an agreement with a contract manufacturer for the manufacture of drug substance of KB003 for our early clinical trials. We believe we will need to secure a new contract manufacturer to satisfy our supply needs for KB003 for any Phase 3 clinical trial. We may need to devote significant expenses and resources in identifying and transitioning to a new manufacturer and there is no assurance that such manufacturer will be

identified and secured on a timely basis. If we are unable to timely secure the manufacture of the drug substance for a Phase 3 clinical trial for KB003, any such trial would be delayed.

If any product candidate that we successfully develop does not achieve broad market acceptance among physicians, patients, healthcare payors and the medical community, the revenue that it generates may be limited.

Even if our product candidates receive regulatory approval, they may not gain market acceptance among physicians, patients, healthcare payors, and the medical community. Coverage and reimbursement of our product candidates by third-party payors, including government payors, generally is also necessary for commercial success. The degree of market acceptance of any approved product candidates will depend on a number of factors, including:

- the efficacy and safety as demonstrated in clinical trials;
- the clinical indications for which the product candidate is approved;
- acceptance by physicians, major operators of hospitals and clinics, and patients of the product candidate as a safe and effective treatment;
- the potential and perceived advantages of product candidates over alternative treatments;
- the safety of product candidates seen in a broader patient group, including its use outside the approved indications;
- the cost of treatment in relation to alternative treatments;
- the availability of adequate reimbursement and pricing by third parties and government authorities;
- relative convenience and ease of administration;
- the prevalence and severity of adverse events;
- the effectiveness of our sales and marketing efforts; and
- unfavorable publicity relating to the product candidate.

If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors, and patients, we may not generate sufficient revenue from that product candidate and may not become or remain profitable.

Reimbursement may be limited or unavailable in certain market segments for our product candidates, which could make it difficult for us to sell our product candidates profitably.

Market acceptance and sales of our product candidates will depend significantly on the availability of adequate insurance coverage and reimbursement from third-party payors for any of our product candidates and may be affected by existing and future health care reform measures. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs they will pay for and establish reimbursement levels. Reimbursement by a third-party payor may depend upon a number of factors including the third-party payor’s determination that use of a product candidate is:

- a covered benefit under its health plan;
- safe, effective, and medically necessary;
- appropriate for the specific patient;
- cost effective; and
- neither experimental nor investigational.

Obtaining coverage and reimbursement approval for a product candidate from a government or other third- party payor is a time-consuming and costly process that could require us to provide supporting scientific, clinical, and cost effectiveness data for the use of our product candidates to the payor. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. We cannot be sure that coverage or adequate reimbursement will be available for any of our product candidates. Also, we cannot be sure that reimbursement amounts will not reduce the demand for, or the price of, our product candidates. If reimbursement is not available or is available only to limited levels, we may not be able to commercialize certain of our product candidates profitably, or at all, even if approved.

In the United States and in certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could affect our ability to sell our product candidates profitably. In particular, the Medicare Modernization Act of 2003 revised the payment methods for many product candidates under Medicare. This has resulted in lower rates of reimbursement. There have been numerous other federal and state initiatives designed to reduce payment for pharmaceuticals.

As a result of legislative proposals and the trend toward managed health care in the United States, third- party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement of new drugs. They may also refuse to provide coverage of approved product candidates for medical indications other than those for which the FDA has granted market approvals. As a result, significant uncertainty exists as to whether and how much third-party payors will reimburse patients for their use of newly approved drugs, which in turn will put pressure on the pricing of drugs. We expect to experience pricing pressures in connection with the sale of our product candidates due to the trend toward managed health care, the increasing influence of health maintenance organizations, and additional legislative proposals as well as country, regional, or local healthcare budget limitations.

If we are unable to establish sales and marketing capabilities or fail to enter into agreements with third parties to market and sell any product candidates we may successfully develop, we may not be able to effectively market and sell any such product candidates.

We do not currently have any infrastructure for the sale, marketing, and distribution of any of our product candidates once approved, if at all, and we must build this infrastructure or make arrangements with third parties to perform these functions in order to commercialize any product candidates for which we may obtain approval. The establishment and development of a sales force, either by us or jointly with a development partner, or the establishment of a contract sales force to market any product candidates we may develop will be expensive and time consuming and could delay any product candidate launch. If we, Sanofi, or any of our future development partners are unable to establish sales and marketing capabilities or any other nontechnical capabilities necessary to commercialize any product candidates we may successfully develop, we will need to contract with third parties to market and sell such product candidates. We may not be able to establish arrangements with third parties on acceptable terms, if at all.

If we are not successful in discovering, developing, acquiring and commercializing additional product candidates, our ability to expand our business will be limited.

A substantial amount of our effort is focused on the continued clinical testing and potential approval of our current product candidates and expanding our product candidates to serve other indications of high unmet medical needs. Research programs to identify other indications require substantial technical, financial and human resources, whether or not any product candidates for other indications are ultimately identified. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for many reasons, including the following:

- the research methodology used may not be successful in identifying potential product candidates;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;

- product candidates we develop may nevertheless be covered by third parties' patents or other exclusive rights;
- a product candidate may on further study be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors, if applicable.

In addition, while our agreement with Sanofi remains in effect, neither we nor our affiliates may develop or commercialize any other anti-*Pa* antibody. This would apply to a future acquiror, except with respect to any anti- *Pa* antibody of the acquiror existing on the date of acquisition and developed thereafter.

If we do not successfully develop and commercialize product candidates for other indications, our business and future prospects may be limited and our business will be more vulnerable to problems that we encounter in developing and commercializing our current product candidates.

If we are acquired by a pharmaceutical company with a significant market capitalization, Sanofi may exercise an option to exclusively assume all aspects of development and commercialization of licensed products in Pa-infected patients with CF or bronchiectasis worldwide, in which case the revenue we would generate from those licensed products would be limited.

Under our license and collaboration agreement with Sanofi, if we are acquired by a top 25 pharmaceutical company based on market capitalization at the time of such acquisition, Sanofi has the option to exclusively assume all aspects of development and commercialization of licensed products to treat *Pa*-infected patients with CF or bronchiectasis worldwide. If Sanofi exercises this option, our rights to participate in development and commercialization of the licensed products in *Pa*-infected patients with CF or bronchiectasis would terminate and the revenue generated from the commercialization of those licensed products would be limited to the amounts Sanofi would be required to pay pursuant to its agreement with us. This provision may adversely impact a company's desire to acquire us.

If we fail to attract and retain key management and clinical development personnel, we may be unable to successfully develop or commercialize our product candidates.

We will need to expand and effectively manage our managerial, operational, financial, and other resources in order to successfully pursue our clinical development and commercialization efforts. As a company with a limited number of personnel, we are highly dependent on the development, regulatory, commercial, and financial expertise of the members of our senior management, in particular David W. Pritchard, our president and chief executive officer, and Geoffrey T. Yarranton, our executive vice president, research and development, and chief scientific officer. The loss of such individuals or the services of any of our other senior management could delay or prevent the further development and potential commercialization of our product candidates and, if we are not successful in finding suitable replacements, could harm our business. Our former chief medical officer resigned in February 2012, and it took us three months to hire our current chief medical officer in May 2012. Our success also depends on our continued ability to attract, retain, and motivate highly qualified management and scientific personnel and we may not be able to do so in the future due to intense competition among biotechnology and pharmaceutical companies, universities, and research organizations for qualified personnel. If we are unable to attract and retain the necessary personnel, we may experience significant impediments to our ability to implement our business strategy.

If we fail to effectively integrate our new executive officers into our organization, the future development and commercialization of our product candidates may suffer, harming future regulatory approvals, sales of our product candidates or our results of operations.

Our chief medical officer joined us in May 2012, and our chief financial officer joined us in July 2012. As a result, certain members of our executive team have not worked together as a group for a significant period of time. Our future performance will depend, in part, on our ability to successfully integrate our newly hired executive officers into our management team and our ability to develop an effective working relationship among senior management. Our failure to integrate these individuals and create effective working relationships among them and other members of management could result in inefficiencies in the development and commercialization of our product candidates, harming future regulatory approvals, sales of our product candidates and our results of operations.

We face potential product liability exposure and, if successful claims are brought against us, we may incur substantial liability for a product candidate and may have to limit its commercialization.

The use of our product candidates in clinical trials and the sale of any product candidates for which we may obtain marketing approval expose us to the risk of product liability claims. Product liability claims may be brought against us, Sanofi, or any of our future development partners by participants enrolled in our clinical trials, patients, health care providers, or others using, administering, or selling our product candidates. If we cannot successfully defend ourselves against any such claims, we would incur substantial liabilities. Regardless of merit or eventual outcome, product liability claims may result in:

- withdrawal of clinical trial participants;
- termination of clinical trial sites or entire trial programs;
- costs of related litigation;
- substantial monetary awards to trial participants or other claimants;
- decreased demand for our product candidates and loss of revenue;
- impairment of our business reputation;
- diversion of management and scientific resources from our business operations; and
- the inability to commercialize our product candidates.

We have obtained limited product liability insurance coverage for our clinical trials domestically and in selected foreign countries where we are conducting clinical trials. Our coverage is currently limited to $10 million per occurrence and $10 million in the aggregate per year. As such, our insurance coverage may not reimburse us or may not be sufficient to reimburse us for any 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 product liability. We intend to expand our insurance coverage for product candidates to include the sale of commercial products if we obtain marketing approval for our product candidates in development; however, we may be unable to obtain commercially reasonable product liability insurance for any product candidates approved for marketing. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us, particularly if judgments exceed our insurance coverage, could decrease our working capital and adversely affect our business.

Our insurance policies are expensive and protect us only from some business risks, which leaves us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter. For example, we do not carry earthquake insurance. In the event of a major earthquake in our region, our business could suffer significant

and uninsured damage and loss. Some of the policies we currently maintain include general liability, employment practices liability, property, auto, workers' compensation, products liability, and directors' and officers' insurance. We do not know, however, if we will be able to maintain existing insurance with adequate levels of coverage. Any significant, uninsured liability may require us to pay substantial amounts, which would adversely affect our working capital and results of operations.

Our employees may engage in misconduct or other improper activities including noncompliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, provide accurate information to regulatory authorities, comply with manufacturing standards we have established, comply with federal and state health care fraud and abuse laws and regulations, report financial information or data accurately, or disclose unauthorized activities to us. In particular, sales, marketing, and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing, and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. Employee misconduct could also involve improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation.

In addition, during the course of our operations our directors, executives, and employees may have access to material, nonpublic information regarding our business, our results of operations, or potential transactions we are considering. We may not be able to prevent a director, executive, or employee from trading in our common stock on the basis of, or while having access to, material, nonpublic information. If a director, executive, or employee was to be investigated or an action was to be brought against a director, executive, or employee for insider trading, it could have a negative impact on our reputation and our stock price. Such a claim, with or without merit, could also result in substantial expenditures of time and money, and divert attention of our management team from other tasks important to the success of our business.

We may encounter difficulties in managing our growth and expanding our operations successfully.

As we seek to advance our product candidates through clinical trials we will need to expand our development, regulatory, manufacturing, marketing, and sales capabilities, collaborate with Sanofi and contract with third parties to provide these capabilities for us. As our operations expand we expect that we will need to manage additional relationships with various development partners, suppliers, and other third parties. Future growth will impose significant added responsibilities on members of management. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend in part on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively. We may not be able to accomplish these tasks and our failure to accomplish any of them could prevent us from successfully growing our company.

Our loan and security agreement contains restrictions that limit our flexibility in operating our business.

In September 2012, we entered into a loan and security agreement with MidCap Financial and drew down $5.0 million under the facility. In December 2012, we drew down an additional $5.0 million under the facility. The agreement contains various covenants that limit our ability to engage in specified types of transactions. These covenants limit our ability to, among other things:

- incur or assume certain debt;
- merge or consolidate;
- change the nature of our business;

- change our organizational structure or type;
- dispose of certain assets;
- grant liens on our assets;
- make certain investments;
- pay dividends; and
- enter into material transactions with affiliates.

A breach of any of these covenants or a material adverse change to our business, operations, or condition (financial or otherwise) could result in a default under the loan. In the case of a continuing event of default under the loan, MidCap Financial could elect to declare all amounts outstanding to be immediately due and payable and terminate all commitments to extend further credit, commence and prosecute bankruptcy and/or other insolvency proceedings, or proceed against the collateral granted to MidCap Financial under the loan. Amounts outstanding under the term loan are secured by all of our existing and future assets (excluding intellectual property, which is subject to a negative pledge arrangement). A default and any accompanying repayment could have a material adverse effect on our business, operating results and financial condition.

We and our development partner, third-party manufacturers and suppliers use biological materials and may use hazardous materials, and any claims relating to improper handling, storage, or disposal of these materials could be time consuming or costly.

We and our development partner, third-party manufacturers and suppliers may use hazardous materials, including chemicals and biological agents and compounds that could be dangerous to human health and safety or the environment. Our operations and the operations of our development partner, third-party manufacturers and suppliers also produce hazardous waste products. Federal, state, and local laws and regulations govern the use, generation, manufacture, storage, handling, and disposal of these materials and wastes. Compliance with applicable environmental laws and regulations may be expensive and current or future environmental laws and regulations may impair our product development efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. We do not carry specific biological or hazardous waste insurance coverage and our property, casualty, and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended.

Our internal computer systems, or those of our development partner, third-party clinical research organizations or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs.

Despite the implementation of security measures, our internal computer systems and those of our development partner, third-party clinical research organizations and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war, and telecommunication and electrical failures. While we have not experienced any such system failure, accident, or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs. For example, the loss of clinical trial data for any of our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications or other data or applications relating to our technology or product candidates, or inappropriate disclosure of confidential or proprietary information, we could incur liabilities and the further development of our product candidates could be delayed.

Healthcare reform measures, when implemented, could hinder or prevent our commercial success.

There have been, and likely will continue to be, legislative and regulatory proposals at the federal and state levels directed at broadening the availability of health care and containing or lowering the cost of health care. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations, and other payors of healthcare services to contain or reduce costs of health care may adversely affect:

- the demand for any drug products for which we may obtain regulatory approval;
- our ability to set a price that we believe is fair for our product candidates;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Governments may impose price controls, which may adversely affect our future profitability.

We intend to seek approval to market our future product candidates in both the United States and in foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions, we will be subject to rules and regulations in those jurisdictions relating to our product candidates. In some foreign countries, particularly in the European Union, the pricing of prescription pharmaceuticals and biologics is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product candidate. If reimbursement of our future products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability.

We, Sanofi, and any of our future development partners will be required to report to regulatory authorities if any of our approved products cause or contribute to adverse medical events, and any failure to do so would result in sanctions that would materially harm our business.

If we, Sanofi, and any of our future development partners are successful in commercializing our products, the FDA and foreign regulatory authorities would require that we, Sanofi, and any of our future development partners report certain information about adverse medical events if those products may have caused or contributed to those adverse events. The timing of our obligation to report would be triggered by the date we become aware of the adverse event as well as the nature of the event. We, Sanofi, and any of our future development partners may fail to report adverse events we become aware of within the prescribed timeframe. We, Sanofi, and any of our future development partners may also fail to appreciate that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of our products. If we, Sanofi, and any of our future development partners fail to comply with our reporting obligations, the FDA or a foreign regulatory authority could take action including criminal prosecution, the imposition of civil monetary penalties, seizure of our products, or delay in approval or clearance of future products.

Our product candidates for which we and our development partner intend to seek approval as biologic products may face competition sooner than anticipated.

With the enactment of the Biologics Price Competition and Innovation Act of 2009 (BPCIA) as part of the Affordable Care Act, an abbreviated pathway for the approval of biosimilar and interchangeable biological products was created. The abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as “interchangeable” based on its similarity to an existing brand product. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the original branded product was approved under a BLA. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact,

implementation, and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement BPCIA may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our biological products.

We believe that any of our product candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

In addition, foreign regulatory authorities may also provide for exclusivity periods for approved biological products. For example, biological products in Europe may be eligible for a 10-year period of exclusivity. However, biosimilar products have been approved under a sub-pathway of the centralized procedure since 2006. The pathway allows sponsors of a biosimilar product to seek and obtain regulatory approval based in part on the clinical trial data of an originator product to which the biosimilar product has been demonstrated to be "similar." In many cases, this allows biosimilar products to be brought to market without conducting the full suite of clinical trials typically required of originators. It is unclear whether we and our development partner would face competition to our products in European markets sooner than anticipated.

We may in the future be subject to various U.S. federal and state laws pertaining to health care fraud and abuse, including anti-kickback, self-referral, false claims and fraud laws, and any violations by us of such laws could result in fines or other penalties.

If one or more of our product candidates is approved, we will likely be subject to the various U.S. federal and state laws intended to prevent health care fraud and abuse. The federal anti-kickback statute prohibits the offer, receipt, or payment of remuneration in exchange for or to induce the referral of patients or the use of products or services that would be paid for in whole or part by Medicare, Medicaid or other federal health care programs. Remuneration has been broadly defined to include anything of value, including cash, improper discounts, and free or reduced price items and services. Many states have similar laws that apply to their state health care programs as well as private payors. Violations of the anti-kickback laws can result in exclusion from federal health care programs and substantial civil and criminal penalties.

The False Claims Act (FCA), imposes liability on persons who, among other things, present or cause to be presented false or fraudulent claims for payment by a federal health care program. The FCA has been used to prosecute persons submitting claims for payment that are inaccurate or fraudulent, that are for services not provided as claimed, or for services that are not medically necessary. The FCA includes a whistleblower provision that allows individuals to bring actions on behalf of the federal government and share a portion of the recovery of successful claims. If our marketing or other arrangements were determined to violate the FCA or anti-kickback or related laws, then our revenue could be adversely affected, which would likely harm our business, financial condition, and results of operations.

State and federal authorities have aggressively targeted medical technology companies for alleged violations of these anti-fraud statutes, based on improper research or consulting contracts with doctors, certain marketing arrangements that rely on volume-based pricing, off-label marketing schemes, and other improper promotional practices. Companies targeted in such prosecutions have paid substantial fines in the hundreds of millions of dollars or more, have been forced to implement extensive corrective action plans or Corporate Integrity Agreements, and have often become subject to consent decrees severely restricting the manner in which they conduct their business. If we become the target of such an investigation or prosecution based on our contractual relationships with providers or institutions, or our marketing and promotional practices, we could face similar sanctions, which would materially harm our business.

Also, the Foreign Corrupt Practices Act and similar worldwide anti-bribery laws generally prohibit companies and their intermediaries from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. We cannot assure you that our internal control policies and procedures will protect us from reckless or negligent acts committed by our employees, future distributors, partners, collaborators or agents. Violations of these laws, or allegations of such violations, could result in fines, penalties, or prosecution and have a negative impact on our business, results of operations and reputation.

Legislative or regulatory healthcare reforms in the United States may make it more difficult and costly for us to obtain regulatory approval of our product candidates and to produce, market, and distribute our products after approval is obtained.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory approval, manufacture, and marketing of regulated products or the reimbursement thereof. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of our current product candidates or any future product candidates. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require:

- changes to manufacturing methods;
- additional studies, including clinical studies;
- recall, replacement, or discontinuance of one or more of our products; and
- additional record keeping.

Each of these would likely entail substantial time and cost and could materially harm our business and our financial results. In addition, delays in receipt of or failure to receive regulatory approvals for any future products would harm our business, financial condition, and results of operations.

Even if we are able to obtain regulatory approval for our product candidates, we will continue to be subject to ongoing and extensive regulatory requirements, and our failure to comply with these requirements could substantially harm our business.

If we receive regulatory approval for our product candidates, we will be subject to ongoing FDA obligations and continued regulatory oversight and review, such as continued safety reporting requirements, and we may also be subject to additional FDA post-marketing obligations. If we are not able to maintain regulatory compliance, we may not be permitted to market our product candidates and/or may be subject to product recalls or seizures.

If the FDA approves any of our product candidates, the labeling, packaging, adverse event reporting, storage, advertising, promotion and record-keeping for our products will be subject to extensive regulatory requirements. The subsequent discovery of previously unknown problems with the products, including adverse events of unanticipated severity or frequency, may result in restrictions on the marketing of the product, and could include withdrawal of the product from the market.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

We have incurred substantial losses during our history and do not expect to become profitable in the foreseeable future and may never achieve profitability. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire. We may be unable to use these losses to offset income before such unused losses expire. Under Section 382 of the Internal Revenue Code, 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 to offset its post-change income may be limited. We have in the past experienced ownership changes that have resulted in limitations on the use of a portion of our net operating loss carryforwards. If we experience further ownership changes our ability to utilize our net operating loss carryforwards could be further limited.

Risks Related to Our Dependence on Third Parties

We are dependent on Sanofi for the development and commercialization of KB001-A, and Sanofi's failure to develop and/or commercialize KB001-A would result in a material adverse effect on our business and operating results.

We have granted Sanofi an exclusive license to KB001, KB001-A and other antibodies directed against the PcrV protein of *Pa* for all indications for most aspects of their development and commercialization. Our development partnership with Sanofi on KB001-A or other antibodies may not be scientifically, medically, or commercially successful due to a number of important factors, including the following:

- Sanofi's obligation to use "diligent efforts" under our agreement leaves Sanofi with significant discretion in determining the efforts and resources that it will apply to the development and commercialization of KB001-A or other antibodies directed against the PcrV protein of *Pa*. The timing and amount of any contingent and royalty payments we may receive under our agreement will depend on, among other things, the efforts, allocation of resources, and successful development and commercialization of our product candidate by Sanofi under our agreement;
- Sanofi holds the rights to commercialize KB001-A, including for *Pa* in CF and bronchiectasis patients, and holds an option to assume primary responsibility for developing and promoting KB001-A for such indications. Sanofi may not choose to exercise its option to develop and promote KB001-A or other licensed products in *Pa*-infected patients with CF or bronchiectasis and has no contractual obligation to do so. If Sanofi does not exercise its option for the CF or bronchiectasis indications, Sanofi will nevertheless retain the exclusive right to perform certain necessary commercial activities (including the exclusive right to sell and distribute KB001-A) with respect to such indications but will have no obligation to perform such activities. In such event, if Sanofi were to decide not to commercialize KB001-A for the CF or bronchiectasis indications, and we nevertheless wished to commercialize KB001-A for either of these indications if approved, we would need to renegotiate with Sanofi certain terms of our agreement but may be unable to do so on reasonable terms, in a timely manner, or at all;
- Sanofi may develop and commercialize, either alone or with others, product candidates that are similar to or competitive with KB001-A or other antibodies directed against the PcrV protein of *Pa* for the indications that we are targeting for KB001-A;
- Sanofi may change the focus of its development and commercialization efforts or pursue higher-priority programs;
- Sanofi may not make timely regulatory submissions for KB001-A;
- subject to our promotional rights in the CF or bronchiectasis indications, Sanofi will have substantial control over the commercialization of KB001-A and other antibodies directed against the PcrV protein of *Pa* for all indications, including in CF or bronchiectasis patients, whether or not Sanofi chooses to exercise its option to develop KB001-A for such indications. Sanofi's commercialization objectives for different indications may not be consistent with our goals and there can be no assurance that Sanofi will want to commercialize KB001-A or other antibodies directed against the PcrV protein of *Pa* in a manner that maximizes our revenue. In addition, we may find that we cannot reach agreement over some of the development and commercialization aspects of KB001-A or other antibodies directed against the PcrV protein of *Pa*, resulting in program delays, termination, or other decisions that might have a material impact on our business;

- Sanofi may fail to manufacture or supply sufficient drug substance of KB001-A for our clinical use, such as our CF study, which could result in program delays;
- Sanofi may fail to manufacture or supply sufficient drug substance of KB001-A for our commercial use, if approved, which could result in lost revenue;
- we and Sanofi may fail to agree on the specific terms of a profit sharing arrangement within the United States for the CF indication in the event that Sanofi elects the shared U.S. territory option;
- Sanofi may utilize our intellectual property rights or take actions related to licensed products in such a way as to invite litigation that could jeopardize or invalidate our intellectual property rights or expose us to potential liability;
- if we are acquired by a pharmaceutical company with a significant market capitalization, Sanofi may exercise its option to exclusively assume all aspects of development and commercialization of licensed products in *Pa*-infected CF and bronchiectasis patients worldwide;
- Sanofi may not comply with all applicable regulatory requirements or may fail to report safety data in accordance with all applicable regulatory requirements;
- Sanofi may terminate the agreement with us for convenience upon 180 days' prior written notice;
- if Sanofi were to breach or terminate the agreement with us, the development and commercialization of KB001-A or other antibodies directed against the PcrV protein of *Pa* could be delayed. We would need to either use our own resources and capabilities to continue the development and commercialization of KB001-A or grant rights to another development or commercial partner;
- if Sanofi were to terminate its arrangements with us, our potential revenue under our agreement with Sanofi, including from potential development and commercial contingent payments and royalties on net sales of licensed products, would be significantly reduced; and
- Sanofi may not dedicate the resources that would be necessary to carry the product candidate through clinical development or may not obtain the necessary regulatory approvals.

Sanofi's failure to develop or effectively commercialize KB001-A or other antibodies directed against the PcrV protein of *Pa* would result in a material adverse effect on our business and results of operations and would likely cause our stock price to decline.

We rely on third parties to conduct our clinical trials. If these third parties do not meet our deadlines or otherwise conduct the trials as required, our clinical development programs could be delayed or unsuccessful and we may not be able to obtain regulatory approval for or commercialize our product candidates when expected or at all.

We do not have the ability to conduct all aspects of our preclinical testing or clinical trials ourselves. We are dependent on Sanofi to conduct the Phase 2 and Phase 3 clinical trials for KB001-A for the prevention of *Pa* VAP and, therefore, the timing of the initiation and completion of these trials is controlled by Sanofi and may occur on substantially different timing from our estimates. We also use CROs to conduct our clinical trials and rely on medical institutions, clinical investigators, CROs, and consultants to conduct our trials in accordance with our clinical protocols and regulatory requirements. Our CROs, investigators, and other third parties play a significant role in the conduct of these trials and subsequent collection and analysis of data.

There is no guarantee that any CROs, investigators, or other third parties on which we rely for administration and conduct of our clinical trials will devote adequate time and resources to such trials or perform as contractually required. If any of these third parties fails to meet expected deadlines, fails to adhere to our clinical protocols, or otherwise performs in a substandard manner, our clinical trials may be extended, delayed, or terminated. If any of our clinical trial sites terminates for any reason, we may experience the loss of follow-up information on subjects enrolled in our ongoing clinical trials unless we are able to transfer those subjects to

another qualified clinical trial site. In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, the integrity of the data generated at the applicable clinical trial site may be jeopardized.

We rely completely on third parties, most of which are sole source suppliers, to supply drug substance and manufacture drug product for our clinical trials and preclinical studies and intend to rely on other third parties to produce commercial supplies of product candidates, and our dependence on third parties could adversely impact our business.

We are completely dependent on third-party suppliers, most of which are sole source suppliers of the drug substance and drug product for our product candidates. If these third-party suppliers do not supply sufficient quantities for product candidates to us on a timely basis and in accordance with applicable specifications and other regulatory requirements, there could be a significant interruption of our supplies, which would adversely affect clinical development of the product candidate. Furthermore, if any of our contract manufacturers cannot successfully manufacture material that conforms to our specifications and with regulatory requirements, we will not be able to secure and/or maintain regulatory approval, if any, for our product candidates.

We will also rely on our contract manufacturers to purchase from third-party suppliers the materials necessary to produce our product candidates for our anticipated clinical trials. There are a small number of suppliers for certain capital equipment and raw materials used to manufacture our product candidates. We do not have any control over the process or timing of the acquisition of these raw materials by our contract manufacturers. Moreover, we currently do not have agreements in place for the commercial production of these raw materials. Any significant delay in the supply of a product candidate or the raw material components thereof for an ongoing clinical trial could considerably delay completion of that clinical trial, product candidate testing, and potential regulatory approval of that product candidate.

We do not expect to have the resources or capacity to commercially manufacture any of our proposed product candidates if approved, and will likely continue to be dependent on third-party manufacturers. Our dependence on third parties to manufacture and supply us with clinical trial materials and any approved product candidates may adversely affect our ability to develop and commercialize our product candidates on a timely basis.

We may not be successful in establishing and maintaining additional development partnerships, which could adversely affect our ability to develop and commercialize product candidates.

In addition to our current development partnership with Sanofi, a part of our strategy is to enter into additional development partnerships in the future, including collaborations with major biotechnology or pharmaceutical companies. We face significant competition in seeking appropriate development partners and the negotiation process is time consuming and complex. Moreover, we may not be successful in our efforts to establish a development partnership or other alternative arrangements for any of our other existing or future product candidates and programs because our research and development pipeline may be insufficient, our product candidates and programs may be deemed to be at too early a stage of development for collaborative effort and/or third parties may not view our product candidates and programs as having the requisite potential to demonstrate safety and efficacy. Even if we are successful in our efforts to establish new development partnerships, the terms that we agree upon may not be favorable to us and we may not be able to maintain such development partnerships if, for example, development or approval of a product candidate is delayed or sales of an approved product candidate are disappointing. Any delay in entering into new development partnership agreements related to our product candidates could delay the development and commercialization of our product candidates and reduce their competitiveness if they reach the market.

Moreover, if we fail to establish and maintain additional development partnerships related to our product candidates:

- the development of certain of our current or future product candidates may be terminated or delayed;
- our cash expenditures related to development of certain of our current or future product candidates would increase significantly and we may need to seek additional financing;
- we may be required to hire additional employees or otherwise develop expertise, such as sales and marketing expertise, for which we have not budgeted; and
- we will bear all of the risk related to the development of any such product candidates.

Risks Related to Intellectual Property

Our success depends on our ability to protect our intellectual property and our proprietary technologies.

Our commercial success depends in part on our ability to obtain and maintain patent protection and trade secret protection for our product candidates, proprietary technologies, and their uses as well as our ability to operate without infringing upon the proprietary rights of others. There can be no assurance that our patent applications or those of our licensors will result in additional patents being issued or that issued patents will afford sufficient protection against competitors with similar technology, nor can there be any assurance that the patents issued will not be infringed, designed around, or invalidated by third parties. Even issued patents may later be found unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. The degree of future protection for our proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. This failure to properly protect the intellectual property rights relating to these product candidates could have a material adverse effect on our financial condition and results of operations.

Composition-of-matter patents on the biological or chemical active pharmaceutical ingredient are generally considered to be the strongest form of intellectual property protection for pharmaceutical products, as such patents provide protection without regard to any method of use. We cannot be certain that the claims in our patent applications covering composition-of-matter of our product candidates will be considered patentable by the U.S. Patent and Trademark Office (USPTO) and courts in the United States or by the patent offices and courts in foreign countries, nor can we be certain that the claims in our issued composition-of-matter patents will not be found invalid or unenforceable if challenged. Method-of-use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products “off-label.” Although off-label prescriptions may infringe or contribute to the infringement of method-of-use patents, the practice is common and such infringement is difficult to prevent or prosecute.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we, Sanofi, or any of our future development partners will be successful in protecting our product candidates by obtaining and defending patents. These risks and uncertainties include the following:

- the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case;
- patent applications may not result in any patents being issued;
- patents that may be issued or in-licensed may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable, or otherwise may not provide any competitive advantage;

- our competitors, many of whom have substantially greater resources than we do and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with, or eliminate our ability to make, use, and sell our potential product candidates;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and
- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop, and market competing product candidates.

Furthermore, we and our development partners rely on the protection of our trade secrets and proprietary know-how. For example, we rely on Novartis, to whom we have licensed our Humaneered® platform, to protect our trade secrets and proprietary know-how that has been licensed to them. Although we have taken steps to protect our trade secrets and unpatented know-how, including entering into confidentiality agreements with third parties, and confidential information and inventions agreements with employees, consultants, and advisors, third parties may still obtain this information or may come upon this or similar information independently. If any of these events occurs or if we otherwise lose protection for our trade secrets or proprietary know-how, the value of this information may be greatly reduced.

Additionally, in the U.S., the central provisions of the Leahy-Smith America Invents Act (AIA) became effective on March 16, 2013. Among other things, this law will switch U.S. patent rights from the present "first-to-invent" system to a "first inventor-to-file" system. This may result in inventors and companies having to file patent applications more frequently to preserve rights in their inventions. This may favor larger competitors that have greater resources to file more patent applications.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition by potential partners or customers in our markets of interest. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected.

If we, Sanofi, or any of our future development partners are sued for infringing intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in that litigation would have a material adverse effect on our business.

Our success also depends on our ability and the ability of Sanofi and any of our future development partners to develop, manufacture, market, and sell our product candidates without infringing upon the proprietary rights of third parties. Numerous U.S.-issued and foreign-issued patents and pending patent applications owned by third parties exist in the fields in which we are developing product candidates, some of which may contain claims that overlap with the subject matter of our intellectual property or are directed at our product candidates. When we become aware of patents held by third parties that may implicate the manufacture, development or commercialization of our product candidates, we evaluate our need to license rights to such patents. For example, we have entered into several licenses for the right to use third-party intellectual property, including with the UCSF and the LICR. If we need to license rights from third parties to manufacture, develop or commercialize our product candidates, there can be no assurance that we will be able to obtain a license on commercially reasonable terms or at all.

Because patent applications can take many years to issue there may be currently pending applications, unknown to us, that may later result in issued patents upon which our product candidates or proprietary

technologies may infringe. Similarly, there may be issued patents relevant to our product candidates of which we are not aware.

There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries generally. If a third party claims that we or any of our licensors, suppliers, or development partners infringe upon a third party's intellectual property rights, we may have to:

- seek to obtain licenses that may not be available on commercially reasonable terms, if at all;
- abandon an infringing product candidate or redesign our products or processes to avoid infringement;
- pay substantial damages including, in an exceptional case, treble damages and attorneys' fees, which we may have to pay if a court decides that the product candidate or proprietary technology at issue infringes upon or violates the third party's rights;
- pay substantial royalties or fees and/or grant cross-licenses to our technology; and/or
- defend litigation or administrative proceedings that may be costly whether we win or lose, and which could result in a substantial diversion of our financial and management resources.

Any such claims against us could also be deemed to constitute an event of default under our loan and security agreement with MidCap Financial. In the case of a continuing event of default under the loan, MidCap Financial could elect to declare all amounts outstanding to be immediately due and payable and terminate all commitments to extend further credit, commence and prosecute bankruptcy and/or other insolvency proceedings, or proceed against the collateral granted to MidCap Financial under the loan.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming and unsuccessful.

Competitors may infringe upon our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, found to be unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

Most of our competitors are larger than we are and have substantially greater resources. They are, therefore, likely to be able to sustain the costs of complex patent litigation longer than we could. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our internal research programs, in-license needed technology, or enter into development partnerships that would help us bring our product candidates to market.

In addition, any future patent litigation, interference, or other administrative proceedings will result in additional expense and distraction of our personnel. An adverse outcome in such litigation or proceedings may expose us, Sanofi or any of our future development partners to loss of our proprietary position, expose us to significant liabilities, or require us to seek licenses that may not be available on commercially acceptable terms, if at all.

Our issued patents could be found invalid or unenforceable if challenged in court.

If we, Sanofi, or any of our future development partners were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, or one of our future product candidates, the defendant could counterclaim that our patent is invalid and/or unenforceable. In patent litigation in the United

States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before the USPTO, even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on such product candidate. Such a loss of patent protection would have a material adverse impact on our business.

We may fail to comply with any of our obligations under existing agreements pursuant to which we license rights or technology, which could result in the loss of rights or technology that are material to our business.

We are a party to technology licenses that are important to our business and we may enter into additional licenses in the future. We currently hold licenses from the Medical College of Wisconsin, UCSF, LICR, BioWa, Lonza, and Sanofi. These licenses impose various commercial, contingent payment, royalty, insurance, indemnification, and other obligations on us. If we fail to comply with these obligations, the licensor may have the right to terminate the license, in which event we would lose valuable rights under our collaboration agreements and our ability to develop product candidates.

We may be subject to claims that our consultants or independent contractors have wrongfully used or disclosed alleged trade secrets of their other clients or former employers to us.

As is common in the biotechnology and pharmaceutical industry, we engage the services of consultants to assist us in the development of our product candidates. Many of these consultants were previously employed at, or may have previously or may be currently providing consulting services to, other biotechnology or pharmaceutical companies including our competitors or potential competitors. We may become subject to claims that our company or a consultant inadvertently or otherwise used or disclosed trade secrets or other information proprietary to their former employers or their former or current clients. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve technological and legal complexity. Therefore, obtaining and enforcing biopharmaceutical patents is costly, time consuming, and inherently uncertain. In addition, Congress may pass patent reform legislation. The Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents we might obtain in the future.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be

less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Risks Related to Our Common Stock

Raising additional funds by issuing securities or through licensing or lending arrangements may cause dilution to our existing stockholders, restrict our operations or require us to relinquish proprietary rights.

To the extent that we raise additional capital by issuing equity securities, the share ownership of existing stockholders will be diluted. Any future debt financing may involve covenants that restrict our operations, including, among other restrictions, limitations on our ability to incur liens or additional debt, pay dividends, redeem our stock, make certain investments, and engage in certain merger, consolidation, or asset sale transactions. In addition, if we raise additional funds through licensing arrangements, it may be necessary to relinquish potentially valuable rights to our product candidates or grant licenses on terms that are not favorable to us.

We have identified a material weakness in our internal control over financial reporting. If we fail to remediate this material weakness and implement and maintain proper and effective internal control over financial reporting in the future, our ability to produce accurate and timely financial statements could be impaired, which could harm our operating results, investors' views of us and, as a result, the value of our common stock.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 and related rules, our management is required to report upon the effectiveness of our internal control over financial reporting in our Annual Report on Form 10-K for the fiscal year ended December 31, 2013. When and if we are a "large accelerated filer" or an "accelerated filer" and are no longer an "emerging growth company," each as defined in the Securities Exchange Act of 1934, as amended (the Exchange Act), our independent registered public accounting firm will also be required to attest to the effectiveness of our internal control over financial reporting. However, for so long as we remain an emerging growth company, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to public companies that are not emerging growth companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404. Once we are no longer an emerging growth company or, if prior to such date, we opt to no longer take advantage of the applicable exemption, we will be required to include an opinion from our independent registered public accounting firm on the effectiveness of our internal controls over financial reporting.

The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing, and possible remediation. To comply with the requirements of being a reporting company under the Exchange Act, we need to upgrade our systems including information technology; implement additional financial and management controls, reporting systems, and procedures; and hire additional accounting and finance staff. Historically we have not had sufficient accounting and supervisory personnel with the appropriate level of technical accounting experience and training necessary or adequate formally documented accounting policies and procedures to support effective internal controls. We have commenced the costly and time consuming process of formally documenting, reviewing, and improving our internal controls over financial reporting and have made efforts to improve our internal controls and accounting policies and procedures, including hiring new accounting personnel and engaging external temporary resources. However, in future periods, we may identify additional deficiencies and weaknesses or fail to remediate previously identified deficiencies in our internal controls.

During our assessment of internal control over financial reporting as of December 31, 2012, we identified a material weakness in the operation of our internal controls over financial reporting. A material weakness is a control deficiency, or combination of control deficiencies, that results in a more than remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected. The material weakness relates to the completeness and accuracy of clinical trial expenses. We have commenced efforts to remediate this material weakness through process and internal control improvements. However, if we cannot correct the material weakness we have identified prior to the end of fiscal year 2013, or if we experience other problems that prevent the favorable assessment of the effectiveness of our internal control over financial reporting as of December 31, 2013, or if our independent registered public accounting firm issues an adverse opinion on internal control over financial reporting, investor confidence and our stock price could be adversely affected. Further, if material weaknesses or deficiencies in our internal controls exist and go undetected, our financial statements could contain material misstatements that, when discovered in the future, could cause us to fail to meet our future reporting obligations and cause the price of our common stock to decline.

Our stock price is volatile and purchasers of our common stock could incur substantial losses.

Our stock price is volatile and from January 31, 2013, the first day of trading of our common stock, to March 15, 2013, our stock had high and low sales prices in the range of 8.00 to $6.10 per share. The market price of our common stock may fluctuate significantly in response to a number of factors. These factors include those discussed in this “Risk Factors” section of this report and others such as:

- delay or failure in initiating or completing preclinical studies or clinical trials, or unsatisfactory results of these trials;
- announcements about us or about our competitors including clinical trial results, regulatory approvals, or new product candidate introductions;
- developments concerning our development partner, licensors or product candidate manufacturers;
- litigation and other developments relating to our patents or other proprietary rights or those of our competitors;
- conditions in the pharmaceutical or biotechnology industries and the economy as a whole;
- governmental regulation and legislation;
- recruitment or departure of members of our board of directors, management team or other key personnel;
- changes in our operating results;
- the financial projections we may provide to the public, any changes in these projections, our failure to meet these projections, or changes in recommendations by any securities analysts that elect to follow our common stock;

- change in securities analysts' estimates of our performance, or our failure to meet analysts' expectations;
- the expiration of market standoff or contractual lock-up agreements;
- announcements regarding equity or debt financing transactions;
- sales or potential sales of substantial amounts of our common stock; and
- price and volume fluctuations in the overall stock market or resulting from inconsistent trading volume levels of our shares.

In recent years, the stock market in general, and the market for pharmaceutical and biotechnological companies in particular, has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to changes in the operating performance of the companies whose stock is experiencing those price and volume fluctuations. Broad market and industry factors may seriously affect the market price of our common stock, regardless of our actual operating performance. These fluctuations may be even more pronounced in the trading market for our stock shortly following our initial public offering.

No public market for our common stock existed prior to our initial public offering, and an active trading market may not develop or be sustained following our initial public offering.

Prior to our initial public offering in February 2013, there was no public market for our common stock. An active trading market may not develop following our initial public offering or, if developed, may not be sustained. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value of your shares. An inactive market may also impair our ability to raise capital to continue to fund operations by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration.

Substantial future sales of shares by existing stockholders, or the perception that such sales may occur, could cause our stock price to decline.

If our existing stockholders, particularly our directors and executive officers and the venture capital funds affiliated with our current and former directors, sell substantial amounts of our common stock in the public market, or are perceived by the public market as intending to sell substantial amounts of our common stock, the trading price of our common stock could decline significantly. As of March 15, 2013, we had 24,147,815 shares of common stock outstanding. Of these shares, 14,697,573 shares are currently subject to contractual lock-up agreements entered into by certain of our stockholders with the underwriters in connection with our initial public offering and will become freely tradable on July 30, 2013, subject to extension or reduction. Upon the expiration of these restrictions contained in these contractual lock-up agreements, except for shares of common stock held by directors, executive officers and our other affiliates, which will be subject to volume limitations under Rule 144 of the Securities Act of 1933, as amended.

Some of our existing security holders have demand and piggyback rights to require us to register with the SEC up to 13,408,735 shares of our common stock, subject to expiration of the contractual lock-up agreements. If we register these shares of common stock, the stockholders would be able to sell those shares freely in the public market, subject to Rule 144 transfer restrictions applicable to affiliates.

We also registered 3,205,899 shares of our common stock that we may issue under our equity plans. Once we issue these shares, they can be freely sold in the public market upon issuance, subject to any vesting restriction, contractual lock-up agreements, or Rule 144 transfer restrictions applicable to affiliates.

If securities analysts do not publish research or publish unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities and industry analysts publish about us or our business. If one or more of the analysts who covers us downgrades our stock or publishes unfavorable research about our business, or if our clinical trials or operating results fail to meet the analysts' expectations, our stock price would likely decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which could cause our stock price and trading volume to decline.

Requirements associated with being a public reporting company will continue to increase our costs significantly, as well as divert significant company resources and management attention.

We have only been subject to the reporting requirements of the Exchange Act and the other rules and regulations of the Securities and Exchange Commission (SEC) since August 2012. We are working with our legal, independent accounting, and financial advisors to identify those areas in which changes should be made to our financial and management control systems to manage our growth and our obligations as a public reporting company. These areas include corporate governance, corporate control, disclosure controls and procedures, and financial reporting and accounting systems. We have made, and will continue to make, changes in these and other areas. Compliance with the various reporting and other requirements applicable to public reporting companies will require considerable time, attention of management, and financial resources. In addition, the changes we make may not be sufficient to allow us to satisfy our obligations as a public reporting company on a timely basis.

Further, the listing requirements of The NASDAQ Global Market require that we satisfy certain corporate governance requirements relating to director independence, distributing annual and interim reports, stockholder meetings, approvals and voting, soliciting proxies, conflicts of interest and a code of conduct. Our management and other personnel will need to devote a substantial amount of time to ensure that we comply with all of these requirements. Moreover, the reporting requirements, rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. These reporting requirements, rules and regulations, coupled with the increase in potential litigation exposure associated with being a public company, could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors or board committees or to serve as executive officers, or to obtain certain types of insurance, including directors' and officers' insurance, on acceptable terms.

In addition, being a public company could make it more difficult or more costly for us to obtain certain types of insurance, including directors' and officers' liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

Any changes we make to comply with these obligations may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis, or at all.

We have never paid and do not intend to pay cash dividends and, consequently, your ability to achieve a return on your investment in our common stock will depend on appreciation in the price of our common stock.

We have never paid cash dividends on any of our capital stock, and we currently intend to retain future earnings, if any, to fund the development and growth of our business. Additionally, our loan and security agreement with MidCap Financial contains covenants that restrict our ability to pay dividends. Therefore, you are not likely to receive any dividends on our common stock for the foreseeable future. Since we do not intend to pay

dividends, your ability to receive a return on an investment in our common stock will depend on any future appreciation in the market value of our common stock. There is no guarantee that our common stock will appreciate or even maintain the price at which you purchased it.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

Our directors, executive officers, and the holders of more than 5% of our common stock together with their affiliates beneficially own approximately 68% of our common stock. These stockholders, acting together, may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

As a newly public company, our stock price may be volatile, and securities class action litigation has often been instituted against companies following periods of volatility of their stock price. Any such litigation, if instituted against us, could result in substantial costs and a diversion of our management's attention and resources.

In the past, following periods of volatility in the overall market and the market price of a particular company's securities, securities class action litigation has often been instituted against these companies. This litigation, if instituted against us, could result in substantial costs and a diversion of our management's attention and resources.

Anti-takeover provisions in our development agreement with Sanofi, as well as in our charter documents and Delaware law, could discourage, delay, or prevent a change in control of our company and may affect the trading price of our common stock.

Under our license and collaboration agreement with Sanofi, in the event we are acquired by a top 25 pharmaceutical company based on market capitalization at the time of such acquisition, Sanofi has the option to exclusively develop and commercialize licensed products to treat *Pa*-infected patients with CF or bronchiectasis patients worldwide, which would limit the amount of revenue we could generate from the commercialization of those licensed products to the amounts Sanofi would be required to pay pursuant to their agreement with us. In addition, our agreement with Sanofi prohibits us or an acquiror of us from developing or commercializing any other anti-*Pa* antibody except with respect to any anti-*Pa* antibody of the acquiror existing on the date of acquisition and developed thereafter. Accordingly, these provisions may discourage or prevent certain pharmaceutical companies from seeking to acquire us.

In addition, we are a Delaware corporation and the anti-takeover provisions of the Delaware General Corporation Law may discourage, delay, or prevent a change in control by prohibiting us from engaging in a business combination with an interested stockholder for a period of three years after the person becomes an interested stockholder, even if a change in control would be beneficial to our existing stockholders.

Our amended and restated certificate of incorporation and amended and restated bylaws may discourage, delay, or prevent a change in our management or control over us that stockholders may consider favorable. Our amended and restated certificate of incorporation and amended and restated bylaws:

- provide that vacancies on our board of directors, including newly created directorships, may be filled only by a majority vote of directors then in office;
- do not provide stockholders with the ability to cumulate their votes; and
- require advance notification of stockholder nominations and proposals.

We are an emerging growth company and the extended transition period for complying with new or revised financial accounting standards and reduced disclosure and governance requirements applicable to emerging growth companies could make our common stock less attractive to investors.

We are an emerging growth company. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We plan to avail ourselves of this exemption from new or revised accounting standards and, therefore, we may not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

For as long as we continue to be an emerging growth company, we also intend to take advantage of certain other exemptions from various reporting requirements that are applicable to other public companies including, but not limited to, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, exemptions from the requirements of holding a nonbinding advisory stockholder vote on executive compensation and any golden parachute payments not previously approved, exemption from the requirement of auditor attestation in the assessment of our internal control over financial reporting and exemption from any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (auditor discussion and analysis). If we do, the information that we provide stockholders may be different than what is available with respect to other public companies.

Investors could find our common stock less attractive because we will rely on these exemptions, which may make it more difficult for investors to compare our business with other companies in our industry. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. In addition, it may be difficult for us to raise additional capital as and when we need it. If we are unable to do so, our financial condition and results of operations could be materially and adversely affected.

We will remain an emerging growth company until the earliest of (i) the end of the fiscal year in which the market value of our common stock that is held by non-affiliates exceeds $700 million as of the end of the second fiscal quarter, (ii) the end of the fiscal year in which we have total annual gross revenue of $1 billion or more during such fiscal year, (iii) the date on which we issue more than $1 billion in non-convertible debt in a three- year period or (iv) December 31, 2017, the end of the fiscal year following the fifth anniversary of the first sale of our common equity securities pursuant to an effective registration statement filed under the Securities Act.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We lease an approximately 40,000 square-foot building consisting of office and laboratory space in South San Francisco, California, which serves as our corporate headquarters. The lease term commenced in July 2011 and has scheduled annual rent increases through the lease expiration in June 2014. We believe that the facility that we currently lease is adequate for our needs for the immediate future and that, should it be needed, additional space can be leased to accommodate any future growth.

ITEM 3. LEGAL PROCEEDINGS

We are currently not party to any material legal proceedings. We may from time to time become involved in litigation relating to claims arising from our ordinary course of business. These claims, even if not meritorious, could result in the expenditure of significant financial and managerial resources.

ITEM 4. MINE SAFETY DISCLOSURES

None.

PART II

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

MARKET INFORMATION

Our common stock has been traded on the NASDAQ Global Select Market since January 31, 2013 under the symbol "KBIO." Prior to such time, there was no public market for our common stock. As a result, we have not set forth quarterly information with respect to the high and low prices for our common stock for the two most recent fiscal years.

HOLDERS OF COMMON STOCK

As of March 15, 2013, there were approximately 113 holders of record of our common stock. Certain shares are held in "street" name and accordingly, the number of beneficial owners of such shares is not known or included in the foregoing number.

DIVIDEND POLICY

We have never declared or paid any cash dividends. We currently expect to retain all future earnings, if any, for use in the operation and expansion of our business, and therefore do not anticipate paying any cash dividends in the foreseeable future. Additionally, our loan and security agreement with MidCap Financial contains covenants that restrict our ability to pay dividends.

USE OF PROCEEDS

On January 31, 2013, our registration statement on Form S-1 (File No. 333-184299), as amended, was declared effective by the SEC for our initial public offering, or IPO. Pursuant to the Registration Statement, we registered the offer and sale of 9,487,500 shares of our common stock with an aggregate offering price of approximately $85.0 million. We sold and issued 8,750,000 shares of our common stock at a price to the public of $8.00 per share for an aggregate offering price of approximately $70.0 million. The offering did not terminate until after the sale of all of the shares registered on the Registration Statement. Leerink Swann acted as the sole book running managers for the offering, and William Blair and Needham & Company acted as co-managers for the offering. After deducting underwriting discounts, commissions and offering expenses paid or payable by us of approximately $8.5 million, the net proceeds from the offering were approximately $61.5 million. No offering expenses were paid or are payable, directly or indirectly, to our directors or officers, to persons owning ten percent or more of any class of equity securities, or to their associates, or to any of our affiliates. The offering commenced on January 31, 2013 and closed on February 5, 2013.

There has been no material change in the expected use of the net proceeds from our initial public offering from that described in the final prospectus filed with the SEC pursuant to Rule 424(b) on January 31, 2013.

RECENT SALE OF UNREGISTERED SECURITIES; ISSUER PURCHASES OF EQUITY SECURITIES

None.

ITEM 6. SELECTED FINANCIAL DATA

The data in the tables below should be read together with our financial statements and accompanying notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" appearing elsewhere in this Annual Report on Form 10-K. The selected financial data in this section is not intended to replace our financial statements and the accompanying notes. Our historical results are not necessarily indicative of our future results.

The statements of operations data for 2012, 2011 and 2010 and the balance sheet data as of December 31, 2012 and 2011 were derived from our audited financial statements included elsewhere in this Annual Report on Form 10-K. The statements of operations data for 2009 and 2008 and the balance sheet data as of December 31, 2010, 2009 and 2008 were derived from our audited financial statements not included in this Annual Report on Form 10-K.

Consolidated Statement of Operations Data

(in thousands, except share and per share information)	Year Ended December 31, 2012	2011	2010	2009	2008
Contract revenue	$ 6,098	$ 20,255	$ 17,712	$ 589	$ 694
Operating expenses:					
Research and development	24,519	18,512	18,893	22,862	24,461
General and administrative	5,061	4,010	4,942	5,190	4,189
Total operating expenses	29,580	22,522	23,835	28,052	28,650
Loss from operations	(23,482)	(2,267)	(6,123)	(27,463)	(27,956)
Other income (expense):					
Interest income (expense)	(140)	43	108	291	815
Other income (expense), net	113	(8)	915	348	(72)
Loss before income taxes	(23,509)	(2,232)	(5,100)	(26,824)	(27,213)
Benefit for income taxes	—	—	—	(19)	(20)
Net loss	$ (23,509)	$ (2,232)	$ (5,100)	$ (26,805)	$ (27,193)
Basic and diluted net loss per common share	$ (11.22)	$ (1.15)	$ (3.02)	$ (18.89)	$ (23.18)
Weighted average common shares outstanding used to calculate basic and diluted net loss per common share	2,095,950	1,933,672	1,689,894	1,419,066	1,173,339

(in thousands)	As of December 31, 2012	2011	2010	2009	2008
Consolidated Balance Sheet Data:					
Cash, cash equivalents and marketable securities	$ 20,298	$ 17,847	33,754	$ 19,873	$ 40,426
Working capital	14,039	10,496	16,121	15,957	37,239
Total assets	24,539	19,347	35,984	22,081	43,458
Notes payable	9,826	—	—	—	—
Convertible preferred stock	102,023	83,178	83,178	83,178	78,186
Accumulated deficit	(98,267)	(74,758)	(72,526)	(67,426)	(40,621)
Total stockholders' equity (deficit)	(94,944)	(72,345)	(70,403)	(65,781)	(39,308)

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

You should read the following discussion and analysis together with our financial statements and the notes to those statements included elsewhere in this Annual Report on Form 10-K. This discussion contains forward-looking statements that involve risks and uncertainties. We use words such as "may," "will," "expect," "anticipate," "estimate," "intend," "plan," "predict," "potential," "believe," "should" and similar expressions to identify forward-looking statements, including statements related to the scope, progress, expansion, and costs of developing and commercializing our product candidates, our anticipated financial results and condition, our expected future contract revenue from Sanofi and our anticipated expenses related to development activities, our clinical trials and the development and potential commercialization of our product candidates. These statements appearing throughout this Annual Report on Form 10-K are statements regarding our intent, belief, or current expectations, primarily regarding our operations. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this Annual Report on Form 10-K. As a result of many factors, such as those set forth under "Risk Factors" and elsewhere in this Annual Report on Form 10-K, our actual results may differ materially from those anticipated in these forward-looking statements. Except as required by law, we undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise after the date of this Annual Report on Form 10-K.

Overview

We are a biopharmaceutical company focused on monoclonal antibody therapeutics for diseases that are a significant burden to society and patients and their families. We have a portfolio of patient-targeted, first-in-class antibodies using our Humaneered® antibody technology to treat serious medical conditions with a primary clinical focus on respiratory diseases and cancer. Our principal pharmaceutical product candidates at the clinical development stage are:

- KB001-A, a Humaneered®, PEGylated, anti-PcrV Fab' antibody that is being developed for the prevention and treatment of *Pa* infections in mechanically ventilated patients and CF patients with chronic *Pa* infections;
- KB003, a Humaneered® anti-GM-CSF monoclonal antibody that is being developed for the treatment of severe asthma inadequately controlled by corticosteroids; and
- KB004, a Humaneered® monoclonal antibody directed against EphA3 which has the potential to offer a novel approach to treating both hematologic malignancies and solid cancer tumors.

In January 2010, we entered into an agreement with Sanofi pursuant to which we granted to Sanofi an exclusive worldwide license to develop, manufacture, and commercialize antibodies directed against the PcrV protein of *Pa* (including KB001-A) for all indications, and Sanofi is solely responsible for research, development, manufacturing, and commercialization. As part of this agreement, we retain the right to develop and promote KB001-A for *Pa* in CF or bronchiectasis patients. Sanofi is focusing its clinical development on prevention of *Pa* VAP. Pursuant to the agreement, we received an initial upfront payment of $35 million and an additional $5 million payment in August 2011 that were recognized as revenue through June 30, 2012. We have the potential to receive additional contingent payments aggregating up to $250 million upon achievement by Sanofi of certain clinical, regulatory and commercial events, together with tiered royalties based upon global net sales of licensed products. However, there can be no assurances that Sanofi will continue to further develop KB001-A or achieve the events that will trigger the contingent payments. As a result, we may not recognize any additional revenue from this arrangement. We are conducting a Phase 2 clinical trial in CF patients infected with *Pa*. As part of Sanofi's clinical development plan for *Pa* VAP, Sanofi is conducting a Phase 1 clinical study in healthy volunteers to evaluate higher doses than those that we previously tested. We understand that the Phase 1 study will be followed, after completion of manufacturing process development and scale-up, by a Phase 2b intravenous study in late 2014 to determine the safety and efficacy of KB001-A in preventing *Pa* VAP and then Sanofi plans a subsequent Phase 3 study. We also

understand that the Phase 2b and Phase 3 trials are being designed as pivotal studies and are intended to serve as a basis for registration of KB001-A for the prevention of *Pa* VAP.

We initiated a 180 patient randomized, double-blind, placebo-controlled Phase 2 clinical trial for KB001-A in CF patients with chronic *Pa* infections in January 2013. In August 2012, we initiated a 150 patient, randomized, double-blind, placebo-controlled, monthly-dose, intravenous Phase 2 clinical trial for KB003 in patients with severe asthma inadequately controlled by corticosteroids. KB004 is in Phase 1 clinical testing for hematological malignancies. We believe the net proceeds from our initial public offering, together with our cash, cash equivalents, and marketable securities, and our borrowing capacity pursuant to the loan and security agreement we entered into with MidCap Financial in September 2012, will be sufficient to complete our KB001-A and KB003 Phase 2 clinical trials as currently projected. If the KB001-A and KB003 Phase 2 clinical trials are successful, we will need to raise additional capital in order to further advance our product candidates towards regulatory approval.

We licensed our proprietary Humaneered® antibody technology to Novartis in 2007 on a non-exclusive basis and received a license fee of $30 million. We are not currently actively pursuing the license of our Humaneered® technology to third parties and we are not expecting to receive future revenue from additional licenses to this technology.

From the date we commenced our operations through 2006, our efforts focused primarily on research, development, and the advancement of our Humaneered® antibody technology. In 2006, we commenced our first clinical trial. We have incurred significant losses to date and, as of December 31, 2012, we had an accumulated deficit of $98.3 million. We have funded our operations primarily through private placements of our equity securities, contract revenue in connection with our collaborations, and grants and borrowings under equipment financing arrangements and our loan and security agreement. As of December 31, 2012, we had cash, cash equivalents, and marketable securities of $20.3 million. On February 5, 2013, we closed our initial public offering of 8,750,000 shares of common stock at an offering price of $8.00 per share, resulting in net proceeds of approximately $61.5 million, after deducting underwriting discounts, commissions and offering expenses. We expect to continue to incur net losses as we develop our drug candidates, expand clinical trials for our drug candidates currently in clinical development, expand our research and development activities, expand our systems and facilities, seek regulatory approvals, and engage in commercialization preparation activities in anticipation of FDA approval of our drug candidates. Specifically, we have incurred, and we expect to continue to incur, substantial expenses in connection with our Phase 2 clinical trials for KB003 in severe asthma patients inadequately controlled by cortiscosteroids and for KB001-A in CF patients with chronic Pa infections. In addition, if a product is approved for commercialization, we will need to expand our organization. Significant capital is required to launch a product and many expenses are incurred before revenue is received. We are unable to predict the extent of any future losses or when we will become profitable, if at all. In December 2012, our board of directors approved a 1-for-3.56147 reverse split of our issued and outstanding capital stock which became effective on January 15, 2013. Upon the effectiveness of the reverse stock split, (i) every 3.56147 shares of issued and outstanding common stock and convertible preferred stock was decreased to one share of common stock or convertible preferred stock, as applicable, (ii) the number of shares of common stock into which each outstanding option to purchase common stock is exercisable was proportionally decreased on a 1-for-3.56147 basis and the number of shares of convertible preferred stock into which each outstanding warrant is exercisable was proportionally decreased on a 1-for-3.56147 basis and, (iii) the exercise price of each outstanding option to purchase common stock and warrant to purchase convertible preferred stock was proportionately increased. All of the share numbers, share prices, exercise prices and other per share information have been adjusted within this Annual Report on Form 10-K, on a retroactive basis, to reflect this 1-for-3.56147 reverse stock split

Critical Accounting Policies and Use of Estimates

Our management’s discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles

generally accepted in the United States (GAAP). The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenue and expenses during the reporting periods. We base our estimates on historical experience and on various other factors that we believe to be reasonable under the circumstances and review our estimates on an ongoing basis. Actual results may differ from these estimates under different assumptions or conditions.

We are an emerging growth company under the JOBS Act. Emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to avail ourselves of this exemption from new or revised accounting standards and, therefore, we may not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

While our significant accounting policies are described in more detail in Note 2 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K, we believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our financial statements.

Revenue Recognition

Our contract revenue is generated primarily through research and development collaboration agreements, which may include nonrefundable, non-creditable upfront fees, funding for research and development efforts, and milestone or other contingent payments for achievements with regards to our licensed products. We have not materially modified any previous collaboration agreements or entered into any new agreements in 2012 or 2011, nor have we received any milestone payments in 2012 or 2011. Therefore, all collaboration agreements have been accounted for in accordance with the accounting guidance applicable to such arrangements prior to our adoption of Accounting Standards Update (ASU) 2009-13, Multiple-Deliverable Revenue Arrangements, and ASU 2010-17, Revenue Recognition—Milestone Method.

We recognize revenue when persuasive evidence of an arrangement exists; transfer of technology has been completed, services have been performed or products have been delivered; the fee is fixed and determinable; and collection is reasonably assured.

For multiple element arrangements, we evaluate whether the components of each arrangement are to be accounted for as separate units of accounting based on certain criteria. Upfront payments for licensing our intellectual property to date have not been separable from the activity of providing research and development services because the license has not been assessed to have stand-alone value separate from the research and development services provided. Such upfront payments are recorded as deferred revenue in the balance sheet and are recognized as contract revenue over the contractual or estimated substantive performance period, which is consistent with the term of the research and development obligations contained in the research and development collaboration agreement.

Payments resulting from our research and development efforts under license agreements are recognized as the activities are performed and are presented on a gross basis. Revenue is recorded gross because we act as a principal, with discretion to choose suppliers, bear credit risk, and perform part of the services.

Substantive, at-risk milestone payments are recognized as revenue when the milestone is achieved and collectability is reasonably assured. When contingent payments are not for substantive and at-risk milestones, revenue is recognized over the estimated remaining term of the related service period or, if there are no continuing performance obligations under the arrangement, upon receipt provided that collection is reasonably assured and other revenue recognition criteria have been satisfied.

Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing contracts and purchase orders, reviewing the terms of our license agreements, 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 monthly in arrears for services performed. We make estimates of our accrued expenses as of each balance sheet date based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. Examples of estimated accrued research and development expenses include fees to:

- contract research organizations and other service providers in connection with clinical studies;
- contract manufacturers in connection with the production of clinical trial materials; and
- vendors in connection with preclinical development activities.

We base our expenses related to clinical studies on our estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and contract research organizations 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 and expense recognition. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial 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. Our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in our reporting changes in estimates in any particular period. Adjustments to prior period estimates have not been material for each of the years ended December 31, 2011 and 2010. In the fourth quarter of 2012, adjustments to increase clinical trial expenses by $657,000 were recorded due to the material weakness in our internal control over financial reporting discussed in Part II, Item 9A, Controls and Procedures, “Material Weakness in Internal Control Over Financial Reporting” of this Annual Report on Form 10-K.

Stock-Based Compensation

Stock-based compensation cost is measured at the grant date, based on the fair value of the award, and is recognized as an expense over the employee’s requisite service period on a straight line basis. We recorded non-cash stock-based compensation expense of $0.8 million, $0.2 million, and $0.3 million, the years ended December 31, 2012, 2011, and 2010, respectively. As of December 31, 2012, we had approximately $2.8 million of total unrecognized compensation expense, net of related forfeiture estimates, which we expect to recognize over a weighted-average period of approximately 3.3 years. We expect to continue to grant stock options in the future, and to the extent that we do, our actual stock-based compensation expense recognized in future periods will likely increase.

Prior to our IPO, our board of directors, with the assistance of management and independent consultants, performed fair value analyses to determine the valuation of our common stock. For grants made on dates for which there was no contemporaneous valuation to utilize in setting the exercise price of our common stock, and given the absence of an active market for our common stock prior to our IPO in January 2013, our board of directors determined the fair value of our common stock on the date of grant based on several factors, including:

- important developments in our operations, most significantly related to the clinical development of our lead drug candidates, KB001-A, KB003, and KB004;
- equity market conditions affecting comparable public companies;

- the likelihood of achieving a liquidity event for the shares of common stock, such as an initial public offering or an acquisition of us, given prevailing market conditions; and
- that the grants involved illiquid securities in a private company.

Results of Operations

General

We have not generated net income from operations, except for the year ended December 31, 2007 during which we recognized a one-time license payment from Novartis, and, at December 31, 2012, we had an accumulated deficit of $98.3 million primarily as a result of research and development and general and administrative expenses. While we may in the future generate revenue from a variety of sources, including license fees, milestone payments, and research and development payments in connection with strategic partnerships, our product candidates are at an early stage of development and may never be successfully developed or commercialized. Accordingly, we expect to continue to incur substantial losses from operations for the foreseeable future, and there can be no assurance that we will ever generate significant revenue or profits.

Contract Revenue

Our recent revenue is comprised primarily of collaboration agreement-related revenue. Collaboration agreement-related revenue includes license fees, payments for research and development services, and milestone and other contingent payments.

Research and Development Expenses

Conducting research and development is central to our business model. For the years ended December 31, 2012, 2011, and 2010, research and development expenses were $24.5 million, $18.5 million, $18.9 million, respectively. We expense both internal and external research and development costs as incurred. We currently track the external research and development costs incurred for each of our KB001-A, KB003, and KB004 projects. We have not tracked our external costs by project since inception. We began tracking our external costs by project beginning January 1, 2008. Our external research and development expenses consist primarily of:

- expenses incurred under agreements with contract research organizations, investigative sites, and consultants that conduct our clinical trials and a substantial portion of our preclinical activities;
- the cost of acquiring and manufacturing clinical trial and other materials; and
- other costs associated with development activities, including additional studies.

Internal research and development costs consist primarily of salaries and related fringe benefit costs for our employees (such as workers compensation and health insurance premiums), stock-based compensation charges, travel costs, lab supplies, and overhead expenses. Internal costs generally benefit multiple projects and are not separately tracked per project.

The following table shows our total research and development expenses for the years ended December 31, 2012, 2011, 2010, and for the period from January 1, 2008 to December 31, 2012:

	Year Ended December 31,			For the Period from January 1, 2008 to December 31, 2012
	2012	2011	2010	
External costs:				
KB001-A	$ 4,996	$ 2,209	$ 1,667	$ 20,295
KB003	7,682	1,433	2,676	22,825
KB004	4,102	5,502	4,781	19,555
Internal costs	7,739	9,368	9,769	46,571
Total research and development	$24,519	$18,512	$18,893	$ 109,246

We expect to continue to incur substantial expenses related to our development activities for the foreseeable future as we continue the Phase 2 clinical trials for our KB001-A CF program and our KB003 severe asthma program and continue our Phase 1 clinical trial for our KB004 program. As product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials, we expect that our research and development expenses will increase in the future. In addition, if our product development efforts are successful, we expect to incur substantial costs to prepare for potential clinical trials and activities beyond the Phase 2 trials for KB001-A and KB003 and the Phase 1 trial for KB004.

General and Administrative Expenses

General and administrative expenses consist principally of personnel-related costs, professional fees for legal, consulting, audit and tax services, rent and other general operating expenses not otherwise included in research and development. For the years ended December 31, 2012, 2011, and 2010, general and administrative expenses were $5.1 million, $4.0 million, $4.9 million, respectively. Upon the effectiveness of our registration statement on Form 10 in August 2012, we became a public reporting company under the Exchange Act. We anticipate general and administrative expenses will increase in future periods, reflecting an expanding infrastructure and increased professional fees associated with being a public reporting company.

Comparison of Years Ended December 31, 2012 and 2011

	For the Year Ended December 31,		Variance
(In thousands)	2012	2011	
Contract revenue	$ 6,098	$20,255	$14,157
Operating expenses:			
Research and development	24,519	18,512	(6,007)
General and administrative	5,061	4,010	(1,051)
Loss from operations	(23,482)	(2,267)	21,215
Interest income (expense)	(140)	43	183
Other income (expense), net	113	(8)	(121)
Net loss	$(23,509)	$ (2,232)	$21,277

Contract revenue in each period related solely to our arrangement with Sanofi in which we licensed the KB001-A program to Sanofi in 2010. Contract revenue decreased $14.2 million in 2012 compared to 2011. This decrease was mainly attributable to the completion of our substantive performance obligations under our agreement with Sanofi. This decrease was partially offset by an additional $1.7 million of contract revenue recognized in 2012 related to the $5.0 million payment received from Sanofi in August 2011 that was being

recognized ratably through the completion of our substantive performance obligations under the agreement. As we have completed all of our substantive performance obligations under our agreement with Sanofi, we expect future contract revenue from Sanofi to be minimal in future periods unless we receive contingent payments or royalties under our agreement.

Research and development expenses increased $6.0 million in 2012 compared to 2011. This was primarily due to a $8.6 million increase related to spending for clinical trial and development expenses, primarily for our KB003 severe asthma program, start up activities for our KB001-A CF program, and ongoing activities for our KB004 program for hematological malignancies, as well as an increase in consulting expenses of $1.3 million to support ongoing development and clinical activities. This was partially offset by a $3.4 million decrease in payroll related expenses, including travel and supplies, resulting from a headcount reduction of 19 employees in our research and development organization primarily during mid to late 2011, and a decrease of $0.5 million in sublicense fees, primarily related to a milestone payment to our sublicensee for KB001-A in 2011. We began enrollment of patients in a Phase 2 clinical trial of KB003 for severe asthma in the third quarter of 2012 and began enrollment of patients in a Phase 2 clinical trial for KB001-A in CF patients with chronic *Pa* infections in January 2013, and as a result, we expect these expenses to increase significantly.

General and administrative expenses increased $1.1 million in 2012 compared to 2011. The increase in general and administrative expenses was primarily due to an increase of $1.0 million in legal, accounting and consulting fees related to being a public reporting company. As we became a publicly traded company in January 2013 though our initial public offering, we expect these expenses to increase, including legal, accounting, investor relations, and director and officer's insurance expenses.

Interest income (expense), increased by $183,000 in 2012 compared to 2011. The increase was due to interest expense related to our loan and security agreement entered into in September 2012, partially offset by interest income of $45,000.

Other income (expense), increased by $121,000 in 2012 compared to 2011. The increase was due to a gain on sale of fixed assets of $146,000 and a gain of $39,000 related to the revaluation of our convertible preferred stock warrant liabilities. The increase was primarily offset by a foreign currency exchange loss of $64,000.

Comparison of Years Ended December 31, 2010 and 2011

	For the Year Ended December 31,		Variance
(In thousands)	2011	2010	
Contract revenue	$20,255	$17,712	$(2,543)
Operating expenses:			
Research and development	18,512	18,893	381
General and administrative	4,010	4,942	932
Loss from operations	(2,267)	(6,123)	(3,856)
Interest income	43	108	65
Other income (expense), net	(8)	915	923
Net loss	$ (2,232)	$ (5,100)	$(2,868)

Contract revenue in each period related solely to our arrangement with Sanofi in which we licensed the KB001-A program to Sanofi in 2010. Contract revenue increased $2.5 million in 2011 compared to 2010. This increase was primarily attributable to an additional $5.0 million non-refundable payment received in August 2011, of which we recognized $3.3 million in contract revenue in the year ended December 31, 2011. This payment represented a second installment of the upfront fees due to us under the Sanofi agreement that was being recognized ratably through March 31, 2012, the estimated period over which our substantive performance

obligations with Sanofi were expected to be completed. This increase was partially offset by a decrease of $1.0 million in reimbursements from Sanofi for our transition efforts related to the collaboration.

Research and development expenses decreased $0.4 million in 2011 compared to 2010. This decrease was attributable to a decrease in clinical trial costs of $0.6 million in 2011 and decreases in consulting and personnel related expenses, including salaries, travel and supplies of $0.6 million. The decrease in clinical trial costs is primarily related to higher spending for our KB003 RA program during 2010, as we discontinued the program during 2011. This decrease was partially offset by initiating patient recruitment for our KB004 Phase 1 clinical trial in 2011. The decrease in personnel related expenses was primarily attributed to a reduction of 19 employees in our research and development organization in 2011. These decreases from the year ended December 31, 2010 were partially offset by an increase in development expenses of $0.9 million as we initiated six-month toxicity studies and subcutaneous formulation feasibility work for our KB001-A CF program as well as ongoing development of flow assay and screening methods for our KB004 program.

General and administrative expenses decreased $0.9 million in 2011 compared to 2010. This decrease is primarily attributable to a decrease in consulting and personnel related expenses, including salaries, travel and supplies of $0.6 million from headcount reduction of 5 employees in our general and administrative organization during 2011, as well as decreases in legal expenses of $0.3 million attributable to fewer foreign patent filings in the year ended December 31, 2011.

Interest income was $43,000 for the year ended December 31, 2011 and $108,000 for the year ended December 31, 2010. The decrease was attributed to lower yields from lower investment balances in our portfolio which consisted primarily of government securities, high grade commercial paper, and money market funds.

Other expense of $8,000 for the year ended December 31, 2011 consists primarily of $48,000 related to the revaluation of our convertible preferred stock warrant liabilities, offset in part by foreign currency transaction gains of $40,000. Other income of $0.9 million for the year ended December 31, 2010 primarily reflects cash grants of $1.0 million received from the Internal Revenue Service under Section 48D of the Internal Revenue Code for the Qualified Therapeutic Discovery Project Program. All conditions to earn the grant were completed in the year ended December 31, 2010.

Income Taxes

As of December 31, 2012, we had net operating loss carryforwards of approximately $93.3 million to offset future federal income taxes which expire in the years 2025 through 2032, and approximately $93.3 million that may offset future state income taxes which expire in the years 2015 through 2032. Current federal and state tax laws include substantial restrictions on the utilization of net operating losses and tax credits in the event of an ownership change. Even if the carryforwards are available, they may be subject to annual limitations, lack of future taxable income, or future ownership changes that could result in the expiration of the carryforwards before they are utilized. At December 31, 2012, we recorded a 100% valuation allowance against our deferred tax assets of approximately $40.2 million, as at that time our management believed it was uncertain that they would be fully realized. If we determine in the future that we will be able to realize all or a portion of our net operating loss carryforwards, an adjustment to our net operating loss carryforwards would increase net income in the period in which we make such a determination.

Liquidity and Capital Resources

Since our inception through December 31, 2012, we financed our operations primarily through private placements of our equity securities, debt financing, interest income earned on cash, cash equivalents, and marketable securities, lines of credit, and payments under agreements with Sanofi and Novartis. Between May and June 2012, we issued 1,672,300 shares of Series E convertible preferred stock at $12.11 per share, resulting in net proceeds of $18.8 million. On February 5, 2013, we closed our initial public offering of 8,750,000 shares

of common stock at an offering price of $8.00 per share, resulting in net proceeds of approximately $61.5 million, after deducting underwriting discounts, commissions and offering expenses. At December 31, 2012, we had cash and cash equivalents of $10.9 million and marketable securities of $9.4 million, totaling $20.3 million. In September 2012, we entered into a loan and security agreement with MidCap Financial that provides for the borrowing of up to $15 million, of which $10 million was drawn in 2012. The remaining $5 million may be drawn at our option. The loan and security agreement provides for the loan to be issued in three tranches: the first tranche of $5 million was issued in September 2012; the second tranche of $5 million was issued in December 2012; and the final tranche may be drawn at our option no later than June 2013.

The following table summarizes the private placements of our convertible preferred stock through December 31, 2012:

($ in thousands) Issue	Year	Number of Shares	Net Proceeds
Series A Convertible Preferred Stock, net	2001-2003	428,922	$ 1,835
Series B-1 Convertible Preferred Stock, net	2004	961,720	4,726
Series B-2 Convertible Preferred Stock, net	2004-2006	4,119,759	21,039
Series C Convertible Preferred Stock, net	2007	1,949,874	19,905
Series D Convertible Preferred Stock, net	2008-2009	3,196,755	35,673
Series E Convertible Preferred Stock, net	2012	1,672,300	18,845
		12,329,330	$ 102,023

As of December 31, 2012, we had approximately $20.3 million in cash, cash equivalents, and marketable securities. On February 5, 2013, we closed our initial public offering of 8,750,000 shares of common stock at an offering price of $8.00 per share, resulting in net proceeds of approximately $61.5 million, after deducting underwriting discounts, commissions and offering expenses. We expect to incur substantial expenditures in the foreseeable future for the development and potential commercialization of our product candidates. Specifically, we have incurred and we expect to continue to incur substantial expenses in connection with our Phase 2 clinical trials for KB003 in severe asthma patients inadequately controlled by corticosteroids and for KB001-A in CF patients with chronic *Pa* infections.

We believe our existing cash, cash equivalents, and marketable securities, including the net proceeds from our initial public offering and our access to funds through the loan and security agreement we entered into with MidCap Financial in September 2012, will be sufficient to sustain operations for at least the next 12 months based on our existing business plan and enable us to complete our KB001-A and KB003 Phase 2 clinical trials as currently projected. If the KB001-A and KB003 Phase 2 clinical trials are successful, we will need to raise additional capital in order to further advance our product candidates towards regulatory approval.

We will continue to require additional financing to develop our products and fund operating losses. We will seek funds through equity or debt financings, collaborative or other arrangements with corporate sources, or through other sources of financing. Adequate additional funding may not be available to us on acceptable terms or at all. Our failure to raise capital as and when needed could have a negative impact on our financial condition and our ability to pursue our business strategies. We anticipate that we will need to raise substantial additional capital, the requirements of which will depend on many factors, including:

- the type, number, costs, and results of the product candidate development programs which we are pursuing or may choose to pursue in the future;
- the scope, progress, expansion, costs, and results of our clinical trials;
- the timing of and costs involved in obtaining regulatory approvals;
- our ability to establish and maintain development partnering arrangements;

- the timing, receipt and amount of contingent, royalty, and other payments from Sanofi or any of our future development partners;
- the emergence of competing technologies and other adverse market developments;
- the costs of maintaining, expanding, and protecting our intellectual property portfolio, including potential litigation costs and liabilities;
- the resources we devote to marketing, and, if approved, commercializing our product candidates;
- the scope, progress, expansion, and costs of manufacturing our product candidates;
- our ability to draw funds from our loan and security agreement; and
- the costs associated with being a public company.

If we are unable to raise additional funds when needed, we may be required to delay, reduce, or terminate some or all of our development programs and clinical trials. We may also be required to sell or license to others technologies or clinical product candidates or programs that we would prefer to develop and commercialize ourselves.

Cash Flows

The following table sets forth the primary sources and uses of cash and cash equivalents for each of the periods presented below:

	Year Ended December 31,		
(In thousands)	2012	2011	2010
Net cash (used in) provided by:			
Operating activities	$(23,906)	$(15,330)	$ 14,401
Investing activities	5,075	9,732	(10,370)
Financing activities	26,440	34	119
Net increase (decrease) in cash and cash equivalents	$ 7,609	$ (5,564)	$ 4,150

Operating Activities

Net cash used in operating activities was $23.9 million and $15.3 million for the years ended December 31, 2012, and 2011, respectively. Net cash provided by operating activities was $14.4 million for the year ended December 31, 2010. The primary use of cash in each of these periods was to fund our operations related to the development of our product candidates. The cash provided by operating activities in 2010 was primarily related to the $36.8 million received from the Sanofi collaboration as well as $1.0 million of grants received from the Internal Revenue Service under Section 48D of the Internal Revenue Code for the Qualified Therapeutic Discovery Project Program. Cash used for the year ended December 31, 2012 increased compared to the same period in 2011, primarily due to a $21.3 million increase in net loss, partially offset by changes in operating assets and liabilities including a reduced decrease in deferred revenue as we completed our activities under our Sanofi collaboration and increases in accounts payable in 2012 attributed to ongoing development and clinical trial activities. The decrease in 2011 compared to 2010 was primarily due to a $33.6 million reduction in the change in our deferred revenue related to the Sanofi arrangement partially offset by a $2.9 million decrease in net loss.

Investing Activities

Cash used in investing activities for the years ended December 31, 2012, 2011, and 2010, consisted primarily of the purchases of marketable securities while cash provided by investing activities consisted

primarily of proceeds from maturities of marketable securities. For the year ended December 31, 2012, there were proceeds from the sale of property and equipment of $0.2 million. Additionally, purchases of property and equipment for the years ended December 31, 2012, 2011, and 2010 were $20,000, $0.5 million, and $0.1 million, respectively.

Financing Activities

Cash provided by financing activities amounted to $26.4 million, $34,000, and $0.1 million for the years ended December 31, 2012, 2011, and 2010, respectively. The net cash provided by financing activities for the year ended December 31, 2012 consisted primarily of the net proceeds of $18.8 million from the issuance of convertible preferred stock and $9.8 million from the drawdown of the debt facility, partially offset by payments of deferred costs of $2.3 million related to our initial public offering.

Contractual Obligations and Commitments

We have lease obligations consisting of an operating lease for our operating facility that commenced in July 2011 and expires in June 2014, for approximately 40,000 square feet. We also sublease approximately 20,000 square feet of our leased space to third parties.

The following table summarizes our contractual obligations as of December 31, 2012:

	Payments due by period				
(in thousands)	Total	Less than 1 year	1 to 3 years	4 to 5 years	After 5 years
Lease obligations	$ 1,822	$ 1,207	$ 615	—	—
Notes payable	12,280	1,183	7,694	3,403	—
Total	$14,102	$ 2,390	$8,309	$3,403	$ —

In September 2012, we entered into a loan and security agreement with MidCap Financial providing for the borrowing of up to $15 million, of which $10 million was required to be drawn. The remaining $5 million may be drawn at our option. The loan and security agreement provides for the loan to be issued in three tranches, the first tranche of $5 million was issued in September 2012, the second tranche of $5 million was issued in December 2012, and the final tranche may be drawn at our option no later than June 2013. The loan has a monthly variable interest rate, reset each month, if applicable, as determined by adding to 600 basis points the greater of: (a) one month LIBOR or (b) 3% (the LIBOR floor). Interest on amounts outstanding are payable monthly in arrears. There is an interest only period to December 31, 2013 followed by straight-line principal payments over 36 months. At the time of final payment, we must pay an exit fee of 3% of the drawn amount. Pursuant to the loan and security agreement, we provided a first priority security interest in all existing and after-acquired assets, excluding intellectual property. In addition, the terms of the loan and security agreement provide MidCap Financial a warrant to purchase shares of our Series E convertible preferred stock equal to 4% of the amount drawn down under the facility divided by the Series E convertible preferred stock exercise price of $12.11. The warrant was exercisable for up to 10 years from the date of issuance but expired upon the completion of our initial public offering in February 2013.

We are obligated to make future payments to third parties under in-license agreements, including sublicense fees, royalties, and payments that become due and payable on the achievement of certain development and commercialization milestones. As the amount and timing of sublicense fees and the achievement and timing of these milestones are not probable and estimable, such commitments have not been included on our balance sheet or in the contractual obligations tables above.

Indemnification

In the normal course of business, we enter into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications. Our exposure under these agreements is unknown because it involves claims that may be made against us in the future, but have not yet been made. To date, we have not paid any claims or been required to defend any action related to our indemnification obligations. However, we may record charges in the future as a result of these indemnification obligations.

In accordance with our amended and restated certificate of incorporation and our amended and restated bylaws, we have indemnification obligations to our officers and directors for specified events or occurrences, subject to some limits, while they are serving at our request in such capacities. We have also entered into indemnification agreements with our directors, executive officers, and key employees. There have been no claims to date, and we have director and officer insurance that may enable us to recover a portion of any amounts paid for future potential claims.

Off-Balance Sheet Arrangements

We currently have no off-balance sheet arrangements, such as structured finance, special purpose entities, or variable interest entities.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risk related to fluctuations in interest rates and market prices. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. However, since a majority of our investments are in short-term FDIC-insured government securities, corporate bonds, and money market funds, we do not believe we are subject to any material market risk exposure. The fair value of our investments, including those included in cash equivalents and marketable securities, was $15.3 million and $17.5 million as of December 31, 2012 and December 31, 2011, respectively.

Our investment policy is to limit credit exposure through diversification and investment in highly rated securities. We, along with our investment advisors, actively review 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. We monitor and evaluate our investment portfolio on a quarterly basis for other-than-temporary impairment charges.

We are also exposed to market risk related to fluctuations in interest rates indexed to LIBOR, which determines the variable interest payments made on our notes payable. However, we do not believe we are subject to any material market risk exposure related to this obligation.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our consolidated financial statements and the reports of our independent registered public accounting firm are included in this Annual Report on Form 10-K on pages F-1 through F-30.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2012. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Based on the evaluation of our disclosure controls and procedures as of December 31, 2012, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, disclosure controls and procedures were not effective at the reasonable assurance level because of the material weakness in internal control over financial reporting described below.

Management's Annual Report on Internal Control Over Financial Reporting

This Annual Report on Form 10-K does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of the company's registered public accounting firm pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 due to a transition period established by the rules of the Securities and Exchange Commission for newly public companies.

Material Weakness in Internal Control Over Financial Reporting

Overview. Management did not perform an assessment regarding the effectiveness of internal control over financial reporting as of December 31, 2012. As a newly public company management is not required to perform an assessment of internal control over financial reporting in our first Annual Report on Form 10-K. Such an assessment will be initially required as of December 31, 2013. However, as of December 31, 2012, a material weakness was identified in the design and operation of our internal control over financial reporting related to the controls over the completeness and accuracy of clinical trial expenses and related accruals and the associated financial statement close process monitoring and review procedures.

Material weakness in internal control over financial reporting. A material weakness is a control deficiency, or a combination of control deficiencies such that there is a reasonable possibility that a material misstatement of interim or annual financial statements will not be prevented or detected on a timely basis. As of December 31, 2012, we did not maintain effective controls over the completeness and accuracy of our clinical trial expenses. Errors were identified in the analysis and preparation of our clinical trial expenses and related balance sheet accounts, including the failure to accrue expenses from third party contract research organizations ("CROs"). These control deficiencies resulted in the misstatement of clinical trial expenses in the fourth quarter of 2012 and certain previously reported periods. The correction of these errors resulted in adjustments to increase clinical trial expenses that were recorded in the fourth quarter ended December 31, 2012. These errors arose from control deficiencies that, in the aggregate, could result in a misstatement to the aforementioned accounts that could result in a material misstatement of our annual or interim financial statements that would not be prevented or detected. Accordingly, management determined that these control deficiencies, in the aggregate, constitute a material weakness.

Notwithstanding the material weakness described above, we believe the Company's financial statements included in this Annual Report on Form 10-K present fairly, in all material respects, the Company's financial position, results of operations and cash flows for the periods presented. Our Chief Executive Officer and Chief Financial Officer have certified to their knowledge that this Annual Report on Form 10-K does not contain any

untrue statements of material fact or omit to state any material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered in this Annual Report.

Plan for Remediation of Material Weakness. We have discussed this material weakness with our independent registered public accounting firm and our Audit Committee. We are taking significant actions to remediate the material weakness related to our internal controls over the completeness and accuracy of our clinical trial expenses and related accruals and the associated financial statement close process monitoring and review procedures. We plan to strengthen our procedures over clinical trial accruals, including the verification of the costs incurred by our CROs. In addition, we are planning to hire additional finance staff and to continue to implement plans to enhance our reporting systems and procedures as well as provide for greater and more consistent oversight in the preparation of clinical trial expenses. We plan to continue to strengthen our internal controls over clinical trial expenses during the remainder of the year. We believe that these corrective actions, taken as a whole, will remediate the control deficiencies identified above, but we will continue to monitor the effectiveness of these actions and intend to make any other changes or take such other actions as we determine to be appropriate.

We are in the process of developing a plan for testing our internal controls and management's related assessment of internal control over financial reporting as provided under Section 404 of the Sarbanes-Oxley Act of 2002. If we are unable to correct the material weakness we have identified prior to the end of fiscal year 2013, or if we experience other problems that prevent the favorable assessment of the effectiveness of our internal control over financial reporting, we will be required to conclude and report that our internal control over financial reporting is not effective as of that date and investor confidence and our stock price could be adversely affected.

Changes in Internal Control Over Financial Reporting

There has been no change in our internal control over financial reporting during the quarter ended December 31, 2012, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations of Controls

Management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent or detect all error and all fraud. Controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or deterioration in the degree of compliance with the policies or procedures. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

ITEM 9B. OTHER INFORMATION

None.

PART III

Certain information required by Part III is omitted from this Report on Form 10-K and is incorporated herein by reference to our definitive Proxy Statement for our 2013 Annual Meeting of Stockholders (the "Proxy Statement"), which we intend to file pursuant to Regulation 14A of the Securities Exchange Act of 1934, as amended, within 120 days after December 31, 2012.

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

We have adopted a Code of Business Conduct and Ethics that applies to all of our directors, officers and employees, including our principal executive officer and principal financial officer. The Code of Business Conduct and Ethics is posted on our website at http://ir.kalobios.com/.

We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding an amendment to, or waiver from, a provision of this Code of Business Conduct and Ethics by posting such information on our website, at the address and location specified above and, to the extent required by the listing standards of The NASDAQ Stock Market, by filing a Current Report on Form 8-K with the SEC, disclosing such information.

The information required by this item is incorporated by reference from the applicable information set forth in "Executive Officers," "Election of Directors," "Information about the Board of Directors and its Committees," and "Security Ownership of Certain Beneficial Owners and Management" which will be included in our definitive Proxy Statement for our 2013 Annual Meeting of Stockholders to be filed with the SEC.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference from the applicable information set forth in "Executive Compensation" and "Director Compensation" which will be included in our definitive Proxy Statement for our 2013 Annual Meeting of Stockholders to be filed with the SEC.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item is incorporated by reference from the applicable information set forth in "Security Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information" which will be included in our definitive Proxy Statement for our 2013 Annual Meeting of Stockholders to be filed with the SEC.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item is incorporated by reference from the applicable information set forth in "Transactions with Related Persons" and "Information about the Board of Directors and its Committees" which will be included in our definitive Proxy Statement for our 2013 Annual Meeting of Stockholders to be filed with the SEC.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item is incorporated by reference from the applicable information set forth in "Other Information — Kalobios Pharmaceuticals Independent Registered Accounting Firm" which will be included in our definitive Proxy Statement for our 2013 Annual Meeting of Stockholders to be filed with the SEC.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

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

(1) FINANCIAL STATEMENTS

Financial Statements—See Index to Consolidated Financial Statements at Item 8 of this Annual Report on Form 10-K.

(2) FINANCIAL STATEMENT SCHEDULES

Financial statement schedules have been omitted in this Annual Report on Form 10-K because they are not applicable, not required under the instructions, or the information requested is set forth in the consolidated financial statements or related notes thereto.

(b) Exhibits. The exhibits listed in the accompanying index to exhibits are filed as part of, or incorporated by reference into, this Annual Report on Form 10-K.

Index to Consolidated Financial Statements
Contents

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of KaloBios Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of KaloBios Pharmaceuticals, Inc. as of December 31, 2012 and 2011, and the related consolidated statements of comprehensive loss, convertible preferred stock and stockholders' deficit, and cash flows for each of the three years in the period ended 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. We were not engaged to perform an audit of the Company's 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, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of KaloBios Pharmaceuticals, Inc. at December 31, 2012 and 2011, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2012, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

Redwood City, California
March 29, 2013

KaloBios Pharmaceuticals, Inc.
Consolidated Balance Sheets

(in thousands, except share and per share information)	December 31, 2012	December 31, 2011
Assets		
Current assets:		
Cash and cash equivalents	$ 10,947	$ 3,338
Marketable securities	9,351	14,509
Contract receivables	87	177
Prepaid expenses and other current assets	871	580
Total current assets	21,256	18,604
Restricted cash	205	205
Property and equipment, net	230	427
Deferred offering costs	2,803	—
Intangible and other assets	45	111
Total assets	$ 24,539	$ 19,347
Liabilities, convertible preferred stock and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 2,448	$ 266
Accrued compensation	628	832
Deferred revenue, short-term	—	5,630
Deferred rent, short-term	101	53
Accrued research and clinical liabilities	3,538	1,079
Other accrued liabilities	502	248
Total current liabilities	7,217	8,108
Deferred rent, long-term	62	163
Notes payable	9,826	—
Other liabilities, long-term	355	243
Total liabilities	17,460	8,514
Commitments and contingencies (Note 9)		
Convertible preferred stock, $0.001 par value: 60,152,555 shares and 39,108,536 sharesauthorized at December 31, 2012, and 2011, respectively; 12,329,330 shares and 10,657,030 shares issued and outstanding at December 31, 2012, and 2011, respectively; aggregate liquidation preference of $105,512 at December 31, 2012	102,023	83,178
Stockholders' deficit:		
Common stock, $0.001 par value: 80,000,000 shares 60,000,000 shares authorized at December 31, 2012, and 2011, respectively; 2,186,695 and 1,986,431 shares issued and outstanding at December 31, 2012, and 2011, respectively	2	2
Additional paid-in capital	3,317	2,412
Accumulated other comprehensive income (loss)	4	(1)
Accumulated deficit	(98,267)	(74,758)
Total stockholders' deficit	(94,944)	(72,345)
Total liabilities, convertible preferred stock and stockholders' deficit	$ 24,539	$ 19,347

See accompanying notes.

KaloBios Pharmaceuticals, Inc.
Consolidated Statements of Comprehensive Loss

(in thousands, except share and per share information)	Year Ended December 31, 2012	2011	2010
Contract revenue	$ 6,098	$ 20,255	$ 17,712
Operating expenses:			
Research and development	24,519	18,512	18,893
General and administrative	5,061	4,010	4,942
Total operating expenses	29,580	22,522	23,835
Loss from operations	(23,482)	(2,267)	(6,123)
Other income (expense):			
Interest income (expense), net	(140)	43	108
Other income (expense), net	113	(8)	915
Net loss	(23,509)	(2,232)	(5,100)
Other comprehensive income (loss):			
Net unrealized gains (losses) on marketable securities	5	2	(13)
Comprehensive loss	$ (23,504)	$ (2,230)	$ (5,113)
Basic and diluted net loss per common share	$ (11.22)	$ (1.15)	$ (3.02)
Weighted average common shares outstanding used to calculate basic and diluted net loss per common share	2,095,950	1,933,672	1,689,894

See accompanying notes.

KaloBios Pharmaceuticals, Inc.
Consolidated Statements of Convertible Preferred Stock and Stockholders' Deficit

(in thousands, except share information)	Convertible Preferred Stock Shares	Convertible Preferred Stock Amount	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Deficit
Balances at December 31, 2009	10,657,030	$ 83,178	1,509,841	$ 1	$ 1,634	$ 10	$ (67,426)	$ (65,781)
Issuance of common stock upon exercise of options and vesting of stock awards	—	—	346,924	1	191	—	—	192
Employee stock-based compensation expense	—	—	—	—	299	—	—	299
Comprehensive loss	—	—	—	—	—	(13)	(5,100)	(5,113)
Balances at December 31, 2010	10,657,030	83,178	1,856,765	2	2,124	(3)	(72,526)	(70,403)
Issuance of common stock upon exercise of options and vesting of stock awards	—	—	129,666	—	67	—	—	67
Employee stock-based compensation expense	—	—	—	—	221	—	—	221
Comprehensive loss	—	—	—	—	—	2	(2,232)	(2,230)
Balances at December 31, 2011	10,657,030	83,178	1,986,431	2	2,412	(1)	(74,758)	(72,345)
Issuance of Series E convertible preferred stock, net of issuance costs of $1,404	1,672,300	18,845	—	—	—	—	—	—
Issuance of common stock upon exercise of options and vesting of stock awards	—	—	200,264	—	84	—	—	84
Employee stock-based compensation expense	—	—	—	—	821	—	—	821
Comprehensive loss	—	—	—	—	—	5	(23,509)	(23,504)
Balances at December 31, 2012	12,329,330	$ 102,023	2,186,695	$ 2	$ 3,317	$ 4	$ (98,267)	$ (94,944)

See accompanying notes.

KaloBios Pharmaceuticals, Inc.
Consolidated Statements of Cash Flows

(in thousands)	Year Ended December 31, 2012	2011	2010
Operating activities:			
Net loss	$(23,509)	$ (2,232)	$ (5,100)
Adjustments to reconcile net loss tonet cash (used in) provided by operating activities:			
Depreciation and amortization	193	484	732
Amortization of intangible assets	111	111	111
Noncash interest expense	22	0	—
Amortization of premium on marketable securities	237	429	375
Stock based compensation expense	821	221	299
Gains on disposal of fixed assets	(146)	—	(4)
Change in fair value of preferred stock warrant liabilities	(39)	48	(2)
Changes in operating assets and liabilities:			
Contract receivables	90	332	(509)
Prepaid expenses and other current assets	(291)	(11)	(102)
Accounts payable	2,007	(908)	487
Accrued compensation	(205)	95	107
Deferred revenue	(5,630)	(13,977)	19,607
Accrued research and clinical liabilities	2,459	45	(1,072)
Other liabilities	27	11	(257)
Deferred rent	(53)	22	(271)
Net cash (used in) provided by operating activities	(23,906)	(15,330)	14,401
Investing activities:			
Purchases of property and equipment	(20)	(463)	(68)
Proceeds from sale of property and equipment	170	—	—
Purchases of marketable securities	(25,507)	(26,974)	(59,344)
Proceeds from maturities of marketable securities	30,432	36,891	49,225
Changes in restricted cash	—	278	(183)
Net cash provided by (used in) investing activities	5,075	9,732	(10,370)
Financing activities:			
Payments of deferred offering costs	(2,329)	—	—
Proceeds from issuance of debt	9,840	—	—
Proceeds from issuances of Series E preferred stock, net	18,845	—	—
Proceeds from issuances of common stock	84	34	119
Net cash provided by financing activities	26,440	34	119
Net increase (decrease) in cash and cash equivalents	7,609	(5,564)	4,150
Cash and cash equivalents, beginning of period	3,338	8,902	4,752
Cash and cash equivalents, end of period	$ 10,947	$ 3,338	$ 8,902
Supplemental cash flow disclosure:			
Cash paid for interest	$ 109	$ —	$ —
Supplemental disclosure of noncash investing and financing activities:			
Warrant issued upon issuance of note payable	$ 79	$ —	$ —

See accompanying notes.

KaloBios Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements

1. Organization and Description of Business

KaloBios Pharmaceuticals, Inc. (the Company) is a biopharmaceutical company whose primary business is to develop monoclonal antibody therapeutics for diseases that represent a significant burden to society and to patients and their families. The Company's primary clinical focus is on respiratory diseases and cancer. The Company was incorporated on March 15, 2000 in California and reincorporated as a Delaware corporation in September 2001. All of the Company's assets are located in California.

The Company has incurred significant losses and had an accumulated deficit of $98.3 million as of December 31, 2012. The Company has financed its operations primarily through the sale of equity securities, grants and the payments received under its agreements with Novartis Pharma AG (Novartis) and Sanofi Pasteur S.A. (Sanofi). The Company completed its initial public offering (IPO) in February 2013. To date, none of the Company's product candidates have been approved for sale and therefore the Company has not generated any revenue from product sales. Management expects operating losses to continue for the foreseeable future. As a result, the Company will continue to require additional capital through equity offerings, debt financing and/or payments under new or existing licensing or collaboration agreements. If sufficient funds on acceptable terms are not available when needed, the Company could be required to significantly reduce its operating expenses and delay, reduce the scope of, or eliminate one or more of its development programs.

2. Summary of Significant Accounting Policies

Basis of Presentation and Use of Estimates

The accompanying consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (GAAP) and include all adjustments necessary for the presentation of the Company's consolidated financial position, results of operations and cash flows for the periods presented. The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries.

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts and disclosures reported in the financial statements and accompanying notes. Actual results could differ materially from those estimates. The Company believes judgment is involved in determining revenue recognition, the fair value-based measurement of stock-based compensation, accruals and warrant valuations. The Company evaluates its estimates and assumptions as facts and circumstances dictate. As future events and their effects cannot be determined with precision, actual results could differ from these estimates and assumptions, and those differences could be material to the consolidated financial statements.

Reverse Stock Split

In December 2012, the Company's board of directors approved a 1-for-3.56147 reverse split of the Company's issued and outstanding capital stock which became effective on January 15, 2013. Upon the effectiveness of the reverse stock split, (i) every 3.56147 shares of issued and outstanding common stock and preferred stock was decreased to one share of common stock or preferred stock, as applicable, (ii) the number of shares of common stock into which each outstanding option to purchase common stock is exercisable was proportionally decreased on a 1-for-3.56147 basis and the number of shares of preferred stock into which each outstanding warrant is exercisable was proportionally decreased on a 1-for-3.56147 basis and, (iii) the exercise price of each outstanding option to purchase common stock and warrant to purchase preferred stock was proportionately increased. All of the share numbers, share prices, exercise prices and other per share information throughout these financial statements have been adjusted, on a retroactive basis, to reflect this 1-for-3.56147 reverse stock split.

Concentration of Credit Risk

Cash, cash equivalents, and marketable securities consist of financial instruments that potentially subject the Company to a concentration of credit risk in the event of a default by the related financial institution holding the securities, to the extent of the value recorded in the balance sheet. The Company invests cash that is not required for immediate operating needs primarily in highly liquid instruments with lower credit risk. The Company has established guidelines relating to the quality, diversification, and maturities of securities to enable the Company to manage its credit risk.

Fair Value of Financial Instruments

Cash, accounts payable and accrued liabilities are carried at cost, which approximates fair value given their short-term nature. Marketable securities, cash equivalents, and warrants for convertible preferred stock are carried at fair value.

The fair value of financial instruments reflects the amounts that would be received upon the sale of an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date (exit price). The fair value hierarchy is based on three levels of inputs that may be used to measure fair value, of which the first two are considered observable, and the third is considered unobservable, as follows:

Level 1 – Quoted prices in active markets for identical assets or liabilities.

Level 2 – Inputs other than those included in Level 1 that are directly or indirectly observable, such as quoted prices for similar assets or liabilities in active markets; quoted prices for identical or similar assets or liabilities in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 – Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The Company measures the fair value of financial assets and liabilities using the highest level of inputs that are reasonably available as of the measurement date. The following tables summarize the fair value of financial assets and liabilities (investments and convertible preferred stock warrant liabilities) that are measured at fair value, and the classification by level of input within the fair value hierarchy:

	Fair Value Measurements as of December 31, 2012			
(in thousands)	Level 1	Level 2	Level 3	Total
Investments:				
Money market funds	$ 5,923	$ —	$ —	$ 5,923
U.S. government-backed securities	—	9,351	—	9,351
Total investments	$ 5,923	$ 9,351	$ —	$15,274
Convertible preferred stock warrant liabilites	$ —	$ —	$ 157	$ 157

	Fair Value Measurements as of December 31, 2011			
(in thousands)	Level 1	Level 2	Level 3	Total
Investments:				
Money market funds	$ 2,973	$ —	$ —	$ 2,973
U.S. treasury notes	3,051	—	—	3,051
Corporate securities	—	6,022	—	6,022
U.S. government-backed securities	—	5,436	—	5,436
Total investments	$ 6,024	$ 11,458	$ —	$17,482
Convertible preferred stock warrant liabilites	$ —	$ —	$ 117	$ 117

The Company's Level 2 investments include U.S. government-backed securities and corporate securities that are valued based upon observable inputs that may include benchmark yields, reported trades, broker/dealer quotes, issuer spreads, two-sided markets, benchmark securities, bids, offers and reference data including market research publications. The fair value of the Company's commercial paper is based upon the time to maturity and discounted using the three-month treasury bill rate. The average remaining maturity of the Company's Level 2 investments as of December 31, 2012 is less than four months and all of these investments are rated by S&P and Moody's at AAA or AA+.

The fair value of the convertible preferred stock warrant liabilities as of December 31, 2012 was calculated using a Black-Scholes option-pricing model, with inputs of the estimated fair value of the underlying common stock at the valuation measurement date of $8.00 per share based upon the price at which common stock was sold in the Company's IPO, the remaining contractual term of the warrants of 2.8 years, the risk-free interest rate of 0.36% based upon the yield of U.S. Treasury instruments with similar durations, the lack of any expected future dividends and the estimated expected volatility of the price of the underlying common stock of 55% based upon the average historic price volatility of a peer group of publicly traded entities.

The fair value of the convertible preferred stock warrant liabilities through December 31, 2011 was calculated by using an Option Pricing Model to allocate the total enterprise value to the various securities within the Company's capital structure. The estimated total enterprise value was $106.9 million at December 31, 2011. The model's inputs reflect assumptions that market participants would use in pricing the instrument in a current period transaction. Inputs to the model included:

Time to liquidity (in years)	2.0
Volatility	53%
Discounted cash flow rate	14%
Risk free interest rate	0.25%
Marketability discount rate	27%

The time to liquidity input was based on the Company's estimate of when potential liquidity could be provided to stockholders. The volatility factor used was based on the average historic price volatility for publicly traded industry peers. The discounted cash flow rate used takes into consideration a company specific risk premium, market risk premium and an assumed risk free rate of return. The risk-free interest rate used was based on the yields of U.S. Treasury securities with maturities similar to the time to liquidity. The marketability discount is used to reflect that private company securities are generally less liquid than a public company.

The following table presents changes in financial instruments measured at fair value using Level 3 inputs:

	Convertible Preferred Stock Warrant Liabilites (in thousands)
Balance at December 31, 2010	$ 69
Unrealized loss included in other income (expense), net	48
Balance at December 31, 2011	$ 117
Issuances	79
Unrealized gain included in other income (expense), net	(39)
Balance at December 31, 2012	$ 157

The estimated fair value of the notes payable as of December 31, 2012, based upon current market rates for similar borrowings, as measured using Level 3 inputs, approximates the carrying amount as presented on the consolidated balance sheet.

Cash, Cash Equivalents, and Marketable Securities

The Company considers all highly liquid investments with an original maturity of 90 days or less at the time of purchase to be cash equivalents. Cash and cash equivalents consist of deposits with commercial banks in checking, interest-bearing and demand money market accounts. The Company invests in marketable securities consisting primarily of certificates of deposit, money market funds, corporate securities, commercial paper, U.S. government-backed securities and U.S. treasury notes. These securities are classified as available-for-sale and carried at estimated fair value, with unrealized gains and losses reported as part of accumulated other comprehensive income (loss), a separate component of stockholders' deficit. The Company may liquidate any of these investments in order to meet the Company's liquidity needs in the next year.

Realized gains and losses from the sale of marketable securities are calculated using the specific- identification method. Realized gains and losses and declines in value judged to be other-than-temporary are included in interest income (expense), net in the consolidated statements of comprehensive loss. To date, the Company has not recorded any impairment charges on its marketable securities related to other-than-temporary declines in market value. In determining whether a decline in market value is other-than-temporary, various factors are considered, including whether the decline is attributed to a change in credit risk, and whether it is more likely-than-not that the Company will hold the security for a period of time sufficient to allow for an anticipated recovery in market value. The Company had no realized gains or losses from the sale of marketable securities for the years ended December 31, 2012, 2011 and 2010.

Restricted Cash

Restricted cash at December 31, 2012 and December 31, 2011 consisted of $0.2 million related to standby letters of credit issued in connection with an operating lease for the Company's corporate headquarters.

Property and Equipment, Net

Property and equipment is stated at cost, less accumulated depreciation and amortization, and depreciated over the estimated useful lives of the respective assets of three years using the straight-line method. Leasehold improvements are amortized on a straight-line basis over the shorter of the useful lives or the noncancelable term of the related lease. Maintenance and repair costs are charged as expense in the statements of comprehensive loss as incurred.

Long-Lived Assets

The Company evaluates the carrying value of its long-lived assets, including intangible assets, whenever events or changes in circumstances indicate that the carrying value of the asset may be impaired. An impairment loss would be recognized when estimated future cash flows expected to result from the use of the asset, including disposition, are less than the carrying value of the asset. To date, the Company has not recorded any impairment charges on its long-lived assets.

The Company's intangible assets consist of intellectual property and know-how acquired, related to developed technology for antibody production, as part of the Company's acquisition of Celscia Therapeutics, Inc., effective January 12, 2004. Such intellectual property and know-how acquired provides the Company with alternative future uses in different research projects. The intellectual property and know-how acquired of $1.0 million is being amortized over the estimated useful life of the technology, which the Company estimates to be nine years. For each of the years ended December 31, 2012, 2011, and 2010, the Company recorded amortization expense of $0.1 million. As of December 31, 2012, the Company's intangible assets were fully amortized.

Deferred Offering Costs

Deferred offering costs as of December 31, 2012, consisting of legal, accounting, printing and filing fees incurred in the preparation of the Company's Registration Statements on Form 10-12G and Form S-1 as part of

the Company's IPO have been capitalized. The deferred offering costs were offset against the IPO proceeds upon the completion of the offering in February 2013. As of December 31, 2012, the Company had capitalized $2.8 million of deferred offering costs on the consolidated balance sheet. No amounts were deferred as of December 31, 2011.

Convertible Preferred Stock Warrant Liabilities

The Company classifies its outstanding warrants exercisable for shares of the Company's Series B-2 and Series E convertible preferred stock as convertible preferred stock warrant liabilities and adjusts the instruments to fair value at the end of each reporting period. At the end of each reporting period, changes in the fair value of the warrant liabilities during the period are recorded as a component of other income (expense), net. The Company will continue to adjust the liabilities for changes in fair value until the completion of the Company's IPO when the warrants will expire or convert into warrants to purchase common stock, at which time the liabilities will be remeasured and reclassified to equity.

Research and Development Expenses

Development costs incurred in the research and development of new products are expensed as incurred, including expenses that may or may not be reimbursed under research and development collaboration arrangements. Research and development costs include, but are not limited to, salaries, benefits, stock-based compensation, laboratory supplies, allocated overhead, fees for professional service providers and costs associated with product development efforts, including preclinical studies and clinical trials. Research and development expenses under collaborative agreements approximate or exceed the revenue recognized under such agreements.

The Company estimates preclinical study and clinical trial expenses based on the services performed, pursuant to contracts with research institutions and clinical research organizations that conduct and manage preclinical studies and clinical trials on its behalf. In accruing service fees, the Company estimates 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 the estimate, the Company will adjust the accrual accordingly. In the fourth quarter of 2012, adjustments to increase clinical trial expenses by $657,000 were recorded. Payments made to third parties under these arrangements in advance of the receipt of the related services are recorded as prepaid expenses until the services are rendered.

Revenue Recognition

The Company recognizes revenue when: (i) persuasive evidence of an arrangement exists; (ii) transfer of technology has been completed, delivery has occurred or services have been rendered; (iii) the fee is fixed or determinable; and (iv) collectability is reasonably assured. Payments received in advance of work performed are recorded as deferred revenue and recognized when earned.

Multiple Element Arrangements

The Company evaluates revenue from agreements that have multiple elements to determine whether the components of the arrangement represent separate units of accounting. Management considers whether components of an arrangement represent separate units of accounting based upon whether certain criteria are met, including whether the delivered element has stand-alone value to the customer. To date, all of the Company's research and development collaboration and license agreements have been assessed to have one unit of accounting. Up-front and license fees received for a combined unit of accounting are deferred and recognized ratably over the projected performance period. Nonrefundable fees where the Company has no continuing performance obligations are recognized as revenue when collection is reasonably assured and all other revenue recognition criteria have been met.

On January 1, 2011, the Company adopted on a prospective basis Financial Accounting Standards Board (FASB) Accounting Standards Update (ASU) 2009-13, *Multiple-Deliverable Revenue Arrangements*, which

amends the criteria related to identifying separate units of accounting and provides guidance on how an arrangement should be separated and the consideration allocated. The adoption of the standard did not impact the Company's financial position or results of operations as of and for the year ended December 31, 2012 or the year ended December 31, 2011 as the Company did not enter into any new arrangements or materially modify any existing arrangements in those periods. However, the adoption of this standard may result in revenue recognition patterns for future agreements that are materially different from the Company's existing multiple- element arrangements.

Research and Development Services

Internal and external research and development costs incurred in connection with collaboration agreements are recognized as revenue in the same period as the costs are incurred and are presented on a gross basis because the Company acts as a principal, has the discretion to choose suppliers, bears credit risk, and performs at least part of the services.

Milestones and Other Contingent Payments

On January 1, 2011, the Company elected to prospectively adopt the milestone method as described in FASB ASU 2010-17, *Milestone Method of Revenue Recognition*. Under the milestone method, contingent consideration received from the achievement of a substantive milestone will be recognized in its entirety in the period in which the milestone is achieved. A milestone is defined as an event having all of the following characteristics: (i) there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved; (ii) the event can only be achieved based in whole or in part on either the company's performance or a specific outcome resulting from the company's performance; and (iii) if achieved, the event would result in additional payments being due to the company.

The Company's future research and development and license agreements may provide for payments to be paid to the Company upon the achievement of development milestones or success fees. Given the challenges inherent in developing biologic products, there may be substantial uncertainty as to whether any such milestones would be achieved at the time the agreements are executed. In addition, the Company will evaluate whether the development milestones meet all of the conditions to be considered substantive. The conditions include: (1) the consideration is commensurate with either of the following: (a) the vendor's performance to achieve the milestone or (b) the enhancement of the value of the delivered item or items as a result of a specific outcome resulting from the vendor's performance to achieve the milestone; (2) it relates solely to past performance, and (3) it is reasonable relative to all the deliverables and payment terms within the arrangement. If the Company considers the development milestones to be substantive, revenue related to such future milestone payments will be recognized as the Company achieves each milestone. The election to adopt the milestone method did not impact the Company's financial position or results of operations as of and for the year ended December 31, 2012, or the year ended December 31, 2011, as the Company did not receive any milestone payments in those periods, and no milestone payments, as defined, are included in any of the Company's existing collaboration agreements as of December 31, 2012.

Prior to the adoption of ASU No. 2010-17, milestone payments that were contingent upon the achievement of substantive at-risk performance criteria were recognized in full upon achievement of those milestone events in accordance with the terms of the related agreement and assuming all other revenue recognition criteria were met. All revenue recognized to date under the Company's collaborative agreements has been nonrefundable.

Stock-Based Compensation Expense

The Company measures employee and director stock-based compensation expense for stock awards at the grant date, based on the fair value-based measurement of the award, and the expense is recorded over the related service period, generally the vesting period, net of estimated forfeitures. The Company calculates the fair value- based measurement of stock options using the Black-Scholes valuation model and the single-option method and recognizes expense using the straight-line attribution approach.

The Company accounts for equity instruments issued to nonemployees based on their fair values on the measurement dates using the Black-Scholes option-pricing model. The fair value-based measurements of the options granted to nonemployees are remeasured as they vest. As a result, the noncash charge to operations for nonemployee options with vesting is affected each reporting period by changes in the fair value of the Company's common stock.

Income Taxes

The Company accounts for income taxes under an asset-and-liability approach. Deferred income taxes reflect the impact of temporary differences between assets and liabilities recognized for tax and financial reporting purposes measured by applying enacted tax rates and laws that will be in effect when the differences are expected to reverse, net operating loss carryforwards and tax credits. Valuation allowances are provided when necessary to reduce net deferred tax assets to an amount that is more likely than not to be realized. The Company's policy is to include interest and penalties related to unrecognized tax benefits within the Company's provision for income taxes.

Comprehensive Loss

Comprehensive loss includes the net loss and all changes in stockholders' deficit during a period, except for those changes resulting from investments by stockholders or distributions to stockholders. Other comprehensive income (loss) consists solely of unrealized gains (losses) on marketable securities.

Net Loss Per Common Share

Basic net loss per common share is calculated by dividing the net loss by the weighted-average number of common shares outstanding during the period, without consideration of common stock equivalents. Diluted net loss per common share is computed by dividing the net loss by the weighted-average number of common shares and common stock equivalents outstanding for the period. Common stock equivalents are only included in the calculation of diluted net loss per common share when their effect is dilutive.

The Company's potential dilutive securities which include convertible preferred stock, unvested restricted stock, stock options, and warrants have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per common share and be antidilutive. Therefore, the denominator used to calculate both basic and diluted net loss per common share is the same in all periods presented.

The following shares subject to outstanding potentially dilutive securities have been excluded from the computations of diluted net loss per common share as the effect of including such securities would be antidilutive:

	December 31,		
	2012	2011	2010
Convertible preferred stock	12,329,330	10,657,030	10,657,030
Unvested common stock	—	139,033	172,402
Warrants to purchase preferred stock	72,029	38,997	38,997
Options to purchase common stock	1,030,795	1,086,299	962,781
	13,432,154	11,921,359	11,831,210

Deferred Rent

The Company records its costs under facility operating lease agreements as rent expense. Rent expense is recognized on a straight-line basis over the non-cancelable term of the operating lease. The difference between the actual amounts paid and amounts recorded as rent expense is recorded to deferred rent.

Segment Reporting

The Company determines its segment reporting based upon the way the business is organized for making operating decisions and assessing performance. The Company has only one operating segment related to the development of pharmaceutical products.

Recent Accounting Pronouncements

In May 2011, the FASB issued ASU No. 2011-04, *Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs*. This ASU is the result of joint efforts by the FASB and International Accounting Standards Board to develop a single, converged fair value framework. While this ASU is largely consistent with existing fair value measurement principles in U.S. GAAP, it expands the existing disclosure requirements of ASC Topic 820, *Fair Value Measurement* and makes other amendments. Many of these amendments were made to eliminate unnecessary wording differences between U.S. GAAP and International Financial Reporting Standards, which could change how fair value measurement guidance in ASC 820 is applied. The Company adopted ASU No. 2011-04 on January 1, 2012, as required. The adoption of this new guidance on a prospective basis did not have a material impact on the consolidated financial statements.

In June 2011, the FASB issued ASU No. 2011-05, *Presentation of Comprehensive Income.* This ASU gives an entity the option to present the total of comprehensive income (loss), the components of net income (loss), and the components of other comprehensive income (loss) either in a single continuous statement of comprehensive income (loss) or in two separate but consecutive statements. The Company adopted ASU No. 2011-05 on January 1, 2012 on a retrospective basis as required and has presented its comprehensive loss and the components of net loss and other comprehensive income (loss) in a single continuous statement of comprehensive income (loss).

3. Investments

At December 31, 2012, the amortized cost and fair value of investments, with gross unrealized gains and losses, were as follows:

(in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Money market funds	$ 5,923	$ —	$ —	$ 5,923
U.S. government-backed securities	9,347	4	—	9,351
Total investments	$ 15,270	$ 4	$ —	$15,274
Reported as:				
Cash and cash equivalents				$ 5,718
Marketable securities				9,351
Restricted cash				205
Total investments				$15,274

At December 31, 2011, the amortized cost and fair value of investments, with gross unrealized gains and losses, were as follows:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Money market funds	$ 2,973	$ —	$ —	$ 2,973
Corporate securities	6,024	—	(2)	6,022
U.S. government-backed securities	5,435	1	—	5,436
U.S. treasury notes	3,051	—	—	3,051
Total investments	$ 17,483	$ 1	$ (2)	$17,482
Reported as:				
Cash and cash equivalents				$ 2,768
Marketable securities				14,509
Restricted cash				205
Total investments				$17,482

As of December 31, 2012, all securities had remaining contractual maturities of less than one year.

4. Property and Equipment

Property and equipment consists of the following:

	December 31	
(In thousands)	2012	2011
Laboratory equipment	$ 1,453	$ 1,508
Computer equipment and software	435	421
Leasehold improvements, furniture and fixtures	1,286	1,282
	3,174	3,211
Accumulated depreciation and amortization	(2,944)	(2,784)
Property and equipment, net	$ 230	$ 427

Depreciation and amortization expense for the years ended December 31, 2012, 2011 and 2010 was $0.2 million, $0.5 million and $0.7 million, respectively.

5. Research and Development Collaboration and License Agreements

All of the contract revenues recognized in the years ended December 31, 2012, 2011, and 2010 was related to the development and commercialization agreement with Sanofi.

Sanofi

In January 2010, the Company and Sanofi entered into an agreement for the development and commercialization of KB001-A, an investigational new biologic for the treatment and prevention of *Pseudomonas aeruginosa (Pa)* infections (the Sanofi agreement). Under the terms of the Sanofi agreement, the Company received an initial upfront non-refundable payment of $35 million and received an additional non-refundable payment of $5 million that represented a second installment of the upfront fees due to the Company under the agreement upon completion of a sublicense negotiation with a third party in August 2011. The Company may also receive development, regulatory and commercial contingent payments for a potential further $250 million, as well as royalties on eventual product sales, if any. These contingent payments do not meet the

definition of milestones since they are based solely on Sanofi's performance and therefore, the milestone method will not be applied to these payments. Sanofi is solely responsible for conducting, at its cost, the research, development, manufacture, and commercialization of the licensed products for the diagnosis, treatment and/or prevention of all human diseases and conditions caused by *Pa*, except that the Company retains responsibility, at the Company's cost, for developing and promoting the products for the diagnosis, treatment and/or prevention of *Pa* in patients with CF or bronchiectasis. Sanofi has an option to obtain rights to participate in the development and promotion of KB001-A and other licensed products for the diagnosis, treatment and/or prevention of *Pa* in patients with CF or bronchiectasis on pre-negotiated terms, either outside of the U.S. or worldwide, at any time up to 90 days after the delivery by the Company to Sanofi of the final clinical study report from the Company's Phase 2 clinical trial of KB001-A in *Pa*-infected patients with CF.

The agreement will remain in effect until all payment obligations under the agreement end. Sanofi may terminate the agreement for convenience, and either Sanofi or the Company may terminate the agreement for material breach of the agreement by the other party. In the event Sanofi terminates the agreement for convenience or the Company terminates due to Sanofi's material breach, worldwide rights to develop, manufacture and commercialize licensed products would revert back to the Company, and Sanofi would grant to the Company a license to allow it to develop, manufacture, and commercialize licensed products worldwide, subject to commercially reasonable financial terms to be negotiated by the parties after such termination. In the event that the Company materially breaches the agreement, Sanofi may terminate the agreement or, rather than terminate the agreement, opt to deduct any damages awarded for the Company's breach against future contingent payments and royalties otherwise payable by Sanofi under the agreement.

The upfront payment of $40 million was recognized over the estimated period of the Company's substantive performance obligations under the agreement. For the years ended December 31, 2010 and 2011, the Company estimated that substantive performance obligations under the agreement would be completed by March 31, 2012. During the three-month period ended March 31, 2012, the Company and Sanofi agreed to amend the 2010 agreement as Sanofi requested that the Company perform additional services. Therefore, in the three-month period ended March 31, 2012, the Company revised its estimate to reflect that the substantive performance obligations under the agreement were expected to be completed by June 30, 2012. The substantive performance obligations under the agreement were completed by June 30, 2012.

Under the terms of the Sanofi agreement, the Company receives specified research and development funding for services performed in connection with KB001-A research and development efforts. Reimbursements received by the Company for these services are recorded as contract revenue when earned as the related services are provided.

Revenue recognized under the Sanofi agreement was as follows:

	Years Ended December 31,		
(In thousands)	2012	2011	2010
Contract revenue:			
Amortization of upfront fees	$5,630	$18,977	$15,393
Reimbursement for development-related activities	468	1,278	2,319
Total contract revenue	$6,098	$20,255	$17,712

During the year ended December 31, 2012, the Company recorded research and development expenses related to materials purchased from Sanofi of $1.9 million.

6. Other Income

In November 2010, the Company received total cash grants of $1.0 million from the Internal Revenue Service under Section 48D of the Internal Revenue Code for the Qualified Therapeutic Discovery Project Program. The grants relate to certain research and development costs the Company incurred in 2009 in connection with its programs. As of December 31, 2010, the Company had incurred the associated expenses underlying the qualified investment and received certification from the Department of Treasury for each project awarded. As of December 31, 2010, there were no remaining performance obligations associated with the grants. The $1.0 million received has been included within other income (expense), net in the accompanying statement of comprehensive loss for the year ended December 31, 2010.

7. Notes Payable

Loan and Security Agreement

In September 2012, the Company entered into a loan and security agreement (the Agreement) with MidCap Financial, SBIC, LP (MidCap Financial), providing for the borrowing of up to $15 million, of which $10 million was required to be drawn. The remaining $5 million may be drawn at the option of the Company. The Agreement provides for the loan to be issued in three tranches: the first tranche of $5 million was issued in September 2012; the second tranche of $5 million was issued in December 2012; and the final tranche may be drawn at the option of the Company no later than June 2013. The loan has a monthly variable interest rate, reset each month, if applicable, as determined by adding to 600 basis points the greater of: (a) one month LIBOR or (b) 3% (the LIBOR floor). Interest on amounts outstanding are payable monthly in arrears. There is an interest only period to December 31, 2013 followed by straight-line principal payments over thirty-six months. At the time of final payment, the Company must pay an exit fee of 3% of the drawn amount. Pursuant to the Agreement, the Company provided a first priority security interest in all existing and after-acquired assets, excluding intellectual property. In addition, the terms of the Agreement provide MidCap Financial a warrant to purchase shares of the Company's Series E convertible preferred stock (Series E Preferred) equal to 4% of the amount drawn down under the facility divided by the Series E Preferred exercise price of $12.11 per share. The warrant expired upon the completion of the Company's proposed IPO.

The Company has the right to prepay all or a portion of the borrowed amounts under the Agreement; however, if the Company exercises this option, the Company must pay a prepayment fee determined by multiplying the outstanding loan amount by 5% if the prepayment occurs through December 31, 2014, 2% if the prepayment occurs in 2015 and 1% if the prepayment occurs in the final year. In the event of default, upon which all amounts borrowed become immediately due and payable, the Company will be subject to the prepayment fee. An event of default includes, but is not limited to, an occurrence such as a payment default, a material adverse change, insolvency, or a change of control.

In connection with the Agreement and the first tranche drawdown of $5 million in September 2012 and second tranche drawdown of $5 million in December 2012, the Company issued a warrant to MidCap Financial to purchase shares of the Company's Series E Preferred in an amount equal to 4% of the amount drawn down under the Agreement divided by the Series E Preferred exercise price of $12.11 per share. The warrant was immediately exercisable and provided for net settlement. Contemporaneously with the issuance of the warrant, the Company recorded a debt discount of $79,000.

Debt issuance costs paid directly to MidCap Financial of $114,000 (financing fees) and the fair value of the warrant issued to MidCap Financial were treated as a discount on the debt and are being accreted using the interest method. Other debt issuance costs for legal fees are included in other assets in the accompanying consolidated balance sheet and are being amortized using the interest method. The accretion of the debt discount and amortization of other debt issuance costs are recorded as interest expense in the consolidated statement of comprehensive loss.

The Company recorded interest expense related to the borrowings of $184,000 for the year ended December 31, 2012. Included in interest expense for this period was interest on principal, amortization of the debt issuance costs, accretion of debt discount, and the accretion of the final exit fee. For the year ended December 31, 2012, the effective interest rate on the amounts borrowed under the Agreement, including the accretion of the debt discount and the accretion of the final payment, was 9.9%.

Future payments as of December 31, 2012 under the Agreement are as follows (in thousands):

2013	$ 1,183
2014	3,995
2015	3,699
2016	3,403
Total minimum payments	12,280
Less amount representing interest	(2,280)
Notes payable, gross	10,000
Discount on notes payable	(186)
Accretion of the final exit fee payment	12
Long-term notes payable	$ 9,826

8. Preferred Stock Warrant Liabilities

In connection with a credit facility obtained in 2005, the Company issued a warrant to purchase 15,599 shares of Series B-2 convertible preferred stock (Series B-2 Preferred) upon the signing of the credit facility agreement in October 2005, which was increased to 38,997 shares of Series B-2 Preferred upon draw down of the loan in December 2006. The warrant was immediately exercisable upon issuance and expires on October 31, 2015. The exercise price per share is $5.13. The warrant converted into a warrant exercisable into the Company's common stock upon the completion of the Company's IPO with the same exercise price per share of $5.13.

In connection with the Agreement with MidCap Financial, in September 2012 and December 2012 the Company issued warrants to purchase shares of Series E Preferred in an amount equal to 4% of the amount drawn down under the Agreement divided by the Series E Preferred exercise price of $12.11 per share. The warrants were immediately exercisable for 33,032 shares of Series E Preferred upon issuance. The Series E Preferred warrant expired upon the completion of the Company's IPO in February 2013.

9. Commitments and Contingencies

Operating Lease

In January 2008, the Company entered into a noncancelable operating lease for its facilities in South San Francisco, California. The lease term commenced in February 2008 and expired in June 2011. In January 2011, the Company renewed the noncancelable operating lease. The lease term commenced in July 2011 and will expire in June 2014. In connection with the renewed lease, the Company issued a standby letter of credit for approximately $0.2 million for the deposit requirement under the terms of the lease. Rent expense is recognized on a straight-line basis over the term of the lease. The Company is also responsible for certain operating expenses. The lease provided an allowance of approximately $0.2 million from the landlord for leasehold improvements that was utilized in the year ended December 31, 2011. This amount has been included in deferred rent in the accompanying December 31, 2012 and 2011 balance sheets and is being amortized over the term of the lease, on a straight-line basis.

Future minimum lease payments are as follows as of December 31, 2012:

(in thousands)	
2013	$1,207
2014	615
Total	$1,822

In January 2009, the Company entered into a sublease agreement, as amended in April 2009, with a third party to sublease a portion of the Company's facility in South San Francisco, California. The sublease had a 29 month term that began February 1, 2009 and ended June 2011. In January 2011, the third party renewed the sublease for the term beginning July 2011 and ending June 2014. In August and December 2011, the third party amended the sublease to include additional space. In March 2012, the Company entered into a sublease agreement with another third party to sublease a portion of the Company's facility in South San Francisco, California. The sublease has a 28 month term that began March 1, 2012 and ends June 2014.

Under the agreements, the Company will receive sublease payments as follows:

(in thousands)	
2013	$1,095
2014	553
Total	$1,648

The sublease income received will be recorded as an offset to the Company's rent expenses.

Rent expense, net of sublease income, was $0.1 million, $0.6 million, and $0.4 million for the years ended December 31, 2012, 2011 and 2010, respectively. Sublease income was $1.0 million, $0.5 million, and $0.4 million for the years ended December 31, 2012, 2011 and 2010, respectively.

Indemnifications

The Company, as permitted under Delaware law and in accordance with its bylaws, has agreed to indemnify its officers and directors for certain events or occurrences, subject to certain limits, while the officer or director is or was serving at the Company's request in such capacity. The term of the indemnification period is equal to the officer's or director's lifetime.

The maximum amount of potential future indemnification is unlimited; however, the Company currently holds director and officer liability insurance. This insurance limits the Company's exposure and may enable it to recover a portion of any future amounts paid. The Company believes that the fair value of these indemnification obligations is minimal. Accordingly, the Company has not recognized any liabilities relating to these obligations for any period presented.

The Company has certain agreements with service providers with which it does business that contain indemnification provisions pursuant to which the Company typically agrees to indemnify the party against certain types of third-party claims. The Company accrues for known indemnification issues when a loss is probable and can be reasonably estimated. The Company would also accrue for estimated incurred but unidentified indemnification issues based on historical activity. As the Company has not incurred any indemnification losses to date, there were no accruals for or expenses related to indemnification issues for any period presented.

10. Convertible Preferred Stock and Stockholders' Deficit

Convertible Preferred Stock

In September and December 2008, the Company issued 1,749,425 shares and 1,015,357 shares, respectively, of Series D convertible preferred stock (Series D Preferred) at a price of $11.57 per share, for gross proceeds of $32.0 million. In March 2009, the Company issued 431,973 shares of Series D Preferred at a price of $11.57 per share, for gross proceeds of $5.0 million.

As of December 31, 2011, convertible preferred stock balances were as follows:

	Shares Authorized	Shares Issued and Outstanding	Carrying Value (In thousands)	Liquidation Amount (In thousands)
Series A	1,527,611	428,922	$ 1,835	$ 2,200
Series B-1	3,425,152	961,720	4,726	4,932
Series B-2	14,811,323	4,119,759	21,039	21,128
Series C	6,944,450	1,949,874	19,905	20,000
Series D	12,400,000	3,196,755	35,673	37,002
	39,108,536	10,657,030	$ 83,178	$ 85,262

In May and June 2012, the Company issued 1,672,300 shares of Series E Preferred at a price of $12.11 per share, for gross proceeds of $20.3 million. As of December 31, 2012, convertible preferred stock balances were as follows:

	Shares Authorized	Shares Issued and Outstanding	Carrying Value (In thousands)	Liquidation Amount (In thousands)
Series A	1,527,611	428,922	$ 1,835	$ 2,200
Series B-1	3,425,152	961,720	4,726	4,932
Series B-2	14,811,323	4,119,759	21,039	21,128
Series C	6,944,450	1,949,874	19,905	20,000
Series D	11,385,196	3,196,755	35,673	37,002
Series E	22,058,823	1,672,300	18,845	20,250
	60,152,555	12,329,330	$ 102,023	$ 105,512

As of December 31, 2012, the Company had six series of outstanding convertible preferred stock: Series A convertible preferred stock (Series A Preferred), Series B-1 convertible preferred stock (Series B-1 Preferred), Series B-2 Preferred, Series C convertible preferred stock (Series C Preferred), Series D Preferred and Series E Preferred. The convertible preferred stock was initially recorded at fair value on the date of issuance, net of issuance costs. All shares of convertible preferred stock were effectively redeemable in the event of a change in control at the applicable original purchase price per share. As all convertible preferred stock was redeemable upon an event outside the control of the Company (i.e., a change in control), the related amounts were presented outside of stockholders' deficit. The carrying value of convertible preferred stock would have been adjusted to redemption value if it became probable that a redemption would occur but no such redemption occurred prior to the conversion of the convertible preferred stock into common stock upon the completion of the Company's IPO.

The redemption amount of outstanding Series A Preferred, Series B-1 Preferred, Series B-2 Preferred, Series C Preferred, Series D Preferred and Series E Preferred is equal to the applicable original purchase price of the stock, or $5.13, $5.13, $5.13, $10.26, $11.57 and $12.11 per share, respectively. The significant rights, privileges, and preferences of the convertible preferred stock were as follows as of December 31, 2012:

Dividend Provisions

Until the earlier of October 31, 2013 and the date on which there is an automatic conversion of all of the outstanding shares of convertible preferred stock, the holders of shares of each series of convertible preferred stock shall be entitled to receive noncumulative dividends prior and in preference to any declaration or payment of any dividend on the common stock at the applicable dividend rate, payable when, as and if declared by the Board of Directors, with any such dividend being paid pari passu among all of the then outstanding shares of convertible preferred stock until the dividend rate for each such outstanding share of convertible preferred stock has been paid in full. The dividend rate shall be $0.43 per annum for each share of Series A Preferred, Series B-1 Preferred and Series B-2 Preferred, $0.8206 per annum for each share of Series C Preferred, $0.93 per annum for each share of Series D Preferred and $0.61 per annum for each share of Series E Preferred.

From October 31, 2013 to the date on which there is an automatic conversion of all of the outstanding shares of convertible preferred stock, the holders of Series E Preferred shall be entitled to receive cumulative dividends of $0.61 per share annually payable whether or not they have been declared by the Board of Directors. All such dividends shall accrue automatically on a daily basis and all accrued and unpaid dividends shall be fully paid quarterly prior to payment of any other dividend. If the dividends are not paid when they are due, the dividend rate increases from $0.61 to $1.21 per share annually until such dividends are paid in full. If other dividends are declared, such dividends shall first be paid *pari passu* among all of the then outstanding shares of Series A Preferred, Series B-1 Preferred, Series B-2 Preferred, Series C Preferred and Series D Preferred until the dividend rate for each such series has been paid in full.

Following the payment of dividends to the convertible preferred stockholders as described above, any declared dividends will be distributed among the holders of convertible preferred and common stock pro rata based upon the number of shares of common stock held by each determined on an as-if converted to common stock basis. No dividends have been declared to date.

Liquidation Preference

In the event of any liquidation, dissolution, winding up or change in control of the Company, the holders of Series E Preferred are entitled to receive a liquidation amount of $12.11 per share plus all cumulative and all declared but unpaid dividends prior and in preference to the holders of Series D Preferred, Series C Preferred, Series B-2 Preferred, Series B-1 Preferred and Series A Preferred and the common stockholders. Following payment of this liquidation amount, if proceeds for distribution remain, the holders of Series D Preferred are entitled to receive a liquidation amount of $11.57 per share plus all declared but unpaid dividends prior and in preference to the holders of Series C Preferred, Series B-2 Preferred, Series B-1 Preferred and Series A Preferred and the common stockholders. Following payment of this liquidation amount, if proceeds for distribution remain, the holders of Series C Preferred are entitled to receive a liquidation amount of $10.26 per share plus all declared but unpaid dividends prior and in preference to the holders of Series B-2 Preferred, Series B-1 Preferred and Series A Preferred and the common stockholders. Following payment of these liquidation amounts, if proceeds for distribution remain, the holders of Series B-2 Preferred are entitled to receive a liquidation amount of $5.13 per share plus all declared but unpaid dividends prior and in preference to the holders of Series B-1 Preferred and Series A Preferred and the common stockholders. Following payment of these liquidation amounts, if proceeds for distribution remain, the holders of the Series B-1 Preferred and Series A Preferred are each entitled to receive a liquidation amount of $5.13 per share plus all declared but unpaid dividends prior and in preference to the common stockholders. Following payment of these liquidation amounts, the convertible preferred and the common stockholders shall share in any remaining proceeds pro rata based on the number of common shares held by each, determined on an as-if converted to common stock basis, until the holders of Series A Preferred, Series B-1 Preferred and Series B-2 Preferred have received an additional $10.26 per share (for a total of $15.39 per share), the holders of Series C Preferred have received an additional $15.39 per share (for a total of $25.64 per share), the holders of Series D Preferred have received an additional $17.34 per share (for a

total of $28.92 per share) and the holders of Series E Preferred have received an additional $18.16 per share (for a total of $30.27 per share). Thereafter, any proceeds remaining for distribution would be distributed pro rata among the common stockholders.

Conversion Rights

Each share of convertible preferred stock is convertible, at the option of the holder, at any time after the date of issuance, into one fully paid and nonassessable share of common stock, subject to certain anti-dilution adjustments. Each share of convertible preferred stock, subject to certain anti-dilution adjustments, will be automatically converted into one fully paid and nonassessable share of common stock upon the earlier of: (i) the Company's IPO with a pre-IPO valuation of at least $225 million that results in gross proceeds to the Company of not less than $30 million, (ii) the effective date of a registration statement on Form S-1 registering for re-sale shares of common stock issued in, or shares of common stock issued upon the conversion of preferred stock issued in, a qualifying private placement, or (iii) the date specified by written consent or agreement of the holders of not less than sixty percent of the then outstanding shares of convertible preferred stock; provided, however, that (x) if such conversion is in connection with a liquidation event in which holders of Series D Preferred would receive an amount less than $28.92 per share, then the automatic conversion of each share of Series D Preferred shall also require the written consent or agreement of the holders of not less than a majority of the then outstanding shares of Series D Preferred and (y) the automatic conversion of each share of Series E Preferred shall also require the written consent or agreement of the holders of not less than sixty percent of the then outstanding shares of Series E Preferred.

Subject to customary exceptions, the Company's amended and restated certificate of incorporation provides anti-dilution protection for holders of the convertible preferred stock in the event the Company issues additional shares of the Company's common stock, options or rights to purchase the Company's common stock or securities convertible into the Company's common stock without consideration or at a price per share that is less than the then effective conversion price of any series of the convertible preferred stock, which is referred to as a dilutive issuance. The Company's amended and restated certificate of incorporation provides that the conversion price shall be adjusted to protect holders of the convertible preferred stock from certain dilutive issuances based on a weighted average formula.

In addition to the anti-dilution protections described above, the conversion price of the convertible preferred stock is subject to adjustments for stock splits, dividends and recapitalizations, among other things.

Voting Rights

The holder of each share of convertible preferred stock shall have the right to one vote for each share of common stock into which such share of convertible preferred stock could be converted. Additionally, specific protective provisions require that certain actions by the Company such as the completion of a liquidation event may be taken only upon the approval of the holders of at least sixty percent of the outstanding shares of convertible preferred stock.

Election of Directors

The holders of convertible preferred stock are entitled to elect two members of the Company's Board of Directors. All remaining members of the Company's Board of Directors are elected by the holders of common and convertible preferred stock, voting together as a single class, on an as-if converted to common stock basis.

Right of First Offer

Each holder of at least 280,782 shares of convertible preferred stock (or the common stock issued upon conversion thereof) has the right to participate in certain future equity issuances of the Company in order to maintain their pro rata ownership percentage of the Company. The right expires upon the earlier of: (i) an initial public offering with a pre initial public offering valuation of at least $225 million and resulting in gross proceeds to

the Company of not less than $30 million; (ii) the effective date of a registration statement on Form S-1 registering for re-sale shares of common stock issued in, or shares of common stock issued upon the conversion of preferred stock issued in, a qualifying private placement, or (iii) the completion of a liquidation event of the Company.

Right of First Refusal and Co-Sale

Holders of convertible preferred stock have a secondary right of first refusal (if not exercised by the Company) and certain rights of co-sale with respect to certain shares of common stock held by common stockholders. The rights expire upon the earlier of: (i) an IPO with a pre-IPO valuation of at least $225 million and resulting in gross proceeds to the Company of not less than $30 million; (ii) the effective date of a registration statement on Form S-1 registering for re-sale shares of common stock issued in, or shares of common stock issued upon the conversion of preferred stock issued in, a qualifying private placement, (iii) the completion of a liquidation event, and (iv) the date specified by written consent or agreement of the holders of not less than sixty percent of the then outstanding convertible preferred stock.

Common Stock

The Company had reserved the following shares of common stock for issuance as of December 31, 2012

Conversion of Series A Preferred	428,922
Conversion of Series B-1 Preferred	961,720
Conversion of Series B-2 Preferred	4,119,759
Exercise and conversion of Series B-2 and Series E Preferred warrants	72,029
Conversion of Series C Preferred	1,949,874
Conversion of Series D Preferred	3,196,755
Conversion of Series E Preferred	1,672,300
Common stock available for grant of stock awards	2,129,055
Common stock options outstanding	1,030,795
	15,561,209

Stock Plans and Stock-Based Compensation

Under the Company's 2001 Stock Plan (the 2001 Plan), the Company was able to grant shares and/or options to purchase up to 3,408,247 shares of common stock to employees, directors, consultants, and other service providers at prices not less than the fair market value at the date of grant for incentive stock options and not less than 85% of the fair market value for nonstatutory options. These options generally vest over four years, expire 10 years from the date of grant, and are generally exercisable at any time following the date of grant. Unvested options exercised are subject to the Company's repurchase right that lapses as the options vest.

The Company's board of directors adopted the 2012 Equity Incentive Plan in July 2012. The 2012 Equity Incentive Plan went into effect and the 2001 Plan was terminated in August 2012. However, the awards under the 2001 Plan outstanding as of and subsequent to the termination of the 2001 Plan will continue to be governed by their existing terms.

Under the 2012 Equity Incentive Plan, the aggregate number of common shares issued shall not exceed the sum of (a) 1,123,131 common shares, (b) the number of common shares reserved under the 2001 Plan that were not issued or subject to outstanding awards under the 2001 Plan upon its termination, and (c) any common shares subject to outstanding options under the 2001 Plan upon its termination that subsequently expire or lapse unexercised and common shares issued pursuant to awards granted under the 2001 Plan that were outstanding

upon its termination and that are subsequently forfeited to or repurchased by the Company; provided, however, that no more than 1,066,975 common shares, in the aggregate, shall be added to the 2012 Equity Incentive Plan pursuant to clauses (b) and (c). In addition, the number of shares reserved for issuance under the 2012 Equity Incentive Plan will be increased automatically on the first business day of each fiscal year of the Company, starting with fiscal year 2013 and ending in fiscal year 2022, by a number equal to the lesser of (a) 5% of the total number of common shares outstanding on December 31 of the prior year, (b) 842,348 common shares, subject to certain adjustments in accordance with the 2012 Equity Incentive Plan, or (c) a number of common shares determined by the Company's board of directors.

Under the 2012 Equity Incentive Plan, the Company may grant shares, stock units, stock appreciation rights, performance cash awards and/or options to employees, directors, consultants, and other service providers. For options, the per share exercise price may not be less than the fair market value of a Company common share on the date of grant. Awards generally vest over four years and expire 10 years from the date of grant. Options generally become exercisable as they vest following the date of grant.

In general, to the extent that awards under the 2012 Equity Incentive Plan are forfeited or lapse without the issuance of shares, those shares will again become available for awards.

The Company's board of directors has discretion to administer the 2012 Equity Incentive Plan. The 2012 Equity Incentive Plan provides that in the event of certain significant corporate transactions, each outstanding award will be treated in the manner described in the definitive transaction agreement. Outstanding options granted under the 2001 Plan will become fully vested unless continued or assumed by a surviving entity in a significant corporate transaction. An individual award agreement or any other written agreement between a participant and the Company may provide that an award will be subject to additional acceleration of vesting and exercisability in the event of certain change in control transactions.

The Company's board of directors may amend or terminate the 2012 Equity Incentive Plan at any time. If the Company's board of directors amends the plan, it need not seek stockholder approval of the amendment unless required by applicable law, regulation or rule. The 2012 Equity Incentive Plan will continue in effect for 10 years from its adoption date, unless the Company's board of directors decides to terminate the plan earlier.

Activity under the Company's stock plans is as follows:

	Shares Available for Grant	Number of Shares Subject to Options Outstanding	Weighted-Average Exercise Price
Balances at December 31, 2009	522,497	1,040,658	$ 1.00
Stock awards granted	(134,530)	—	
Options granted	(145,375)	145,375	1.46
Options canceled	76,098	(76,098)	1.07
Options exercised	—	(147,154)	0.82
Balances at December 31, 2010	318,690	962,781	1.07
Additional shares authorized	912,544	—	
Stock awards granted	(72,441)	—	
Options granted	(324,585)	324,585	1.46
Options canceled	165,980	(165,980)	1.25
Options exercised	—	(35,087)	0.96
Stock awards canceled and forfeited	11,462	—	
Balances at December 31, 2011	1,011,650	1,086,299	1.18
Additional shares authorized	1,123,131	—	
Options granted	(444,607)	444,607	4.77
Options canceled	421,987	(421,987)	1.26
Options exercised	—	(78,124)	1.08
Stock awards canceled and forfeited	16,894	—	
Balances at December 31, 2012	2,129,055	1,030,795	2.68
Options vested and expected to vest at December 31, 2012		979,255	2.68

In February 2010, the Company authorized awards to executive officers for a total of 153,026 shares of common stock. Awards of 56,998 shares of common stock vested in January 2011 based on the attainment in 2010 of certain agreed-upon performance milestones as determined by the Board of Directors. In January 2011, the Company authorized awards to executive officers for a total of 141,795 shares of common stock. In January and July 2012, all outstanding awards of common stock vested based on the attainment in 2011 and 2012 of certain agreed-upon performance milestones as determined by the Board of Directors. The Company recorded total stock-based compensation expense of $401,000, $52,000 and $92,000 for the years ended December 31, 2012, 2011 and 2010, respectively, related to these stock awards. At December 31, 2012, no shares of common stock were subject to repurchase related to these awards.

Additional information regarding options outstanding as of December 31, 2012 is as follows:

	Options Outstanding and Exercisable	
Exercise Price	Number of Shares Outstanding	Weighted-Average Remaining Contractual Life (In Years)
$0.50	37,240	2.28
0.53	45,625	4.02
0.89	15,723	4.54
1.03	182,754	5.31
1.21	177,387	6.13
1.46	128,020	7.75
2.17	66,394	9.19
4.74	349,574	9.58
11.36	28,078	9.81
	1,030,795	

At December 31, 2012, 592,950 shares of the 1,030,795 options outstanding were vested. The weighted-average remaining contractual life of options exercisable at December 31, 2012 and 2011 is 6 years and 6.4 years, respectively. The aggregate intrinsic value of options outstanding and exercisable at December 31, 2012 and 2011 was $8.9 million and $1.1 million, respectively. The aggregate intrinsic value of options vested and expected to vest, net of expected forfeitures, at December 31, 2012 was $10.4 million with an average remaining contractual life of 7.4 years.

The Company estimated the fair value-based measurement of each stock award on the date of grant using the Black-Scholes option-pricing model. The Company does not believe that it is able to rely on its historical exercise and post-vesting termination activity to provide accurate data for estimating its expected term for use in determining the fair value-based measurement of its options. Therefore, the Company has opted to use the simplified method for estimating the expected term of its options. The risk-free interest rate assumptions are based on the yield of U.S. Treasury instruments with similar durations as the expected term of the related awards. The expected dividend yield assumption is based on the Company's absence of dividend payouts. Expected volatility is based on the average volatility of a peer group of publicly traded entities. Forfeitures are estimated such that the Company only recognizes expense for those shares expected to vest, and adjustments are made if actual forfeitures differ from those estimates.

The weighted-average fair value-based measurement of employee and director stock options granted under the Company's stock plans in the years ended December 31, 2012, 2011, and 2010 were $6.98, $0.82, and $1.07 per share, respectively. The fair value-based measurement of employee and director stock options granted under the Company's stock plans was estimated at the date of grant using the Black-Scholes model with the following assumptions:

	Year Ended December 31,		
	2012	2011	2010
Expected term	6 years	6 years	6 years
Expected volatility	57-59%	58-60%	87-88%
Risk-free interest rate	0.8-1.4%	1.9-2.7%	1.5-2.9%
Expected dividend yield	0%	0%	0%

The Company has historically granted stock options at exercise prices not less than the fair market value of its common stock as determined by the board of directors based on input from management. The determination of the estimated fair value of the Company's common stock on the date of grant is based on a number of objective and subjective factors including: recent sales of convertible preferred stock to investors; comparable rights and preferences of other outstanding equity securities; progress of research and development efforts and milestones attained; results of operations, financial position and levels of debt and available capital resources of the Company; perspective provided by valuation analyses of the Company's common stock performed by third- party valuation specialists; and the likelihood of a liquidity event such as an initial public offering or the sale of the Company given prevailing market and biotechnology sector conditions.

Total employee and director stock-based compensation expense recognized was as follows:

	Years Ended December 31,		
(In thousands)	2012	2011	2010
General and administrative	$ 423	$ 93	$ 152
Research and development	398	128	147
	$ 821	$ 221	$ 299

At December 31, 2012, the Company had $2.8 million of total unrecognized compensation expense, net of estimated forfeitures, related to outstanding stock options that will be recognized over a weighted-average period of 3.3 years.

The total intrinsic value of options exercised was $607,000 for the year ended December 31, 2012. The total intrinsic value of options exercised in the years ended December 31, 2011, and 2010 was not significant.

11. Income Taxes

Deferred tax assets and liabilities reflect the net tax effects of net operating loss and tax credit carryovers and the temporary differences between the carrying amounts of assets and liabilities for financial reporting and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets are as follows (in thousands):

	December 31,	
	2012	2011
Deferred Tax Assets:		
Net operating Losses	$ 37,162	$ 26,699
Research & Other Credits	2,008	2,029
Deferred Revenue	—	1,559
Other	1,030	750
Total Deferred Tax Assets	40,200	31,037
Valuation Allowance	(40,200)	(31,037)
Net Deferred Tax Assets	$ —	$ —

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

	Years Ended December 31,		
	2012	2011	2010
Statutory rate	-34.0%	-34.0%	-34.0%
Valuation Allowance	33.4%	31.0%	40.8%
Nondeductible Warrant Expense	-0.1%	0.0%	0.0%
Nondeductible Stock Compensation	0.6%	2.6%	3.2%
R&D expense adjustment related to Grants received	0.0%	0.0%	-10.4%
Other	0.1%	0.4%	0.4%
Effective tax rate	0.0%	0.0%	0.00%

Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by $9.2 million, $0.8 million and $2.6 million during 2012, 2011 and 2010, respectively.

At December 31, 2012, the Company had federal net operating loss carryforwards of approximately $93.3 million, which expire in the years 2025 through 2032, and state net operating loss carryforwards of approximately $93.3 million, which expire in the years 2015 through 2032.

At December 31, 2012, the Company had federal research and development credit carryforwards of approximately $1.7 million, which expire in the years 2022 through 2031 and state research and development credit carryforwards of approximately $1.8 million. The state research and development credit carryforwards can be carried forward indefinitely.

During 2010, the Company completed a Section 382 study in accordance with the Internal Revenue Code of 1986, as amended and similar state provisions. The study concluded that the Company has experienced several ownership changes since inception. This causes the Company ‘s utilization of its net operating loss and tax credit carryforwards to be subject to substantial annual limitations. These results are reflected in the above carryforward amounts and deferred tax assets. The Company’s ability to utilize its net operating loss and tax credit carryforwards may be further limited as a result of subsequent ownership changes. All such limitations could result in the expiration of carryforwards before they are utilized.

The Company recognizes the financial statement effects of a tax position when it is more likely than not, based on the technical merits, that the position will be sustained upon examination.

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows (in thousands):

Beginning at January 1, 2010	$ 850
Additions based on tax positions related to current year	172
Balance at December 31, 2010	1,022
Additions based on tax positions related to current year	3
Balance at December 31, 2011	1,025
Additions based on tax positions related to prior year	39
Additions based on tax positions related to current year	5
Balance at December 31, 2012	$1,069

There were no interest or penalties related to unrecognized tax benefits. Substantially all of the unrecognized tax benefit, if recognized, would affect the Company's tax expense. The Company does not anticipate that the amount of existing unrecognized tax benefits will significantly increase or decrease within the next 12 months

The Company files income tax returns in the U.S. federal jurisdiction and California. The United States federal corporation income tax returns beginning with the 2000 tax year remain subject to examination by the Internal Revenue Service (IRS). The California corporation income tax returns beginning with the 2000 tax year remain subject to examination by the California Franchise Tax Board.

12. Employee Benefit Plan

The Company has established a 401(k) tax-deferred savings plan (the 401(k) Plan), which permits participants to make contributions by salary deduction pursuant to Section 401(k) of the Internal Revenue Code. The Company is responsible for administrative costs of the 401(k) Plan. The Company may, at its discretion, make matching contributions to the 401(k) Plan. No employer contributions have been made to date.

13. Restructuring Charges

For the year ended December 31, 2011, the Company initiated a reduction in workforce resulting in an aggregate restructuring charge of approximately $1.1 million, consisting of severance and benefit payments for terminated employees. The activity in the accrued restructuring balance, included within accrued compensation on the balance sheet, was as follows for the year ended December 31, 2012 and 2011:

(in thousands)	
Beginning at December 31, 2010	$ —
Additions based on charges during the year	1,096
Deductions based on payments during the year	(641)
Balance at December 31, 2011	455
Deductions based on payments during the period	(455)
Balance at December 31, 2012	$ —

Of the $1.1 million restructuring charges, $0.9 million was included as part of research and development expenses and $0.2 million was included as part of general and administrative expenses in the consolidated statements of comprehensive loss for the year ended December 31, 2011.

14. Subsequent Events

Termination Agreement and Waiver

In November 2012, the Company and certain holders of the Company's convertible preferred stock entered into a termination agreement and waiver pursuant to which the parties agreed, subject to and upon the completion of the Company's IPO, to: (i) waive certain provisions of the Investor Rights Agreement (IRA), including the right to register shares in the offering; (ii) terminate certain provisions of the IRA; (iii) terminate the Company's Amended and Restated Right of First Refusal and Co-Sale Agreement; and (iv) terminate the Company's Amended and Restated Voting Agreement.

Preferred Stock Conversion Rights

In January 2013, the Company's stockholders amended the terms of the automatic conversion of the Company's convertible preferred stock such that all outstanding shares of convertible preferred stock converted into common stock effective immediately prior to the Company's IPO, which was completed in February 2013. The price per share in the IPO had been approved by a majority of the Company's Board of Directors including certain specific directors.

Initial Public Offering

The Company closed an IPO in February 2013, selling 8,750,000 shares of common stock. The IPO price was $8.00 per share. As a result of the IPO, the Company received gross proceeds of approximately $70.0 million, which resulted in net proceeds to the Company of approximately $61.5 million, after underwriting and other expenses of approximately $8.5 million (comprising of $4.9 million in underwriting discounts and commissions and $3.6 million in estimated other offering expenses).

The sale of common stock in the IPO triggered the weighted average anti-dilution provisions set forth in the Company's amended and restated certificate of incorporation. At the IPO price of $8.00 per share, the per share conversion rate for the Company's Series C convertible preferred stock, Series D convertible preferred stock and Series E convertible preferred stock into common stock was approximately 1:1.09, 1:1.14 and 1:1.15, respectively. The conversion rate for the Company's Series A and Series B convertible preferred stock was 1:1. As a result of the offering, the 12,329,330 shares of the Company's convertible preferred stock outstanding automatically converted into 13,210,843 shares of the Company's common stock.

The closing of the Company's IPO triggered the conversion of the Company's warrant exercisable for Series B-2 convertible preferred stock into a warrant for common stock and the related reclassification of the related convertible preferred stock warrant liabilities to additional paid-in capital. The warrant to purchase shares of the Company's Series E Preferred expired upon the closing of the Company's IPO in February 2013.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

KALOBIOS PHARMACEUTICALS, INC.

By: /s/ David W. Pritchard
David W. Pritchard
President, Chief Executive Officer, and Director

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints David W. Pritchard and Jeffrey H. Cooper, and each of them, as his true and lawful attorneys-in-fact and agents, with full power of substitution for him, and in his name in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with 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 and necessary to be done therewith, as fully 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, and any of them, 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, as amended, this report on Form 10-K 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/ DAVID W. PRITCHARD David W. Pritchard	President, Chief Executive Officer and Director *(Principal Executive Officer)*	March 29, 2013
/s/ JEFFREY H. COOPER Jeffrey H. Cooper	Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 29, 2013
/s/ JAMES I. HEALY, M.D., PH.D. James I. Healy, M.D., Ph.D.	Director, Chairman of the Board	March 29, 2013
/s/ DENISE GILBERT, PH.D. Denise Gilbert, Ph.D.	Director	March 29, 2013
/s/ DENNIS HENNER, PH.D. Dennis Henner, Ph.D.	Director	March 29, 2013
/s/ TED W. LOVE, M.D. Ted W. Love, M.D.	Director	March 29, 2013
/s/ GARY LYONS Gary Lyons	Director	March 29, 2013
/s/ BRIGITTE SMITH Brigitte Smith	Director	March 29, 2013
/s/ RAYMOND M. WITHY, PH.D. Raymond M. Withy, Ph.D.	Director	March 29, 2013

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EXHIBIT INDEX

Exhibit	Description
3.2(2)	Amended and Restated Certificate of Incorporation of the Registrant
3.3(2)	Amended and Restated Bylaws of the Registrant
4.1(2)	Specimen of Stock Certificate evidencing shares of Common Stock
4.2(6)	Amended and Restated Investors' Rights Agreement, dated May 2, 2012, by and among the Registrant and the other parties thereto
4.3(1)	Warrant to Purchase Shares of Series B-2 Preferred Stock, dated October 31, 2005
4.4(7)	Warrant to Purchase Stock, dated September 5, 2012
10.1(1)*	2001 Stock Plan
10.2(3)*	Form of Notice of Grant and Stock Option Agreement under the 2001 Plan
10.3(3)*	Form of Notice of Grant and Stock Option Agreement under the 2001 Plan (Outside Directors)
10.4(3)*	Form of Notice of Grant and Stock Option Agreement under the 2001 Plan (Executive Grants)
10.5(3)*	Form of Notice of Grant and Stock Option Agreement under the 2001 Plan (Senior Management)
10.6(3)*	Form of Notice of Exercise under the 2001 Stock Plan (Early Exercise)
10.7(5)*	2012 Equity Incentive Plan, effective upon effectiveness of this Registration Statement
10.8(3)*	Form of Notice of Grant and Stock Option Agreement under the 2012 Equity Incentive Plan
10.9(1)*	2012 Employee Stock Purchase Plan
10.10(3)	Form of Director and Officer Indemnification Agreement
10.11(6)†	Development, Commercialization, Collaboration and License Agreement, dated January 8, 2010, by and between the Registrant and Sanofi Pasteur S.A.
10.12(5)†	Development and License Agreement, dated May 11, 2004, by and between the Registrant and the Ludwig Institute for Cancer Research
10.13(5)†	License Agreement, dated April 7, 2006, by and between the Registrant and the Ludwig Institute for Cancer Research
10.14(5)†	Exclusive License Agreement, dated April 6, 2004, by and between the Registrant and The Regents of the University of California
10.15(6)†	Non-Exclusive License Agreement, dated October 15, 2010, by and between the Registrant, BioWa, Inc. and Lonza Sales AG
10.16(5)†	License Agreement, dated March 16, 2007, by and between the Registrant and Novartis International Pharmaceutical Ltd.
10.17(4)*	Employment Offer Letter, dated August 15, 2006, by and between the Registrant and David Pritchard
10.18(4)*	Employment Offer Letter, dated February 1, 2011, by and between the Registrant and Jonathan Leff
10.19(4)*	Employment Offer Letter, dated January 8, 2004, by and between the Registrant and Geoffrey Yarranton
10.20(4)*	Letter Agreement, dated December 18, 2008, by and between the Registrant and David Pritchard

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Exhibit	Description
10.21(4)*	Letter Agreement, dated April 6, 2011, by and between the Registrant and Jonathan Leff
10.22(4)*	Letter Agreement, dated April 6, 2006, by and between the Registrant and Geoffrey Yarranton
10.23(4)*	Letter Agreement, dated April 20, 2007, by and between the Registrant and Geoffrey Yarranton
10.24(4)*	Letter Agreement, dated December 18, 2008, by and between the Registrant and Geoffrey Yarranton
10.25(4)	Lease, dated January 19, 2011, by and between Britannia Pointe Grand Limited Partnership and the Registrant
10.26(4)	Sublease Agreement, dated January 19, 2011, by and between the Registrant and Alios Biopharma, Inc.
10.27(4)	First Amendment to Sublease, dated August 1, 2011, by and between the Registrant and Alios Biopharma, Inc.
10.28(4)	Second Amendment to Sublease, dated December 13, 2011, by and between the Registrant and Alios Biopharma, Inc.
10.29(4)	Sublease Agreement, dated March 1, 2012, by and between the Registrant and Compugen, Inc.
10.30(5)*	Employment Offer Letter, dated April 23, 2012, by and between the Registrant and Jeffrey H. Cooper
10.31(5)*	Letter Agreement, dated July 5, 2012, by and between the Registrant and Jeffrey H. Cooper
10.32(5)*	Employment Offer Letter, dated April 18, 2012, by and between the Registrant and Néstor A. Molfino
10.33(5)*	Letter Agreement, dated May 29, 2012, by and between the Registrant and Néstor Molfino
10.34(7)	Loan and Security Agreement, by and between the Registrant and MidCap Financial SBIC, LP, dated as of September 5, 2012
10.35(1)†	Supply Agreement, dated October 1, 2010, by and between the Registrant and Sanofi Pasteur S.A., as amended by Amendment No. 1 to the Agreement, dated May 24, 2012
10.36(8)	Termination Agreement and Waiver, dated October 5, 2012 by and among the Registrant and the other parties thereto
23.1	Consent of independent registered public accounting firm
31.1	Certification of Chief Executive Officer of the Registrant, as required by Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer of the Registrant, as required by Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification by the Chief Executive Officer, as required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 36 of Title 18 of the United States Code (18 U.S.C. §1350).
32.2**	Certification by the Chief Financial Officer, as required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 36 of Title 18 of the United States Code (18 U.S.C. §1350).
101.INS***	XBRL Instance Document
101.SCH***	XBRL Taxonomy Extension Schema Document
101.CAL***	XBRL Taxonomy Extension Calculation Linkbase Document

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Exhibit	Description
101.DEF***	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB***	XBRL Taxonomy Extension Label Linkbase Document
101.PRE***	XBRL Taxonomy Extension Presentation Linkbase Document

† Confidential treatment has been granted with respect to certain portions (indicated by asterisks) of this exhibit. Omitted portions have been filed separately with the SEC

* Indicates management contract or compensatory plan

** The certifications attached as Exhibits 32.1 and 32.2 that accompanies this Annual Report on Form 10-K are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Form 10-K, irrespective of any general incorporation language contained in such filing.

*** Pursuant to Rule 406T of Regulation S-T, the Interactive Data Files in Exhibit 101 hereto are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and otherwise are not subject to liability under those sections

(1) Filed as an exhibit to Registrant's Registration Statement on Form S-1 (File No. 333-184299) filed on October 5, 2012

(2) Filed as an exhibit to the Registrant's Registration Statement on Form S-1 (File No. 333-184299) filed on January 15, 2013

(3) Filed as an exhibit to the Registrant's Registration Statement on Form 10-12G (File No. 000-54735) filed on June 12, 2012

(4) Filed as an exhibit to Amendment No. 1 to the Registrant's Registration Statement on Form 10-12G (File No. 000-54735) filed on July 19, 2012

(5) Filed as an exhibit to Amendment No. 2 to the Registrant's Registration Statement on Form 10-12G (File No. 000-54735) filed on August 7, 2012

(6) Filed as an exhibit to Amendment No. 3 to the Registrant's Registration Statement on Form 10-12G (File No. 000-54735) filed on September 12, 2012

(7) Filed as an exhibit to the Registrant's Current Report on Form 8-K filed on September 7, 2012

(8) Filed as an exhibit to the Registrant's Current Report on Form 8-K filed on October 12, 2012

EXHIBIT 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statement (Form S-8 No. 333-183725) pertaining to the 2001 Stock Plan and 2012 Equity Incentive Plan of KaloBios Pharmaceuticals, Inc. of our report dated March 29, 2013, with respect to the consolidated financial statements of KaloBios Pharmaceuticals, Inc. included in this Annual Report (Form 10-K) for the year ended December 31, 2012.

/s/ Ernst & Young LLP

Redwood City, California
March 29, 2013

Exhibit 31.1

CERTIFICATIONS

I, David W. Pritchard, certify that:

1. I have reviewed this Annual Report on Form 10-K of KaloBios Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3 Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) [Omitted pursuant to SEC Release No. 33-8238];

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

March 29, 2013

/s/ David W. Pritchard

David W. Pritchard
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS

I, Jeffrey H. Cooper, certify that:

1. I have reviewed this Annual Report on Form 10-K of KaloBios Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) [Omitted pursuant to SEC Release No. 33-8238];

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

March 29, 2013

/s/ Jeffrey H. Cooper

Jeffrey H. Cooper
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of KaloBios Pharmaceuticals, Inc. (the "Company") on Form 10-K for the period ended December 31, 2012 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, David W. Pritchard, the Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. Information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

March 29, 2013

/s/ David W. Pritchard
David W. Pritchard
President and Chief Executive Officer
(Principal Executive Officer)

A signed original of this written statement required by Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. Section 1350), has been provided to KaloBios Pharmaceuticals, Inc. and will be retained by KaloBios Pharmaceuticals, Inc. and furnished to the Securities and Exchange Commission or its staff upon request. This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of KaloBios Pharmaceuticals, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

Exhibit 32.2

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of KaloBios Pharmaceuticals, Inc. (the "Company") on Form 10-K for the period ended December 31, 2012 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jeffrey H. Cooper, the Senior Vice President, Finance and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. Information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

March 29, 2013

/s/ Jeffrey H. Cooper
Jeffrey H. Cooper
Chief Financial Officer
(Principal Financial Officer)

A signed original of this written statement required by Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. Section 1350), has been provided to KaloBios Pharmaceuticals, Inc. and will be retained by KaloBios Pharmaceuticals, Inc. and furnished to the Securities and Exchange Commission or its staff upon request. This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of KaloBios Pharmaceuticals, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.