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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, 2014

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.)

442 Littlefield 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 ☒

The aggregate market value of voting common equity held by non-affiliates of the registrant was approximately $72 million computed by reference to the sales price of $2.28 as reported by the NASDAQ Global Market on June 30, 2014. The number of shares held by non-affiliates is based on Schedules 13D and 13G filed by certain stockholders for the year ended December 31, 2014 and subsequent reports, if any, filed by certain stockholders pursuant to Section 16 of the Securities Exchange Act of 1934, as amended. This calculation does not reflect a determination that certain persons are affiliates of the registrant for any other purpose. The number of outstanding shares of the registrant's common stock on March 9, 2015 was 32,922,178 shares.

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 201 5, to be filed within 120 days of the registrant's fiscal year ended December 31, 2014.

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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," "might," "will," "objective," "intend," "should," "could," "can," "would," "expect," "believe," "anticipate," "project," "target," "design," "estimate," "predict," "potential," "plan" or the negative of these terms, and similar expressions intended to identify forward-looking statements, and similar expressions and comparable terminology intended to identify forward-looking statements. 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. 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 and ability to obtain 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 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.

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. We qualify all of our forward-looking statements by these cautionary statements.

PART I

ITEM 1. BUSINESS

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 first-in-class, antibodies to treat serious medical conditions. Historically, our clinical focus had included both respiratory diseases and cancer, however as a result of the recent termination of our respiratory programs, our clinical development efforts going forward will be focused solely in oncology, including both hematologic malignancies as well as potentially solid tumors. By focusing on disease-specific targets and patient selection criteria in developing our 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.

With each of our antibody programs, we have developed a new or utilized an existing screen or diagnostic method that we believed may identify those individuals most likely to benefit from our therapies. We believe this 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 more than 400 subjects with no evidence of immunogenicity.

We have advanced three monoclonal antibodies to the clinical development stage. 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:

- KB004, a Humaneered ® anti -EphA3 monoclonal antibody that has the potential to offer a novel approach to treating both hematologic malignancies and solid tumors. In a Phase 1 dose escalation study KB004 was found to be generally safe and well tolerated and is currently being developed as a therapeutic for myelodysplastic syndrome (MDS) and myelofibrosis (MF).

- KB003, a Humaneered ® anti-granulocyte macrophage colony- stimulating factor (anti-GM-CSF) monoclonal antibody that was being developed for the treatment of severe asthma inadequately controlled by corticosteroids. However, based on results of the phase 2 data released in early 2014, we have discontinued development of this antibody in severe asthma. As the study showed KB003 was generally safe and well tolerated, we are currently reviewing the potential of certain orphan oncology indications for KB003 where there is a strong scientific rationale and which fit with our strategic focus on oncology going forward.

- KB001-A, a Humaneered ® , PEGylated, anti-PcrV modified antibody fragment (Fab') antibody that was being developed for the prevention and treatment of *Pseudomonas aeruginosa (Pa)* infections in mechanically ventilated patients and cystic fibrosis (CF) patients with chronic *Pa* lung infections. However, based on results of the phase 2 data released in early 2015, we have discontinued development of this product in all indications and are exploring potentially out-licensing this product as it does not fit with our revised strategic focus on oncology therapeutics.

Our goal is to become a leading biopharmaceutical company focused on the development of first-in-class, monoclonal antibody therapeutics that address serious medical needs in oncology. We seek to identify and develop products that may treat multiple indications through proof-of-concept studies. Key elements of our strategy are to:

- Advance the clinical development of our lead product candidate, KB004 for the treatment of cancer, while evaluating other potential oncology indications for KB003, our anti-GM-CSF monoclonal antibody, going forward; and

- Seek to secure development partnerships with large pharmaceutical and biotechnology companies to develop and commercialize our products for potential indications where the development cost or commercial requirements warrant it, while we retain rights in specialty or orphan indications.

Financial Resources

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. On October 1, 2013, we closed a secondary offering of our common stock, selling 8,625,000 shares of common stock at an offering price of $4.00 per share, resulting in net proceeds of approximately $32.0 million, including the exercise of the overallotment option by the underwriters and after underwriting discounts, commissions and offering expenses.

Since our inception, we have been financing our operations primarily through private placements and our initial and secondary public offerings of our equity securities, interest income earned on cash, cash equivalents, and marketable securities, borrowings from 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, borrowings from lines of credit, or other sources. In order to maintain adequate capital to fund the continued development of our product candidates, management continues to evaluate a number of alternatives, including but not limited to: (i) seeking additional partner(s) for our programs to provide capital for future development and to share in development costs, (ii) undertaking reductions in operating spending, and (iii) evaluating various means to raise additional capital, such as debt or equity offerings. Regardless of any actions we take to address our cash position in the near term, we will also need to raise additional capital in order to further advance our product candidates towards regulatory approval. If management is unsuccessful in these efforts, based on our current levels of operating spending our current capital may not be sufficient in some scenarios to fund our operations for the next twelve months. Our ability to access capital when needed is not assured and, if not achieved on a timely basis, could materially harm our business, financial condition and results of operations. Further, any failure to raise capital could be deemed a material adverse change under our loan and security agreement with MidCap Financial and that may, in turn, result in the lender declaring the loan in default and demanding repayment of the principal, accrued interest, the exit fee and a prepayment fee. These conditions could raise substantial doubt about our ability to continue as a going concern. The Report of Independent Registered Public Accounting Firm at the beginning of the Consolidated Financial Statements section of this Form 10-K includes an explanatory paragraph about the Company’s ability to continue as a going concern.

Our Product Candidates

We have advanced three antibodies to the clinical development stage, as follows:

KaloBios Patient-Targeted Product Candidates

Program	Status	Expected Next Step(s)	Screen
KB004 (Anti-EphA3)			
Hematologic Malignancies	• Phase 1 dose escalation completed • Phase 2 study in progress	Enrollment of Phase 2 study commenced in first quarter of 2014	EphA3 expression
KB003 (Anti-GM-CSF)			
Hematologic Malignancies	• Phase 1 protocol completed	Commencement of Investigator sponsored trial in Chronic Myelomonocytic Leukemia	GM-CSF hyper-sensitivity
Severe Asthma	• Phase 1/2 complete with KB002 • Phase 2 with KB003 completed	Clinical study report completed and filed with US FDA	Airway reversibility
KB001-A (Anti-PcrV of *Pa*)			
Prevention of *Pa* VAP	• Phase 1/2 complete with KB001 • High dose Phase 1 with KB001 -A complete	Evaluating potential to out-license program	*Pa* colonization
CF Patients Infected with *Pa*	• Phase 1/2 complete with KB001 • Phase 2 with KB001 -A completed Q1 2015	Evaluating potential to out-license program	*Pa* infection

Product Development Program: KB004

Overview

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. KB004 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 completed the Phase 1 dose escalation portion of the KB004-01 clinical study in 2014, primarily treating patients with acute myelogenous leukemia (AML) as well as patients with myelodysplastic syndrome (MDS) and myelofibrosis (MF). Based on interim data from that study, earlier in 2014, we commenced dosing in the low-dose cohort of our Phase 2 study in AML patients with EphA3 expression while we completed the Phase 1 dose escalation portion in multiple hematologic malignancies in an effort to determine the dose to be used for the high-dose cohorts in that Phase 2 study. In the second half of 2014, upon completion of the Phase 1 dose escalation portion of the study, we declared the high dose for the Phase 2 cohort expansion portion of the study and proceeded with plans to commence enrollment in the high-dose cohorts. We have also validated an immunohistochemistry assay for the Phase 2 selected indications.

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 attacking specific cancer-related targets 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 of anti-cancer therapeutics 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 acute myelogenous leukemia (AML), chronic myelogenous leukemia (CML), myelodysplastic syndrome (MDS), myeloproliferative neoplasms (MPN), multiple myeloma (MM), myelofibrosis (MF), chronic lymphocytic leukemia (CLL) or acute lymphoblastic leukemia (ALL). EphA3 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. Our data suggests that 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 selectively cells over expressing EphA3. Whenever AML stem cells were detected by flow cytometry, 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, gastric cancer and glioblastoma is a marker of poor prognosis.

To date, our anti-EphA3 antibody 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 dose limiting toxicities (DLTs) in doses up to 100 mg/kg/week.

KB004 Clinical Development Program

In February 2014, we commenced dosing in the low-dose cohort of the Phase 2 expansion portion of a Phase 1/2 trial in which we pre- screen subjects for EphA3 expression and assess the activity of KB004. We were planning on enrolling three cohorts, one low-dose and one high-dose in AML patients, and one high-dose cohort in MDS patients. However, based on the full results of the Phase 1 portion of the study, we have now discontinued the AML cohort. We will be evaluating patient data in real-time in the Phase 2 study and will be prepared to potentially expand any cohort in

the event we see evidence of clinically significant response levels, and are also evaluating adding other potential indications such as multiple myeloma to the Phase 2 study.

During 2014, we completed the Phase 1 dose escalation portion in hematologic malignancies for KB004. The study was designed to be composed of subjects with hematologic malignancies, including subjects with 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 maximum tolerated dose (MTD), and the safety and PK profile for KB004. Doses will be escalated until an MTD is determined, defined as the highest dose reached level with less than 33% of subjects experiencing a dose limiting toxicity (DLT). We declared 250mg as the high-dose to be used for the Phase 2 cohort expansion portion of the study based on commercial dosing practicalities and the pharmacokinetics observed in patients in the Phase 1 portion of the study.

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, and can be resolved with standard treatment. Under the original protocol, three subjects 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. 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 drug related intracranial hemorrhage in clinical studies of KB004, including at doses higher than those tested prior to the amendment.

During 2014, based on interim data from the Phase 1 dose escalation portion of the study, we commenced enrollment in a low-dose cohort of AM patients at a 20mg dose. In addition, in late 2014, upon completion of the Phase 1 portion of the study and the declaration of the high-dose at 250mg, we proceeded with plans to commence enrollment in three high-dose cohorts; one cohort of AML patients, one cohort of MDS patients and one cohort of MF patients. After further evaluation of the patient data from the Phase 1 dose escalation portion of the study, we elected to terminate both the low-dose and the high-dose AML cohorts in the Phase 2 portion of this study, and to proceed only with enrolling the high-dose MDS and MF cohorts going forward. We are currently working to enroll the remaining cohorts as quickly as possible, and are also evaluating the potential of adding additional cohorts to the study, in indications such as multiple myeloma.

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

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, autoimmune and other 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 scientific literature, excessive GM- CSF may be involved in tissue damage associated with inflammatory diseases including asthma and Rheumatoid Arthritis (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 focused on treating severe asthma with a monthly, subcutaneous formulation of KB003, and in light of our most recent Phase 2 data, are evaluating whether to pursue other indications in the future. In our Phase 2 study which concuded in early 2014, severe asthma subjects were prescreened based on lung function according to a “reversibility” criterion defined as having a ≥12% improvement in FEV1 from baseline after administration of a beta agonist, as this patient segment showed a positive trend in responding to our precursor KB002 antibody in our Phase 1/2 clinical study.

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 any future clinical studies in this program. Data from our single-dose, Phase 1 and Phase 1/2 clinical trials with monoclonal antibody KB002, the chimeric predecessor to the Humaneered® KB003, supported 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. With FDA approval, we conducted a 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 RA market and chose to redirect our study of KB003 to severe asthma patients 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 which was completed in early 2014. Results from that trial showed that the primary endpoint was not met, although a significant effect was shown in certain pre-specified subgroups. No trend toward significance was shown in the secondary endpoint. As a result of these data, in early 2014 we announced that we have terminated further independent development of KB003 in asthma and are evaluating whether to pursue development in other indications.

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).

Table 3 summarizes the 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 ½	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	160	Severe asthma inadequately controlled by inhaled corticosteroids	Randomized, double-blind, placebo-controlled, monthly dose, intravenous	• Generally safe and well tolerated • Did not meet primary endpoint • Program discontinued for severe asthma

Based on these 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 enrolled 160 subjects randomized equally between KB003 and placebo. Eligible subjects were screened for a history of asthma inadequately controlled by high-dose inhaled corticosteroids, FEV1 function, and Asthma Control Questionnaire (ACQ) scores. Subjects were also pre-screened for reversibility, a demonstrated FEV1 bronchodilator response of more than 12% from baseline. Subjects received intravenous fixed doses of KB003 or placebo at multiple time points through week 20. The primary endpoint was change in FEV1 through week 24. Secondary endpoints included exacerbation, effect on asthma control, asthma symptoms, use of rescue therapies, and safety. We completed enrollment in this trial in the third quarter of 2013 and reported top-line data in January 2014. While we did see FEV1 improvement in certain pre-defined subgroups, the study did not meet the primary endpoint of overall improvement in FEV1, nor did it demonstrate statistically significant reductions in exacerbations or improvement in ACQ scores. As a result, we have discontinued development of KB003 in severe asthma. However, as the study did show KB003 was generally safe and well tolerated, we are currently evaluating other potential indications for KB003 that are consistent with our strategic focus in oncology and where there may be a strong scientific rationale for an anti- GM-CSF mechanism of action. As a result of that evaluation, and the refinement of our strategic focus in early 2015 to oncology therapeutics, we are planning to explore KB003 as a therapeutic in certain niche oncology indications such as CMML.

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

Product Development Program: KB001-A

Overview

KB001-A, is a Humaneered®, recombinant, PEGylated, anti-Pseudomonas PcrV high- affinity Fab’ antibody that was being developed for the prevention and treatment of infections by *Pa*, a gram negative bacteria that can cause 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 was 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 was being targeted for the treatment of both hospitalized patients on mechanical ventilation susceptible to *Pa* (>48 hours on mechanical ventilation) to prevent *Pa* ventilator-associated pneumonia (VAP), and CF patients infected with *Pa.* Identification of the pathogen to determine patient eligibility was conducted using standard laboratory culture tests or another diagnostic method. KB001-A was being developed as a single intravenous dose of KB001-A to prevent *Pa* VAP, as well as for CF patients infected with *Pa* as a chronic intravenous dose.

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 with the exception that we 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. Under this agreement, Sanofi was 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* aside from CF or bronchiectasis. Subject to the terms of the agreement, Sanofi had an option to obtain rights to participate in the development and promotion of licensed products for the CF or bronchiectasis indications, 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 was 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 conducted a Phase 1 clinical study in healthy volunteers to evaluate higher doses than those that we previously tested.

In July 2014, the Company and Sanofi executed an agreement (the Termination Agreement) under which the Sanofi agreement was terminated. As a result of the Termination Agreement, KaloBios regained full global rights to license, develop, manufacture and commercialize KB001-A in all indications, as well as a non-exclusive license to the

KB001-A manufacturing process developed by Sanofi. In consideration for entering into the Termination Agreement, Sanofi will be entitled to royalties on net sales of KB001-A if approved, subject to a $40 million cap on the aggregate royalties to be paid. In addition, Sanofi will be entitled to receive up to 10% of certain sub-license payments or other milestone payments received in the event KaloBios successfully re-partners KB001-A, subject to a separate $40 million cap on the aggregate amount of sub-license payments to be shared with Sanofi.

In January 2013, we launched a 180 patient, 16-week, randomized, placebo- controlled, repeat-dose, Phase 2 clinical trial for the treatment of *Pa* infections in CF patients, to investigate the efficacy and safety of intravenously administered KB001-A. The primary endpoint was 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 planned to use this trial to support pivotal trials of KB001-A.

In January 2015, we announced preliminary top-line data from this 182 patient Phase 2 study of KB001-A in CF patients with Pa lung infections. The study failed to meet its primary endpoint as there was no notable improvement in the time to need antibiotics between patients treated with KB001-A and those treated with placebo. In addition, there was no clinically significant improvement in patient reported outcomes or in FEV1 over the course of the study, both of which were secondary endpoints in the study. As a result of this outcome, we have discontinued development of KB001-A as a treatment for Pa lung infections in CF patients and are evaluating the potential to out-license KB001-A as it no longer aligns with our revised strategic focus in oncology therapeutics.

Chronic Pa Infections in CF Patients

CF, the most common genetic disease in Caucasian populations, is characterized by an accumulation of mucus with abnormally high viscosity, 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. In2013, the FDA and the EMA granted 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 KB001-A molecule has been optimized as a Fab' antibody (fragment) 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 covalently attached to the Fab' fragment to generate the KB001-A molecule, which is a process called PEGylation.

We believe the possibility of developing resistance to KB001-A in a pathogenic strain of *Pa* is low because, unlike current antibiotics, 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.

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 1	26	Healthy volunteers	Placebo-controlled, double-blind, single-dose, dose escalation, intravenous at doses exceeding those evaluated in KB001 healthy volunteer study	• Safe and well tolerated, with no serious or severe treatment-emergent adverse events • There were no safety signals identified based on clinical laboratory parameters, vital sign, or ECG
Phase 2	182	CF patients infected with *Pa*	Randomized, double-blind, placebo-controlled, repeat dose, intravenous	• Generally safe and well tolerated • Did not meet primary endpoint • Program discontinued

We were 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. Any future clinical and preclinical studies for this program would 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.

Sanofi continued 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.

In July 2014, the Company and Sanofi executed an agreement (the Termination Agreement) under which the Sanofi agreement was terminated. As a result of the Termination Agreement, KaloBios regained full global rights to license, develop, manufacture and commercialize KB001-A in all indications, as well as a non-exclusive license to the

KB001-A manufacturing process developed by Sanofi. At this time, we do not have any plans for further development of KB001-A in Pa VAP or in any other indication, and are evaluating the potential to out-license this program.

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.

Based on the results observed in the Phase 1 study, we were developing KB001-A as a treatment to reduce lung inflammation in CF patients with chronic *Pa* infection. Although elastase is a marker of neutrophilic inflammation, it is unknown if its reduction will result in a meaningful near-term clinical benefits to patients. We therefore began enrollment of 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 and completed enrollment in July 2014. The primary endpoint was 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 received 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 was conducted primarily in North America, in conjunction with the Cystic Fibrosis Foundation Therapeutic Development Network.

In January 2015, we announced preliminary top-line data from the 182 patient Phase 2 study of KB001-A in CF patients with Pa lung infections. The study failed to meet its primary endpoint as there was no notable improvement in the time to need antibiotics between patients treated with KB001-A and those treated with placebo. In addition, there was no clinically significant improvement in patient reported outcomes or in FEV1 over the course of the study, both of which were secondary endpoints in the study. As a result of this outcome, we have discontinued development of KB001-A as a treatment for Pa lung infections in CF patients and are evaluating the potential to out-license KB001-A as it no longer aligns with our revised strategic focus in oncology therapeutics.

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 250 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. We are not actively pursuing third party licensing of our proprietary Humaneered® technology at this time.

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

For indications where the development costs or commercial requirements warrant it, 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, the Company and Sanofi entered into an agreement for the development and commercialization of KB001, the precursor to 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. Sanofi was 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 retained responsibility, at the Company’s cost, for developing and promoting the products for the diagnosis, treatment and/or prevention of Pa in patients with cystic fibrosis (CF) or bronchiectasis. Under the terms of the Sanofi agreement, the Company received specified research and development funding for services performed in connection with KB-001-A

research and development efforts and could have also received contingent payments based on the occurrence of development, regulatory or commercial events, and royalties on any product sales.

In July 2014, the Company and Sanofi executed an agreement (the Termination Agreement) under which the Sanofi agreement was terminated. As a result of the Termination Agreement, KaloBios regains full global rights to license, develop, manufacture and commercialize KB001-A in all indications, as well as a non-exclusive license to the KB001-A manufacturing process developed by Sanofi. In consideration for entering into the Termination Agreement, Sanofi will be entitled to royalties on net sales of KB001-A if approved, subject to a $40 million cap on the aggregate royalties to be paid. In addition, Sanofi will be entitled to receive up to 10% of certain sub-license payments or other milestone payments received in the event KaloBios successfully re-partners KB001-A, subject to a separate $40 million cap on the aggregate amount of sub-license payments to be shared with Sanofi.

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 in the United States.

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*. 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, 2014 amounted to $1.3 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. 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, 2014 amounted to $1.3 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, 2014 amounted to $549,000. 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 12 issued U.S. patents, with another issued U.S. patent owned jointly with a third party. We have an exclusive license to seven U.S. patents and we own 37 issued foreign patents, four of which are owned jointly with a third party. We have 69 patent applications pending globally, including 12 non-provisional patent applications in the United States, which include one that is solely owned by us and two 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 we developed and own an issued U.S. composition of matter patent covering KB004 and related Humaneered® anti-EphA3 antibodies which is 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.

Competition in cancer drug development is intense, with hundreds of compounds in clinical trials by large pharmaceutical and biotechnology companies. Many of these companies are focused on targeted therapies, with many of those in hematology/oncology indications. 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.

We have an agreement with a contract manufacturer for the manufacture of drug substance and drug product of KB003 for our early clinical trials. As a result of the outcome of our phase 2 trial of KB003 in severe asthma patients, and our discontinuation of development of KB003 for severe asthma, we are re-evaluating this agreement and may seek to negotiate changes to or reductions in the committed activities under this agreement depending on potential future development plans for KB003 in other indications.

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.

Sanofi was responsible for the manufacture of KB001-A drug substance for our development and promotion activities in our retained indications and had sub-contracted with a contract manufacturer for the production of drug substance for Sanofi's Phase 1 trial and our Phase 2 trial. During 2014, we entered into a direct agreement with that contract manufacturer for further production and supply. As a result of discontinuing further development of KB001-A, we have halted any further production under that agreement.

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 $2 million, and the manufacturer and/or sponsor under an approved BLA are also subject to annual product and establishment user fees, currently exceeding $100 thousand per product and $500 thousand 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.

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. 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.

A reference biologic is currently 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.

Companion Diagnostics

The FDA regulates the sale or distribution, in interstate commerce, of medical devices, including in vitro diagnostics (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 approvalsimultaneously with approval of the biologic. See Item 1A, "Risk Factors," for further discussion of risks regarding companion diagnostics.

Orphan Drugs

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. In October, 2013, KB001-A received Orphan Drug designation from 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, manufacture 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.

Employees

As of December 31, 2014, we had 35 employees, 32 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.

About KaloBios

We were incorporated on March 15, 2000 in California and reincorporated as a Delaware corporation in September 2001. Our principal offices are located at 442 Littlefield 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."

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 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, 2014, we had $40.7 million in cash, cash equivalents, and investments. We utilized $35.9 million of cash in operating activities during the year ended December 31, 2014.

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 and 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 approval for marketing, 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, primarily to advance our lead program, KB004, in clinical trials. The amount of capital we will require and the timing of our need for additional capital will depend on many other 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, or delays in, our clinical trials;
- the timing of and costs involved in obtaining regulatory approvals;
- our ability to establish and maintain development partnering arrangements and any associated funding;
- the timing, receipt and amount of contingent, royalty, and other payments from any future development partners;
- the emergence of competing products or 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 sourcing, timing, scope, progress, expansion, and costs of manufacturing our product candidates;
- the timing of repayment of current loans, and our ability to draw funds from any future 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 and our initial and secondary public offerings of our equity securities, interest income earned on cash, cash equivalents, and marketable securities, borrowings from 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, borrowings from lines of credit, or other sources. In order to maintain adequate capital to fund the continued development of our product candidates, management continues to evaluate a number of alternatives, including but not limited to: (i) seeking additional partner(s) for our programs to provide capital for future development and to share in development costs, (ii) undertaking reductions in operating spending, and (iii) evaluating various means to raise additional capital, such as debt or equity offerings. Regardless of any actions we take to address our cash position in the near term, we will also need to raise additional capital in order to further advance our product candidates towards regulatory approval. If management is unsuccessful in these efforts, based on our current levels of operating spending our current capital may not be sufficient in some scenarios to fund our operations for the next twelve months. Our ability to access capital when needed is not assured and, if not achieved on a timely basis, could materially harm our business, financial condition and results of operations. Further, any failure to raise capital could be deemed a material adverse change under our loan and security agreement with MidCap Financial and that may, in turn, result in the lender declaring the loan in default and demanding repayment of the principal, accrued interest, the exit fee and a prepayment fee. These conditions could raise substantial doubt about our ability to continue as a going concern. The Report of Independent Registered Public Accounting Firm at the beginning of the Consolidated Financial Statements section of this Form 10-K includes an explanatory paragraph about the Company's ability to continue as a going concern.

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 commercialization of our product candidates. Additional funding may not be available to us on a timely basis or at acceptable terms, if 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 on less than favorable terms, if at all.

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

As of December 31, 2014, we had an accumulated deficit of $178.2 million, and for the year ended December 31, 2014, we incurred a net loss of $38.0 million. We have incurred net losses each year since our inception except for the year ended December 31, 2007. 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 continue our development and clinical trial efforts. Our ability to achieve and sustain profitability depends on obtaining regulatory approvals for and successfully commercializing our 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 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.

Our product candidates are at an early stage of development and may not be successfully developed or commercialized. We have had to discontinue the development of prior product candidates.

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 one product candidate in Phase 2 clinical trials, KB004, and we have recently discontinued development of KB001-A in CF patients with Pa lung infections and KB003 in severe asthma. None of our product candidates have advanced into a pivotal study and it may be years before such a 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 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.

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

We have recently announced our mutual agreement with Sanofi to terminate our prior development partnership for KB001-A. In addition to our prior partnership with Sanofi, a part of our strategy is to enter into 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. Although our decision with Sanofi was mutual, we cannot predict the impact of that decision on the likelihood of our ability to enter into future partnerships for KB001-A or for our other programs. 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, among other reasons, 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 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.

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, and in May 2014, we drew down the final $5.0 million available 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. A material adverse change means a material impairment in the perfection or priority of the lender's lien in the collateral or in the value of the collateral; a material adverse change in the business, operations, or condition (financial or otherwise) of the Company, taken as a whole; or a material impairment of the prospect of repayment of any portion of the obligations. 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.

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 market acceptance and favorable reimbursement status 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.

We have and may continue to experience delays in commencing or conducting our clinical trials, in receiving data from third parties or in the continuation or 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 any new product candidates, we are required to submit the results of preclinical testing to the FDA as part of an Investigational New Drug (IND) application, along with other information including information about product candidate chemistry, manufacturing, and controls and our proposed clinical trial protocol. In doing so, we rely in part on preclinical, clinical, and quality data previously generated by other third parties for regulatory submissions. In addition, for our programs already underway, we are required to report or provide information to appropriate regulatory authorities in order to continue with our testing programs. If we are unable to make timely regulatory submissions for any of our programs, it will delay our plans for our clinical trials. If those third parties do not make the required data available to us, we will likely have to identify and contract with another CMO, and/or 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. Moreover, 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 enrolling qualified subjects to participate in a clinical trial;
- 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 and maintaining sufficient quantities of a product candidate for use in clinical trials, either as a result of transferring the manufacturing of a product candidate to another site or manufacturer, deferring ordering or production of product in order to conserve resources or mitigate risk, having product in inventory become no longer suitable for use in humans, or other reasons that reduce or delay availability of drug supply;
- obtaining and maintaining institutional review board (IRB) or ethics committee approval to conduct a clinical trial at an existing or prospective site;
- 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; readiness of any companion diagnostic necessary to ensure that the study enrolls the target population; or
- undergoing a clinical trial put on clinical hold at any time by the FDA during product candidate development.

Once a clinical trial has begun, recruitment and enrollment of subjects may be slower than we anticipate. Numerous companies and institutions are conducting clinical studies in similar patient populations which can result in competition for qualified patients. 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 Institutional Review Board (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;
- inability to provide timely supply of drug product;
- 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, if any of our future development partners do not develop the licensed product candidates in the time and manner that we expect, or at all, the clinical development efforts related to these licensed product candidates could be delayed or terminated. In addition, our ability to enforce our partners' obligations under any future collaboration efforts may be limited due to time and resource constraints, competing corporate priorities of our future partners, and other factors.

Any delays in the commencement of our clinical trials may delay or preclude our ability to further develop or 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 or any of our future development partners experience delays in the completion of, or if we 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.

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, approval, 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 or any of our future development partners' clinical trials;
- we 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 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 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 or any of our future development partners' clinical data insufficient for approval.

With respect to foreign markets, approval procedures vary widely 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 caution 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, 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 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 substantial inherent risk. We 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.

For example, we recently announced the termination of development in *Pa* lung infections in CF patients of KB001-A, our most advanced product candidate, because the Phase 2 study we were conducting did not meet its primary or secondary endpoints, despite promising results in prior studies of a precursor molecule, KB001. In early 2014, we announced termination of development in severe asthma of KB003, also based on negative Phase 2 results despite earlier positive data from studies of KB002, a precursor molecule.

Furthermore, our Phase 2 expansion trial for KB004, currently enrolling and underway, may not be successful.

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 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 expertise of the members of our senior management. We recently announced the retirement of David W. Pritchard, our president and chief executive officer, and in a subsequent reduction in force we announced the elimination of our chief medical officer position. We cannot predict the impact of the loss of such individuals or the loss of services of any of our other senior management, should they occur. Such losses 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 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 recent events, intense competition among biotechnology and pharmaceutical companies, universities, and research organizations for qualified personnel. We have initiated a search for permanent chief executive officer and at this time do not plan to replace the CMO position, although we are actively recruiting for additional senior staff with oncology expertise in light of our dedication to oncology. 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 any 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.

We are currently conducting a search for a permanent chief executive officer. There can be no assurance that we can identify and hire such a candidate on a timely basis, or at all. Even if we are successful in locating a permanent chief executive officer, that person will not have worked with our senior executive team. Our future performance will depend, in part, on our ability to successfully integrate any newly hired chief executive officer into our management team and our ability to develop an effective working relationship among senior management. Our failure to integrate this individual and create effective working relationships among the 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.

Any product candidate we 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 have not yet successfully 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 may not be able to obtain regulatory approval or commercialize such product candidate.

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

We are in the initial phases of developing an in vitro EphA3 diagnostic, currently in the CLIA validated laboratory format, which is intended to identify patients who are likely to benefit from KB004. We have amended our study protocol prior to initiation of the Phase 2 expansion phase to include EphA3 positive tumor status as an inclusion criterion.

The FDA regulates companion 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 a 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 product until it is ready to approve or clear the in vitro companion diagnostic device. It is possible 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 any in vitro companion diagnostics.

Because our companion diagnostic candidate is at an early stage of development, and because we have not yet decided whether to pursue a reference lab-based test or a kit, we have yet to seek a meeting with the FDA to discuss our companion diagnostic test in development. We therefore do not 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 delay or 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.

Competition in cancer drug development including hematology/oncology 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. In addition, the development program that we undertake may change from time to time due to clinical or non-clinical results, competitive developments, regulatory changes, recruitment, resource or other constraints in running clinical studies and other factors.

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

We are, and will for the foreseeable future continue to be, wholly dependent on third party contract manufacturers for the timely supply of adequate quantities of our products which meet or exceed requisite quality and production standards for use in clinical and nonclinical studies. Given the extensive risks, scope, complexity, cost, regulatory requirements and commitment of resources associated with developing the capabilities to manufacture one or more of our products, we have no present plan or intention of developing in-house manufacturing capabilities for nonclinical, clinical or commercial scale production, beyond our current supervision and management of our third party contract manufacturers. In addition, in order to balance risk and conserve financial and human resources, we have and may continue from time to time to defer commitment to production of product, which could result in delays to the continued progress of our clinical and nonclinical testing.

In addition to the foregoing, the process of manufacturing our products is complex, highly regulated and subject to several risks, including but not limited to the following:

- The process of manufacturing biologics 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, plant closures, capacity constraints, competing customer priorities or changes in corporate strategy or priorities, process changes or failures, changes in business models or operations, materials or labor shortages, natural disasters, power failures and numerous other factors.

- We are wholly dependent upon third party CMOs for the timely supply of adequate quantities of requisite quality product for our nonclinical, clinical and, if approved by regulatory authorities, commercial scale production.

- 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.

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 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 payers, if applicable.

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 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 or with restrictions, 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 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.

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 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. 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. Our recent history may result in an increase in premium costs or otherwise affect the terms of coverage available to us. 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.

As with any business, 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, non-public 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, 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.

We and our future development partners, 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 future development partners, 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 future 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 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 and any of our future development partners are successful in commercializing our products, the FDA and foreign regulatory authorities would require that we 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 and any of our future development partners may fail to report adverse events we become aware of within the prescribed timeframe. We 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 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 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 dissimilar 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. Finally, there is a risk that the 12-year exclusivity period could be reduced which could negatively affect our products.

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 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. Therefore, the timing of the initiation and completion of these trials is uncertain and may occur on substantially different timing from our estimates. We also use clinical research organizations (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. We are continually evaluating potential alternate sources of supply but there can be no assurance that any such suppliers would be available, acceptable or successful. 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.

Having recently terminated our development partnership with Sanofi, we will not continue development or commercialization of KB001-A without a future development partner. Our development and/or commercialization of KB004, KB003 and any other future products may also depend in whole or in part on a future development partner. Our inability to successfully identify and enter into a development partnership, or the failure of any new partner to develop and/or commercialize one or more of our products, could result in a material adverse effect on our business and operating results.

In 2014, we announced the mutual termination of our exclusive license to Sanofi of KB001, KB001-A and other antibodies directed against the PcrV protein of *Pa* for all indications for most aspects of their development and commercialization. Before that termination, we were dependent on Sanofi to carry out its contractual obligations, and did not have significant control over their efforts or the outcome of those efforts. Now that our development partnership with Sanofi on KB001-A or other antibodies has terminated, we will not continue further development of KB001-A unless we enter into a new partnership(s) for that further development of KB001-A. We also intend to explore development and/or commercial partnerships for KB004 and any other of our future products. Any new partnership for one or more of our products, assuming we are able to successfully identify and enter into such a transaction(s), may not be scientifically, medically, technically or commercially successful due to a number of important factors, including the following:

- Regardless of the standard of effort required under any new partnership agreement, any new partner will likely have significant discretion in determining the efforts and resources that it will apply to the development and commercialization of our product;

- The timing and amount of any contingent, royalty or other payments we may receive under any new agreement have yet to be determined and will depend on, among other things, the efforts, allocation of resources, and successful development and commercialization of our product candidate by the new partner under any such agreement;

- A new partner, if any, may change the focus of its development and commercialization efforts or pursue higher- priority programs;
- A new partner, if any, may not make timely regulatory submissions;
- The terms of any new partnership agreement have yet to be identified, and may not be optimal for us in any number of respects, including but not limited to the amount, timing and contingencies associated with any payments or funding to us; the degree of control or influence we may have over any partners' efforts; the indications, territories, responsibilities, rights, obligations and recourse available to us under any partnership agreement; and the other economic and non-economic terms of any partnership agreement;
- If a new partner negotiates for clinical supply manufacturing rights, such partner may fail to manufacture or supply sufficient drug substance of our product for our clinical use, which could result in program delays;
- If a new partner negotiates for commercial supply manufacturing rights, such partner may fail to manufacture or supply sufficient drug substance of our product for our commercial use, if approved, which could result in delays and lost revenue;
- Any new partner 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;
- Any new partner may not comply with all applicable regulatory requirements or may fail to report safety data in accordance with all applicable regulatory requirements;
- If a new partner were to breach or terminate any agreement with us, the development and commercialization of our product could be delayed. We would need to either use our own resources and capabilities to continue the development and commercialization of our product or grant rights to another development or commercial partner, which may not be available on reasonable terms, or at all;
- If any new partner were to terminate any future partnership arrangements with us, our potential revenue under such an agreement, including from potential development and commercial contingent payments and royalties on net sales of licensed products, would be significantly reduced or eliminated; and
- Any new partner 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 to market our product.

Our or any new partner's failure to develop, manufacture or effectively commercialize our product would result in a material adverse effect on our business and results of operations and would likely cause our stock price to decline.

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. In addition, we may not have adequate resources to devote to the substantial costs of enforcing intellectual property rights in affected jurisdictions. Any 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 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, with or without oppositions being filed by competitors or other third parties;

- 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 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 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 UCSF and 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, 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 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 payments, 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 we intend to seek patent protection only in selected countries. 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. For example, on September 3, 2013 we entered into an At-the-Market Issuance Sales Agreement with MLV & Co. LLC (MLV) under which, subject to certain conditions, we may offer and sell shares of our common stock having an aggregate offering price of up to $50,000,000 from time to time through MLV, acting as agent.

On October 1, 2013, we completed a secondary offering of common stock which resulted in dilution of our existing shareholders. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance could result in further dilution to our stockholders.

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 grant potentially valuable rights to our product candidates or grant licenses on terms that are not favorable to us.

Our independent registered public accounting firm has included an explanatory paragraph relating to our ability to continue as a going concern in its report on our audited financial statements.

Our independent registered public accounting firm included an explanatory paragraph in its report on our financial statements for the year ended December 31, 2014 stating that our recurring net losses at December 31, 2014 raise substantial doubt about our ability to continue as a going concern. If we are unable to obtain sufficient funding, our business, prospects, financial condition and results of operations will be materially and adversely affected and we may be unable to continue as a going concern. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our financial statements, and it is likely that investors will lose all or a part of their investment. We may also be forced to make reductions in spending, including delaying or curtailing our ongoing or future clinical programs. Future reports from our independent registered public accounting firm may also contain statements expressing doubt about our ability to continue as a going concern. If we seek additional financing to fund our business activities in the future and there remains doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding on commercially reasonable terms or at all.

We previously identified and have remediated a material weakness in our internal control over financial reporting. Any failure to maintain effective internal control over financial reporting could result in our failure to meet our reporting obligations and cause investors to lose confidence in our reported financial information, which in turn could cause the trading price of our common stock to decline.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 and related rules, our management was 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, 2014. When and if we are no longer an ‘‘emerging growth company,’’ 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.

Although we have determined that our internal control over financial reporting was effective as of December 31, 2014, as indicated in our Management Report on Internal Control over Financial Reporting, included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2014, we must continue to monitor and assess our internal control over financial reporting. If our management identifies one or more material weaknesses in our internal control over financial reporting in the future and such weakness remains uncorrected at fiscal year-end, we will be unable to assert such internal control is effective at fiscal year-end. If we are unable to assert that our internal control over financial reporting is effective at fiscal year-end (or if our independent registered public accounting firm concludes that we have a material weakness in our internal controls or, after we are no longer an emerging growth company, is unable to express an opinion on the effectiveness of our internal controls), we could lose investor confidence in the accuracy and completeness of our financial reports, which would likely have an adverse effect on our business and stock price.

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 9, 2015, our stock had high and low sales prices in the range of $8.25 to $0.36 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 and the resulting impact on ongoing product development;
- announcements regarding equity or debt financing transactions;
- sales or potential sales of substantial amounts of our common stock;
- 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;
- any 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; 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.

In a particular case, following the announcement of our failed Phase 2 study of KB001-A, on February 23, 2015, we received a notice of possible delisting from the NASDAQ Stock Exchange, as our stock declined below $1.00 per share for over thirty (30) business days as required by NASDAQ regulations. We are evaluating possible measures to return our share price to above $1.00 so that our listing would not be affected, and generally we have a period of 180 days from the date of the notice to do so. There can be no assurance that we will be successful in doing so. Any de-listing of our shares could affect the liquidity of our stock, even if we retain a public company listing through other channels.

An active trading market for our common stock may not develop or be sustained or may be volatile.

Our initial public offering was completed in February 2013, and we subsequently completed a secondary public offering of additional common shares later in 2013. Nevertheless, we continue to have a limited number of shares publicly available for purchase. An active trading market may not develop 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. In addition, the public market for our shares may be extremely volatile in light of the results of our operations, our limited resources, the number of products we may have in development at any given time, and numerous other factors.

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 December 31, 2014, we had 32,992,178 shares of common stock outstanding. On July 31, 2013, 14,697,573 shares that were previously subject to contractual lock-up agreements entered into by certain of our stockholders with the underwriters in connection with our initial public offering became freely tradable, except for shares of common stock held by directors, executive officers and our other affiliates, which are subject to volume limitations under Rule 144 of the Securities Act of 1933, as amended. As of December 25, 2013, approximately 5,409,636 shares that were previously subject to contractual lock-up agreements entered into by certain of our stockholders with the underwriters in connection with our follow-on public offering became freely tradable, except for shares of common stock held by directors, executive officers and our other affiliates, which are subject to volume and other limitations under Rule 144 under the Securities Act.

Certain holders or our common stock have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for our stockholders or ourselves. These shares will be able to be sold freely in the public market upon issuance.

We have also registered 4,325,912 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 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, as recently occurred with respect to KB001-A and KB003 and their respective Phase 2 study results, 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 39% of our common stock as of December 31, 2014. 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 public company, our stock price has been 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 sometimes 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 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.

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 leased a 40,000 square-foot building consisting of office and laboratory space in South San Francisco, California, which served as our corporate headquarters. We also subleased approximately 20,000 square feet of our leased space to third parties. The lease commenced in July 2011 and expired in June 2014. We did not renew this lease upon its termination in June 2014.

In December 2013, we entered into a new lease for a 24,351 square-foot building consisting of office and laboratory space at 442 Littlefield Avenue, South San Francisco, California, which is serving as our new corporate headquarters. The new lease commenced in July 2014 and will expire in 2019. The lease agreement provides that we have the option to terminate the lease after 36 months, subject to additional fees and expenses. And at the end of the five year term of the new lease, we have the option to extend its term for an additional five years at the then current fair market value rental rate determined in accordance with the terms of the Lease.

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 trading on The NASDAQ Global Market under the symbol "KBIO" since it began trading on January 31, 2013. Prior to this date, there was no public market for our common stock. The following table sets forth the high and low intraday sale prices per share of our common stock for the periods indicated as reported by The NASDAQ Global Market.

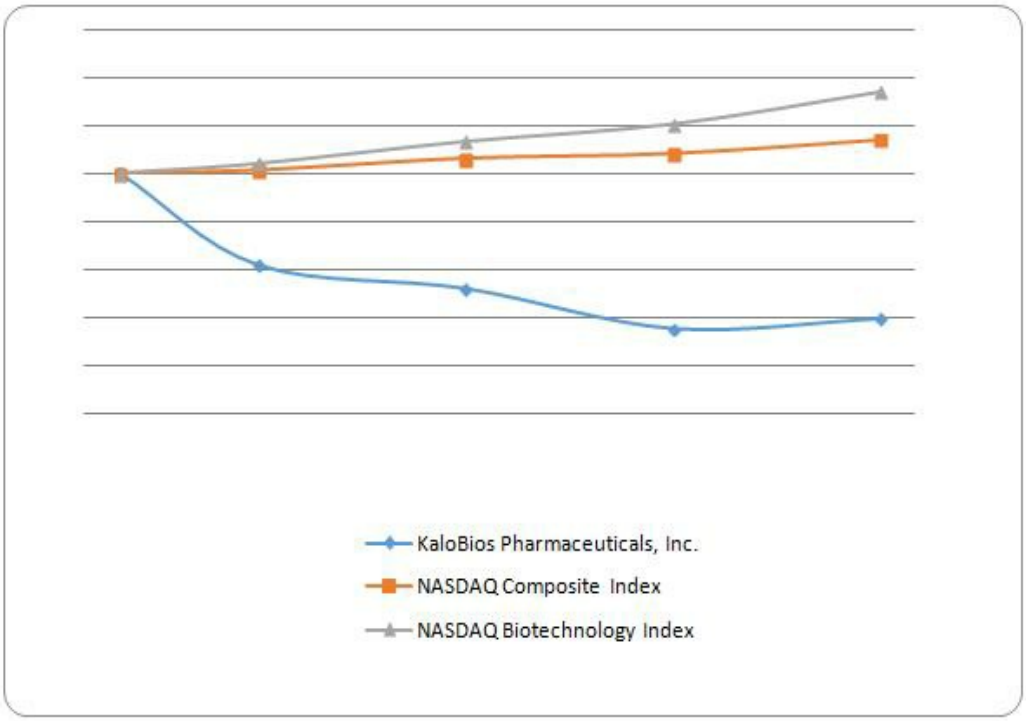
	High	Low
2014		
4th Quarter	$ 2.15	$ 1.49
3rd Quarter	$ 2.40	$ 1.36
2nd Quarter	$ 2.80	$ 1.66
1st Quarter	$ 5.61	$ 2.56

HOLDERS OF COMMON STOCK

As of March 9, 2015, we had 32,992,178 shares of common stock outstanding held by approximately 35 stockholders of record. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

STOCK PERFORMANCE GRAPH

The following graph illustrates a comparison of the total cumulative stockholder return on our common stock since January 31, 2013, which is the date our common stock first began trading on the NASDAQ Global Market, to two indices: the NASDAQ Composite Index and the NASDAQ Biotechnology Index. The stockholder return shown in the graph below is not necessarily indicative of future performance, and we do not make or endorse any predictions as to future stockholder returns. This graph shall not be deemed "soliciting material" or be deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities under that Section, and shall not be deemed to be incorporated by reference into any of our filings under the Securities Act, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.



$100 investment in stock or index	Ticker	January 1, 2014	March 31, 2014	June 30, 2014	September 30, 2014	December 31, 2014
KaloBios Pharmaceuticals, Inc.	KBIO	$ 100	$ 62	$ 52	$ 35	$ 39
NASDAQ Composite Index	IXIC	$ 100	$ 101	$ 106	$ 108	$ 114
NASDAQ Biotechnology Index	NBI	$ 100	$ 104	$ 113	$ 120	$ 134

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, SBIC, LP (MidCap Financial) contains covenants that restrict our ability to pay dividends.

PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS

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 2014, 2013 and 2012 and the balance sheet data as of December 31, 2014 and 2013 were derived from our audited financial statements included elsewhere in this Annual Report on Form 10-K. The statements of operations data for 2011 and 2010 and the balance sheet data as of December 31, 2012, 2011 and 2010 were derived from our audited financial statements not included in this Annual Report on Form 10-K.

	Years Ended December 31,				
	2014	2013	2012	2011	2010
	(in thousands, except share and per share information)				
Consolidated Statements of Operations Data					
Contract revenue	$ —	$ 44	$ 6,098	$ 20,255	$ 17,712
Operating expenses:					
Research and development	26,573	32,640	24,519	18,512	18,893
General and administrative	10,145	8,313	5,061	4,010	4,942
Total operating expenses	36,718	40,953	29,580	22,522	23,835
Loss from operations	(36,718)	(40,909)	(23,482)	(2,267)	(6,123)
Other (expense) income:					
Interest income	88	86	44	43	108
Interest (expense)	(1,214)	(1,086)	(184)	—	—
Other (expense) income, net	(154)	(39)	113	(8)	915
Loss before income taxes	(37,998)	(41,948)	(23,509)	(2,232)	(5,100)
Benefit for income taxes	—	—	—	—	—
Net loss	$ (37,998)	$ (41,948)	$ (23,509)	$ (2,232)	$ (5,100)
Other comprehensive (loss) income:					
Net unrealized (loss) gain on marketable securities	(11)	(1)	5	2	(13)
Comprehensive loss	(38,009)	(41,949)	(23,504)	(2,230)	(5,113)
Basic and diluted net loss per common share	$ (1.15)	$ (1.73)	$ (11.22)	$ (1.15)	$ (3.02)
Weighted average common shares outstanding used to calculate basic and diluted net loss per common share	32,979,288	24,270,407	2,095,950	1,933,672	1,689,894

	December 31,				
	2014	2013	2012	2011	2010
	(in thousands)				
Consolidated Balance Sheet Data:					
Cash, cash equivalents and marketable securities	$ 40,713	$ 76,731	$ 20,298	$ 17,847	$ 33,754
Working capital	24,192	66,340	14,039	10,496	16,121
Total assets	42,977	78,704	24,539	19,347	35,984
Notes payable	10,928	9,968	9,826	—	—
Convertible preferred stock	—	—	102,023	83,178	83,178
Accumulated deficit	(178,213)	(140,215)	(98,267)	(74,758)	(72,526)
Total stockholders' equity (deficit)	24,613	60,536	(94,944)	(72,345)	(70,403)

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. Historically, our clinical focus had included both on respiratory diseases and cancer, however as a result of the recent termination of our respiratory programs, our clinical development efforts going forward will be focused solely in oncology, including both hematologic malignancies as well as potentially solid tumors. Our principal pharmaceutical product candidates that we have advanced to the clinical development stage are:

- KB004, a Humaneered ® anti -EphA3 monoclonal antibody that has the potential to offer a novel approach to treating both hematologic malignancies and solid tumors. In a Phase 1 dose escalation study KB004 was found to be generally safe and well tolerated and is currently being developed as a therapeutic for myelodysplastic syndrome (MDS) and myelofibrosis (MF).

- KB003, a Humaneered ® anti-granulocyte macrophage colony- stimulating factor (anti-GM-CSF) monoclonal antibody that was being developed for the treatment of severe asthma inadequately controlled by corticosteroids. However, based on results of the phase 2 data released in early 2014, we have discontinued development of this antibody in severe asthma. As the study showed KB003 was generally safe and well tolerated, we are currently reviewing the potential of certain orphan oncology indications for KB003 where there is a strong scientific rationale and which fit with our strategic focus on oncology going forward.

- KB001-A, a Humaneered ® , PEGylated, anti-PcrV modified antibody fragment (Fab') antibody that was being developed for the prevention and treatment of *Pseudomonas aeruginosa (Pa)* infections in mechanically ventilated patients and cystic fibrosis (CF) patients with chronic *Pa* lung infections. However, based on results of the phase 2 data released in early 2015, we have discontinued development of this product in all indications and are exploring potentially out-licensing this product as it does not fit with our revised strategic focus on oncology therapeutics.

In January 2010, we entered into an agreement with Sanofi pursuant to which we granted 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 was solely responsible for research, development, manufacturing, and commercialization. As part of this agreement, we retained the right to develop and promote KB001-A for the treatment of *Pa* lung infections in CF or bronchiectasis patients. Sanofi focused its clinical development on prevention of *Pa* ventilator associated pneumonia (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 September 30, 2012.

As part of the agreement with Sanofi, we retained responsibility for developing and promoting the product for the diagnosis, treatment, and/or prevention of *Pa* in patients with CF or bronchiectasis, and are conducting a Phase 2 clinical trial in CF patients with chronic *Pa* infections. Subject to the terms of the agreement, Sanofi had 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 conducted a Phase 1 clinical safety study in healthy volunteers to evaluate higher doses than those that we previously tested. That study was successfully completed, dosing patients at levels up to 30 mg/kg with no safety issues noted. Sanofi had further indicated that they have completed their manufacturing process development and were preparing for GMP manufacturing runs to provide material for a potential Phase 2b intravenous study to begin mid-year 2015 to determine the safety and efficacy of KB001-A in preventing *Pa* VAP.

In July 2014, as a result of our requests for Sanofi to return the rights to KB001-A, we executed an agreement with Sanofi (the Termination Agreement) under which the original Sanofi collaboration agreement was terminated. As a result of the Termination Agreement, we regained full global rights to license, develop, manufacture and commercialize KB001-A in all indications, as well as a license to the KB001-A manufacturing process developed by Sanofi. In consideration for entering into the Termination Agreement, Sanofi will be entitled to royalties on net sales of KB001-A if approved, subject to a $40 million cap on the aggregate royalties to be paid. In addition, Sanofi will be entitled to receive up to 10% of certain sub-license payments or other milestone payments received in the event we successfully re-partner KB001-A, subject to a separate $40 million cap on the aggregate amount of sub-license or other payments to be shared with Sanofi.

In July 2014, we announced that we had completed enrollment of our 180-patient, randomized, double-blind, placebo-controlled, intravenous Phase 2 clinical trial of KB001-A in CF patients with chronic *Pa* infections. We reported top-line data on this study in early January 2015, noting that the study failed to meet its primary endpoint of improvement in time to need antibiotics. In addition, there was no meaningful improvement noted in the secondary endpoints of patient reported outcomes and FEV1. As a result, we have discontinued development of KB001-A and are evaluating the possibility of out-licensing the compound as it no longer aligns with our revised strategic focus in oncology therapeutics. We also completed the Phase 1 dose escalation study of KB004 in subjects with hematologic cancer in 2014 and entered the Phase 2 expansion portion of the clinical testing of KB004 in which enrollment is ongoing. Finally, we completed our 160-patient, randomized, double-blind, placebo-controlled, intravenous Phase 2 clinical trial of KB003 in patients with severe asthma inadequately controlled by corticosteroids in February 2014. We have discontinued development of KB003 in severe asthma, but are planning on evaluating KB003 in orphan oncology indications consistent with our revised clinical focus in oncology.

In order to maintain adequate capital to fund the continued development of our product candidates, management continues to evaluate a number of alternatives, including but not limited to: (i) seeking additional partner(s) for our programs to provide capital for future development and to share in development costs, (ii) undertaking reductions in operating spending, and (iii) evaluating various means to raise additional capital, such as debt or equity offerings. Regardless of any actions we take to address our cash position in the near term, we will also need to raise additional capital in order to further advance our product candidates towards regulatory approval. If management is unsuccessful in these efforts, based on our current levels of operating spending our current capital may not be sufficient in some scenarios to fund our operations for the next twelve months.

We licensed our proprietary Humaneered® antibody technology to Novartis in 2007 on a non-exclusive basis and received a license fee of $30 million at that time. 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, 2014, we had an accumulated deficit of $178.2

million. We have funded our operations primarily through private and public 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. On February 5, 2013, we closed our initial public offering (IPO) 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. On October 1, 2013 we closed a public offering of 8,625,000 shares of common stock at an offering price of $4.00 per share, resulting in net proceeds of approximately $32.0 million, after deducting underwriting discounts, commissions and offering expenses. As of December 31, 2014, we had cash, cash equivalents, and investments of $40.7 million.

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 Food and Drug Administration (FDA) approval of our drug candidates. Specifically, we have incurred substantial expenses in connection with our Phase 2 clinical trial for KB003 in severe asthma patients inadequately controlled by corticosteroids, and would expect to continue to incur additional expenses as we evaluate KB003 in other indications. In addition, we have incurred and we expect to continue to incur substantial expenses for our Phase 2 clinical trial of KB001-A in CF patients with chronic *Pa* infections and our Phase 1 and Phase 2 clinical trials for our KB004 oncology program. Significant capital is required to continue to develop and to launch a product and many expenses are incurred before revenue is received, if any. We are unable to predict the extent of any future losses or when we will receive revenue or become profitable, if at all.

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 our financial statements in conformity with GAAP requires our 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. Our management believes judgment is involved in determining revenue recognition, valuation of financing derivative, the fair value-based measurement of stock-based compensation, accruals and warrant valuations. Our management evaluates 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. If our assumptions change, we may need to revise our estimates, or take other corrective actions, either of which may also have a material adverse effect on our statements of operations, liquidity and financial condition.

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.

Accrued 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. 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 these costs, we estimate the time period over which services will be performed for which we have not been invoiced 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.

Stock-Based Compensation

Our stock-based compensation expense for stock options is estimated at the grant date based on the award's fair value as calculated by the Black-Scholes option pricing model and is recognized as expense over the requisite service period. The Black-Scholes option pricing model requires various highly judgmental assumptions including expected volatility and expected term. The expected volatility is based on the historical stock volatilities of several of our publicly listed peers over a period equal to the expected terms of the options as we do not have a sufficient trading history to use the volatility of our own common stock. To estimate the expected term, we have opted to use the simplified method which is the use of the midpoint of the vesting term and the contractual term. If any of the assumptions used in the Black-Scholes option pricing model changes significantly, stock-based compensation expense may differ materially in the future from that recorded in the current period. In addition, we are required to estimate the expected forfeiture rate and only recognize expense for those shares expected to vest. We estimate the forfeiture rate based on historical experience and our expectations regarding future pre-vesting termination behavior of employees. To the extent our actual forfeiture rate is different from our estimate, stock-based compensation expense is adjusted accordingly.

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 material collaboration agreements or entered into any new agreements in 2014 or 2013, nor have we received any milestone payments in 2014 or 2013. 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.

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. At December 31, 2014, we had an accumulated deficit of $178.2 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. We expense both internal and external research and development costs as incurred. We currently track external research and development costs incurred by project for each of our clinical programs (KB001-A, KB003, and KB004). We began tracking our external costs by project beginning January 1, 2008, and we have continued to refine our systems and our methodology in tracking external research and development costs. 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.

Other research and development costs consist primarily of internal research and development costs such as 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, overhead expenses such as rent and utilities, and external costs not allocated to one of our clinical programs. Internal research and development 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, 2014, 2013, 2012, and for the period from January 1, 2008 to December 31, 2014:

(In thousands)	Year Ended December 31, 2014	2013	2012	For the Period from January 1, 2008 to December 31, 2014
External costs:				
KB001-A	$ 7,100	$ 6,703	$ 4,996	$ 32,580
KB003	4,349	11,975	7,682	40,163
KB004	5,738	5,702	4,102	31,640
Other research and development costs	9,386	8,260	7,739	64,076
Total research and development	$26,573	$32,640	$24,519	$ 168,459

We expect to continue to incur substantial expenses related to our development activities for the foreseeable future as we continue product development including continuing the Phase 2 expansion portion of our KB004 trial in hematologic malignancies and evaluating KB003 in certain orphan oncology indications, as well as concluding our Phase 2 clinical trial for our KB001-A CF program completed in January 2015. Historically, we have incurred significant costs related to our respiratory programs KB001-A and KB003 and oncology for KB004, however, due to the termination of our respiratory programs, we expect our clinical development efforts going forward would be focused solely on the KB004 program, while we will continue to evaluate KB003 in certain orphan oncology, and we expect our research and development expenses will not increase in the upcoming year. 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 ongoing Phase 2 trial for KB004 and any trials we commence to evaluate KB003 in oncology indications.

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, 2014, 2013, and 2012, general and administrative expenses were $10.1 million, $8.3 million and $5.1 million, respectively.

Comparison of Years Ended December 31, 2014 and 2013

(In thousands)	Year Ended December 31, 2014	2013	Increase/ (Decrease) in thousands	%
Contract revenue	$ —	$ 44	$ (44)	(100)
Operating expenses:				
Research and development	26,573	32,640	(6,067)	(19)
General and administrative	10,145	8,313	1,832	22
Loss from operations	(36,718)	(40,909)	4,191	(10)
Interest income	88	86	2	2
Interest (expense)	(1,214)	(1,086)	(128)	12
Other (expense) income, net	(154)	(39)	(115)	295
Net loss	$(37,998)	$(41,948)	$ 3,950	(9)

Contract revenue in each period was related solely to our arrangement with Sanofi in which we licensed the KB001-A program to Sanofi in 2010. Contract revenue decreased $44,000 in 2014 compared to 2013, and was mainly attributable to the completion of our substantive performance obligations in mid 2012 under our agreement with Sanofi. As we have terminated our agreement with Sanofi in the quarter ended September 30, 2014, we do not expect future contract revenue from Sanofi.

Research and development expenses decreased $6.1 million in 2014 compared to 2013. The decrease was primarily attributed to a $7.6 million decrease in external spending for clinical trial expenses for our KB003 severe asthma program, offset by a $1.1 million increase in other research and development costs and an increase of $0.4 million external spend on our KB001-A CF program. We began enrollment of patients in a Phase 2 clinical trial in hematalogic malignancies of KB004 in the quarter ended March 31, 2014. While we expect external costs for our KB004 program to increase in 2015, and we expect external expenses on KB001-A will continue to decrease significantly in 2015 as a result of the trial being completed in the first quarter of 2015 and our discontinuing development of KB001-A for CF patients with chronic Pa infections, we expect a decrease in total research and development expense in 2015.

General and administrative expenses increased $1.8 million in 2014 compared to 2013. The increase in general and administrative expenses was primarily due to increases in personnel related expense of $1.0 million, as well as an increase in consulting, insurance, facilities and other fees of $0.8 million related to being a public reporting company. We do not expect an increase in general and administrative expenses in 2015.

Interest expense, net, increased by $0.1 million in 2014 compared to 2013, due to interest expense related to our loan and security agreement with MidCap Financial entered into in September 2012 and amended in June 2013.

Other income (expense), net decreased by $115,000 in 2014 compared to 2013, primarily due to the recording of the financing derivative liability and realized foreign currency exchange gains.

Comparison of Years Ended December 31, 2013 and 2012

	Year Ended December 31,		Increase/ (Decrease)	
(In thousands)	**2013**	**2012**	**in thousands**	**%**
Contract revenue	$ 44	$ 6,098	$ (6,054)	(99)
Operating expenses:				
Research and development	32,640	24,519	8,121	33
General and administrative	8,313	5,061	3,252	64
Loss from operations	(40,909)	(23,482)	(17,427)	74
Interest income	86	44	42	95
Interest (expense)	(1,086)	(184)	(902)	490
Other income (expense), net	(39)	113	(152)	(135)
Net loss	$(41,948)	$(23,509)	$ (18,439)	78

Contract revenue in each period was related solely to our arrangement with Sanofi in which we licensed the KB001-A program to Sanofi in 2010. Contract revenue decreased $6.1 million in 2013 compared to 2012, and was mainly attributable to the completion of our substantive performance obligations in mid 2012 under our agreement with Sanofi.

Research and development expenses increased $8.1 million in 2013 compared to 2012. The increase was primarily attributed to a $4.3 million increase in external spending for clinical trial expenses for our KB003 severe asthma program, a $1.7 million increase in external spend on our KB001-A CF program, and a $1.6 million increase in external spend for our KB004 program for hematological malignancies, as well as an out of period adjustment of $0.5 million of 2012 related expenses recorded in 2013. We began enrollment of patients in a Phase 2 clinical trial in CF patients of KB001-A with chronic *Pa* infections in the quarter ended March 31, 2013, and continued enrollment of patients in the Phase 1 clinical trial in hematologic malignancies of KB004 throughout 2013.

General and administrative expenses increased $3.3 million in 2013 compared to 2012. The increase in general and administrative expenses was primarily due to increases in personnel related expense of $1.4 million, as well as an increase in legal, accounting, consulting, insurance, and other fees of $1.9 million related to being a public reporting company.

Interest expense, net, increased by $0.9 million in 2013 compared to 2012, due to interest expense related to our loan and security agreement with MidCap Financial entered into in September 2012 and amended in June 2013.

Other income (expense), net decreased by $0.2 million in 2013 compared to 2012, primarily due to one-time gains recorded in 2012 related to the sale of fixed assets and the revaluation of our convertible preferred stock warrant liabilities.

Income Taxes

As of December 31, 2014, we had net operating loss carryforwards of approximately $168.5 million to offset future federal income taxes which expire in the years 2025 through 2034, and approximately $168.5 million that may offset future state income taxes which expire in the years 2015 through 2034. 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, 2014, we recorded a 100% valuation allowance against our deferred tax assets of approximately $41.4 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, we have financed our operations primarily through proceeds from the public offerings of our common stock, private placements of our preferred stock, debt financings, interest income earned on cash, and cash equivalents, and marketable securities, borrowings against lines of credit, and receipts from agreements with Sanofi and Novartis. At December 31, 2014, we had cash and cash equivalents of $10.9 million and marketable securities of $29.8 million, totaling $40.7 million.

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)	**2014**	**2013**	**2012**
Net cash (used in) provided by:			
Operating activities	$ (35,939)	$(38,815)	$(23,906)
Investing activities	(8,220)	(13,920)	5,075
Financing activities	862	96,008	26,440
Net (decrease) increase in cash and cash equivalents	$ (43,297)	$ 43,273	$ 7,609

Net cash used in operating activities was $35.9 million, $38.8 million and $23.9 million for the years ended December 31, 2014, 2013 and 2012, respectively. The primary use of cash in each of these periods was to fund our operations related to the development of our product candidates. Net cash used for the year ended December 31, 2014 decreased compared to 2013, primarily due to a $4.7 million decrease in net loss adjusted for noncash items, offset by a net decrease in operating liabilities. The increase in net cash used in 2013 compared to 2012 was primarily due to an $18.4 million increase in net loss adjusted for non-cash items, as well as net changes in operating assets and liabilities.

Net cash used in investing activities was $8.2 million and $13.9 million for the years ended December 31, 2014 and 2013, respectively, as compared to net cash provided by investing activities of $5.1 million for the year ended December 31, 2012. For 2014 and 2013, our purchases of short-term investments exceeded the cash generated by maturities of our short-term investments.

Net cash provided by financing activities was $0.9 million, $96.0 million and $26.4 million for the years ended December 31, 2014, 2013, and 2012, respectively. The cash provided by financing activities in 2014 related primarily to the draw down the final tranche of $5.0 million in May 2014 under the Midcap loan and security agreement, partially

offset by principal payments under this agreement. The cash provided by financing activities in 2013 was primarily due to the net proceeds of $65.1 million from our IPO in February 2013 and net proceeds of $32.0 million from our equity public offering in October 2013.

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 winding down our Phase 2 clinical trial for KB001-A in CF patients with chronic *Pa* infections, for our ongoing Phase 2 clinical trials for our KB004 development program in hematologic malignancies and for any clinical trials we initiate to evaluate KB003 as an oncology therapeutic.

In order to maintain adequate capital to fund the continued development of our product candidates, management continues to evaluate a number of alternatives, including but not limited to: (i) seeking additional partner(s) for our programs to provide capital for future development and to share in development costs, (ii) undertaking reductions in operating spending, and (iii) evaluating various means to raise additional capital, such as debt or equity offerings. Regardless of any actions we take to address our cash position in the near term, we will also need to raise additional capital in order to further advance our product candidates towards regulatory approval. If management is unsuccessful in these efforts, based on our current levels of operating spending our current capital may not be sufficient in some scenarios to fund our operations for the next twelve months. Our ability to access capital when needed is not assured and, if not achieved on a timely basis, could materially harm our business, financial condition and results of operations. Further, any failure to raise capital could be deemed a material adverse change under our loan and security agreement with MidCap Financial and that may, in turn, result in the lender declaring the loan in default and demanding repayment of the principal, accrued interest, the exit fee and a prepayment fee. These conditions could raise substantial doubt about our ability to continue as a going concern. The Report of Independent Registered Public Accounting Firm at the beginning of the Consolidated Financial Statements section of this Form 10-K includes an explanatory paragraph about the Company's ability to continue as a going concern.

We will continue to require additional financing to develop our products and fund operations. 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 would 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 current or any future 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.

At-The-Market Issuance Sales Agreement

On September 3, 2013 we entered into an At-the-Market Issuance Sales Agreement with MLV & Co. LLC (MLV) under which, subject to certain conditions, we may offer and sell shares of our common stock having an aggregate offering price of up to $50.0 million from time to time through MLV, acting as agent. As of December 31, 2014, we had made no sales of common stock under the At-the-Market Issuance Sales Agreement.

Contractual Obligations and Commitments

Our contractual obligations consist primarily of obligations under lease agreements and our notes payable obligations. The following table summarizes our contractual obligations at December 31, 2014 and the effect such obligations are expected to have on our liquidity and cash flow in future years.

	Payments due by period				
(in thousands)	**Total**	**Less than 1 year**	**1 to 3 years**	**4 to 5 years**	**After 5 years**
Lease obligations	$ 3,410	$ 700	$2,282	$ 428	$ —
Notes payable	11,856	5,947	5,909	—	—
Research contractual obligations	1,558	1,558	—	—	—
Total	$16,824	$ 8,205	$8,191	$ 428	$ —

Operating Leases

We leased a 40,000 square-foot building consisting of office and laboratory space in South San Francisco, California, which served as our corporate headquarters. We also subleased approximately 20,000 square feet of our leased space to third parties. The lease commenced in July 2011 and expired in June 2014. We did not renew this lease upon its termination in June 2014.

In December 2013, we entered into a new lease for a 24,351 square-foot building consisting of office and laboratory space at 442 Littlefield Avenue, South San Francisco, California, which is serving as our new corporate headquarters. The new lease commenced in July 2014 and will expire in 2019. The lease agreement provides that we have the option to terminate the lease after 36 months, subject to additional fees and expenses. And at the end of the five year term of the new lease, we have the option to extend its term for an additional five years at the then current fair market value rental rate determined in accordance with the terms of the Lease.

Notes Payable

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 was to 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 which we are currently accreting. Pursuant to the loan and security agreement, we provided a first priority security interest in all existing and after- acquired assets, excluding intellectual property. If we choose to prepay the loan, or if the loan is determined to be in default and early repayment is required, we

would also pay a fee ranging from 1% to 2% of the outstanding loan balance at the date of default. An event of default may include the lender determining that our ability to repay the loan is at risk. 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.

In June 2013, the Company entered into the Amendment to extend the draw down date for the final tranche of $5.0 million from June 2013 to May 2014. In addition, the final tranche was changed from an optional draw down to a required draw down. In connection with the Amendment, the Company issued a warrant to purchase up to 49,548 shares of the Company's common stock with an exercise price of $12.11 per share. The warrant expires in June 2023, on the tenth anniversary of its issuance date. The warrants issued to Midcap Financial had an initial fair value of $130,000, which represent financing fees, and are included in other assets in the accompanying consolidated balance sheet and are being amortized as non-cash interest expense over the remaining term of the Agreement using the effective interest method. The Company estimated the fair values of these warrants using the Black-Scholes option-pricing model, based on the inputs for the estimated fair value of the underlying common stock at the valuation measurement date, the contractual term of the warrant, risk-free interest rates, expected dividend rates and expected volatility of the price of the underlying common stock. Pursuant to this Amendment, the Company drew down the final tranche of $5.0 million in May 2014.

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 on or before 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 ranging from 1% to 2% of the amount due on the loan and a step up in interest rate of 5%. 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. The Company's ability to access capital when needed is not assured and, if not achieved on a timely basis, could materially harm its business, financial condition and results of operations. Further, any failure to raise capital could be deemed a material adverse change under our loan and security agreement with MidCap Financial and that may, in turn, result in the lender declaring the loan in default and demanding repayment of the principal, accrued interest, the exit fee and a prepayment fee. Therefore, the Company has classified the long-term portion of notes payable as current, however, the above table discloses the contractual payments under the loan and security agreement with MidCap Financial.

The Company recorded a financing derivative liability resulting from an embedded derivative related to the prepayment feature the loan and security agreement with MidCap Financial. The fair value of this derivative was determined using Level 3 inputs, or significant unobservable inputs. The value of the financing derivative was determined by comparing the difference between the fair value of the notes payable with and without the financing derivative by calculating the respective present values from future cash flows using a 14% discount rate, adjusted for the probability of the occurrence of an event of default under the loan and security agreement with MidCap Financial. The 14% discount rate assumption was based on an effective borrowing rate under the current circumstances considering the quoted borrowing rate for the Company and the imputed fair value of any additional financial instruments that may be required to be extended to the lender in order to obtain such debt financing. The probability of the occurrence of an event of default under the loan and security agreement with MidCap Financial was based on management's judgment. Refer to Note 6 for additional details regarding the loan and security agreement with MidCap Financial.

Contracts

On May 21, 2013, the Company entered into an agreement with a third party for the manufacturing of KB003 clinical supply for future clinical trials. Despite the termination of the KB003 development program in severe asthma during the first quarter of 2014, the Company is continuing to evaluate other potential indications for KB003. Under that agreement the third party will perform a range of related services, including process development, optimization, validation, formulation development, regulatory assistance, stability testing and related activities. In addition, we had entered into an agreement with a separate third party to produce supply of KB001-A. As of December 31, 2014, there

were no remaining commitments for services and in February 2015, this agreement was cancelled. The above table reflects payments to be made to these third parties in 2015.

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 $39.3 million and $75.8 million as of December 31, 2014 and December 31, 2013, 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-27.

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, Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2014. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by us in the reports that we file or submit 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 us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. Based on this evaluation, Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2014 at the reasonable assurance level.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended). Our management, Chief Executive Officer and Chief Financial Officer assessed the effectiveness of our internal control over financial reporting as of December 31, 2014. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (1992 Framework) ("COSO") in *Internal Control—Integrated Framework*. Based on that assessment and using the COSO criteria, our management, Chief Executive Officer and Chief Financial Officer have concluded that, as of December 31, 2014, our internal control over financial reporting was effective.

This Annual Report on Form 10-K does not include an attestation report of our registered public accounting firm due to a transition period established by the Jumpstart Our Business Startups Act, or JOBS Act, for emerging growth companies.

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, 2014, 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

On or about March 12, 2014, the Company entered into new Employment Agreements (the "Employment Agreements") with our Chief Executive Officer, certain of our other named executive officers (together, the "Executives") and certain other officers. The Employment Agreements are intended to provide greater consistency of employment terms between the Company and its senior management team. The Employment Agreements provide for a three-year term, with automatic one-year renewal periods at the end of that term unless either party provides notice of intent to terminate. Each member of the senior management team, including the Executives, is and will continue to be an at-will employee of the Company.

The Employment Agreements for the Executives also provide that if employment is terminated by the Company without cause or if the applicable Employment Agreement is not renewed by the Company, then the terminated Executive will become eligible to receive the following severance benefits, subject to the execution of a release of claims: (i) nine months (twelve months with respect to the CEO) of salary continuation, (ii) an amount equal to the cost of nine months (twelve months with respect to the CEO) of COBRA coverage less the active rate for such coverage, payable as a lump sum, (iii) a pro-rated incentive bonus assuming at least nine months (twelve months with respect to the CEO) of employment in the then current calendar year, and (iv) nine months (twelve months with respect to the CEO) of accelerated vesting of then unvested equity awards.

The Employment Agreements for the Executives further provide that if, within one year following a Change in Control, employment is terminated by the Company without cause or by the Executive for good reason, then the terminated Executive will become eligible to receive the following severance benefits, subject to the execution of a release of claims: (i) fifteen months (eighteen months with respect to Mr. Pritchard) of salary continuation, (ii) an amount equal to the cost of fifteen months (eighteen months with respect to the CEO) of COBRA coverage less the active rate for such coverage, payable as a lump sum, (iii) 125% (150% with respect to the CEO) of his target incentive bonus and (iv) full vesting of all then unvested equity awards.

On January 8, 2015, the Company announced that David W. Pritchard, President and Chief Executive Officer, has decided to retire, effective immediately, and has also resigned his position as a member of the company's Board of Directors. The company has named Herb C. Cross, chief financial officer, as interim CEO pending a search for a new chief executive officer.

The foregoing description of the Employment Agreements is qualified in its entirety by reference to the full text of the Employment Agreements, which are filed as Exhibits 10.39 through 10.42 to this Form 10-K and are incorporated by reference herein.

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 2014 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 2014 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 2014 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 2014 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 2014 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.

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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, 2014 and 2013, and the related consolidated statements of comprehensive loss, convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2014. 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, 2014 and 2013, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2014, in conformity with U.S. generally accepted accounting principles.

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

/s/ Ernst & Young LLP

Redwood City, California
March 16, 2015

KaloBios Pharmaceuticals, Inc.

Consolidated Balance Sheets

(in thousands, except share and per share data)

	December 31,	
	2014	2013
Assets		
Current assets:		
Cash and cash equivalents	$ 10,923	$ 54,220
Marketable securities	29,790	22,511
Contract receivables	—	44
Prepaid expenses and other current assets	1,532	742
Restricted cash	—	205
Total current assets	42,245	77,722
Restricted cash	193	—
Property and equipment, net	414	276
Other assets	125	706
Total assets	$ 42,977	$ 78,704
Liabilities, and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,822	$ 3,197
Accrued compensation	1,400	1,091
Deferred rent, short-term	16	160
Accrued research and clinical liabilities	3,470	3,309
Notes payable, short-term	10,928	3,182
Financing derivative	89	—
Other accrued liabilities	328	443
Total current liabilities	18,053	11,382
Deferred rent, long-term	311	—
Notes payable, long-term	—	6,786
Total liabilities	18,364	18,168
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.001 par value: 85,000,000 shares and 47,500,000 shares authorized at December 31, 2014 and December 31, 2013 respectively; 32,992,178 and 32,931,092 shares issued and outstanding at December 31, 2014 and December 31, 2013 respectively	33	33
Additional paid-in capital	202,801	200,715
Accumulated other comprehensive income	(8)	3
Accumulated deficit	(178,213)	(140,215)
Total stockholders' equity	24,613	60,536
Total liabilities and stockholders' equity	$ 42,977	$ 78,704

See accompanying notes.

KaloBios Pharmaceuticals, Inc.

Consolidated Statements of Operations and Comprehensive Loss

(in thousands, except share and per share data)

	Year Ended December 31,		
	2014	2013	2012
Contract revenue	$ —	$ 44	$ 6,098
Operating expenses:			
Research and development	26,573	32,640	24,519
General and administrative	10,145	8,313	5,061
Total operating expenses	36,718	40,953	29,580
Loss from operations	(36,718)	(40,909)	(23,482)
Other (expense) income:			
Interest income	88	86	44
Interest expense	(1,214)	(1,086)	(184)
Other (expense) income, net	(154)	(39)	113
Net loss	(37,998)	(41,948)	(23,509)
Other comprehensive (loss) income:			
Net unrealized (loss) gain on marketable securities	(11)	(1)	5
Comprehensive loss	$ (38,009)	$ (41,949)	$ (23,504)
Basic and diluted net loss per common share	$ (1.15)	$ (1.73)	$ (11.22)
Weighted average common shares outstanding used to calculate basic and diluted net loss per common share	32,979,288	24,270,407	2,095,950

See accompanying notes

KaloBios Pharmaceuticals, Inc.

Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)

(in thousands, except share and per share data)

(in thousands, except share information)	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
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
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)
Conversion of preferred stock to common stock	(12,329,330)	(102,023)	13,211,120	13	102,010	—	—	102,023
Reclassification of preferred stock warrants liability to additional paid-in capital in conjunction with the conversion of the convertible preferred stock to common stock upon initial public offering	—	—	—	—	157	—	—	157
Issuance of common stock upon initial public offering, net of issuance costs	—	—	8,750,000	9	61,477	—	—	61,486
Issuance of common stock upon equity offering, net of issuance costs	—	—	8,625,000	9	32,020			32,029
Issuance of common stock upon exercise of stock options	—	—	158,277	—	164	—	—	164
Stock-based compensation expense	—	—	—	—	1,440	—	—	1,440
Issuance of warrants in connection with credit facility	—	—	—	—	130			130
Comprehensive loss	—	—	—	—	—	(1)	(41,948)	(41,949)
Balances at December 31, 2013	—	$ —	32,931,092	$ 33	$ 200,715	$ 3	$ (140,215)	$ 60,536
Issuance of common stock upon exercise of stock options and ESPP conversion	—	—	61,086	—	73	—	—	73
Stock-based compensation expense	—	—	—	—	2,013	—	—	2,013
Comprehensive loss	—	—	—	—	—	(11)	(37,998)	(38,009)
Balances at December 31, 2014	—	$ —	32,992,178	$ 33	$ 202,801	$ (8)	$ (178,213)	$ 24,613

See accompanying notes.

KaloBios Pharmaceuticals, Inc.

Consolidated Statements of Cash Flows

(in thousands)

	Year Ended December 31,		
	2014	**2013**	**2012**
Operating activities:			
Net loss	$(37,998)	$(41,948)	$(23,509)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	310	298	193
Amortization of intangible assets	—	—	111
Noncash interest expense	217	173	22
Financing derivative	89	—	—
Amortization of premium on marketable securities	495	416	237
Stock based compensation expense	2,013	1,440	821
Loss (gain) on disposal of fixed assets	—	—	(146)
Change in fair value of preferred stock warrant liabilities	—	—	(39)
Changes in operating assets and liabilities:			
Contract receivables	44	43	90
Prepaid expenses and other assets	(257)	(435)	(291)
Accounts payable	(1,375)	1,223	2,007
Accrued compensation	309	463	(205)
Deferred revenue	—	—	(5,630)
Accrued research and clinical liabilities	161	(229)	2,459
Other liabilities	(114)	(256)	27
Deferred rent	167	(3)	(53)
Net cash used in operating activities	(35,939)	(38,815)	(23,906)
Investing activities:			
Purchase of marketable securities	(54,163)	(46,852)	(25,507)
Proceeds from maturities of marketable securities	46,379	26,035	30,432
Proceeds from sales of marketable securities	—	7,241	—
Purchases of property and equipment	(448)	(344)	(20)
Proceeds from sale of property and equipment	—	—	170
Change in restricted cash	12	—	—
Net cash (used in) provided by investing activities	(8,220)	(13,920)	5,075
Financing activities:			
Proceeds from issuance of common stock in initial public offering, net of underwriting costs	—	65,100	—
Proceeds from the sale of common stock, net of underwriting costs	—	32,430	—
Payments of offering related costs	—	(1,686)	(2,329)
Proceeds from issuance of notes payable	5,000	—	9,840
Principal payments under notes payable	(4,211)	—	—
Proceeds from issuance of common stock	73	164	84
Proceeds from issuances of Series E preferred stock, net	—	—	18,845
Net cash provided by financing activities	862	96,008	26,440
Net (decrease) increase in cash and cash equivalents	(43,297)	43,273	7,609
Cash and cash equivalents, beginning of period	54,220	10,947	3,338
Cash and cash equivalents, end of period	$ 10,923	$ 54,220	$ 10,947
Supplemental cash flow disclosure:			
Cash paid for interest	$ 990	$ 890	$ 109
Supplemental disclosure of noncash financing activities:			
Conversion of preferred stock to common stock and additional paid-in capital	$ —	$102,023	$ —
Reclassification of preferred stock warrants liability to additional paid-in capital	$ —	$ 157	$ —
Issuance of common stock warrants in connection with a loan amendment	$ —	$ 130	$ —
Issuance of preferred stock warrant issued with 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. Historically, our clinical focus had included both on respiratory diseases and cancer, however as a result of the recent termination of our respiratory programs, our clinical development efforts going forward will be focused solely in oncology, including both hematologic malignancies as well as potentially solid tumors. 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 $178.2 million as of December 31, 2014. 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. The Company's ability to access capital when needed is not assured and, if not achieved on a timely basis, could materially harm its business, financial condition and results of operations. Further, any failure to raise capital could be deemed a material adverse change under our loan and security agreement with MidCap Financial and that may, in turn, result in the lender declaring the loan in default and demanding repayment of the principal, accrued interest, the exit fee and a prepayment fee. These conditions could raise substantial doubt about the Company's ability to continue as a going concern. Therefore, the Company has classified the notes payable as current. The Report of Independent Registered Public Accounting Firm at the beginning of the Consolidated Financial Statements section of this Form 10-K includes an explanatory paragraph about the Company's ability to continue as a going concern.

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. These financial statements have been prepared on a basis which assumes that the Company will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business.

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, valuation of financing derivative, 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.

KaloBios Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

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 (marketable securities 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, 2014			
(in thousands)	**Level 1**	**Level 2**	**Level 3**	**Total**
Investments:				
Money market funds	$9,663	$ —	$ —	$ 9,663
Federal agency securities	—	13,770	—	13,770
Commercial paper	—	1,500	—	1,500
Corporate debt securities	—	14,520	—	14,520
Total assets measured at fair value	$9,663	$29,790	—	$39,453
Financing derivative	—	—	89	89
Total liabilities measured at fair value	$ —	$ —	$ 89	$ 89

KaloBios Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

(in thousands)	Fair Value Measurements as of December 31, 2013			
	Level 1	Level 2	Level 3	Total
Investments:				
Money market funds	$53,511	$ —	$ —	$53,511
Federal agency securities	—	12,301	—	12,301
Commercial paper	—	8,249	—	8,249
Corporate debt securities	—	1,961	—	1,961
Total assets measured at fair value	$53,511	$22,511	$ —	$76,022

The Company's Level 2 investments include U.S. government-backed agency 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, 2014 is less than four months and all of these investments are rated A3/A-/A- or P1/A1/F1, or higher by Moody's, S&P and Fitch. There were no transfers between Level 1 and Level 2 during the periods presented.

The Company recorded a financing derivative liability resulting from an embedded derivative related to the prepayment feature the loan and security agreement with MidCap Financial. The fair value of this derivative was determined using Level 3 inputs, or significant unobservable inputs. The value of the financing derivative was determined by comparing the difference between the fair value of the notes payable with and without the financing derivative by calculating the respective present values from future cash flows using a 14% discount rate, adjusted for the probability of the occurrence of an event of default under the loan and security agreement with MidCap Financial. The 14% discount rate assumption was based on an effective borrowing rate under the current circumstances considering the quoted borrowing rate for the Company and the imputed fair value of any additional financial instruments that may be required to be extended to the lender in order to obtain such debt financing. The probability of the occurrence of an event of default under the loan and security agreement with MidCap Financial was based on management's judgment. Refer to Note 6 for additional details regarding the loan and security agreement with MidCap Financial.

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

	Fair Value Measurements of Level 3 Liabilities (in thousands)
Balance at December 31, 2012	$ 157
Reclassification to additional paid-in capital upon conversion to common stock warrant	(157)
Balance at December 31, 2013	$ —
Financing derivative	89
Balance at December 31, 2014	$ 89

The estimated fair value of the notes payable as of December 31, 2014, 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.

KaloBios Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

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' equity. 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 other 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 year ended December 31, 2014, $2,700 realized gain for the year ended December 31, 2013, and no realized gains or losses for the year ended December 31, 2012.

Restricted Cash

Restricted cash at December 31, 2014 and December 31, 2013 consisted of $0.2 million and $0.2 million related to standby letters of credit issued in connection with an operating lease for the Company's corporate headquarters and certain insurance policy coverage maintained by the Company.

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.

Convertible Preferred Stock Warrant Liabilities and Common Stock Warrants

Prior to the Company's IPO, outstanding warrants to purchase shares of the Company's Series B-2 and Series E preferred stock were classified as other liabilities. The initial liability recorded was adjusted for changes in the fair values of the Company's preferred stock warrants during each reporting period and was recorded as a component of other income (expense) in the statement of operations and comprehensive loss for that period.

KaloBios Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

Upon the closing of the Company's initial public offering (IPO) and the conversion of the underlying preferred stock to common stock, the Company's warrants to purchase shares of Series B-2 preferred stock were converted into warrants to purchase shares of the Company's common stock. The aggregate fair value of these warrants upon the closing of the IPO was $157,000 which was reclassified from liabilities to additional paid-in capital, a component of stockholders' equity, and the Company ceased recording any further related periodic fair value adjustments. The Company estimated the fair values of these warrants using the Black-Scholes option-pricing model, based on the inputs for the estimated fair value of the underlying convertible preferred stock at the valuation measurement date, the remaining contractual term of the warrant, risk-free interest rates, expected dividend rates and expected volatility of the price of the underlying convertible preferred stock. These estimates were based on subjective assumptions.

The warrant to purchase shares of the Company's Series E preferred stock expired upon the closing of the Company's IPO in February 2013.

On June 19, 2013, the Company entered into an amendment (the Amendment) to a loan and security agreement (the Agreement) with MidCap Financial, SBIC, LP (MidCap Financial). In connection with the Amendment, the Company issued a warrant to purchase up to 49,548 shares of the Company's common stock with an exercise price of $12.11 per share. The warrant expires in June 2023, on the tenth anniversary of its issuance date. The warrants issued to Midcap Financial had an initial fair value of $130,000, which represent financing fees, and are included in other assets in the accompanying consolidated balance sheet and are being amortized as non-cash interest expense over the remaining term of the Agreement using the effective interest method. The Company estimated the fair values of these warrants using the Black-Scholes option-pricing model, based on the inputs for the estimated fair value of the underlying common stock at the valuation measurement date, the contractual term of the warrant, risk-free interest rates, expected dividend rates and expected volatility of the price of the underlying common stock.

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. 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. All revenue recognized to date under the Company's collaborative agreements has been nonrefundable.

KaloBios Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

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.

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 have been 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

The Company has adopted 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. Contingent payments which do not meet the definition of a milestone are recognized in the same manner as the consideration for the combined unit of accounting. If the Company has no remaining performance obligations under combined unit if accounting, any contingent payments would be recognized as revenue upon the achievement of the triggering event.

The Company's research and development and license agreements 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. Substantive milestones are recognized as revenue upon achievement of the milestone and when collectability is reasonably assured.

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.

KaloBios Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

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 values of the options granted to nonemployees are re-measured 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 represents net loss adjusted for the change during the periods presented in unrealized gains and losses on available-for-sale securities less reclassification adjustments for realized gains or losses included in net loss. The unrealized gains or losses are reported on the Consolidated Statements of Comprehensive Loss.

Net Loss Per Common Share

Basic net loss per common share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding during the period, without consideration for potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common shares and potentially dilutive securities outstanding for the period determined using the treasury-stock and if-converted methods. For purposes of the diluted net loss per share calculation, convertible preferred stock, stock options and common and preferred stock warrants are considered to be potentially dilutive securities but are excluded from the calculation of diluted net loss per share because their effect would be anti-dilutive and therefore, basic and diluted net loss per share were the same for all periods presented.

The Company's potential dilutive securities which include convertible preferred 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.

KaloBios Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

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:

	Year Ended December 31,		
	2014	2013	2012
Convertible preferred stock	—	—	12,329,330
Warrants to purchase preferred stock	—	—	72,029
Options to purchase common stock	2,677,774	1,820,784	1,030,795
Warrants to purchase common stock	88,545	88,545	—
	2,766,319	1,909,329	13,432,154

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.

3. Investments

At December 31, 2014, 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	$ 9,663	$ —	$ —	$ 9,663
Federal agency securities	13,774	—	(4)	13,770
Commercial paper	1,499	1	—	1,500
Corporate debt securities	14,525	—	(5)	14,520
Total investments	$ 39,461	$ 1	$ (9)	$ 39,453
Reported as:				
Cash and cash equivalents				$ 9,470
Marketable securities				29,790
Restricted cash				193
Total investments				$ 39,453

KaloBios Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

At December 31, 2013, 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	$ 53,511	$ —	$ —	$ 53,511
Federal agency securities	12,301	—	—	12,301
Commercial paper	8,246	3	—	8,249
Corporate debt securities	1,961	—	—	1,961
Total investments	$ 76,019	$ 3	$ —	$ 76,022
Reported as:				
Cash and cash equivalents				$ 53,306
Marketable securities				22,511
Restricted cash				205
Total investments				$ 76,022

As of December 31, 2014, all securities had average remaining contractual maturities of less than four months.

4. Property and Equipment

Property and equipment consists of the following:

	December 31,	
(In thousands)	2014	2013
Laboratory equipment	$ 552	$ 1,453
Computer equipment and software	519	493
Leasehold improvements, furniture and fixtures	277	1,571
	1,348	3,517
Accumulated depreciation and amortization	(934)	(3,241)
Property and equipment, net	$ 414	$ 276

Depreciation and amortization expense for the years ended December 31, 2014, 2013 and 2012 was $310,000, $298,000 and $193,000, respectively.

5. Research and Development Collaboration and License Agreements

All of the contract revenues recognized in the years ended December 31, 2014, 2013, and 2012 was related to the development and commercialization agreement with Sanofi.

Sanofi

In January 2010, the Company and Sanofi had entered into an agreement for the development and commercialization of KB001, the precursor to 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. Sanofi was solely responsible

KaloBios Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

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 retained responsibility, at the Company's cost, for developing and promoting the products for the diagnosis, treatment and/or prevention of Pa in patients with cystic fibrosis (CF) or bronchiectasis. Under the terms of the Sanofi agreement, the Company received specified research and development funding for services performed in connection with KB001-A research and development efforts and could have also received contingent payments based on the occurrence of development, regulatory or commercial events, and royalties on any product sales. Reimbursements received by the Company for these services were recorded as contract revenue when earned as the related services were provided.

The upfront payment of $40 million was recognized over the estimated period of the Company's substantive performance obligations under the agreement. 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, 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:

	Year Ended December 31,		
(In thousands)	**2014**	**2013**	**2012**
Contract revenue:			
Amortization of upfront fees	$ —	$ —	$ 5,630
Reimbursement for development-related activities	—	44	468
Total contract revenue	$ —	$ 44	$ 6,098

During the year ended December 31, 2014, 2013 and 2012, the Company recorded research and development expenses related to materials purchased from Sanofi of nil, $1.1 million and nil, respectively.

In July 2014, the Company and Sanofi executed an agreement (the Termination Agreement) under which the Sanofi agreement was terminated. As a result of the Termination Agreement, KaloBios regains full global rights to license, develop, manufacture and commercialize KB001-A in all indications, as well as a non-exclusive license to the KB001-A manufacturing process developed by Sanofi. In consideration for entering into the Termination Agreement, Sanofi will be entitled to royalties on net sales of KB001-A if approved, subject to a $40 million cap on the aggregate royalties to be paid. In addition, Sanofi will be entitled to receive up to 10% of certain sub-license payments or other milestone payments received in the event KaloBios successfully re-partners KB001-A, subject to a separate $40 million cap on the aggregate amount of sub-license payments to be shared with Sanofi.

KaloBios Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

6. Notes Payable

Loan and Security Agreement

In September 2012, the Company entered into the 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 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, prior to the amendment described below, the final tranche could have been 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 until December 31, 2016. 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. If we choose to prepay the loan, or if the loan is determined to be in default and early repayment is required, we would also pay a fee ranging from 1% to 2% of the outstanding loan balance at the date of default. An event of default may include the lender determining that our ability to repay the loan is at risk. In addition, the terms of the Agreement provided 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 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 on or before 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 ranging from 1% to 2% of the amount due on the loan and a step up in interest rate of 5%. 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. The Company's ability to access capital when needed is not assured and, if not achieved on a timely basis, could materially harm its business, financial condition and results of operations. Further, any failure to raise capital could be deemed a material adverse change under our loan and security agreement with MidCap Financial and that may, in turn, result in the lender declaring the loan in default and demanding repayment of the principal, accrued interest, the exit fee and a prepayment fee. Therefore, the Company has classified notes payable as current.

In connection with the Agreement and the first tranche draw down of $5 million in September 2012 and second tranche draw down of $5 million in December 2012, the Company issued a warrant to MidCap Financial to purchase shares of the Company's Series E Preferred. 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 non-cash interest expense in the consolidated statements of comprehensive loss.

In June 2013, the Company entered into the Amendment to extend the draw down date for the final tranche of $5.0 million from June 2013 to May 2014. In addition, the final tranche was changed from an optional draw down to a required draw down. In connection with the Amendment, the Company issued a warrant to purchase up to 49,548 shares of the Company's common stock with an exercise price of $12.11 per share. The warrant expires on the tenth

KaloBios Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

anniversary of its issuance date. The warrants issued to Midcap Financial had an initial fair value of $130,000, which represent financing fees, and are included in other assets in the accompanying consolidated balance sheet and are being amortized as non- cash interest expense over the remaining term of the Agreement using the effective interest method. The Company estimated the fair values of these warrants using the Black-Scholes option-pricing model, based on the inputs for the estimated fair value of the underlying common stock at the valuation measurement date, the contractual term of the warrant, risk-free interest rates, expected dividend rates and expected volatility of the price of the underlying common stock. Pursuant to this Amendment, the Company drew down the final tranche of $5.0 million in May 2014.

The Company recorded interest expense related to the borrowings of $1.2 million and $1.1 million for the years ended December 31, 2014 and 2013. 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, 2014, 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 10%.

Future payments as of December 31, 2014 under the Agreement, assuming no adjustments to the variable rate of interest of 9% as of December 31, 2014, are as follows (in thousands):

2015	5,947
2016	5,909
Total minimum payments	11,856
Less amount representing interest	(1,067)
Notes payable, gross	10,789
Discount on notes payable	(53)
Accretion of the final exit fee payment	192
Carrying value of notes payable	$ 10,928

7. Warrants to Purchase Common Stock

On June 19, 2013, in connection with the Amendment to its debt agreement with MidCap Financial, the Company issued a warrant to purchase up to 49,548 shares of the Company's common stock with an exercise price of $12.11 per share. The warrant expires in June 2023. The Company recorded the initial value of the warrants in equity and other assets in the accompanying consolidated balance sheet, with the deferred other asset to be amortized over the remaining term of the debt using the effective interest method.

In addition, the Company has outstanding warrants to purchase an aggregate of 38,997 shares of common stock at $5.13 per share which will expire on October 31, 2015.

8. Commitments and Contingencies

Operating Leases

The Company's noncancelable operating lease for its former facilities in South San Francisco, California expired in June 2014. In connection with the lease, the Company has issued a standby letter of credit for approximately $0.2 million for the deposit requirement under the terms of the lease. The Company was 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 had been included in deferred rent in

KaloBios Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

the accompanying balance sheets and was being amortized over the term of the lease, on a straight-line basis. Rent expense is recognized on a straight-line basis over the term of the lease.

In December 2013, the Company entered into a lease agreement for a new facility in South San Francisco, California. The new lease commenced in July 2014 and will expire in 2019. The Company moved into the new premises in June 2014 and received a rent holiday so that rental payments did not start until October 2014. Per the terms of the lease agreement, the Company has the option to terminate the lease after 36 months, subject to additional fees and expenses. If the Company elects not to terminate the lease, it will receive a rent holiday in July 2017 and August 2017. At the end of the five year term of the new lease, the Company has the option to extend its term for an additional five years at the then current fair market value rental rate determined in accordance with the terms of the Lease.

As of December 31, 2014, future minimum lease payments due under our lease are as follows:

(in thousands)	
2015	$ 700
2016	759
2017	680
2018	843
2019	428
Total	$ 3,410

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 second sublease agreement with another third party to sublease a portion of the Company's facility in South San Francisco, California. The sublease had a 28 month term that began March 1, 2012 and ended June 2014. Under the agreements, the Company received sublease payments of $553,000 in 2014. The sublease income received is recorded as an offset to the Company's rent expenses.

Rent expense, net of sublease income, was $0.4 million, nil and $0.1 million for the years ended December 31, 2014, 2013 and 2012, respectively. Sublease income was $0.6 million, $1.1 million and $1.0 million for the years ended December 31, 2014, 2013 and 2012, 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.

KaloBios Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

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.

9. Stockholders' Equity

Initial Public Offering

The Company closed its initial public offering 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 (comprised of $4.9 million in underwriting discounts and commissions and $3.6 million in other offering expenses).

Shelf Registration

In September 2013, the Company filed a shelf registration statement on Form S-3 with the SEC. The Shelf Registration was declared effective by the SEC on September 18, 2013 and permitted the Company to sell, from time to time, up to $100.0 million of common stock, warrants/and or units in one or more offerings and in any combination.

Common Stock Offering

In October 2013, under the Shelf Registration, the Company issued and sold 8,625,000 shares of the Company's common stock. The price to the public in this offering was $4.00 per share for gross proceeds of $34.5 million, including the exercise of the overallotment option by the underwriters, which resulted in net proceeds of approximately $32.0 million, after underwriting and other expenses of approximately $2.5 million (comprised of $2.1 million in underwriting discounts and commissions and $0.4 million in other expenses).

Preferred Stock

In February 2013, upon the closing of the IPO the Company amended and restated its certificate of incorporation to authorize zero shares of preferred stock upon the completion of its IPO.

Common Stock

In February 2013, the Company amended and restated its certificate of incorporation to increase the authorized common stock to 47,500,000 shares upon the completion of the IPO of its common stock.

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Notes to Consolidated Financial Statements (Continued)

The Company had reserved the following shares of common stock for issuance as of December 31, 2014:

Warrants to purchase common stock Options:	88,545
Outstanding under the 2012 Equity Incentive Plan	2,122,000
Outstanding under the 2001 Equity Incentive Plan	555,774
Available for future grants under the 2012 Equity Incentive Plan	1,218,925
Total common stock reserved for future issuance	3,985,244

2012 Equity Incentive Plan

In July 2012, the Company's board of directors adopted the 2012 Equity Incentive Plan (2012 Plan). Under the 2012 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 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 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 Plan. The 2012 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 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 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.

2001 Equity Incentive Plan

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.

Upon the 2012 Equity Incentive Plan taking effect, the 2001 Plan was thereafter 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.

2012 Employee Stock Purchase Plan

The Employee Stock Purchase Plan, or ESPP provides eligible employees with the opportunity to acquire an ownership interest in the Company through periodic payroll deductions, based on a six-month look-back period, at a price equal to the lesser of 85% of the fair market value of the ordinary shares at either the beginning or ending of the relevant offering period. The ESPP is structured as a qualified employee stock purchase plan under Section 423 stock bonus plan under Section 401(a) of the Internal Revenue Code of 1986 and is not subject to the provisions of the Employee Retirement Income Security Act of 1974. The ESPP will terminate on January 15, 2033 unless sooner terminated. There were 168,469 shares initially authorized for issuance under the plan, and the first offering period commenced on June 1, 2014 and ended on October 31, 2014. The second offering period commenced on November 1, 2014 and will end on April 30, 2015.

Stock Option Activity

The following table summarizes stock option activity for the year ended December 31, 2014:

	Number of Shares	Weighted-Average Exercise Price (Per Share) (1)	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands) (2)
Balances at December 31, 2013	1,820,784	$ 4.46		
Options granted	1,298,500	4.24		
Options forfeited	(258,969)	5.81		
Options expired	(126,123)	5.49		
Options exercised(3)	(56,418)	1.17		
Balances at December 31, 2014	2,677,774	4.24	5.60	$ 239
As of December 31, 2014:				
Options vested and expected to vest(4)	2,407,005	4.22	5.56	$ 234
Exercisable	1,172,747	3.93	5.05	$ 215

(1) The weighted average price per share is determined using exercise price per share for stock options.

(2) The aggregate intrinsic value is calculated as the difference between the exercise price of the option and the fair value of our common stock for in-the-money options at December 31, 2014.

(3) The total intrinsic value of stock options exercised was $187,000, $787,000 and $607,000 for the years ended December 31, 2014, 2013 and 2012.

KaloBios Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

(4) The stock options outstanding and exercisable by exercise price at December 31, 2014 are as follows:

	Stock Options Outstanding			Stock Options Exercisable	
Range of Exercise Prices	Number of Shares	Weighted-Average Remaining Contractual Life In Years	Weighted-Average Exercise Price Per Share	Number of Shares	Weighted-Average Exercise Price Per Share
$0.50 - $1.85	537,787	4.68	$ 1.29	351,235	$ 1.12
$1.87 - $4.74	644,987	6.05	$ 3.41	255,641	$ 3.68
$5.25 - $5.41	755,000	5.30	$ 5.39	177,391	$ 5.38
$5.57 - $6.00	710,000	6.10	$ 5.93	374,730	$ 5.95
$6.42 - $6.42	30,000	8.19	$ 6.42	13,750	$ 6.42
	2,677,774	5.60	$ 4.24	1,172,747	$ 3.93

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 for the year ended December 31, 2012 related to these stock awards.

The total fair value of options vested for the years ended December 31, 2014, 2013 and 2012 were $3.2 million, $1.6 million and $97,000, respectively.

Stock-Based Compensation

Our stock-based compensation expense for stock options is estimated at the grant date based on the award's fair value as calculated by the Black-Scholes option pricing model and is recognized as expense over the requisite service period. The Black-Scholes option pricing model requires various highly judgmental assumptions including expected volatility and expected term. The expected volatility is based on the historical stock volatilities of several of our publicly listed peers over a period equal to the expected terms of the options as we do not have a sufficient trading history to use the volatility of our own common stock. To estimate the expected term, we have opted to use the simplified method which is the use of the midpoint of the vesting term and the contractual term. If any of the assumptions used in the Black-Scholes option pricing model changes significantly, stock-based compensation expense may differ materially in the future from that recorded in the current period. In addition, we are required to estimate the expected forfeiture rate and only recognize expense for those shares expected to vest. We estimate the forfeiture rate based on historical experience and our expectations regarding future pre-vesting termination behavior of employees. The Company reviews its estimate of the expected forfeiture rate annually, and stock-based compensation expense is adjusted accordingly.

The weighted-average fair value-based measurement of stock options granted under the Company's stock plans in the years ended December 31, 2014, 2013, and 2012 were $2.73, $3.03 and $6.98 per share, respectively. The fair

KaloBios Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

value- based measurement of 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,		
	2014	2013	2012
Expected term	6 years	6 years	6 years
Expected volatility	68 - 76%	57 - 59%	57 - 59%
Risk-free interest rate	1.8 - 1.9%	0.9 - 2.1%	0.8 - 1.4%
Expected dividend yield	0%	0%	0%

Total stock-based compensation expense recognized was as follows:

	Year Ended December 31,		
(In thousands)	2014	2013	2012
General and administrative	$1,026	$ 731	$423
Research and development	987	709	398
	$2,013	$1,440	$821

At December 31, 2014, the Company had $3.4 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 2.5 years.

10. Income Taxes

No provision for federal income taxes has been recorded for the years ended December 31, 2014, 2013 and 2012.

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,	
	2014	2013
Deferred tax assets:		
Net operating losses	$ 37,715	$ 53,099
Research & other credits	1,527	2,227
Other	2,172	1,447
Total deferred tax assets	41,414	56,773
Valuation allowance	(41,414)	(56,773)
Net deferred tax assets	$ —	$ —

KaloBios Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

A reconciliation of the statutory tax rates and the effective tax rates for the years ended December 2014, 2013, and 2012 is as follows:

	Year Ended December 31,		
	2014	2013	2012
Statutory rate	34 %	34 %	34 %
Valuation Allowance	(33.3)%	(33.8)%	(33)%
Nondeductible Stock Compensation	(0.7)%	(0.2)%	(0.6)%
Effective tax rate	— %	— %	— %

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 decreased by $15.4 million during 2014 and increased by $16.6 million and $9.2 million during 2013 and 2012, respectively.

At December 31, 2014, the Company had federal net operating loss carryforwards of approximately $168.5 million, which expire in the years 2025 through 2034, and state net operating loss carryforwards of approximately $168.5 million, which expire in the years 2015 through 2034.

At December 31, 2014, the Company had federal research and development credit carryforwards of approximately $2.8 million, which expire in the years 2022 through 2034 and state research and development credit carryforwards of approximately $2.0 million. The state research and development credit carryforwards can be carried forward indefinitely.

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 adopted Financial Accounting Standards Board Interpretation ASC 740, Income Taxes (previously Accounting for Uncertainties in Income Taxes - an interpretation of FASB Statement No. 48 ("FIN 48") effective January 1, 2009. FASB ASC 740 requires that the Company recognize 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.

KaloBios Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

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

Beginning at January 1, 2012	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
Additions based on tax positions related to prior year	18
Additions based on tax positions related to current year	109
Balance at December 31, 2013	1,196
Additions based on tax positions related to current year	297
Balance at December 31, 2014	$ 1,493

There were no interest or penalties related to unrecognized tax benefits. Substantially all of the unrecognized tax benefit, if recognized to offset future taxable income would affect the Company's tax rate. The Company does not anticipate that the amount of existing unrecognized tax benefits will significantly increase or decrease within the next 12 months. Because of net operating loss carryforwards, substantially all of the Company's tax years remain open to federal tax and state tax examination.

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.

11. 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.

12. Subsequent Event

In January 2015, the Company announced preliminary top-line data from the 182 patient Phase 2 study of KB001-A in CF patients with Pa lung infections. The study failed to meet its primary endpoint as there was no notable improvement in the time to need antibiotics between patients treated with KB001-A and those treated with placebo. In addition, there was no clinically significant improvement in patient reported outcomes or in FEV1 over the course of the study, both of which were secondary endpoints in the study. As a result of this outcome, the Company discontinued development of KB001-A as a treatment for Pa lung infections in CF patients and is evaluating the potential to out-license KB001-A as it no longer aligns with the Company's revised strategic focus in oncology therapeutics. As a result of this outcome, and the resulting shift in operating focus, the Company elected to terminate certain committed manufacturing activities with external contract manufacturing organizations, or CMOs on certain of its programs. As a result of the termination of these activities, the Company recorded charges of $1.6 million in the fiscal 2014 financial statements representing estimated termination costs for those contractual commitments relating to that manufacturing activity that no longer has identifiable future benefit to the Company.

KaloBios Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

13. Quarterly Financial Data (unaudited)

The following tables summarize the unaudited quarterly financial data for the last two fiscal years (in thousands, except per share data):

	2014 Quarter Ended			
	March 31,	June 30,	September 30,	December 31,
Total revenue	$ —	$ —	$ —	$ —
Loss from operations	(10,160)	(9,534)	(7,709)	(9,315)
Net loss	(10,408)	(9,814)	(8,063)	(9,713)
Basic and diluted net loss per common share	$ (0.32)	$ (0.30)	$ (0.24)	$ (0.29)
Weighted average common shares outstanding used to calculate basic and diluted net loss per common share	32,966,471	32,981,396	32,981,725	32,987,354

	2013 Quarter Ended			
	March 31,	June 30,	September 30,	December 31,
Total revenue	$ 16	$ 15	$ 9	$ 4
Loss from operations	(8,323)	(11,571)	(11,087)	(9,928)
Net loss	(8,574)	(11,809)	(11,329)	(10,236)
Basic and diluted net loss per common share	$ (0.55)	$ (0.49)	$ (0.47)	$ (0.31)
Weighted average common shares outstanding used to calculate basic and diluted net loss per common share	15,607,379	24,189,819	24,263,745	32,925,194

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/ Herb C. Cross
Herb C. Cross
Interim Chief Executive Officer, and Chief Financial Officer

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Herb Cross, as his true and lawful attorney-in-fact and agent, 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 attorney-in-fact and agent, 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 attorney-in-fact and agent and 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/ Herb C. Cross Herb C. Cross	Interim President, Chief Executive Officer and Chief Financial Officer (Principal Executive Officer and Principal Financial and Accounting Officer)	March 16, 2015
/s/ Ted W. Love, M.D. Ted W. Love, M.D.	Director, Chairman of the Board	March 16, 2015
/s/ Denise Gilbert, Ph.D. Denise Gilbert, Ph.D.	Director	March 16, 2015
/s/ Laurie Smaldone Alsup, M.D. Laurie Smaldone Alsup, M.D.	Director	March 16, 2015
/s/ Gary Lyons Gary Lyons	Director	March 16, 2015
/s/ Robert A. Baffi, Ph.D., MBA Robert A. Baffi, Ph.D., MBA	Director	March 16, 2015
/s/ Raymond M. Withy, Ph.D. Raymond M. Withy, Ph.D.	Director	March 16, 2015

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, by and between the Registrant and MidCap Financial SBIC, LP, dated as of September 5, 2012
4.4(9)	Warrant to Purchase Stock, by and between the Registrant and MidCap Financial SBIC, LP, dated as of June 19, 2013.
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
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

10.37(10)*	Form of Notice of Grant and Stock Option Agreement under the 2012 Equity Incentive Plan (Outside Directors)
10.38(10)*	Incentive Bonus Plan
10.39(10)*	Employment Agreement, dated March 12, 2014, by and between the Registrant and David W. Pritchard
10.40(10)*	Employment Agreement, dated March 12, 2014, by and between the Registrant and Herb C. Cross
10.41(10)*	Employment Agreement, dated March 12, 2014, by and between the Registrant and Donald R. Joseph
10.42(10)*	Employment Agreement, dated March 12, 2014, by and between the Registrant and Geoffrey T. Yarranton
10.43(10)	Lease, dated December 6, 2013, by and between Bayside Acquisition, LLC and the Registrant
10.44(9)	Amendment No. 1 to Loan and Security Agreement, by and between KaloBios Pharmaceuticals, Inc. and MidCap Financial SBIC, LP, dated as of June 19, 2013
10.45(11)*	Amended and Restated Employment Agreement, dated April 28, 2014, by and between the Registrant and David W. Pritchard.
10.46(11)*	Amended and Restated Employment Agreement, dated April 28, 2014, by and between the Registrant and Herb C. Cross.
10.47(11)*	Amended and Restated Employment Agreement, dated April 28, 2014, by and between the Registrant and Donald R. Joseph.
10.48(11)*	Amended and Restated Employment Agreement, dated April 28, 2014, by and between the Registrant and Geoffrey T. Yarranton.
10.49(11)*	Employment Agreement, dated April 28, 2014, by and between the Registrant and Nestor A. Molfino.
10.50(11)	Amendment to License Agreement, dated October 9, 2008, by and between the Registrant and the Ludwig Institute for Cancer Research.
10.51(11)	Amendment to License Agreement, dated June 8, 2011, by and between the Registrant and the Ludwig Institute for Cancer Research.
10.52(12) †	Termination Agreement, by and between KaloBios Pharmaceuticals Inc. and Sanofi Pasteur S.A., dated as of July 24, 2014.
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
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.

(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

(9) Filed as an exhibit to Registrant's Current Report on Form 8-K (File No. 001-35798) filed on June 24, 2013.

(10) Filed as an exhibit to Registrant's Annual Report on Form 10-K (File No. 001-35798) filed on March 13, 2014.

(11) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q (File No. 001-35798) filed on May 8, 2014.

Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q (File No. 001-35798) filed on November 6, 2014.

EXHIBIT 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statement (Form S -3 No. 333-190972) of KaloBios Pharmaceuticals, Inc. and in the related Prospectuses and 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 16, 2015, 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, 2014.

/s/ Ernst & Young LLP

Redwood City, California
March 16, 2015

Exhibit 31.1

CERTIFICATIONS

I, Herb C. Cross, 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (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 16, 2015

/s/ Herb C. Cross
Herb C. Cross
Interim Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS

I, Herb C. Cross, 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (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 16, 2015

/s/ Herb C. Cross
Herb C. Cross
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, 2014 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Herb C. Cross, the Interim 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 16, 2015

/s/ Herb C. Cross
Herb C. Cross
Interim 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, 2014 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Herb Cross, the 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 16, 2015

/s/ Herb C. Cross
Herb C. Cross
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.