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, 2015
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.)

1000 Marina Boulevard, Ste. 250
Brisbane, CA 94005
(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:
None.

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

Common Stock, $0.001 par value.

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 ☒

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Section 12, 13 or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court. Yes ☐ No ☒

The aggregate market value of the registrant's voting stock held by non-affiliates as of June 30, 2015 was approximately $13,689,280 based on the closing price of $3.84 of the Common Stock of the registrant as reported on the NASDAQ Global Market on such date, as adjusted to account for the registrant's one-for-eight reverse stock split. As of August 30, 2016, there were 14,897,993 shares of the registrant's Common Stock, par value $0.001 per share, outstanding.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains statements that discuss that discuss future events or expectations, projections of results of operations or financial condition, trends in our business, business prospects and strategies and other "forward-looking" information. In some cases, you can identify "forward-looking statements" by words like "may," "will," "should," "expects," "plans," "anticipates," "believes," "estimates," "predicts," "intends," "potential" or "continue" or the negative of those words and other comparable words. These statements may relate to, among other things, our expectations regarding the scope, progress, expansion, and costs of researching, developing and commercializing our product candidates; our intent to in-license or acquire additional product candidates; our opportunity to benefit from various regulatory incentives and the application of our Responsible Pricing Model; expectations for our financial results, revenue, operating expenses and other financial measures in future periods; and the adequacy of our sources of liquidity to satisfy our working capital needs, capital expenditures, and other liquidity requirements. Actual events or results may differ materially due to known and unknown risks, uncertainties and other factors such as:

- *the uncertainties inherent in the development and launch of any new pharmaceutical product;*
- *our ability to successfully and timely complete clinical trials for our drug candidates in clinical development;*
- *our ability to obtain the necessary U.S. and international regulatory approvals for our drug candidates and to qualify for or benefit from various regulatory incentives;*
- *the scope and validity of intellectual property and other competitive protection for our drug candidates;*
- *our ability to identify, in-license and acquire additional product candidates or to form partnerships for the sale, licensing, collaborative development or marketing of our existing product candidates;*
- *our ability to maintain or engage third-party manufacturers to manufacture, supply, store and distribute supplies of our drug candidates for our clinical trials;*
- *our lack of profitability and the need for additional capital to operate our business; and*
- *the success of any product.*

These are only some of the factors that may affect the forward-looking statements contained in this annual report. For a discussion identifying additional important factors that could cause actual results to vary materially from those anticipated in the forward-looking statements, see "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Risk Factors" in this Annual Report on Form 10-K. You should review these risk factors for a more complete understanding of the risks associated with an investment in our securities. However, we operate in a competitive and rapidly changing environment and new risks and uncertainties emerge, are identified or become apparent from time to time. It is not possible for us to predict all risks and uncertainties that could have an impact on the forward-looking statements contained in this annual report. You should be aware that the forward-looking statements contained in this annual report are based on our current views and assumptions. We undertake no obligation to revise or update any forward-looking statements made in this annual report to reflect events or circumstances after the date hereof or to reflect new information or the occurrence of unanticipated events, except as required by law. The forward-looking statements in this annual report are intended to be subject to protection afforded by the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

PART I

ITEM 1. BUSINESS

Overview

We are a biopharmaceutical company focused on developing medicines for patients with neglected and rare diseases, with an ancillary focus on pediatric conditions, and on executing our Responsible Pricing Model in the commercialization of our products that may be approved. Our lead product candidate is benznidazole for the treatment of Chagas disease, a parasitic illness that can lead to long-term heart, intestinal and neurological problems. We are developing one of our proprietary monoclonal antibodies, lenzilumab (formerly known as KB003), for the treatment of chronic myelomonocytic leukemia, or CMML, and potentially for the treatment of juvenile myelomonocytic leukemia, or JMML, both of which are rare hematologic cancers with high unmet medical need. We are exploring development of another of our proprietary monoclonal antibodies, ifabotuzumab (formerly known as KB004), for the treatment of certain rare solid and hematologic cancers. With a focus on neglected, rare and orphan diseases, we believe we have the opportunity to benefit from various regulatory incentives, such as orphan drug exclusivity, breakthrough therapy designation, fast track designation, accelerated approval, priority review and priority review vouchers, or PRV, where available, that provide for certain periods of exclusivity, expedited review and/or other benefits.

Upon approval of any of our products, we intend to apply our Responsible Pricing Model, which focuses on affordability for patients and payers, transparency for all stakeholders, and delivery of a reasonable return in recognition of the risks we are taking in our development efforts.

Benznidazole is an oral small molecule antiprotozoal for the treatment of Chagas disease, which is also known as American trypanosomiasis. Benznidazole has undergone numerous clinical trials and studies that show efficacy against Chagas disease and we believe is the current preferred treatment for Chagas disease in the countries where it is approved. No treatments for Chagas disease are approved by the United States Food and Drug Administration, or FDA, for use in the United States. On June 30, 2016, we acquired certain worldwide rights relating to benznidazole for human use from Savant Neglected Diseases, LLC, or Savant, and we are focused on the development necessary to seek and obtain FDA approval of benznidazole. We believe benznidazole as a treatment for Chagas disease could qualify for priority review and potentially other FDA regulatory incentives, and to receive a PRV if FDA approves the drug for marketing.

Lenzilumab is a recombinant monoclonal antibody, or mAb, that neutralizes soluble granulocyte-macrophage colony-stimulating factor, or GM-CSF, a critical cytokine for the growth of certain hematologic malignancies and solid tumors. Consistent with our strategic focus on neglected and rare diseases, in July 2016, we initiated dosing in a Phase 1 clinical trial in patients with CMML to identify the maximum tolerated dose, or MTD, or recommended Phase 2 dose of lenzilumab and to assess lenzilumab's safety, pharmacokinetics, and clinical activity.

Ifabotuzumab is an anti-EphA3 mAb that has the potential to offer a novel approach to treating both solid tumors and hematologic malignancies. EphA3 is aberrantly expressed on the tumor cell surface of certain cancers. We have completed the Phase 1 dose escalation portion of a Phase 1/2 clinical trial in ifabotuzumab in multiple hematologic malignancies and are evaluating whether to conduct further studies of ifabotuzumab in rare solid tumors such as glioblastoma, other brain cancers in children and rare hematologic cancer indications. We also have an additional drug candidate, KB001-A, a recombinant, PEGylated, anti-Pseudomonas PcrV high-affinity Fab' antibody that we are no longer developing, but which is being considered for partnering or out-licensing.

Lenzilumab, ifabotuzumab and KB001-A were each developed with our proprietary, patent-protected Humaneered® technology, which consists of methods for converting antibodies (typically murine) into engineered, high-affinity antibodies designed for human therapeutic use, typically for chronic conditions.

Our strategy also involves identifying, acquiring, developing and supporting the commercialization of additional treatments for neglected and rare diseases. We believe the treatment of neglected and rare diseases represents an opportunity to enter underserved patient populations and serve specialty markets. We also believe our focus on neglected and rare diseases provides us the opportunity to benefit from various regulatory incentives referenced above. The potential opportunities afforded by these regulatory programs provide an important incentive to support our efforts to develop medicines for patients with neglected and rare diseases and to apply our Responsible Pricing Model for any of our approved products.

Our company has undergone a significant transformation in the last year. As a result of challenges facing us at the time, on December 29, 2015, we filed a voluntary petition for bankruptcy protection under Chapter 11 of Title 11 of the U.S. Bankruptcy Code. On June 30, 2016, our Second Amended Plan of Reorganization, dated May 9, 2016, as amended, or the Plan, became effective and we emerged from our Chapter 11 bankruptcy proceedings. For further information on our bankruptcy and emergence from bankruptcy, see "Bankruptcy."

Our Strategy

We are a biopharmaceutical company focused on developing medicines for patients with neglected and rare diseases and using our Responsible Pricing Model for our products that may be approved, with an ancillary interest in pediatric conditions. We plan to achieve our objectives through the following strategies, which we believe reflect an innovative and responsible business model that differentiates our approach from more traditional approaches used by drug development companies:

- ***Develop and support the commercialization of benznidazole for the treatment of the neglected Chagas disease.*** We believe that benznidazole as a treatment for Chagas disease is a model opportunity to deliver on our strategy to provide treatments for patients with neglected and rare diseases. Chagas disease affects an estimated 8 to10 million people globally, including approximately 300,000 or more people in the United States according to U.S. Centers for Disease Control estimates, and is responsible for an estimated 12,500 annual global deaths. Nevertheless, there are currently no approved drugs in the United States for the treatment of Chagas disease. We believe that manufacturing issues have in the past led to an uncertain and inconsistent worldwide drug supply of benznidazole. On June 30, 2016, we acquired certain worldwide rights related to benznidazole for human use from Savant. We are now working to develop benznidazole for the treatment of Chagas disease in order to seek and obtain FDA approval. We believe that benznidazole is eligible for approval under Section 505(b)(2) of the U.S. Federal Food, Drug, and Cosmetic Act, or the FDCA, pursuant to which an applicant may rely on investigations not conducted by or for the applicant to show that a drug is safe and effective. We also believe that benznidazole is eligible for a five-year period of marketing exclusivity as a new chemical entity, if approved, under the Drug Price Competition and Patent Term Restoration Act, commonly referred to as the Hatch-Waxman Act. We may also seek orphan drug designation for benznidazole, which could confer seven years of marketing exclusivity. In addition, since Chagas disease is listed by FDA as a Neglected Tropical Disease, we may receive a PRV if our version of benznidazole is the first version approved by FDA.

- ***Develop and support the commercialization of lenzilumab for the treatment of CMML and potentially JMML.*** Lenzilumab has shown a favorable safety profile to date and has been studied in more than 90 human subjects in clinical studies in either healthy adults or adults with autoimmune diseases. We completed Phase 1 and Phase 1/2 clinical trials of lenzilumab's precursor, KB002, a Phase 2 clinical trial of lenzilumab in patients with severe asthma and the run-in safety portion of a Phase 2 clinical trial in patients with rheumatoid arthritis, but no longer plan to develop lenzilumab for these indications. In July 2016, we initiated dosing in a Phase 1 clinical trial in patients with CMML to identify the MTD or recommended Phase 2 dose of lenzilumab and to assess lenzilumab's safety, pharmacokinetics, and clinical activity. Depending on the initial results in CMML, we plan to study lenzilumab in JMML, a rare pediatric form of leukemia, where the primary treatment alternative in some patients is a bone marrow stem cell transplant. We believe that both CMML and JMML would qualify as orphan conditions, and we intend to seek orphan designation for this product for these conditions. Further, if FDA agrees that JMML is a rare pediatric disease, we may receive a PRV if lenzilumab is approved by FDA for use in JMML.

- ***Evaluate development of ifabotuzumab for the treatment of rare adult and pediatric solid tumors and hematologic cancers.*** Prior to our bankruptcy and reorganization, we began enrolling patients in the Phase 2 cohort expansion portion of our Phase 1/2 clinical trial for ifabotuzumab as a potential therapeutic for myelodysplastic syndrome, or MDS, and myelofibrosis. We suspended this study in connection with our bankruptcy and reorganization. Consistent with our strategic focus, we are now evaluating opportunities to study the use of ifabotuzumab in rare solid tumors like glioblastoma, pediatric cancers and certain rare hematologic cancer indications. We believe that some of these conditions would qualify as Orphan conditions, and if we develop ifabotuzumab we would submit the product for orphan designation for this product for these conditions. Further, if FDA agrees that the pediatric uses qualify as rare pediatric diseases, we may receive a PRV if ifabotuzumab is approved by FDA for use in these rare pediatric conditions.

- ***In-license or acquire additional products and product candidates that align with our mission to treat neglected and rare diseases***. We intend to identify and in-license or acquire additional product candidates across various stages of development that treat neglected and rare diseases, including pediatric conditions. With this strategic focus, we believe we will have the opportunity to benefit from various regulatory incentives, such as orphan drug designations and exclusivities, PRVs where available, and FDA's expedited programs, such as breakthrough therapy designation and priority review. The Orphan Drug Act provides incentives for the development of drugs and biological products intended to treat rare diseases or conditions, which generally are diseases or conditions affecting less than 200,000 individuals in the United States, or those affecting more than that number but for which there is no reasonable expectation that the cost of developing and making the drug available in the United States for such disease or condition will be recovered from sales in the United States of such drug. If a sponsor demonstrates that a drug or biologic is intended to treat a rare disease or condition, FDA generally grants orphan drug designation to the product for that use, as long as other requirements are met, including that the drug is not the same drug as an already approved drug for the same rare disease or condition. The benefits of orphan drug status include research and development tax credits, exemption from user fees, and if the sponsor is the first to obtain approval for that drug product for the rare disease or condition, seven years of exclusivity during which FDA generally may not approve any other application for the same product for the same indication, and while we do not know if it will be the case for any product candidates that we pursue, product candidates with orphan designations appear to have higher rates of approval, faster trials and shorter FDA review time. Under the FDCA, FDA is also authorized to award a PRV upon the approval of a new drug application, or NDA, or a biologic license application, or BLA, for neglected tropical disease and rare pediatric disease product candidates that meet certain criteria. PRVs can be used for the acceleration of review and approval of a different product candidate by several months. A PRV may be used by the sponsor that obtains it or it may be sold or transferred to another sponsor that may use it to obtain priority review for a different application. We may also seek product candidates that could qualify for FDA's expedited programs, namely priority review, fast track, breakthrough therapy and accelerated approval, or for regulatory exclusivities and other incentives provided for new chemical entities and qualified infectious disease products. The opportunity and benefits of these programs provide an important incentive to support our efforts to develop medicines for patients with neglected and rare diseases and in certain instances provide us with multiple paths for value creation.

- ***When products are approved for marketing, apply our Responsible Pricing Model***. We intend to responsibly price any approved products. We define 'responsible pricing' as affordable for patients and payers, transparent for stakeholders, and delivering a reasonable return for us and our shareholders. We plan to price our products at overall cost, plus a reasonable and transparent profit margin, if and when they are approved. We will intend to publicly share the key elements that make up the pricing of our products and seek input from key stakeholders on what would constitute a reasonable return. We do not intend to take arbitrary price increases on our products and plan to limit any increase to no more than the rate of inflation or Consumer Price Index and to no more than once a year, if at all. With respect to benznidazole, we plan to ensure patients, irrespective of their ability to pay, will have access to benznidazole, if and when we receive approval of benznidazole for the treatment of Chagas disease in the United States. In developing countries, we plan to make benznidazole available at or near cost and plan to work with partners on creating access programs to ensure patients in need receive the medication.

- ***Seek impact and socially responsible investors as additional funding sources.*** To date, we have only recognized revenue from payments for funded research and development and for license or collaboration fees and have relied on private and public financing sources to fund our operations. As a means to further our strategy, we also intend to seek impact and socially responsible investors whose interests align with our mission and strategies. Impact and socially responsible investment, or SRI, aims to maximize both financial gain and social good, including through the promotion of consumer protection and human rights. Access to SRI sources continues to grow. According to The Forum for Sustainable and Responsible Investment, total U.S.-domiciled assets under management using SRI strategies increased 76 percent from $3.74 trillion at the start of 2012 to $6.57 trillion at the start of 2014 alone.

Benznidazole

Overview

Benznidazole is an oral small molecule antiprotozoal nitroimidazole derivative for the treatment of Chagas disease that has undergone decades of real-world treatment outside the United States and numerous clinical tests and studies. Chagas disease is a parasitic disease typically transmitted by insects, sometimes by congenital (mother-to-child) transmission during pregnancy, blood transfusions or infected organ transplants, and rarely through oral ingestion of the parasite. While many cases are asymptomatic during the acute phase of the infection which can last several weeks, up to approximately a third of people infected may develop serious complications 10 to 30 years following infection and where people have symptoms, they can persist for years and range from mild to deadly. The disease affects millions of people in the Americas, including an estimated 300,000 in the United States for all phases of the disease. We believe benznidazole is the preferred treatment for Chagas disease where it is approved, but it is not approved for marketing in the United States. Based on clinical trials outside of the United States, we believe that benznidazole has been shown to be a useful treatment for Chagas disease in the majority of acute phase patients, particularly children, and studies conducted outside the United States suggest possible benefits in some chronically infected patients. On June 30, 2016, we acquired certain worldwide rights relating to benznidazole for human use from Savant. We are working to obtain FDA approval for benznidazole for the treatment of Chagas disease.

Chagas Disease

Chagas disease is a parasitic disease caused by the protozoan *Trypanosoma cruzi*, or *T. cruzi*. The disease is typically transmitted through the feces of the triatomine bug, commonly known as the kissing bug. Transmission may occur in connection with a bite from this bug. Chagas disease may also be transmitted from mother-to-child transmission during pregnancy or through blood transfusions or infected organ transplants. Chagas has acute and chronic stages and is sometimes symptomless. Some infected individuals develop clinical symptoms in a four-to-eight week period following infection. This mild acute phase is typically characterized by non-specific flu-like and other symptoms such as fever and malaise. The acute stage is not associated with symptoms at all in a large majority of cases. However, during this phase, severe manifestations such as acute myocarditis or meningoencephalitis may also be experienced and in a small proportion of patients, especially children, can lead to serious consequences or death. After the acute phase, a chronic infection may persist for years or decades, again sometimes without symptoms. If left untreated, chronic Chagas disease may result in organ and tissue damage. Approximately 20 to 30% of chronic cases lead to serious complications, most commonly cardiac or intestinal, over the course of 10 to 30 years. Cardiac complications may include heart arrhythmias, chronic inflammation, conduction system damage and apical aneurysms. Up to 10% of chronic cases lead to severe damage to the digestive system, predominantly affecting the esophagus and/or colon. Some patients also develop neurological complications. In some cases, chronic Chagas disease may lead to premature death.

Chagas disease causes a substantial disease burden in Latin America and the United States. It has disproportionate effects on poor populations. An estimated 8 to10 million people are infected globally, and there are an estimated 300,000 infected individuals in the United States, at all stages of infection. The disease kills approximately 12,500 people annually. According to the Drugs for Neglected Diseases Initiative, cases have been increasing in other parts of the world, though World Health Organization, or WHO, studies showed a significant decline in certain Latin American countries from 1983 to 2000. While acute cases are relatively few in the United States, many cases may be undiagnosed. In addition, there are an estimated 30,000 to 45,000 Chagas-related cardiomyopathy cases in the United States. Cases have also been reported in Europe and Asia, with one study estimating the presence of between 68,000 and 123,000 infected individuals in Europe alone, with approximately half of these in Spain. Cases of Chagas disease have also been reported to be increasing in Japan, Canada and Australia, primarily as a result of migration patterns.

Efforts to control Chagas disease include efforts to control the vector insects, such as insecticide use and roof repair (the bugs often live in cracks in houses), efforts to protect people from kissing bug bites, including bed nets, as well as education and medication. However, despite the wide incidence and prevalence of Chagas disease, the WHO has designated Chagas disease a neglected tropical disease and FDA added it to the list of neglected tropical diseases in August 2015. There are currently no approved vaccines or preventative treatments for Chagas disease in the United States. Drugs currently used to treat Chagas disease are benznidazole and nifurtimox, which are currently only available in the United States through a compassionate use protocol from the CDC or through clinical trials.

Background and Mechanism of Action

Benznidazole was first introduced by a predecessor of Roche Holdings Ltd. in 1971. Roche later transferred the patent (which has since expired) and technology for benznidazole, as well as the benznidazole active pharmaceutical ingredient and tablets, to a Brazilian government-run laboratory, Laboratório Farmacêutico do Estado de Pernambuco, or LAFEPE. LAFEPE subsequently received approval for benznidazole production from the Brazilian government. LAFEPE developed a pediatric dosage in 2011. LAFEPE and the Argentine laboratory ELEA, which is affiliated with the Argentinian conglomerate Grupo Insud/Chemo Group, are the only current producers of benznidazole. ELEA uses the trade name Abarax for the drug. As third parties, including the advocacy group Doctors Without Borders, have noted, the worldwide drug supply of benznidazole has historically experienced manufacturing issues that have led to an uncertain and inconsistent worldwide drug supply.

Benznidazole acts by interfering with protein biosynthesis in *T. cruzi*. Benznidazole influences cytokine production and stimulates host phagocytosis. Reductive metabolites of benznidazole create highly-reactive oxygen species in *T. cruzi*, leading to alkylation and oxidative damage of vital elements such as DNA and RNA in the parasite.

Benznidazole has undergone numerous clinical trials, including trials conducted outside the United States and not under an investigational new drug application, or IND, with FDA. We believe these trials support safety and efficacy in the treatment of Chagas disease. Studies have shown that benznidazole may cure more than 60% of patients in the acute phase and 90% of congenitally infected infants in the first year of life. Two randomized, double-blind, placebo-controlled trials of benznidazole for children aged 6 to 12 years with asymptomatic *T. cruzi* infections demonstrated approximately 60% efficacy, as assessed by negative serology results 3 to 4 years after-treatment. In a 2006 non-randomized, non-blinded trial, benznidazole treatment appeared to slow the development and progression of Chagas cardiomyopathy in adults. The side effects of benznidazole include allergic dermatitis, peripheral nerve disorder, anorexia, weight loss, and insomnia.

Development Plans

As previously noted, no treatments for Chagas disease are currently approved for marketing in the United States. On June 30, 2016, we acquired from Savant certain regulatory and non-intellectual property assets relating to benznidazole and any product containing benznidazole and an exclusive license of certain intellectual property rights related to benznidazole. We are now working to obtain FDA approval for benznidazole for the treatment of Chagas disease based primarily on data in three categories: (1) clinical trials previously conducted by others for which we have obtained a right to access and use the underlying data, which we plan to analyze, organize, and present to FDA in an NDA; (2) clinical trials reported in the literature for which the underlying data may or may not have been submitted to FDA, and to which we have not obtained rights of access, use, or reference; and (3) to the extent required by FDA, bioavailability and/or bioequivalence studies and non-clinical studies that we will perform to bridge the clinical trial data described above using prior formulations of benznidazole to our current formulation, which we believe to be comparable to the prior formulations.

Based on our planned approach, we believe that benznidazole is eligible for approval under Section 505(b)(2) of the FDCA. Under that section, an applicant seeking approval of an NDA may rely in part or in whole on investigations not conducted by or for the applicant, and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted, to show that the applicant's drug is safe and effective. The second category of data described above, on which we anticipate relying to some extent in establishing benznidazole's safety and efficacy, consists of data to which we do not and will not have a contractual right of access, reference, or use, but which we may legally reference by virtue of the FDCA. Most of the data on which we intend to rely, however, are foreign clinical data to which we have obtained or plan to obtain a right of access and use, which we will analyze, organize, and present to FDA in an NDA, and that FDA will need to find acceptable together with the other data we present. Because the clinical safety and efficacy data on which we intend to rely were derived from studies using a prior formulation of benznidazole, as noted above in the description of the third category of data on which we anticipate relying, FDA may require us to perform bridging studies to confirm the comparability of our current formulation and the prior formulations. FDA may also require bridging studies to confirm the comparability of patient populations, medical practice, and other potential variables between the prior clinical trial conditions and the proposed conditions of use for the drug in the United States.

Although we believe our planned approach will provide FDA with sufficient clinical safety and efficacy data on which to base an approval, FDA may request additional information or data that we may not have and that we may not be able to obtain.

We also believe benznidazole would qualify as a new chemical entity, a designation that carries with it five years of exclusivity under the Hatch-Waxman Act upon approval. In addition, we may seek orphan drug designation for benznidazole. FDA has previously granted orphan drug designation to sponsors of both benznidazole and nifurtimox for treatment of Chagas disease, and we are continuing to evaluate our eligibility to obtain orphan drug designation for benznidazole in treating Chagas disease, based on current facts. Because an independent assessment is made by FDA each time that a sponsor requests orphan drug designation, there is no assurance that we will be granted that designation if we seek it. New chemical entity and orphan drug designations are further discussed in the "Government Regulation" section below.

We plan to ensure patients, irrespective of their ability to pay, will have access to benznidazole if and when we receive approval of benznidazole for the treatment of Chagas disease in the United States. The scope and availability of prescription drug insurance coverage, or other means to pay for pharmaceutical treatments, is uncertain for patients with Chagas disease in the United States. If we do not obtain approval for benznidazole in the United States, we may still make benznidazole available in developing countries. If we make benznidazole available in developing countries, we expect to make benznidazole available at or near cost in those countries and plan to work with partners to create access programs to ensure patients in need receive the medication.

In August 2015, FDA added Chagas disease to the list of designated neglected tropical diseases whose product applications, if approved, may result in the award of a PRV. We believe that the approval of benznidazole as a treatment for Chagas disease could result in the issuance of a PRV, which then could be used by us for a different product candidate or sold or transferred for other value to another sponsor that may use it to obtain priority review for its own product candidate. We consider the issuance of a PRV to be the largest potential value driver for benznidazole. The regulatory regime for PRVs is further discussed in the "Government Regulation" section below.

Lenzilumab

Overview and Mechanism of Action

Lenzilumab, which we previously referred to as KB003, is a recombinant antibody designed to target and neutralize human GM-CSF, a central actor in leukocyte differentiation, autoimmunity and inflammation. We used our proprietary and patented Humaneered antibody development platform to develop lenzilumab. We are currently developing lenzilumab for use in patients with CMML and plan to investigate its potential use in patients with JMML depending on the results of studies in CMML. The GM-CSF receptor is expressed on myeloblasts and other progenitor cells, and binding results in differentiation and maturation into monocytes. 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, excessive GM-CSF may be involved in tissue damage associated with inflammatory diseases. The results of anti-GM-CSF in ex-vivo studies suggest lenzilumab has potential in treating certain oncology conditions, including CMML and JMML, as well as asthma, chronic obstructive pulmonary disease, RA and multiple sclerosis.

Lenzilumab is a Humaneered version of KB002, a low picomolar affinity, novel chimeric mAb that we licensed from Ludwig Institute for Cancer Research, or LICR. Data from our single-dose, Phase 1 and Phase 1/2 clinical trials with KB002 supported our clinical trials with lenzilumab. In these studies, KB002 appeared to be well tolerated. Lenzilumab targets the same binding site as KB002 and has been shown to be functionally similar and appeared generally safe in our clinical trials. We conducted a repeat-dose, Phase 2 clinical trial of lenzilumab in RA with the inclusion of a safety run-in portion. On completing the run-in safety portion of this trial, which showed lenzilumab to be well tolerated with no clinically significant adverse events, we reassessed the increasingly competitive RA market and chose to redirect our study of lenzilumab to severe asthma patients inadequately controlled by corticosteroids. Results from a subsequent randomized, double-blinded, placebo-controlled, repeat dose, intravenous Phase 2 clinical trial of asthma trial showed that the primary endpoint was not met, although a significant effect was shown in certain pre-specified subgroups. As a result of these data, we terminated development of lenzilumab in asthma.

Development Program

We believe that lenzilumab holds particular promise in CMML, a rare form of hematologic cancer with no FDA-approved treatment options and a three-year overall survival rate of 20% and median overall survival of 20 months, and potentially JMML, a rare pediatric form of leukemia. CMML is a clonal stem cell disorder of which monocytosis is a key feature. CMML has features of MDS, including abnormal, dysplastic bone marrow cells; cytopenia; transfusion dependence; and of myeloproliferative neoplasms, including overproduction of white blood cells, organomegaly (e.g., splenomegaly and hepatomegaly) and extramedullary disease. About 15 to 20% of CMML cases progress to acute myeloid leukemia, or AML. According to the American Cancer Society, approximately 1,100 individuals in the United States are newly diagnosed annually with CMML, with the majority of these new patients being age 60 or older. These patients are typically unsuitable for stem cell transplants. Preclinical studies have shown lenzilumab can be used to cause apoptosis in CMML cells by depriving them of GM-CSF. Given our strategic focus on neglected and rare diseases, in July 2016, we initiated dosing in a Phase 1 clinical trial in patients with CMML to identify the MTD or recommended Phase 2 dose of lenzilumab and to assess lenzilumab's safety, pharmacokinetics, and clinical activity. The study will enroll up to 18 patients. Depending on the results of the CMML study, we also intend to investigate the potential treatment of the rarer JMML (approximately 420 new cases annually in the United States), which mostly affects children aged four and younger, with lenzilumab. We believe that lenzilumab may be eligible for a rare pediatric disease PRV if approved for JMML. We also believe lenzilumab in CMML or JMML could qualify for orphan drug designation and potentially several other FDA incentives.

An IND for a Phase 1/2 CMML monotherapy study of lenzilumab is now in effect. In July 2016, we began to enroll patients in a multicenter, open-label, repeat-dose, Phase 1 study consisting of a dose escalation phase and a dose expansion phase to evaluate the safety, pharmacokinetics, and clinical activity of lenzilumab in patients with previously-treated CMML who are no longer responsive to previous treatment. The primary endpoint of this study is the safety of lenzilumab, as measured by the number of participants with adverse events, at various doses in order to determine a recommended Phase 2 dose. The secondary endpoint is clinical activity of lenzilumab, as measured by changes in spleen size, blood and bone marrow measurements of disease, clinical symptoms and other measures.

Ifabotuzumab

Ifabotuzumab is a Humaneered mAb 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 ifabotuzumab prototype and EphA3 intellectual property.

Ifabotuzumab binds to the EphA3 receptor, which 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. EphA3 is a tyrosine kinase receptor 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. EphA3 expression has been documented in a number of tumor types, including AML, chronic myelogenous leukemia, chronic lymphocytic leukemia, MDS, myelofibrosis, multiple myeloma, melanoma, breast cancer, non-small cell lung cancer, colorectal cancer, gastric cancer, renal cancer, glioblastoma, and prostate cancer. Publications related to certain cancers have indicated that EphA3 tumor cell expression correlates with cancer growth and a poor prognosis.

Anti-EphA3 treatment has shown encouraging preclinical results in multiple experiment types, including patient primary tumor cell assays, colony forming assays, and xenograft mouse models. Upon binding to EphA3, ifabotuzumab causes cell killing to occur either through antibody-dependent, cell-mediated cytotoxity or through direct apoptosis, and in the case of tumor neovasculature through cell rounding and blood vessel disruption. Given the differential expression pattern of EphA3, ifabotuzumab may have the potential to kill cancer cells and the tumor stem cell microenvironment, providing for long-term responses while sparing normal cells. Prior to our bankruptcy, we were conducting a Phase 1/2 trial of ifabotuzumab in multiple hematologic malignancies.

The most common adverse event attributed to ifabotuzumab in our trial 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 or lysis of leukemic cells, and can be resolved with standard treatment. Under the original protocol of the dose escalation portion of our Phase 1/2 study, 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. After discussing the status of the trial with 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 FDA. Following those changes in 2011, there have been no additional events of drug related intracranial hemorrhage in our clinical studies of ifabotuzumab, including at doses higher than those tested prior to the protocol amendment.

In 2014, we completed the Phase 1 dose escalation portion of our study, primarily treating patients with AML as well as patients with MDS and myelofibrosis. Based on interim data from that study, we commenced dosing in the low-dose cohort of the Phase 2 portion in AML patients with EphA3 expression while we completed the dose escalation portion. In the second half of 2014, upon completion of the Phase 1 dose escalation portion, we announced 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 initial Phase 2 selected indications. In connection with our restructuring, we suspended enrollment in the study. However, consistent with our strategic focus, we are now evaluating opportunities to study the use of ifabotuzumab in rare adult and pediatric solid tumors, including glioblastoma, and certain rare hematologic cancer indications.

Our Humaneered Technology

Our proprietary and patented Humaneered technology platform is a method for converting existing antibodies (typically murine) into engineered, high-affinity human antibodies designed for therapeutic use, particularly for chronic conditions. We have developed or in-licensed targets or research (mouse) antibodies, typically from academic institutions, and then applied our Humaneered technology to them. Lenzilumab, ifabotuzumab and KB001-A are all Humaneered antibodies or antibody fragments. Together, our Humaneered antibodies have been tested clinically in more than 200 patients with no evidence of serious immunogenicity. We believe our Humaneered antibodies are closer to human antibodies than chimeric or conventionally humanized antibodies, are prone to being rejected less and may bind better to the target. Specifically, our Humaneered technology generates an antibody from an existing antibody with the required specificity as a starting point and, we believe, 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 we believe means our Humaneered antibodies are less likely to induce an inappropriate immune response in broad patient populations when used chronically than chimeric or conventionally humanized antibodies;
- 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.

In March 2007, we granted Novartis a non-exclusive license to our proprietary Humaneered technology after applying our Humaneered technology to several antibodies for them. Under the license agreement, Novartis is able to develop Humaneered antibodies to create its own therapeutics. We have also Humaneered antibodies to certain targets under predefined criteria for five U.S. and Japanese biotechnology and pharmaceutical companies 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. As we are focused on progressing our current portfolio of antibodies through clinical development and out-licensing, we are not currently dedicating additional resources to the research of additional Humaneered antibodies.

KB001-A

KB001-A is a Humaneered, PEGylated, anti-PcrV modified antibody fragment (Fab') antibody that was being developed for the prevention and treatment of *Pseudomonas aeruginosa,* or *Pa*, infections in mechanically ventilated patients and cystic fibrosis (CF), patients with chronic *Pa* lung infections. The only currently approved treatments for *Pa* are antibiotics, and while there is a broad array of available antibiotics, mortality and morbidity remains high due to bacterial antibiotic resistance, variable levels of antibiotic penetration into the target area and co-morbidities. 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. Initial Phase 1 and Phase 1/2 trials of KB001-A's precursor, KB001, and a Phase 1 trial of KB001-A did not show significant safety problems and indicated trends toward improved clinical outcomes in pneumonia prevention in mechanically ventilated patients and CF patients with chronic *Pa* infections. However, based on its failure to meet a primary endpoint of a Phase 2 trial, we have discontinued development of this product. We are not currently allocating resources to KB001-A. We are actively seeking out-licensing or other partnership opportunities to help fund KB001-A's further clinical development.

Intellectual Property

Licensing and Collaborations

Savant Agreement

On June 30, 2016, we entered into an Agreement for the Manufacture, Development and Commercialization of Benznidazole for Human Use, or the MDC Agreement, with Savant, pursuant to which we acquired certain worldwide rights relating to benznidazole, including certain regulatory and non-intellectual property assets related to benznidazole and any product containing benznidazole and an exclusive license of certain intellectual property assets, including know-how and processes, relating to benznidazole. Savant retains the right to use the licensed intellectual property for veterinary uses. The MDC Agreement provides that we may jointly conduct development activities with Savant with respect to any product containing benznidazole, while we will be solely responsible for commercializing the product. Under the MDC Agreement, we will fund the development program for the product and will reimburse Savant for its work associated with the development program.

As required by the MDC Agreement, we made payments to Savant totaling $2,687,500, consisting of the remaining portion of an initial payment (excluding a previously paid deposit of $500,000) in the amount of $2,500,000, an initial monthly joint development program cost payment of $87,500, and reimbursement of $100,000 of Savant's legal fees. The MDC Agreement provides for regulatory and other milestone payments of up to $21 million if we receive approval from FDA and from other non-US regulatory agencies and certain other contingent payments. Additionally, we will pay Savant royalties in the mid-teens on any net sales of any benznidazole product on a product-by-product and country-by-country basis, which royalty will be reduced to the high single digits in the United States if a PRV is not granted subsequent to regulatory approval of any benznidazole product. The MDC Agreement also provides that Savant is entitled to a portion of the amount we receive upon the sale, if any, of a PRV regarding any benznidazole product. In addition, we also entered into a security agreement pursuant to which we granted Savant a continuing senior security interest in the assets and rights acquired by us pursuant to the MDC Agreement and certain future assets developed from those acquired assets.

The Ludwig Institute for Cancer Research

In May 2004, we entered into a license agreement with the Ludwig Institute for Cancer Research, or LICR, pursuant to which LICR granted to us an exclusive license under intellectual property rights and materials related to chimeric anti-GM-CSF antibodies that formed the basis for the lenzilumab 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 lenzilumab. 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 the 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, 2015 amounted to $1.5 million.

Other License Agreements

Novartis

In April 2007, we entered into an agreement with Novartis granting a non-exclusive 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.

LICR and ifabotuzumab

In 2006, we entered into a license agreement with LICR pursuant to which LICR granted to us certain exclusive rights to the ifabotuzumab prototype and EphA3-related intellectual property. Under the agreement, we obtained 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 any 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, 2015 amounted to $586,000.

University of California, San Francisco and the Medical College of Wisconsin

In April 2004, we exclusively licensed rights from University of California, San Francisco, or 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 any sub-licensees. Aggregate payments made to UCSF under this license through December 31, 2015 amounted to $1.4 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 use commercially reasonable efforts to develop, manufacture, partner or sell licensed products and market the products using commercially reasonable efforts to meet market demands.

Sanofi

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 but retained rights relating to *Pa* in patients with CF or bronchiectasis. In July 2014, we executed an agreement with Sanofi under which the Sanofi agreement was terminated. As a result of the termination of the agreement, we 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 terminating the 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 payments to be shared with Sanofi.

BioWa and Lonza

In October 2010, we entered into a license agreement with BioWa, Inc., or BioWa, and Lonza Sales AG, or Lonza, pursuant to which BioWa and Lonza granted us non-exclusive, royalty-bearing, sub-licensable license under certain know-how and patents related to antibody expression and antibody-dependent cellular cytotoxicity enhancing technology using BioWa and Lonza's Potelligent® CHOK1SV technology. This technology is used to enhance the cell killing capabilities of antibodies and is currently used by us in connection with our development of ifabotuzumab. Under this agreement, we owe annual license fees, milestone payments in connection with certain regulatory and sales milestones and royalties in the low single digits on net sales of products developed under the agreement. The agreement expires upon the expiration of royalty payment obligations under the agreement, is terminable at will by us upon written notice, is terminable by BioWa and Lonza if we challenge or otherwise oppose any licensed patents under the agreement, and is terminable by either party upon the occurrence of an uncured material breach or insolvency.

Patents and Trade Secrets

We use a combination of patent, trade secret and other intellectual property protections to protect our product candidates. Patent and trade secret protection is important to our business. Our success will depend in part on our ability to obtain, maintain, defend and enforce patent rights for and to extend the life of patents covering lenzilumab, ifabotuzumab and our Humaneered technology, 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, if available, in the United States and select foreign countries for the technology we develop. 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.

Using our Humaneered technology, we developed and own a composition of matter patent covering lenzilumab and related Humaneered anti-GM CSF antibodies that 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 also 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 ifabotuzumab and related Humaneered anti EphA3 antibodies, which is currently expected to expire in 2030. The patents to our Humaneered technology cover methods of producing human antibodies that are very specific for target antigens using only a small region from mouse antibodies.

Research and Development

We have previously dedicated a significant portion of our resources to our efforts to develop our product candidates, particularly KB001-A, lenzilumab and ifabotuzumab. We incurred research and development expenses of $16.7 million and $26.6 million during the years ended December 31, 2015 and 2014, respectively. We anticipate that a significant portion of our operating expenses will continue to be related to clinical development in 2016 as we focus on the development necessary to seek and obtain FDA approval of benznidazole and restart our development of lenzilumab and potentially ifabotuzumab. We do not currently plan to devote significant or any resources to pure research activities.

Manufacturing

We outsource basic development activities, including the development of 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.

In addition, pursuant to the MDC Agreement, we acquired certain agreements for the third-party manufacture of drug substance and drug product for benznidazole, though we continue to evaluate our manufacturing approach and strategy.

Sales and Marketing

We do not currently have the sales and marketing infrastructure in place that would be necessary to sell and market products. As our drug candidates progress, while we may build the infrastructure that would be needed to successfully market and sell any successful drug candidate, we currently anticipate seeking strategic alliances and partnerships with third parties. The establishment of a sales and marketing operation can be expensive, complicated and time consuming and could delay any product candidate launch. Whether directly or through third parties, we intend to responsibly price any approved products using our Responsible Pricing Model, which could make it more difficult to enter into arrangements with third parties on acceptable terms, if at all, even if such a model were attractive to payers, clinicians and patients.

Competition

We compete in an industry characterized by rapidly advancing technologies, intense competition, a changing regulatory and legislative landscape and a strong emphasis on the benefits of intellectual property protection and regulatory exclusivities. Our competitors include pharmaceutical companies, other biotechnology companies, academic institutions, government agencies and other private and public research organizations. We compete with these parties for therapies for neglected and rare diseases and in recruiting highly qualified personnel. Our product candidates, if successfully developed and approved, may compete with established therapies, with new treatments that may be introduced by our competitors, including competitors relying to a large extent on our drug approvals under Section 505(b)(2) of the FDCA or on our biologics approvals under Section 351(k) of the Public Health Service Act, or with generic copies of our product approved by FDA under an abbreviated new drug application, or ANDA, referencing our drug products. Many of our competitors and potential competitors have substantially greater scientific, research, and product development capabilities, as well as greater financial, marketing, sales and human resources capabilities 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 with respect to their products than we may be in developing, commercializing, and achieving widespread market acceptance for our products. If a competitor obtains approval for an orphan drug that is the same drug or the same biologic as one of our candidates before we do, we will be blocked from obtaining FDA approval for seven years from the date of the competitor's approval, unless we can establish that our product is clinically superior to the previously-approved competitor's product or we can meet another exception, such as by showing that the competitor has failed to provide an adequate supply of its product to patients after approval. 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 non-competitive before we can recover the expenses related to developing and supporting the commercialization of any of our product candidates. Developments by competitors may render our product candidates obsolete or noncompetitive. After one of our product candidates is approved, FDA may also approve a generic version with the same dosage form, safety, strength, route of administration, quality, performance characteristics and intended use as our product. These generic equivalents would be less costly to bring to market and could generally be offered at lower prices, thereby limiting our ability to gain or retain market share.

The acquisition or licensing of pharmaceutical products is also very competitive, and a number of more established companies, which have acknowledged strategies to in-license or acquire products, may have competitive advantages as may other emerging companies taking similar or different approaches to product acquisitions. The more established companies may have a competitive advantage over us due to their size, cash flows, institutional experience and historical corporate reputation.

Benznidazole, Chagas Disease Therapeutics and Priority Review Voucher Competition

Other companies are either developing benznidazole for treatment of Chagas disease in the United States or are developing drug candidates that could compete with benznidazole for the treatment of Chagas disease in the future. We understand that Chemo Research, S.L. and ELEA (both associated with Grupo Insud) intend to seek FDA approval of benznidazole for the treatment of Chagas disease. Chemo Research, S.L. obtained orphan drug designation for benznidazole in Chagas disease in 2014. If a competitor with orphan drug designation for benznidazole for treating Chagas disease obtains approval before we do, we will be blocked by the competitor's orphan drug exclusivity from receiving approval for benznidazole for seven years from the date of the competitor's approval, unless we can meet an exception, such as by showing that the competitor has failed to provide an adequate supply of its product to patients after approval. Additionally, benznidazole is currently produced by LAFEPE and ELEA, and nifurtimox is currently produced by Bayer, for use in certain Latin American countries. Even if benznidazole is not approved in the United States, we will compete against LAFEPE and ELEA for distribution of benznidazole if we make benznidazole available in these countries. There are also a number of ongoing non-commercial studies of benznidazole for the treatment of Chagas disease.

Although there are no drugs for the treatment of Chagas disease commercially available in the United States, nifurtimox is also used to treat Chagas disease and is available in the United States through the CDC, as is benznidazole on a limited basis under a compassionate use protocol. Our understanding is that obtaining either drug can be burdensome and time-consuming for clinicians and patients and that many patients ultimately do not obtain treatment. Specifically, our understanding is that under the CDC protocol, patients require several confirmatory diagnostic tests and can often be lost to follow up. In addition, the CDC has been beset with sourcing problems because it sources from Latin American manufacturers who have had product supply issues. We are also aware of several other treatments undergoing commercial development for the treatment of Chagas disease. Bayer, which initially developed Lampit™ (the active ingredient of which is nifurtimox), annually supplies it to the WHO. Bayer is currently undertaking multiple clinical studies of nifurtimox for Chagas disease, including a Phase 3 study of a pediatric formulation. Bayer has obtained orphan drug designation for nifurtimox in Chagas disease as has MetronomX Therapeutics, LLC.

Other compounds that have undergone or are undergoing preclinical studies or clinical trials for Chagas disease include posaconazole, ravuconazole, Eisai Co. Ltd.'s E1224, and VNI, which has been studied at Vanderbilt University. In 2015, Merck Sharp & Dohme completed a Phase 2 proof-of-activity study of Noxafil® (posaconazole) in the treatment of asymptomatic chronic Chagas disease. Recent trials led by Eisai failed to show a benefit of E1224 (fosravuconazole) over benznidazole either in monotherapy or in combination with benznidazole. Eisai has also conducted research with the Broad Institute to discover and develop new therapeutic agents for Chagas disease, including a compound known as ML341. Eisai, Shionogi & Co. Ltd., Takeda Pharmaceutical Ltd. and AstraZeneca plc are members of the Neglected Tropical Diseases Drug Discovery booster program, which aims in part to accelerate early stage drug discovery for Chagas disease. Other than Merck's trial, most of these programs are in the pre-clinical or early clinical stages of development and we believe will take many years to reach the market, if at all.

Current legislation allows for issuance of a PRV upon approval of a product for the treatment of Chagas disease, provided that the product contains no active ingredient that has been approved by FDA in any other marketing application. Therefore, non-benznidazole treatments for Chagas disease may qualify, in some circumstances, if successfully approved, for PRVs. However, if any other drug with benznidazole as the active ingredient is approved by FDA, regardless of whether that approval is accompanied by a PRV, subsequently approved forms of benznidazole will not result in a PRV upon approval.

Lenzilumab and CMML/JMML Competition

Stem cell treatment is the only current way to cure patients with CMML or JMML. Adult patients with CMML unsuitable for stem cell transplants are frequently treated with injectable formulations of azacitidine, which is available as Celgene Corporation's Vidaza® or as a generic, or decitabine, available as Otsuka America Pharmaceutical, Inc.'s Dacogen® or as a generic. Some patients with high white blood cell counts are treated with hydroxyurea, which was introduced in the 1960s and is available in generic formulations and under the brand names Droxia® and Hydrea®. We are also aware of numerous open trials for the treatment of CMML, including clinical trials of treatments under development by Celgene (CC-486 (oral azacitidine) and Revlimid® (lenalidomide)), Novartis (panobinostat), Incyte Corporation and Novartis (Jafaki® (ruxolitinib), Millenium Pharmaceuticals, Inc. (pevonedistat plus azacitidine), Stemline Therapeutics, Inc. (SL-401) and Kura Oncology, Inc. (tipifarnib). There are also open trials for JMML, including of Amgen Inc.'s Enbrel® (etanercept) and of tipifarnib and azacitidine. We anticipate that as new treatments are approved, they may be used in combination with other existing treatments for CMML and JMML.

Ifabotuzumab Competition

Numerous drugs are under development or approved for treatment of glioblastoma, MDS, myelofibrosis and for cancer and hematologic indications generally. Glioblastoma is also sometimes treated with surgery, radiotherapy and chemotherapy with temozolomide. MDS may be treated with transfusion therapy, immunosuppressive therapy, chemotherapy, Revlamid, azacitidine and/or decitabine. Myelofibrosis may be treated with stem cell transplants and various therapeutic treatments for anemia and enlarged spleen.

Government Regulation

Drug Development and Approval in the U.S.

As a biopharmaceutical company operating in the United States, we are subject to extensive regulation by FDA and by other federal, state, and local regulatory agencies. FDA regulates our products under the FDCA, the Public Health Service Act, or the PHSA, and their implementing regulations. Under the FDCA, new drugs marketed in the United States generally must be FDA-approved under an NDA. Under the PHSA, an FDA-approved BLA is required to market a biological product, or biologic, in the United States. These laws and regulations set forth, among other things, requirements for preclinical and clinical testing, development, approval, labeling, manufacture, storage, record keeping, reporting, distribution, import, export, advertising, and promotion of our products and product candidates.

Applications Relying on the Applicant's Clinical Data

The approval process for a full NDA under Section 505(b)(1) of the FDCA, containing full reports of investigations of safety and effectiveness for the product, and BLAs under the PHSA require the conduct of extensive studies and the submission of large amounts of data by the applicant. The drug development process for these applications will generally include the following phases:

Preclinical Testing. Before testing any compound in human subjects in the United States, a company must generate extensive preclinical data. Preclinical testing generally includes laboratory evaluation of product chemistry and formulation, as well as toxicological and pharmacological studies in several animal species to assess the quality and safety of the product. Animal studies must be performed in compliance with FDA's Good Laboratory Practice, or GLP, regulations and the United States Department of Agriculture's Animal Welfare Act.

IND Application. Human clinical trials in the United States cannot commence until an IND application is submitted and becomes effective. A company must submit preclinical testing results to FDA as part of the IND, and FDA must evaluate whether there is an adequate basis for testing the drug in initial clinical studies in human volunteers. Unless FDA raises concerns, the IND becomes effective 30 days following its receipt by FDA. Once human clinical trials have commenced, FDA may stop the clinical trials by placing them on "clinical hold" because of concerns about the safety of the product being tested, or for other reasons.

Clinical Trials. Clinical trials involve the administration of the drug to healthy human volunteers or to patients, under the supervision of a qualified investigator. The conduct of clinical trials is subject to extensive regulation, including compliance with FDA's bioresearch monitoring regulations and Good Clinical Practice, or GCP, requirements, which establish standards for conducting, recording data from, and reporting the results of clinical trials. GCP requirements are intended to assure that the data and reported results are credible and accurate, and that the rights, safety, and well-being of study participants are protected.

Clinical trials must be conducted under protocols that detail the study objectives, parameters for monitoring safety, and the efficacy criteria, if any, to be evaluated. Each protocol is submitted to FDA as part of the IND. In addition, each clinical trial must be reviewed, approved, and conducted under the auspices of an Institutional Review Board, or IRB, at the institution conducting the clinical trial. Companies sponsoring the clinical trials, investigators, and IRBs also must comply with regulations and guidelines for obtaining informed consent from the study subjects, complying with the protocol and investigational plan, adequately monitoring the clinical trial, and timely reporting of adverse events. Foreign studies conducted under an IND must meet the same requirements that apply to studies being conducted in the United States. Data from a foreign study not conducted under an IND may be submitted in support of an NDA or BLA if the study was conducted in accordance with GCP and FDA is able to validate the data. A study sponsor is required to publicly post certain details about active clinical trials and clinical trial results on government or independent websites (e.g., http://clinicaltrials.gov).

Human clinical trials are typically conducted in three sequential phases, although the phases may overlap with one another:

- Phase 1 clinical trials include the initial administration of the investigational drug to humans, typically to a small group of healthy human subjects, but occasionally to a group of patients with the targeted disease or disorder. Phase 1 clinical trials generally are intended to determine the metabolism and pharmacologic actions of the drug, the side effects associated with increasing doses, and, if possible, to gain early evidence of effectiveness.

- Phase 2 clinical trials generally are controlled studies that involve a relatively small sample of the intended patient population, and are designed to develop data regarding the product's effectiveness, to determine dose response and the optimal dose range, and to gather additional information relating to safety and potential adverse effects.

- Phase 3 clinical trials are conducted after preliminary evidence of effectiveness has been obtained and are intended to gather additional information about safety and effectiveness necessary to evaluate the drug's overall risk-benefit profile, and to provide a basis for physician labeling. Generally, Phase 3 clinical development programs consist of expanded, large-scale studies of patients with the target disease or disorder to obtain statistical evidence of the efficacy and safety of the drug at the proposed dosing regimen, or with the safety, purity, and potency of a biological product.

The sponsoring company, FDA, or the IRB may suspend or terminate a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk. Further, success in early-stage clinical trials does not assure success in later-stage clinical trials. Data obtained from clinical activities are not always conclusive and may be subject to alternative interpretations that could delay, limit, or prevent regulatory approval.

NDA Applications Relying on Data Other than the Applicant's Data

As an alternative path to FDA approval, an applicant may submit its NDA under Section 505(b)(2) of the FDCA. Both NDA pathways have the same standards with respect to the scope and amount of data required to establish safety and efficacy for the applicant's product. However, whereas applications under 505(b)(1) rely solely on the applicant's own data, Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by, or for, the applicant, and for which the applicant has not otherwise obtained a right of reference.

Specifically, a 505(b)(2) application may rely on both published scientific literature and on FDA's prior findings of safety and efficacy for a similar or comparable approved drug product. If the 505(b)(2) applicant can establish that reliance on previous FDA findings of safety and effectiveness is scientifically and legally appropriate, it may eliminate the need to conduct certain preclinical or clinical studies and rely instead on FDA's prior findings for the approved reference drug. FDA may still require companies to perform additional studies or measurements, including clinical trials, to support any change from the reference drug. FDA may then approve the new product candidate for all, or some, of the label indications for which the reference drug has been approved, as well as for any new indication sought by the 505(b)(2) applicant. While the 505(b)(2) pathway is most often used for modifications to formulations or for uses for products previously approved by FDA under the 505(b)(1) pathway, we believe it is an appropriate pathway for benznidazole, and we intend to use it to submit our NDA for benznidazole, which would allow us to rely, at least in part, on literature and clinical data generated by third-party entities. We cannot guarantee that FDA will allow us to seek approval for benznidazole under the 505(b)(2) pathway. If FDA does not allow us to utilize this pathway, we may need to conduct original clinical trials to generate data necessary for approval, a process that may require significant financial resources and extend the approval process. Even if FDA allows us to use the 505(b)(2) pathway, it may conclude that our data fails to demonstrate adequate safety and efficacy to obtain regulatory approval.

NDA/BLA Submission and Review

After completing clinical testing of an investigational drug or biologic product, a sponsor must prepare and submit an NDA or BLA for review and approval by FDA. NDAs and BLAs are comprehensive, multi-volume applications that include, among other things, the results of preclinical and clinical studies, information about the product's composition, and the sponsor's plans for manufacturing, packaging, and labeling the product. A 505(b)(2) NDA may also rely upon studies and data not generated by the NDA applicant. When an NDA or BLA is submitted, FDA conducts a preliminary review to determine whether the application is sufficiently complete to be accepted for filing. If it is not, FDA may refuse to file the application and may request additional information, in which case the application must be resubmitted with the supplemental information and review of the application is delayed.

FDA performance goals, which are target dates and other aspirational measures of agency performance to which the agency, Congressional representatives, and industry agree through negotiations that occur every five years, generally provide for action on NDA and BLA applications within 10 months of submission, or 10 months from acceptance for filing for an NDA involving a new molecular entity or for an original BLA. FDA is not expected to meet those target dates for all applications, however, and the deadline may be extended in certain circumstances, such as when the applicant submits new data late in the review period. In practice, the review process is often significantly extended by FDA requests for additional information or clarification. In some circumstances, FDA can expedite the review of new drugs and biologics deemed to qualify for priority review, such as those intended to treat serious or life threatening conditions that demonstrate the potential to address unmet medical needs. In those cases, the targeted action date is six months from submission, or for drugs constituting new molecular entities and biologics constituting original biological products, six months from the date that FDA accepts the application for filing.

As part of its review, FDA may refer an NDA or BLA to an advisory committee for evaluation and a recommendation as to whether the application should be approved. Although FDA is not bound by the recommendation of an advisory committee, the agency usually has followed such recommendations. FDA may also determine that a Risk Evaluation and Mitigation Strategy, or REMS, is necessary to ensure that the benefits of a new product outweigh its risks, and that the product can therefore be approved. A REMS may include various elements, ranging from a medication guide or patient package insert to limitations on who may prescribe or dispense the drug, depending on what FDA considers necessary for the safe use of the drug. Under the Pediatric Research Equity Act, NDAs and BLAs must include an assessment, generally based on clinical study data, of the safety and effectiveness of the subject drug or biological product in relevant pediatric populations, unless the requirement is waived or deferred.

After review of an NDA or BLA, FDA may determine that the product cannot be approved, or may determine that it can only be approved if the applicant cures deficiencies in the application, in which case the agency endeavors to provide the applicant with a complete list of the deficiencies in correspondence known as a Complete Response Letter, or CRL. A CRL may request additional information, including additional preclinical or clinical data. Even if such additional information and data are submitted, FDA may decide that the NDA still does not meet the standards for approval. Data from clinical trials are not always conclusive and FDA may interpret data differently than the sponsor interprets them. Additionally, as a condition of approval, FDA may impose restrictions that could affect the commercial success of a drug or require post-approval commitments, including the completion within a specified time period of additional clinical studies, which often are referred to as “Phase 4” studies or “post-marketing requirements.” Obtaining regulatory approval often takes a number of years, involves the expenditure of substantial resources, and depends on a number of factors, including the severity of the disease in question, the availability of alternative treatments, and the risks and benefits demonstrated in clinical trials.

Post-approval modifications to the drug or biologic product, such as changes in indications, labeling, or manufacturing processes or facilities, may require a sponsor to develop additional data or conduct additional preclinical or clinical trials. The proposed changes would need to be submitted in a new or supplemental NDA or BLA, which would then require FDA approval.

Regulatory Exclusivities

Hatch-Waxman Act

The Hatch-Waxman Act established the ANDA and 505(b)(2) approval pathways to facilitate the approval of generic and follow-on drug products. At the same time, the Act provides periods of regulatory exclusivity to incentivize innovator drug development. If a product is a “new chemical entity,” or NCE, generally meaning that the active moiety has never before been approved by FDA, the Act provides a five-year period starting from the product’s approval date during which FDA may not accept for filing any application for a drug containing the same active moiety. Because it takes time for FDA to review and approve an application once it has been accepted for filing, five-year NCE exclusivity often effectively means that the ANDA or 505(b)(2) application is not approved for a period well beyond five years from approval of the RLD. We believe that benznidazole will qualify for five-year NCE exclusivity.

Notwithstanding NCE exclusivity, an ANDA or 505(b)(2) application may be submitted after four years if the applicant makes a certification, known as a Paragraph IV certification due to its statutory citation, challenging a listed patent belonging to the holder of the original NDA, also referred to as the reference listed drug, or RLD. Once FDA accepts for filing an ANDA or 505(b)(2) application containing a Paragraph IV certification, no matter when the certification is made, the applicant must within 20 days provide notice to the RLD NDA holder and patent owner that the application with patent challenge has been submitted, and provide the factual and legal basis for the applicant's assertion that the patent is invalid or not infringed. If the NDA holder or patent owner files suit against the ANDA or 505(b)(2) applicant for patent infringement within 45 days of receiving the Paragraph IV notice, FDA is prohibited from approving the ANDA or 505(b)(2) application for a period of 30 months from the date of receipt of the notice. If the RLD has NCE exclusivity and the notice is given and suit is filed during the fifth year of exclusivity, the 30-month stay does not begin until five years after the RLD approval. FDA may approve the proposed product before the expiration of the 30-month stay if a court finds the patent invalid or not infringed or if the court shortens the period because the parties have failed to cooperate in expediting the litigation.

Qualified Infectious Disease Product

Under the Generating Antibiotic Incentives Now, or GAIN, provisions of the FDA Safety and Innovation Act, or FDASIA, signed into law in July 2012, FDA may designate a small-molecule drug product as a "qualified infectious disease product", or QIDP. In order to receive this designation, a drug must be an antibacterial or antifungal drug for human use intended to treat serious or life-threatening infections, including those caused by either (1) an antibacterial or antifungal resistant pathogen, including novel or emerging infectious pathogens, or (2) a "qualifying pathogen" found on a list established and maintained by FDA. FDA promulgated a Final Rule in June 2014 listing 21 qualifying pathogens. Although none of our current product candidates meet the criteria for a QIDP, with our focus on rare and neglected diseases, we may develop or acquire a qualifying product in the future.

A sponsor may request designation as a QIDP before submitting an NDA. Upon approval, the designated product will receive an additional five years of exclusivity beyond any period of exclusivity to which it would have previously been eligible. In addition, a QIDP will receive the benefit of expedited review programs including priority review and Fast Track designation.

Biologics Price Competition and Innovation Act

In 2010, the Biologics Price Competition and Innovation Act, or BPCIA, was enacted, creating an abbreviated approval pathway for biologic products that are biosimilar to, and possibly interchangeable with, reference biological products licensed under a BLA. The BPCIA also provides innovator manufacturers of original reference biological products 12 years of exclusive use before biosimilar versions can be licensed in the United States. This means that FDA may not approve an application for a biosimilar version of a reference biological product until 12 years after the date of approval of the reference biological product (with a potential six-month extension of exclusivity if certain pediatric studies are conducted and the results reported to FDA), although a biosimilar application may be submitted four years after the date of licensure of the reference biological product. Additionally, the BPCIA establishes procedures by which the biosimilar applicant must provide information about its application and product to the reference product sponsor, and by which information about potentially relevant patents is shared and litigation over patents may proceed in advance of approval, although the interpretation of those procedures has been subject to litigation and appears to continue to evolve. The BPCIA also provides a period of exclusivity for the first biosimilar to be determined by FDA to be interchangeable with the reference product.

FDA approved the first biosimilar product under the BPCIA in 2015, and the agency continues to refine the procedures and standards it will apply in implementing this approval pathway. FDA has released guidance documents interpreting specific aspects of the BPCIA in each of the last four years.

Orphan Drug Designation

The Orphan Drug Act provides incentives for the development of drugs and biological products intended to treat rare diseases or conditions. Rare diseases and conditions generally are those affecting less than 200,000 individuals in the United States, but also include diseases or conditions affecting more than 200,000 individuals in the United States if there is no reasonable expectation that the cost of developing and making available in the United States a drug for such disease or condition will be recovered from sales in the United States of such drug.

If a sponsor demonstrates that a drug, including a biological product, is intended to treat a rare disease or condition, and meets certain other criteria, FDA grants orphan drug designation to the drug for that use. FDA may grant multiple designations for the same drug for the same indication, until that drug is approved. The first drug approved with an orphan drug designated indication is granted seven years of orphan drug exclusivity for that indication. During that period, FDA generally may not approve any other application for the same drug for the same indication, although there are exceptions, most notably when the later product is shown to be clinically superior to the product with exclusivity. FDA can also revoke a product's orphan drug exclusivity under certain circumstances, including when the holder of the approved orphan drug application is unable to assure the availability of sufficient quantities of the drug to meet patient needs.

A sponsor of a product application that has received an orphan drug designation is also granted tax incentives for clinical research undertaken to support the application. In addition, FDA will typically coordinate with the sponsor on research study design for an orphan drug and may exercise its discretion to grant marketing approval on the basis of more limited product safety and efficacy data than would ordinarily be required, based on the limited size of the applicable patient population.

Expedited Programs for Serious Conditions

FDA has implemented a number of expedited programs to help ensure that therapies for serious or life-threatening conditions, and for which there is unmet medical need, are approved and available to patients as soon as it can be concluded that the therapies' benefits justify their risks. Among these programs are the following:

Fast Track Designation

FDA may designate a product for fast track review if it is intended, whether alone or in combination with one or more other drugs, for the treatment of a serious or life-threatening disease or condition and where non-clinical or clinical data demonstrates the potential to address unmet medical need for such a disease or condition. A product can also receive fast track review if it is designated as a QIDP.

For fast track products, sponsors may have greater interactions with FDA and FDA may initiate review of sections of a fast track product's NDA before the application is complete. This rolling review may be available if FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast track product may be effective. The sponsor must also provide, and FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. Furthermore, FDA's time period goal for reviewing a fast track application does not begin until the last section of the complete NDA is submitted. Finally, the fast track designation may be withdrawn by FDA if FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Breakthrough Therapy

A product may be designated as a breakthrough therapy if it is intended, either alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the features of Fast Track designation, as well as more intensive FDA interaction and guidance. FDA may take certain actions with respect to breakthrough therapies, including holding meetings with the sponsor throughout the development process; providing timely advice to the product sponsor regarding development and approval; involving more senior staff in the review process; assigning a cross-disciplinary project lead for the review team; and taking other steps to design efficient clinical trials.

Accelerated Approval

Under the accelerated approval pathway, FDA may approve a drug or biologic based on a surrogate endpoint that is reasonably likely to predict clinical benefit; qualifying products must target a serious or life-threatening illness and provide meaningful therapeutic benefit to patients over existing treatments. In clinical trials, a surrogate endpoint is a measurement of laboratory or clinical signs of a disease or condition that substitutes for a direct measurement of how a patient feels, functions, or survives. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. A product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or to confirm a clinical benefit during post-marketing studies, would allow FDA to withdraw the drug from the market on an expedited basis. All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by FDA. Although none of our current product candidates meet the criteria for accelerated approval, with our focus on rare and neglected diseases, we may develop or acquire a qualifying product in the future.

Priority Review

FDA may designate a product for priority review if it is a drug that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. FDA generally determines, on a case-by-case basis, whether the proposed drug represents a significant improvement in safety and effectiveness when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting drug reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, and evidence of safety and effectiveness in a new subpopulation. A priority designation is intended to direct overall attention and resources to the evaluation of such applications, and will shorten FDA's goal for taking action on a marketing application from the standard ten months to an accelerated six months.

Tropical Disease PRVs

Under Section 524 of the FDCA, FDA is authorized to award PRVs to the sponsors of NDAs and BLAs for products targeting specific tropical diseases. A product only qualifies for a PRV if it contains active ingredients that have never before been approved by FDA. The Food and Drug Administration Amendments Act of 2007 contained a list of sixteen initial qualifying tropical diseases; FDA classified Chagas disease and another disease as PRV-eligible diseases in a 2015 order. A sponsor receives a PRV at the time that their eligible product is approved.

The PRV program allows the voucher holder to obtain priority review for a product application that would otherwise not receive priority review, shortening FDA's target review period to six months following the 60-day filing date, or four months shorter than the standard review period. The voucher may be used by the sponsor who receives it, or it may be sold to another sponsor for use in that sponsor's own marketing application. The sponsor who uses the voucher is required to pay additional user fees on top of the standard user fee for reviewing an NDA or BLA. We believe that the approval of benznidazole as a treatment for Chagas disease could result in the issuance of a PRV under the current program if our version of benznidazole is the first version approved by FDA.

Rare Pediatric Disease PRVs

FDA's rare pediatric disease PRV program allows FDA to grant PRVs to NDA or BLA sponsors who receive approval for a product targeting a rare pediatric disease, defined as a disease that affects fewer than 200,000 individuals in the U.S., primarily aged from birth to 18 years. As with the tropical disease PRV program, PRV-holders can redeem their voucher to receive an accelerated six-month FDA action goal instead of the standard ten-month window, or they may transfer or sell their PRV to another sponsor. We believe that lenzilumab or other future product candidates that we may develop or acquire may qualify for a PRV under this program.

Authorization for the current pediatric PRV program is scheduled to expire on October 1, 2016, unless renewed by Congress. The Advancing Hope Act of 2016, which was placed on the Senate Legislative Calendar in April 2016, would allow FDA to approve products with a pediatric PRV through September 2027. There is no certainty as to whether the current pediatric PRV will be renewed, or if it is renewed, what changes there may be.

Employees

As of December 31, 2015, we had 9 employees, and as of June 30, 2016 we had 6 employees and several full and part-time consultants. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

Bankruptcy

In January 2015, shortly after announcing that our Phase 2 clinical trial of KB001-A had not met its primary or secondary endpoints, we implemented a cost reduction plan that primarily consisted of workforce reductions. On November 5, 2015, as part of a further effort to reduce operating costs, we announced a restructuring plan that would reduce our workforce and change the focus of our development programs. The restructuring plan provided that we would pursue strategic alternatives, such as a potential sale of the Company or its assets or further restructuring efforts. On November 13, 2015, we announced that after discussions of various strategic alternatives, we concluded that it was unlikely that a viable transaction could be reached within the timeframe allowed by our then-limited cash resources. On November 18, 2015, an outside investor group acquired a majority of our outstanding shares and one of the investors was appointed our chief executive officer and chairman. In December 2015, we issued and sold shares of common stock to investors in a private placement, whom we refer to as the PIPE Investors. Shortly thereafter, on December 17, 2015, our then-chief executive officer and chairman was arrested on charges of securities fraud, securities fraud conspiracy and wire fraud conspiracy, was terminated as our chief executive officer and resigned from our board of directors. Three other directors and our interim chief financial officer resigned between December 17 and December 28, 2015. Our independent registered accounting firm also resigned on December 8, 2015. Finally, in December 2015, three putative class action lawsuits were filed against us and the PIPE Investors threatened a lawsuit against us for return of the funds they paid in the private placement.

As a result of these events and other challenges facing us at the time, on December 29, 2015, we filed a voluntary petition for bankruptcy protection under Chapter 11 of the U.S. Bankruptcy Code. The filing was made in the United States Bankruptcy Court for the District of Delaware, or the Bankruptcy Court (Case No. 15-12628 (LSS)). During the pendency of our bankruptcy proceedings, we entered into a Debtor-in-Possession Credit and Security Agreement, or the Credit Agreement, pursuant to which we received $3 million in funds for working capital, bankruptcy-related costs, costs related to our plan of reorganization, payment of certain fees to the lenders and other costs associated with the ordinary course of business.

On May 9, 2016, we filed with the Bankruptcy Court a Second Amended Plan of Reorganization, or the Plan, and related amended disclosure statement pursuant to Chapter 11 of the Bankruptcy Code. On June 16, 2016, the Bankruptcy Court entered an order confirming the Plan.

On June 30, 2016, the Plan became effective and we emerged from our Chapter 11 bankruptcy proceedings. In connection with the emergence, we entered into the MDC Agreement with Savant, pursuant to which we acquired certain worldwide rights relating to benznidazole. In two separate issuances, pursuant to a Securities Purchase Agreement and in repayment of our obligations under the Credit Agreement, on June 30, 2016, we issued an aggregate of 9,497,515 shares of our common stock to the lenders in the Credit Agreement. In accordance with the Plan, we also issued or became obligated to issue promissory notes or shares of our common stock to certain other parties.

Available Information

We were incorporated in 2000 and reincorporated as a Delaware corporation in September 2001. Our principal offices are located at 1000 Marina Boulevard, Suite 250, Brisbane, CA 94005-1878, and our telephone number is (650) 243-3100. Our website address is www.kalobios.com. Our common stock is currently traded over-the-counter. We operate in a single segment.

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.

ITEM 1A. RISK FACTORS

Risks Related to Our Business and Industry

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

We have incurred net losses each year since our inception except for the year ended December 31, 2007. For the fiscal year ended December 31, 2015 we incurred a net loss of $35.4 million, and we have an accumulated deficit of $213.6 million as of December 31, 2015. Furthermore, on December 29, 2015, we filed a voluntary petition for bankruptcy protection under the Bankruptcy Code. On June 30, 2016, our Second Amended Plan of Reorganization, or the Plan, dated May 9, 2016, as amended, became effective and we emerged from our Chapter 11 bankruptcy proceedings. See "Bankruptcy" in Item 1 of this Annual Report and see "Risks Related to Our Bankruptcy" below for further information on our bankruptcy and emergence from bankruptcy.

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 future development partners succeed in commercializing any of our product candidates. Because of the numerous risks and uncertainties associated with developing and commercializing our product candidates, we are unable to predict the extent of any future losses or when we will become profitable, if at all.

We will need substantial additional capital to develop and commercialize our product candidates and to continue as a going concern, but our access to capital funding is uncertain.

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. In connection with our emergence from bankruptcy, we closed an $11 million financing that provided the funds required to exit our Chapter 11 proceeding as well as our current working capital. However, we will require substantial additional capital to support our business efforts, including obtaining regulatory approvals for benznidazole or other product candidates, clinical trials and other studies, and, if approved, the commercialization of our product candidates. The amount of capital we will require and the timing of our need for additional capital will depend on many factors, including:

- the type, number, timing, progress, costs, and results of the product candidate development programs that we are pursuing or may choose to pursue in the future;
- the scope, progress, expansion, costs, and results of our pre-clinical and 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 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 scope, progress, expansion and costs of manufacturing our product candidates; and
- the costs associated with being a public company.

We anticipate that in the future we will seek additional financing from a number of sources, including, but not limited to, the sale of equity or debt securities, strategic collaborations, and licensing of our product candidates. Additional funding may not be available to us on a timely basis or at acceptable terms, if at all. Our ability to access capital when needed is not assured and, if not achieved on a timely basis, would materially harm our business, financial condition and results of operations. If adequate funds are not available, we may be required to delay, reduce the scope of, or eliminate one or more of our development programs. 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 and on less than favorable terms, if at all.

If management is unsuccessful in efforts to raise additional capital, based on our current levels of operating expenses, our current capital is not expected to be sufficient to fund our operations for the next twelve months. These conditions raise substantial doubt about our ability to continue as a going concern.

Our auditor has expressed substantial doubt about our ability to continue as a going concern and absent additional financing we may be unable to remain a going concern.

If we are unsuccessful in our efforts to raise additional capital, based on our current levels of operating expenses, our current capital is not expected to be sufficient to fund our operations for the next twelve months. These conditions 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 included in Part II, Item 8, "Financial Statements and Supplementary Data" of this Annual Report on Form 10-K includes an explanatory paragraph about our ability to continue as a going concern.

The Consolidated Financial Statements for the year ended December 31, 2015 were prepared on the basis of a going concern, which contemplates that we will be able to realize our assets and discharge liabilities in the normal course of business. Our ability to meet our liabilities and to continue as a going concern is dependent upon the availability of future funding. The financial statements do not include any adjustments that might be necessary if we are unable to continue as a going concern.

In addition, our current financial situation, and the presence of the explanatory paragraph about our ability to continue as a going concern, could also make it more difficult to raise the capital necessary to address our current needs.

Our business is highly dependent on the success of our current product candidates, benznidazole, lenzilumab and ifabotuzumab. We cannot be certain that we will be able to obtain regulatory approval for, or successfully commercialize, any of these product candidates.

We have recently made the strategic decision to focus our efforts on neglected and rare diseases. We have a limited pipeline of product candidates and are not conducting active research at this time for discovery of new molecules or antibodies. We are currently dependent on the successful continued development and regulatory approval of our current product candidates for our future business success. We are investing, and will continue to invest, a significant portion of our time and financial resources in the approval of benznidazole and the development of lenzilumab, and may undertake additional development efforts for ifabotuzumab.

We intend to pursue the 505(b)(2) approval pathway under the U.S. Federal Food, Drug, and Cosmetic Act, or the FDCA, for benznidazole, which would allow us to rely, at least in part, on literature and clinical data generated by third-party entities. We cannot guarantee that FDA, will allow us to seek approval for benznidazole under the 505(b)(2) pathway. If FDA does not allow us to utilize this pathway, we may need to conduct original clinical trials to generate data necessary for approval, a process that may require significant financial resources and extend the approval process. Even if FDA allows us to use the 505(b)(2) pathway, it may conclude that our data fail to demonstrate adequate safety and efficacy to obtain regulatory approval.

We will need to successfully enroll and complete clinical trials of ifabotuzumab and lenzilumab, and obtain regulatory approvals to market all of our products. The future clinical, regulatory and commercial success of our product candidates is subject to a number of risks, including the following:

- we may not be able to enroll adequate numbers of eligible patients in the clinical trials we propose to conduct;
- we may not have sufficient financial and other resources to complete the clinical trials;
- we may not be able to provide acceptable evidence of safety and efficacy for our product candidates;

- the results of our clinical trials may not meet the level of statistical or clinical significance, or product safety, required by FDA for marketing approval;
- we may not be able to obtain, maintain and enforce our patents and other intellectual property rights; and
- we may not be able to obtain and maintain commercial manufacturing arrangements with third-party manufacturers or establish commercial-scale manufacturing capabilities.

Furthermore, even if we do receive regulatory approval to market any of our product candidates, any such approval may be subject to limitations on the indicated uses for which we may market the product. If any of our product candidates are unsuccessful, that could have a substantial negative impact on our business.

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

Our product candidates other than benznidazole are in the early stage of development and will require substantial clinical development, testing, and regulatory approval prior to commercialization. None of our product candidates other than benznidazole 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 FDA regulatory approval process and are commercialized. We have discontinued the development of prior product candidates after they failed to meet clinical endpoints in non-pivotal trials. 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 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.

For benznidazole, FDA may disagree with our belief that sufficient clinical safety and efficacy data exist to support FDA approval in treating Chagas disease, and other factors may also prevent us from obtaining approval or from commercializing the drug successfully.

No treatments for Chagas disease are currently approved for marketing in the United States. On June 30, 2016, we acquired from Savant certain regulatory and non-intellectual property assets relating to benznidazole and any product containing benznidazole and an exclusive license of certain intellectual property rights related to benznidazole. We are now working to obtain FDA approval for benznidazole for the treatment of Chagas disease based primarily on data in three categories: (i) clinical trials previously conducted by others for which we have obtained a right to access and use the underlying data, which we plan to analyze, organize, and present to FDA in a new drug application, or NDA; (ii) clinical trials reported in the literature and described in unpublished reports of investigations, for which the underlying data may or may not have been submitted to FDA, and to which we have not obtained rights of access, use, or reference; and (iii) to the extent required by FDA, bioavailability and/or bioequivalence studies and non-clinical studies that we will perform to bridge the clinical trial data described above using prior formulations of benznidazole to our current formulation, which we believe to be comparable to the prior formulations.

For the first category of data, it may turn out that the data to which we obtained rights from Savant and all other data to which we are able to obtain rights are collectively insufficient to establish the clinical safety or efficacy of benznidazole. Even if those data are sufficient, we may be unable to analyze, organize, translate, and present those data adequately to convince FDA that those data establish benznidazole's safety and efficacy, even if also supported by strong data in the second category of data described above. Although an FDA regulation, 21 C.F.R. §312.120, permits sponsors to submit and rely on foreign clinical data not collected under a U.S. investigational new drug application, or IND, and another regulation, 21 C.F.R. §314.106, permits sponsors to rely solely on foreign clinical data as a basis for marketing approval, we may not be able to satisfy the conditions imposed by those regulations. Moreover, our understanding is that in reality FDA rarely grants approval based solely on foreign data, and ordinarily requires some bridging data to account for potentially material differences in patient populations, standards of medical practice, and other variables. We may not be able to generate adequate bridging data. In addition, as discussed further below with respect to the third category of data, FDA may find that even if the data in the first two categories are adequate to establish the safety and efficacy of the prior formulation of benznidazole, our current formulation of benznidazole is not comparable to the prior formulation and, consequently, that the existing clinical safety and efficacy data to which we have rights do not establish the safety and efficacy of our current formulation of benznidazole.

For the second category of data described above, on which we anticipate needing to rely, at least to some extent, to support the first category in establishing benznidazole's safety and efficacy, these data may not themselves be adequate to cure all deficiencies or gaps in the first category of data. Even if adequate, FDA may find the data unconvincing or unreliable, may refuse to rely on them because FDA is not able to review the underlying raw data, may find that reliance under section 505(b)(2) is inappropriate without contractual rights of reference such as because some or all are foreign data never previously submitted to or reviewed by FDA, or may reject the data for other reasons.

For the third category of data described above, it may turn out that our current formulation of benznidazole is not comparable to the prior formulation used in the clinical trials on which we intend to rely. Even if the two formulations are in fact comparable, FDA may reject our bridging data because FDA does not have sufficient information on the prior formulation, because our bridging studies are inadequate and we are unable to supplement or correct them, or for other reasons. In addition, FDA may require lengthy, expensive, or difficult bridging studies for which we have inadequate resources or expertise to complete successfully.

If any of the above risks are realized, we may be unable to obtain FDA approval for benznidazole, and even if we do obtain approval, we may not be able to commercialize it successfully and may not be able to generate sufficient revenue to continue our business, or may suffer from delays, additional costs, or other obstacles that will material harm our business.

We focus on neglected and rare diseases, which may create additional risks and challenges.

Given the small number of patients who have certain of the indications that we are targeting and the fact that we intend to treat neglected diseases with certain of our drug candidates, our profitability and growth depend on successfully identifying patients with these diseases and obtaining coverage and reimbursement of our product candidates by third-party payers, including government payers. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, and market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases, and, as a result, the number of patients with these diseases may turn out to be lower than expected. Our effort to identify patients with diseases we seek to treat is in early stages, and we cannot accurately predict the number of patients for whom treatment might be possible.

We may not be able to initiate or continue clinical trials if we are unable to locate a sufficient number of eligible patients willing and able to participate in the clinical trials required by FDA or other non-United States regulatory agencies. In addition, if others develop product candidates for the treatment of the same or similar diseases, we would potentially compete with them for the enrollment in these rare patient populations, which may adversely impact the rate of patient enrollment in and the timely completion of our current and planned clinical trials. Additionally, insufficient patient enrollment may be a function of many other factors, including the size and nature of the patient population, the nature of the protocol, the proximity of patients to clinical sites, the timing and magnitude of disease symptom presentation, the availability of effective treatments for the relevant disease, and the eligibility criteria for the clinical trial. Our inability to identify and enroll a sufficient number of eligible patients for any of our current or future clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Delays in patient enrollment in the future as a result of these and other factors may result in increased costs or may affect the timing or outcome of our clinical trials, which could prevent us from completing these trials and adversely affect our ability to advance the development of our product candidates.

Additionally, the potentially addressable patient population for each of our product candidates may be limited or may not be amenable to treatment with our product candidates, and new patients may become increasingly difficult to identify or gain access to, which would adversely affect our results of operations and our business. Finally, even if we obtain significant market share for our product candidates, because the potential target populations are very small and in some cases may not have access to medical coverage, whether through insurance or government programs, we may never achieve profitability despite obtaining such market share.

Our business model is predicated on expected benefits from various regulatory incentives, such as orphan drug exclusivity, breakthrough therapy designation, fast track designation, priority review and priority review vouchers, or PRVs, and we may not ultimately qualify for or benefit from these arrangements.

Because we focus on developing drugs as treatments for neglected and rare diseases, we may seek various regulatory incentives, such as orphan drug exclusivity, breakthrough therapy designation, fast track designation, accelerated approval, priority review and PRVs, where available, that provide for certain periods of exclusivity, expedited review and/or other benefits, and we may also seek similar designations elsewhere in the world. We also anticipate benefitting from New Chemical Entity, or NCE, status under the Hatch-Waxman Act for benznidazole and other future drug candidates that qualify. Often, regulatory agencies have broad discretion in determining whether or not products qualify for such regulatory incentives and benefits. We cannot guarantee that we will be able to receive orphan drug or NCE status from FDA or equivalent regulatory designations elsewhere. We also cannot guarantee that we will obtain breakthrough therapy or fast track designation, which may provide certain potential benefits such as more frequent meetings with FDA to discuss the development plan, intensive guidance on an efficient drug development program, and potential eligibility for rolling review or priority review. Legislative developments in the U.S., including recent proposed legislation that would restrict eligibility for PRVs, may affect our ability to qualify for these programs in the future.

Even if we are successful in obtaining beneficial regulatory designations by FDA or other regulatory agency for our product candidates, such designations may not lead to faster development or regulatory review or approval, and it does not increase the likelihood that our product candidates will receive marketing approval. We may not be able to obtain or maintain such designations for our product candidates, and our competitors may obtain these designations for their product candidates, which could impact our ability to develop and commercialize our product candidates or compete with such competitors, which would adversely impact our business, financial condition or results of operations.

Our business model is predicated on the availability of PRVs, particularly for benznidazole, but our product candidates may not qualify for or receive a PRV, and changes to the applicable programs could limit our ability to benefit from a PRV.

Under Section 524 of the FDCA, FDA is authorized to award PRVs to the sponsors of NDAs and BLAs for novel products targeting specific tropical diseases. Similarly, FDA's rare pediatric disease PRV program allows FDA to grant PRVs to NDA or BLA sponsors who receive approval for a product targeting a rare pediatric disease, defined as a disease that affects fewer than 200,000 individuals in the U.S., primarily aged from birth to 18 years. Under these PRV programs, PRV-holders can redeem their voucher to receive an accelerated six-month FDA action goal instead of the standard ten-month window, or they may sell or transfer their PRV to another sponsor. See "Government Regulation—Tropical Disease PVRs" and "—Rare Pediatric Disease PVRs" in Item 1 of this Annual Report for more information on the PRV programs.

We believe that benznidazole and lenzilumab or other future product candidates that we may develop or acquire may qualify for PRVs, and in particular we believe investors in our company place significant value on the potential to obtain a PRV for benznidazole. We have no assurance, however, that benznidazole, lenzilumab or any other product candidate we pursue in the future will qualify for a PRV, including because another party may receive FDA approval for a product containing an active ingredient in our products prior to our receiving approval, which is a particular risk in the case of benznidazole. Furthermore, we have no assurance that there will be a market for the sale of PRVs, or that the PRV programs will not be restricted, changed or eliminated or that, with respect to certain elements, will be left to expire. There currently is legislation that has been proposed in Congress that would have adverse effects on the availability of the PRV programs, including by preventing tropical disease PRVs from being awarded to products, like benznidazole, that are already approved in countries outside the U.S. Restrictions and changes to, or the elimination or expiration of, the PRV programs would have an adverse effect on our business and potential for realizing value from our focus on neglected and rare diseases, which could impact the willingness of investors to provide additional capital and our ability to ultimately return value to our shareholders.

There is a limited amount of information about us upon which investors can evaluate our product candidates and business prospects, including because we have a limited operating history developing product candidates, have not yet successfully commercialized any products, have recently changed our strategy and our management team, and only recently emerged from bankruptcy.

We have recently changed our strategy and our management team, and only recently emerged from bankruptcy. This means that we have a new management team managing our business, which now has a different strategic focus that it did before. We also more generally have a limited operating history developing clinical-stage product candidates. All of these factors could make it more difficult for us to be successful or for investors to be able to evaluate our business and prospects. In addition, as an early-stage clinical development company, we have limited experience in development activities, including conducting clinical trials, or seeking and obtaining regulatory approvals. We are also heavily dependent at this time on external consultants for scientific and regulatory expertise. We have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in the biopharmaceutical area. For example, to execute our business plan we will need to successfully:

- complete development activities and successfully submit for regulatory approval an NDA for benznidazole;
- 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, manufacturing, 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 FDA as part of an IND, along with other information including information about product candidate chemistry, manufacturing, and controls and our proposed clinical trial protocol. 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 third party, 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, 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, or 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, or 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;
- developing 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 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 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 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 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 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 future development partners experience delays in the completion of, or if we or any 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 may 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 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 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 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.

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 future development partners' clinical trials;
- we or any future development partners may be unable to demonstrate to the satisfaction of 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 that 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 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;
- such authorities may find deficiencies in the manufacturing processes or facilities of third-party manufacturers with which we or any future development partners contract for clinical and commercial supplies; or
- the approval policies or regulations of such authorities may significantly change in a manner rendering our or any 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 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 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 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 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 populations for their intended 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. 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. In addition, serious adverse or undesirable side effects may emerge or be identified during later stages of development that were not observed in earlier stages. 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 or Biologic License Application, or BLA, to FDA and even fewer are approved for commercialization.

If we fail to attract and retain key management and clinical development personnel, we may be unable to successfully manage our business and 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 heavily affected by turnover and highly dependent on the expertise of the members of our senior management, in particular our Chief Executive Officer, Dr. Cameron Durrant. Furthermore, we rely on third party consultants for a variety of services, and our Interim Chief Financial Officer is not an employee of ours, but instead provides services to us pursuant to a consulting arrangement we have entered into with a third party that employs him. 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, or the difficulty in replacing such individuals. 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, scientific and other expert personnel and we may not be able to do so in the future due to recent events, and intense competition from other biotechnology and pharmaceutical companies, universities, and research organizations for qualified personnel. Many of these competitors have substantially greater financial, technical and human resources than we do. If we are unable to attract and retain the necessary personnel, we may experience significant impediments to our ability to implement our business strategy.

Any product candidate we or any 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 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 three subjects deemed possibly related to the study drug by the study investigator in our ifabotuzumab Phase 1 clinical trial and, as a result, we amended our clinical protocol, which caused a delay in our program, but which resulted in no similar subsequent events.

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, except for benznidazole, for which the safety profile is well known and which we will document in our NDA primarily through foreign clinical data. 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 candidates.

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

We compete in an industry characterized by rapidly advancing technologies, intense competition, a changing regulatory and legislative landscape and a strong emphasis on the benefits of intellectual property protection and regulatory exclusivities. Our competitors include pharmaceutical companies, other biotechnology companies, academic institutions, government agencies and other private and public research organizations. We compete with these parties for therapies for neglected and rare diseases and in recruiting highly qualified personnel. Our product candidates, if successfully developed and approved, may compete with established therapies, with new treatments that may be introduced by our competitors, including competitors relying to a large extent on our drug approvals under section 505(b)(2) of the FDCA or on our biologics approvals under section 351(k) of the Public Health Service Act, or with generic copies of our products approved by FDA under an abbreviated new drug application, or ANDA, referencing our drug products. We believe that competitors are actively developing competing products to our product candidates, including other companies that are pursuing benznidazole for treatment of Chagas disease in the United States. See “Competition” in Item 1 of this Annual Report for a discussion of competition with respect to our current product candidates.

Many of our competitors and potential competitors have substantially greater scientific, research, and product development capabilities, as well as greater financial, marketing, sales and human resources capabilities 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 with respect to their products than we may be in developing, commercializing, and achieving widespread market acceptance for our products. If a competitor obtains approval for an orphan drug that is the same drug or the same biologic as one of our candidates before we do, we will be blocked from obtaining FDA approval for seven years from the date of the competitor's product, unless we can establish that our product is clinically superior to the previously-approved competitor's product or we can meet another exception, such as by showing that the competitor has failed to provide an adequate supply of its product to patients after approval. 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 non-competitive before we can recover the expenses related to developing and supporting the commercialization of any of our product candidates. Developments by competitors may render our product candidates obsolete or noncompetitive. After one of our product candidates is approved, FDA may also approve a generic version with the same dosage form, safety, strength, route of administration, quality, performance characteristics and intended use as our product. These generic equivalents would be less costly to bring to market and could generally be offered at lower prices, thereby limiting our ability to gain or retain market share.

The acquisition or licensing of pharmaceutical products is also very competitive, and a number of more established companies, which have acknowledged strategies to in-license or acquire products, may have competitive advantages as may other emerging companies taking similar or different approaches to product acquisitions. The more established companies may have a competitive advantage over us due to their size, cash flows, institutional experience and historical corporate reputation.

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:

- We, and our contract manufacturers, must comply with FDA's current Good Manufacturing Practice, or cGMP, regulations and guidance. 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 FDA and comparable agencies in other jurisdictions to confirm compliance with applicable regulatory requirements. Any failure to follow cGMP or other regulatory requirements or any 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 a failure to 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 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, adverse publicity, 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.

- 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.

- 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.

We may not be successful in identifying potential product candidates or obtaining necessary rights to product candidates for our development pipeline through acquisitions and in-licenses.

We do not intend to develop product candidates from our own original research. Our strategy involves identifying, acquiring, developing and supporting the commercialization of additional treatments for neglected and rare disease. However, we may be unable to identify, acquire or in-license any product candidates from third parties for various reasons, including because we are focusing on a specific type of product candidates, and we may be unable to identify product candidates that we believe are an appropriate strategic fit for our company.

The in-licensing and acquisition of product candidates is a competitive area, and a number of more established companies are also pursuing strategies to in-license or acquire product candidates that we may consider attractive. These established companies may have a competitive advantage over us due to their size, financial resources and greater clinical development and commercialization capabilities. Furthermore, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to in-license or acquire the relevant product candidate on terms that would allow us to generate an appropriate return on our investment.

In addition, we expect that competition for the in-licensing or acquisition of product candidates that are attractive to us may increase in the future, which may mean fewer suitable opportunities for us as well as higher acquisition or licensing prices. If we are unable to successfully obtain rights to suitable product candidates, our business, financial condition and prospects for growth could suffer.

If any product candidate that we successfully develop does not achieve broad market acceptance among physicians, patients, healthcare payers 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 payers, and the medical community. Coverage and reimbursement of our product candidates by third-party payers, including government payers, 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 payers, 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 payers for any of our product candidates and may be affected by existing and future health care reform measures. Government authorities and third-party payers, 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 payer may depend upon a number of factors including the third-party payer'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 payer 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 payer. 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 payers 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 FDA has granted market approvals. As a result, significant uncertainty exists as to whether and how much third-party payers will reimburse patients for their use of newly approved drugs, which in turn will put pressure on the pricing of drugs. Even with our focus on our Responsible Pricing Model, we could be subject to 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 the sales and marketing infrastructure in place that would be necessary to sell and market products. As our drug candidates progress, while we may build the infrastructure that would be needed to successfully market and sell any successful drug candidate, we currently anticipate seeking strategic alliances and partnerships with third parties, particularly for any drug candidates that we determine would require larger sales efforts. The establishment of a sales and marketing operation can be expensive and time consuming and could delay any product candidate launch. Whether directly or through third parties, we intend to responsibly price any approved products using our Responsible Pricing Model, which could make it more difficult to enter into arrangements with third parties on acceptable terms, if at all.

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

We intend to seek approval to market our future product candidates in the United States and potentially 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 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 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 or have insufficient insurance protection, 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. 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, which could have a material adverse effect on our 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 or similar regulations of comparable foreign regulatory authorities, failure to provide accurate information to FDA or comparable foreign regulatory authorities, failure to comply with manufacturing standards, failure to comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, failure to report financial information or data accurately, violations of anti-bribery laws, or failure to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare 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 the improper use of confidential information obtained in the course of our business, which could result in civil or criminal legal actions, regulatory sanctions, or serious harm to our reputation. We have adopted a Code of Business Conduct and Ethics and other corporate policies, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

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

We and any 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 partners, 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 partners, 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 payers 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.

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 future development partners are successful in commercializing our products, FDA and foreign regulatory authorities would require that we and any 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 future development partners may fail to report adverse events we become aware of within the prescribed timeframe. We and any 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 future development partners fail to comply with our reporting obligations, 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, or the BPCIA, as part of the Affordable Care Act, an abbreviated pathway for the approval of biosimilar and interchangeable biological products was created. The abbreviated regulatory pathway establishes legal authority for 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 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 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 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 biological products under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for biosimilar 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 payers. 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 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 False Claims Act 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 False Claims 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 False Claims Act 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 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 FDA approves any of our product candidates, the labeling, manufacturing, packaging, storage, distribution, export, adverse event reporting, storage, advertising, promotion and record-keeping for our products will be subject to extensive regulatory requirements. Violations of these regulatory requirements or the subsequent discovery of previously unknown problems with the products, including adverse events of unanticipated severity or frequency, may result in:

- the issuance of warning or untitled letters;
- requirements to conduct post-marking clinical trials;
- restrictions on the marketing and distribution of the product, including potential withdrawal of the product from the market;
- suspension of ongoing clinical trials;
- the issuance of product recalls, import and export restrictions, seizures, and detentions; and
- the issuance of injunctions, or imposition of other civil and/or criminal penalties.

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 Bankruptcy

Despite having emerged from bankruptcy, we cannot be certain that the residual effects of the bankruptcy proceedings will not adversely affect our operations going forward.

Because of the residual risks and uncertainties associated with Chapter 11 bankruptcy proceedings, the ultimate impact that events that occurred in connection with or that may occur subsequent to these proceedings will have on our reputation, business, financial condition and results of operations cannot be accurately predicted or quantified. Due to uncertainties, many risks exist, including the following:

- key business partners could terminate their relationships or require financial assurances or enhanced performance;
- the ability to renew existing contracts and negotiate favorable terms from suppliers, partners and others may be adversely affected;
- the ability to attract, motivate and/or retain key executives and employees may be adversely affected;
- employees may be distracted from performance of their duties or more easily attracted to other employment opportunities; and
- other costs of operations, including obtaining insurance, could be more expensive.

The occurrence of one or more of these events, or others related to our emergence from bankruptcy, could have a material and adverse effect on our operations, financial condition and reputation. We cannot assure you that having been subject to bankruptcy protection will not adversely affect our operations in the future.

We have experienced significant changes in our management team, Board of Directors and business strategy in connection with our bankruptcy and our emergence from bankruptcy.

We emerged from bankruptcy with a new management team and a substantially changed Board of Directors, as well as a new business plan and strategy focused on the treatment of neglected and rare diseases. The new management team and directors have different backgrounds, experiences and perspectives from those individuals who previously served and, thus, may have different views on the issues that will determine our future. In the future, we may have additional turnover in the members of our management team or the Board. Any such future turnover may require time, effort and cost and may divert the attention of the management team and Board away from our operations and business objectives. Additionally, we may not be successful in our efforts to pivot our business strategy to focus on neglected and rare diseases.

Our actual financial results may vary significantly from the projections filed with the Bankruptcy Court and, as a result of our bankruptcy, our historical financial information is not comparable to future financial information.

In connection with the Plan, we were required to prepare projected financial information to demonstrate to the Bankruptcy Court the feasibility of the Plan and our ability to continue operations upon emergence from bankruptcy. These projections were limited by the information available to us as of the date they were prepared and reflected numerous assumptions concerning anticipated future performance and prevailing and anticipated market and economic conditions that were and continue to be beyond our control and that may not materialize. Projections are inherently subject to uncertainties and to a wide variety of significant business, economic and competitive risks. Therefore, variations from the projections may be material. These projections were prepared solely for the purpose of the bankruptcy proceedings, have not been incorporated into this report, have not been, and will not be, updated on an ongoing basis and should not be considered or relied upon by investors.

Additionally, as a result of the consummation of the Plan and the transactions contemplated thereby, our financial condition and results of operations from and after our emergence from bankruptcy may not be comparable to the financial condition or results of operations reflected in our historical financial statements.

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 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. From time to time, we experience delays from our drug substance suppliers. To date, such delays have been manageable. However, 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, including affecting our ability to enroll in and timely progress clinical trials. Furthermore, if any of our contract manufacturers cannot successfully manufacture material that conforms to our specifications and with regulatory requirements, we will not be able to secure and/or maintain regulatory approval, if any, for our product candidates.

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

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

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

Part of our strategy is to enter into development partnerships and licensing agreements. We face significant competition in seeking appropriate partners and the negotiation process is time consuming and complex. Even if we are successful in securing a development partnership, we may not be able to continue it. For example, in July 2014, we terminated our prior development partnership with Sanofi for KB001-A. 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 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

If we fail to adequately protect or enforce our intellectual property rights or secure rights to patents of others, the value of our intellectual property rights would diminish, and our business and competitive position would suffer.

Our success, competitive position and future revenues will depend in part on our ability and the abilities of our licensors and licensees to obtain and maintain patent protection for our products, methods, processes and other technologies, to preserve our trade secrets, to prevent third parties from infringing on our proprietary rights and to operate without infringing the proprietary rights of third parties. We have an active patent protection program that includes filing patent applications on new compounds, formulations, delivery systems and methods of making and using products and prosecuting these patent applications in the United States and abroad. As patents issue, we also file continuation applications as appropriate. Although we have taken steps to build a strong patent portfolio, we cannot predict:

- the degree and range of protection any patents will afford us against competitors, including whether third parties find ways to invalidate or otherwise circumvent our licensed patents;
- if and when patents will issue in the United States or any other country;
- whether or not others will obtain patents claiming aspects similar to those covered by our licensed patents and patent applications;
- whether we will need to initiate litigation or administrative proceedings to protect our intellectual property rights, which may be costly whether we win or lose;
- whether any of our patents will be challenged by our competitors alleging invalidity or unenforceability and, if opposed or litigated, the outcome of any administrative or court action as to patent validity, enforceability or scope;
- whether a competitor will develop a similar compound that is outside the scope of protection afforded by a patent or whether the patent scope is inherent in the claims modified due to interpretation of claim scope by a court;
- whether there were activities previously undertaken by a licensor that could limit the scope, validity or enforceability of licensed patents and intellectual property; or
- whether a competitor will assert infringement of its patents or intellectual property, whether or not meritorious, and what the outcome of any related litigation or challenge may be.

Our success also depends upon the skills, knowledge and experience of our scientific and technical personnel, our consultants and advisors as well as our licensors, sublicensees and contractors. To help protect our proprietary know-how and our inventions for which patents may be unobtainable or difficult to obtain, we rely on trade secret protection and confidentiality agreements. To this end, we require all employees, consultants and board members to enter into agreements that prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business. These agreements may not provide adequate protection for our trade secrets, know-how or other proprietary information in the event of any unauthorized use or disclosure or the lawful development by others of such information. If any of our trade secrets, know-how or other proprietary information is disclosed, the value of our trade secrets, know-how and other proprietary rights would be significantly impaired, and our business and competitive position would suffer.

Due to legal and factual uncertainties regarding the scope and protection afforded by patents and other proprietary rights, we may not have meaningful protection from competition.

Our long-term success will substantially depend upon our ability to protect our proprietary technologies from infringement, misappropriation, discovery and duplication and avoid infringing the proprietary rights of others. Our patent rights, and the patent rights of biopharmaceutical companies in general, are highly uncertain and include complex legal and factual issues. These uncertainties also mean that any patents that we own or may obtain in the future could be subject to challenge, and even if not challenged, may not provide us with meaningful protection from competition. Patents already issued to us or our pending applications may become subject to dispute, and any dispute could be resolved against us.

If we infringe the rights of third parties, we could be prevented from selling products and be forced to defend against litigation and pay damages.

If our products, methods, processes and other technologies infringe the proprietary rights of other parties, we could incur substantial costs and may have to:

- obtain licenses, which may not be available on commercially reasonable terms, if at all;
- redesign our products or processes to avoid infringement;
- stop using the subject matter claimed in patents held by others, which could cause us to lose the use of one or more of our drug candidates;
- pay damages; or
- defend litigation or administrative proceedings that may be costly whether we win or lose and that could result in a substantial diversion of our management resources.

Although we have not received any claims of infringement by any third parties to date, we expect that as our drug candidates move further into clinical trials and commercialization and our public profile is raised, we will be more likely to be subject to such claims.

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.

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

There is a limited trading market for our securities. An active trading market for our common stock may not develop or be sustained and the market price of our securities is subject to volatility.

On January 13, 2016, our common stock was delisted from the NASDAQ Global Market, and our common stock is no longer listed on any national or regional securities exchange. Although our common stock is listed for quotation on the OTC Pink marketplace operated by OTC Markets Group, Inc., trading is limited and we cannot predict whether an active market for our common stock will ever develop in the future. In the absence of an active trading market:

- investors may have difficulty buying and selling shares of our common stock;
- market visibility for shares of our common stock may be limited;
- a lack of visibility for shares of our common stock may have a depressive effect on the market price for shares of our common stock; and
- significant sales of our common stock, or the expectation of these sales, could materially and adversely affect the market price of our common stock.

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 additional intellectual property assets by using our shares as consideration.

The OTC Pink marketplace is a relatively unorganized, inter-dealer, over-the-counter market that provides significantly less liquidity than NASDAQ, the NYSE or the NYSE MKT. No assurance can be given that an active market will develop for the common stock or as to the liquidity of the trading market for the common stock. The common stock may be traded only infrequently in transactions arranged through brokers or otherwise, and reliable market quotations may not be available. We intend to re-list on a national exchange. However, no assurances can be given regarding our ability to do so in a timely manner or at all.

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. 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.

We have identified material weaknesses in our internal control over financial reporting and may be unable to maintain effective control over financial reporting.

In the course of the preparation and external audit of our consolidated financial statements for the fiscal year ended December 31, 2015, we and our independent registered public accounting firm identified "material weaknesses" in our internal control over financial reporting related to our limited number of accounting and financial reporting personnel and high levels of turnover in our personnel responsible for performing activities related to our internal control over financial reporting. A material weakness in internal control over financial reporting is a deficiency, or combination of deficiencies, in internal control over financial reporting that results in more than a reasonable possibility that a material misstatement of annual or interim consolidated financial statements will not be prevented or detected on a timely basis. We identified the following material weaknesses: (i) an inability to complete our financial statement close process in a timely and accurate manner; (ii) an insufficient degree of segregation of duties amongst our accounting and financial reporting personnel; and (iii) a lack of technical competency in review and approval of financial reporting processes.

During 2016, management intends to work to remediate the material weaknesses identified above, which could include the addition of accounting and financial reporting personnel and/or the engagement of accounting and personnel consultants on a limited-time basis until we add a sufficient number of personnel. However, our current financial position could make it difficult for us to add the necessary resources.

Any material weaknesses in our internal control over financing reporting in the future could adversely affect investor confidence, impair the value of our common stock and increase our cost of raising capital.

If we are unable to remediate our material weakness over financial controls, we discover that we were unsuccessful in doing so, or we identify other material weaknesses or significant deficiencies in the future, our operating results might be harmed, we may fail to meet our reporting obligations or fail to prevent or detect material misstatements in our financial statements. Any such failure could, in turn, affect the future ability of our management to certify that internal control over our financial reporting is effective. Inferior internal control over financial reporting could also subject us to the scrutiny of the SEC and other regulatory bodies which could cause investors to lose confidence in our reported financial information and could subject us to civil or criminal penalties or stockholder litigation, which could have an adverse effect on our results of operations and the market price of our common stock.

In addition, if we or our independent registered public accounting firm identify deficiencies in our internal control over financial reporting, the disclosure of that fact, even if quickly remedied, could reduce the market's confidence in our financial statements and harm our share price. Furthermore, deficiencies could result in future non-compliance with Section 404 of the Sarbanes-Oxley Act of 2002. Such non-compliance could subject us to a variety of administrative sanctions, including review by the SEC or other regulatory authorities.

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 August 30, 2016, our stock had high and low sales prices in the range of $45.82 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 Annual Report on Form 10-K 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.

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

We 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.

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 76% of our common stock as of August 30, 2016. 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.

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, executive officers and the holders of more than 5% of our common stock, or their affiliates or associates, 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 August 30, 2016, we had 14,897,993 shares of common stock outstanding, of which 11,296,885 shares were held by directors, officers and stockholders who hold greater than 5% of our common stock.

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 a company's common stocks often is based in part on the research and reports that securities and industry analysts publish about the company. We are not currently aware of any well-known analysts that are covering our common stock, and without analyst coverage it could be hard to generate interest in investments in our common stock. Furthermore, if analyst coverage does develop, and an analyst downgrades our stock or publishes unfavorable research about our business, or if our clinical trials or operating results fail to meet the analysts' expectations, our stock price would likely decline.

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. 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.

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. For example, in December 2016, several putative class action lawsuits were filed against us, all of which were settled prior to our emergence from bankruptcy. Additional 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 lease a facility in Brisbane, California. The lease commenced in April 2016 and will expire in March 2017. At the end of the one-year term of the new lease, we have the option to extend its term for an additional one year at the then current fair market value rental rate determined in accordance with the terms of the lease.

ITEM 3. LEGAL PROCEEDINGS

We filed for protection under Chapter 11 of Title 11 of the United States Bankruptcy Code on December 29, 2015, in the United States Bankruptcy Court for the District of Delaware, or the Bankruptcy Court (Case No. 15-12628 (LSS). Our Second Amended Plan of Reorganization, dated May 9, 2016, as amended, or the Plan, was approved by the Bankruptcy Court on June 16, 2016 with an effective date of June 30, 2016, or the Effective Date. As of the Effective Date, approximately 195 proofs of claim were outstanding (including claims that were previously identified on the Schedules) totaling approximately $32.0 million.

Securities Class Action Litigation

On December 18, 2015, a putative class action lawsuit (captioned Li v. KaloBios Pharmaceuticals, Inc. et al., 5:15-cv-05841-EJD) was filed against us in the United States District Court for the Northern District of California, or the Class Action Court, alleging violations of the federal securities laws by Martin Shkreli, our former Chairman and Chief Executive Officer. On December 23, 2015, a putative class action lawsuit was filed against us in the Class Action Court (captioned Sciabacucchi v. KaloBios Pharmaceuticals, Inc. et al., 3:15-cv-05992-CRB), similarly alleging violations of the federal securities laws by Mr. Shkreli. On December 31, 2015, a putative class action lawsuit was filed against us in the Class Action Court (captioned Isensee v. KaloBios Pharmaceuticals, Inc. et al., Case No. 15-cv-06331-EJD) also alleging violation of the federal securities laws by Mr. Shkreli. On April 28, 2016, the Class Action Court consolidated the cases, which we refer to collectively as the Securities Class Action Litigation, and appointed certain plaintiffs as lead plaintiffs. The lead plaintiffs in the Securities Class Action Litigation were seeking damages of $20.0 million on behalf of all the affected members of the class represented in the Securities Class Action Litigation, or the Securities Class Action Members.

On June 16, 2016, a settlement stipulation, or the Securities Class Action Settlement, was approved by the Bankruptcy Court. Subject to the approval of the Class Action Court, the Securities Class Action Settlement required us to issue 300,000 shares of common stock and submit a payment of $250,000 the Securities Class Action Members and advance insurance proceeds of $1.25 million to the Securities Class Action Members. We refer to the consideration owed to the Securities Class Action Members under the Securities Class Action Settlement as the Securities Class Action Settlement Consideration. Subject to the final approval of the Securities Class Action Settlement, any Securities Class Action Member is entitled to share in the Securities Class Action Settlement Consideration. The Securities Class Action Settlement provides for releases and related injunctions to be granted for the benefit of, among others, us, Ronald Martell, Herb Cross and all of our past, present and future directors, officers and employees, excluding Mr. Shkreli. Alternatively, Securities Class Action Members may exclude themselves from the Securities Class Action Settlement and are thereby not bound by the terms of the Securities Class Action Settlement nor entitled to receive any amount of the Securities Class Acton Settlement Consideration. Such individuals remain free to assert claims against us and such claims were subordinated to the level of our common stock and otherwise remain subject to our objection. Our agreement to the Securities Class Action Settlement was not in any way an admission of our wrongdoing or liability.

PIPE Litigation

On January 7, 2016, certain investors, or the PIPE Claimants, filed a lawsuit (captioned *Gregory Rea, et al. v. KaloBios Pharmaceuticals, Inc.*, Adv. Pro. No. 16-50001 (LSS)) in the Bankruptcy Court against us, alleging implied trust theories, breach of contract, fraud and violations of the federal securities laws in connection with the PIPE Claimants' purchase of our common stock in a private placement equity transaction in December 2015. The PIPE Claimants also raised certain other objections to our bankruptcy proceeding. The PIPE Claimants sought an aggregate total of approximately $6.9 million in damages.

On May 9, 2016, the Bankruptcy Court entered an order approving a settlement stipulation between us and the PIPE Claimants, or the PIPE Settlement. Under the PIPE Settlement, we were required to issue 327,608 shares of common stock and submit a payment of $250,000 to the PIPE Claimants. The PIPE Settlement was contingent on certain conditions set forth therein, including the effectiveness of the Plan. In connection with the effectiveness of the Plan, and per the terms of the PIPE Settlement, we became obligated to issue 327,608 shares to the PIPE Claimants and make a payment of $250,000 to the PIPE Claimants for the purpose of satisfying expenses related to the PIPE Settlement. Our agreement to the PIPE Settlement was not in any way an admission of our wrongdoing or liability.

Claim by Marek Biestek

Marek Biestek was a director of the Company who, while not a plaintiff in the above described adversary proceedings, filed a proof of claim alleging damages from the private placement and filed an objection to the confirmation of our Plan. To resolve his objection to the Plan, we settled with him individually by issuing him 3,750 additional shares of common stock. Mr. Biestek, as a former director of the company, was excluded from the Securities Class Action Members and therefore received nothing from the Securities Class Action Litigation.

Governance Agreement

Pursuant to the terms of the Plan, on the Effective Date we entered into a governance agreement, or the Governance Agreement, with Mr. Shkreli, which provides for certain terms and conditions regarding the acquisition, disposition, holding and voting of our securities by Mr. Shkreli.

Releases, Exculpation, Injunction and Discharge Provisions

The Plan provides certain releases, including the following: (i) releases by us, subject to certain exclusions, of claims and causes of action against (a) our officers, directors, employees, advisors and certain related persons who acted in such capacity on or after the Petition Date and (b) the Black Horse Entities and Nomis, as well as their respective current and former directors and officers, partners, advisors and certain other related parties, or collectively, the Released Parties; (ii) releases by holders of claims and interests, subject to certain exclusions, of claims and causes of action against us and Released Parties; (iii) mutual releases between us and the PIPE Claimants, for the benefit of each and certain related parties, as contemplated by the PIPE Settlement; and (iv) releases as contemplated by the Securities Class Action Settlement. All our claims and causes of action or those of our bankruptcy estate not expressly released by us under the Plan or pursuant to another Bankruptcy Court order are expressly reserved to us under the Plan.

The Plan also contains certain exculpation provisions, which include exculpation from liability, subject to certain exceptions for acts and omissions that are the result of willful misconduct or gross negligence, in favor of us and our directors, officers, employees, advisors and certain other related persons and entities who served in such capacity on or after the Petition Date relating to the bankruptcy proceedings, the negotiation and formulation of the Plan and the related disclosure statement, and the confirmation, consummation and administration of the Plan.

The Plan provides for a discharge of all claims against us to the fullest extent provided under section 1141(d)(1)(A) of the Bankruptcy Code.

Additional Information

For additional information on the foregoing bankruptcy proceeding, including with respect to our bankruptcy related financing arrangements, our arrangements with Savant and details on the governance agreement, see Note 2 and 16 to our Consolidated Financial Statements included in Part II, Item 8, “Financial Statements and Supplementary Data” of this Annual Report on Form 10-K, which are incorporated by reference into this Item.

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 is currently quoted on the OTC Pink marketplace operated by OTC Markets Group, Inc. Previously, our common stock was listed on the NASDAQ Global Market under the symbol "KBIO" from its beginning of trading on January 31, 2013 through January 13, 2016. Prior to January 31, 2013, 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
2015		
4th Quarter	$ 45.82	$ 0.44
3rd Quarter	$ 5.08	$ 0.38
2nd Quarter	$ 0.71	$ 0.41
1st Quarter	$ 1.95	$ 0.36
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 August 30, 2016, we had 14,897,993 shares of common stock outstanding held by approximately 47 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.

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.

Recent Sales of Unregistered Securities and Repurchases of Equity Securities

During the applicable periods, we did not have any sales of unregistered securities that were not previously reported and we did not repurchase any of our equity securities.

ITEM 6. SELECTED FINANCIAL DATA

Information requested by this Item is not applicable as we are electing scaled disclosure requirements available to Smaller Reporting Companies with respect to this Item.

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, 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 developing medicines for patients with neglected and rare diseases, with an ancillary focus on pediatric conditions, and on executing our Responsible Pricing Model in the commercialization of our products that may be approved. Our lead product candidate is benznidazole for the treatment of Chagas disease, a parasitic illness that can lead to long-term heart, intestinal and neurological problems. We are developing one of our proprietary monoclonal antibodies, lenzilumab (formerly known as KB003), for the treatment of chronic myelomonocytic leukemia, or CMML, and potentially for the treatment of juvenile myelomonocytic leukemia, or JMML, both of which are rare hematologic cancers with high unmet medical need. We are exploring development of another of our proprietary monoclonal antibodies, ifabotuzumab (formerly known as KB004), for the treatment of certain rare solid and hematologic cancers. With a focus on neglected, rare and orphan diseases, we believe we have the opportunity to benefit from various regulatory incentives, such as orphan drug exclusivity, breakthrough therapy designation, fast track designation, accelerated approval, priority review and priority review vouchers, or PRVs, where available, that provide for certain periods of exclusivity, expedited review and/or other benefits.

Upon approval of any of our products, we intend to apply our Responsible Pricing Model, which focuses on affordability for patients and payers, transparency for all stakeholders, and delivery of a reasonable return in recognition of the risks we are taking in our development efforts.

Benznidazole is an oral small molecule antiprotozoal for the treatment of Chagas disease, which is also known as American trypanosomiasis. Benznidazole has undergone numerous clinical trials and studies that show efficacy against Chagas disease and we believe is the current preferred treatment for Chagas disease in the countries where it is approved. No treatments for Chagas disease are approved by the United States Food and Drug Administration, or FDA, for use in the United States. We recently acquired certain worldwide rights relating to benznidazole for human use from Savant Neglected Diseases, LLC, or Savant, and we are focused on the development necessary to seek and obtain FDA approval of benznidazole. We believe benznidazole as a treatment for Chagas disease could qualify for priority review and potentially other FDA regulatory incentives, and to receive a PRV if FDA approves the drug for marketing.

Lenzilumab is a recombinant monoclonal antibody, or mAb, that neutralizes soluble granulocyte-macrophage colony-stimulating factor, or GM-CSF, a critical cytokine for the growth of certain hematologic malignancies and solid tumors. Consistent with our strategic focus on neglected and rare diseases, in July 2016, we initiated dosing in a Phase 1 clinical trial in patients with CMML to identify the maximum tolerated dose, or MTD, or recommended Phase 2 dose of lenzilumab and to assess lenzilumab's safety, pharmacokinetics, and clinical activity.

Ifabotuzumab is an anti-EphA3 mAb that has the potential to offer a novel approach to treating both solid tumors and hematologic malignancies. EphA3 is aberrantly expressed on the tumor cell surface of certain cancers. We have completed the Phase 1 dose escalation portion of a Phase 1/2 clinical trial in ifabotuzumab in multiple hematologic malignancies and are evaluating whether to conduct further studies of ifabotuzumab in rare solid tumors such as glioblastoma, other brain cancers in children and rare hematologic cancer indications. We also have an additional drug candidate, KB001-A, a recombinant, PEGylated, anti-Pseudomonas PcrV high-affinity Fab' antibody that we are no longer developing, but which is being considered for partnering or out-licensing.

Lenzilumab, ifabotuzumab and KB001-A were each developed with our proprietary, patent-protected Humaneered® technology, which consists of methods for converting antibodies (typically murine) into engineered, high-affinity antibodies designed for human therapeutic use, typically for chronic conditions.

Our strategy also involves identifying, acquiring, developing and supporting the commercialization of additional treatments for neglected and rare diseases. We believe the treatment of neglected and rare diseases represents an opportunity to enter underserved patient populations. We also believe our focus on neglected and rare diseases provides us the opportunity to benefit from various regulatory incentives referenced above. The potential opportunities afforded by these regulatory programs provide an important incentive to support our efforts to develop medicines for patients with neglected and rare diseases and to apply our Responsible Pricing Model for any of our approved products.

Our company has undergone a significant transformation in the last year. As a result of challenges facing us at the time, on December 29, 2015, we filed a voluntary petition for bankruptcy protection under Chapter 11 of Title 11 of the U.S. Bankruptcy Code. On June 30, 2016, our Second Amended Plan of Reorganization, dated May 9, 2016, as amended, or the Plan, became effective and we emerged from our Chapter 11 bankruptcy proceedings. For further information on our bankruptcy and emergence from bankruptcy, see Part I, Item 1, "Business—Bankruptcy" and Notes 2 and 16 to the Consolidated Financial Statements included in Part II, Item 8, "Financial Statements and Supplementary Data" of this Annual Report on Form 10-K.

We have incurred significant losses and had an accumulated deficit of $213.6 million as of December 31, 2015. 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 development activities and seek regulatory approvals. 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.

We will require substantial additional capital to support our business efforts, including obtaining regulatory approvals for benznidazole or other product candidates, clinical trials and other studies, and, if approved, the commercialization of our product candidates. We anticipate that in the future we will seek additional financing from a number of sources, including, but not limited to, the sale of equity or debt securities, strategic collaborations, and licensing of our product candidates. Additional funding may not be available to us on a timely basis or at acceptable terms, if at all. Our ability to access capital when needed is not assured and, if not achieved on a timely basis, would materially harm our business, financial condition and results of operations. If adequate funds are not available, we may be required to delay, reduce the scope of, or eliminate one or more of our development programs. 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 and on less than favorable terms, if at all.

If management is unsuccessful in efforts to raise additional capital, based on our current levels of operating expenses, our current capital is not expected to be sufficient to fund our operations for the next twelve months. These conditions 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 included in Part II, Item 8, "Financial Statements and Supplementary Data" of this Annual Report on Form 10-K includes an explanatory paragraph about our ability to continue as a going concern.

The consolidated financial statements for the year ended December 31, 2015 were prepared on the basis of a going concern, which contemplates that we will be able to realize our assets and discharge liabilities in the normal course of business. Our ability to meet our liabilities and to continue as a going concern is dependent upon the availability of future funding. The financial statements do not include any adjustments that might be necessary if we are unable to continue as a going concern.

On January 13, 2016, our common stock was suspended from the Nasdaq Global Market and began trading on the over-the-counter market under the KBIOQ symbol. On January 26, 2016, NASDAQ filed a Form 25 with the Securities and Exchange Commission to complete the delisting of our common stock, and the delisting was effective on February 5, 2016.

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, or 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 3 to our consolidated financial statements included in Part II, Item 8, "Financial Statements and Supplementary Data" of 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 to date has been generated primarily through license agreements and research and development collaboration agreements. Contract revenue 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 did not materially modify any previous material collaboration agreements or enter into any new such agreements from 2011 through the end of 2015. 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, or ASU, 2009-13, Multiple-Deliverable Revenue Arrangements, and ASU 2010-17, Revenue Recognition—Milestone Method, each of which we adopted on a prospective basis on January 1, 2011.

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.

Liabilities Subject to Compromise

Liabilities subject to compromise is our estimate of known or potential pre-petition claims to be resolved in connection with our Chapter 11 bankruptcy case. Such claims remain subject to future adjustments. Payment terms for liabilities subject to compromise are established as part of the Plan.

We applied Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, 852, *Reorganizations*, which is applicable to companies under bankruptcy protection, and requires amendments to the presentation of key financial statement line items. It requires that the financial statements for periods subsequent to the Chapter 11 filing distinguish transactions and events that are directly associated with the reorganization from the ongoing operations of the business. Revenues, expenses, realized gains and losses, and provisions for losses that can be directly associated with the reorganization and restructuring of the business must be reported separately as reorganization items in the Consolidated Statements of Operations and Comprehensive Loss. The balance sheet must distinguish pre-petition liabilities subject to compromise from both those pre-petition liabilities that are not subject to compromise and from post-petition liabilities. Liabilities that may be subject to a plan of reorganization must be reported at the amounts expected to be allowed in our Chapter 11 case, even if they may be settled for lesser amounts as a result of the plan of reorganization or negotiations with creditors. In addition, cash used by reorganization items are disclosed separately in the Consolidated Statements of Cash Flow. As of December 31, 2015, we had not incurred or paid significant amounts related to our reorganization.

Recently Issued Accounting Pronouncements

For a discussion of new accounting pronouncements, see Note 3, *Summary of Significant Accounting Policies* in the notes to the consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

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, 2015, we had an accumulated deficit of $213.6 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.

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 track external research and development costs incurred by project for each of our clinical programs. 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 costs 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, 2015 and 2014:

	Year Ended December 31,		For the Period from January 1, 2008 to
(In thousands)	**2015**	**2014**	**December 31, 2015**
External Costs:			
KB001-A	$ 1,176	$ 7,100	$ 33,756
Lenzilumab	340	4,349	40,503
Ifabotuzumab	5,199	5,738	36,839
Internal Costs	10,006	9,386	74,082
Total research and development	$ 16,721	$ 26,573	$ 185,180

We expect to continue to incur substantial expenses related to our research and development activities for the foreseeable future as we continue product development including working to obtain FDA approval for benznidazole for the treatment of Chagas disease, continuing the Phase 1clinical trial of lenzilumab in patients with CMML, and evaluating whether to conduct further studies of ifabotuzumab. Historically, we have also incurred significant costs related to KB001-A, our former respiratory program for lenzilumab and the development of ifabotuzumab for other oncology indications than those for which we are currently considering development. Depending on the results of our development efforts for lenzilumab in CMML and if we decide to move forward with conducting further studies of ifabotuzumab, we expect to incur substantial costs to prepare for potential clinical trials and activities for lenzilumab in JMML and for ifabotuzumab.

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, 2015 and 2014, general and administrative expenses were $14.3 million and $10.1 million, respectively.

Comparison of Years Ended December 31, 2015 and 2014

(In thousands)	Year Ended December 31, 2015	2014	Increase/ (Decrease) in thousands	%
Operating expenses:				
Research and development	$ 16,721	$ 26,573	$ (9,852)	(37)
General and administrative	14,296	10,145	4,151	41
Litigation accrual expense	3,335	-	3,335	100
Loss from operations	(34,352)	(36,718)	(2,366)	(6)
Interest income	29	88	(59)	(67)
Interest expense	(842)	(1,214)	(372)	(31)
Other expense, net	(213)	(154)	59	38
Net loss	$ (35,378)	$ (37,998)	$ (2,620)	7

Research and development expenses decreased $9.9 million in 2015 compared to 2014. The decrease is primarily attributable to the termination of our respiratory development program for KB001-A and our lenzilumab development program for asthma. We expect our research and development expenses will decrease in 2016 as compared to 2015, primarily due to the suspension of essentially all development projects until after our emergence from bankruptcy on June 30, 2016.

General and administrative expenses increased $4.2 million in 2015 compared to 2014. The increase in general and administrative expenses was primarily due to severance and restructuring costs as well as stock based compensation in connection with the December 2015 warrant issuance, offset by a decrease in personnel expense from reductions in our workforce. We expect our general and administrative expenses to decrease in 2016.

Litigation accrual expense increased $3.3 million in 2015 compared to 2014. There was no litigation accrual expense in 2014. The increase in litigation accrual expense is due to the accrual as of December 31, 2015 for the settlement of both the PIPE and class action lawsuits.

Interest expense decreased by $0.4 million in 2015 compared to 2014, due to the early payoff of our loan and security agreement with MidCap Financial SBIC LP, entered into in September 2012 and amended in 2013 and 2015, or the Loan and Security Agreement.

Other expense, net increased by $59,000 in 2015 compared to 2014, primarily due to the recording of the financing derivative liability and realized foreign currency exchange gains.

Income Taxes

As of December 31, 2015, we had net operating loss carryforwards of approximately $123.4 million to offset future federal income taxes which expire in the years 2025 through 2035, and approximately $123.2 million that may offset future state income taxes which expire in the years 2016 through 2035. 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, 2015, we recorded a 100% valuation allowance against our deferred tax assets of approximately $53.7 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 deferred tax assets, an adjustment to our valuation allowance 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 and private placements 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, 2015, we had cash and cash equivalents of $8.4 million. In November 2015, we announced a board-approved restructuring plan to reduce costs and extend the cash runway in order to allow us to evaluate strategic alternatives for our product candidates and the Company as a whole. As part of the restructuring plan, we elected to exercise our prepayment right under the Loan and Security Agreement to repay the loan in full and paid MidCap Financial $6.6 million in full settlement of the remaining outstanding principal balance, accrued interest, an exit fee and a reduced prepayment fee of 1%. In addition, we undertook a reduction in force that eliminated the positions of 17 employees, or more than 60% of our workforce, which resulted in restructuring charges of approximately $1.4 million recorded in the fourth quarter of 2015.

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)	**2015**	**2014**
Net cash (used in) provided by:		
Operating activities	$ (29,063)	$ (35,939)
Investing activities	30,097	(8,220)
Financing activities	(3,526)	862
Net (decrease) increase in cash and cash equivalents	$ (2,492)	$ (43,297)

Net cash used in operating activities was $29.1 million and $35.9 million for the years ended December 31, 2015 and 2014, 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 in operating activities for the year ended December 31, 2015 decreased by $6.8 million compared to 2014, due to a $8.4 million decrease in net loss adjusted for noncash items, offset by a net decrease in operating liabilities of $1.6 million.

Net cash provided by investing activities was $30.1 million for the year ended December 31, 2015, while net cash used in investing activities was $8.2 million for the year ended December 31, 2014 for a net increase in cash provided by investing activities of $38.3 million. In 2015, our proceeds from maturities of marketable securities exceeded our purchases of marketable securities by $29.7 million while in 2014, our purchases of marketable securities exceeded our proceeds from maturities of marketable securities by $7.8 million.

Net cash used in financing activities was $3.5 million for the year ended December 31, 2015, while net cash provided by financing activities was $0.9 million for the year ended December 31, 2014 for a net decrease in cash provided by investing activities of $4.4 million. In 2015, our use of cash related to payments against our notes payable was $11.7 million, offset by proceeds from the issuance of common stock of $8.2 million, while in 2014, our net proceeds from the issuance of notes payable and principal payments against our notes payable was $0.8 million.

In connection with our emergence from bankruptcy, we closed an $11 million financing that provided the funds required to exit our Chapter 11 proceeding as well as our current working capital. However, we will require substantial additional capital to support our business efforts, including obtaining regulatory approvals for benznidazole or other product candidates, clinical trials and other studies, and, if approved, the commercialization of our product candidates. The amount of capital we will require and the timing of our need for additional capital will depend on many factors, including:

- the type, number, timing, progress, costs, and results of the product candidate development programs that we are pursuing or may choose to pursue in the future;
- the scope, progress, expansion, costs, and results of our pre-clinical and 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 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 scope, progress, expansion and costs of manufacturing our product candidates; and
- the costs associated with being a public company.

We anticipate that in the future we will seek additional financing from a number of sources, including, but not limited to, the sale of equity or debt securities, strategic collaborations, and licensing of our product candidates. Additional funding may not be available to us on a timely basis or at acceptable terms, if at all. Our ability to access capital when needed is not assured and, if not achieved on a timely basis, would materially harm our business, financial condition and results of operations. If adequate funds are not available, we may be required to delay, reduce the scope of, or eliminate one or more of our development programs. 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 and on less than favorable terms, if at all.

If management is unsuccessful in efforts to raise additional capital, based on our current levels of operating expenses, our current capital is not expected to be sufficient to fund our operations for the next twelve months. These conditions 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 included elsewhere in this Annual Report on Form 10-K includes an explanatory paragraph about our ability to continue as a going concern.

On July 13, 2015, we effected a one-for-eight reverse stock split of our outstanding common stock pursuant to an amendment to our certificate of incorporation. As a result of the reverse stock split, each eight shares of our common stock were combined into one share of common stock. The reverse stock split was effective with respect to stockholders of record at the close of business on July 13, 2015, and trading of our common stock on the Nasdaq Global Market began on a split-adjusted basis on July 14, 2015. The reverse stock split was accounted for retroactively and is reflected in our common stock, warrant, stock option and restricted stock activity as of and for the years ended December 31, 2015 and 2014. Unless stated otherwise, all share data in this Annual Report on Form 10-K have been adjusted, as appropriate, to reflect the reverse stock split.

On January 13, 2016, our common stock was suspended from the Nasdaq Global Market and began trading on the over-the-counter market under the KBIOQ symbol. On January 26, 2016, NASDAQ filed a Form 25 with the Securities and Exchange Commission to complete the delisting of our common stock, and the delisting was effective on February 5, 2016. Although our common stock is listed for quotation on the OTC Pink marketplace operated by OTC Markets Group, Inc., trading is limited and an active market for our common stock may never develop in the future, which could harm our ability to raise capital to continue to fund operations.

Contractual Obligations and Commitments

Our contractual obligations consist primarily of obligations under our lease agreement. The following table summarizes our contractual lease obligations at December 31, 2015 and the effect such obligation is 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	$ 391	$ 327	$ 64	$ —	$ —
Total	$ 391	$ 327	$ 64	$ —	$ —

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 lease agreement for a facility in South San Francisco, California. The lease commenced in July 2014 and was set to expire in 2019. We moved into the 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, we had the option to terminate the lease after 36 months, subject to additional fees and expenses. In March 2016, we entered into a termination agreement, or the Lease Termination Agreement, related to the lease of this facility. The Lease Termination Agreement, approved by order of the Bankruptcy Court issued March 15, 2016, waived all damages related to early termination of the lease, relieved us of March rental expenses and set an effective termination date of March 31, 2016. Concurrent with the termination of this lease, we entered into a lease agreement for a new facility in Brisbane, California. The new lease commenced in April 2016 and will expire in March 2017. At the end of the one-year term of the new lease, we have the option to extend its term for an additional one year at the then current fair market value rental rate determined in accordance with the terms of the lease. The minimum lease payments presented in the table above include payments due under the new lease and the 2016 payments under the prior lease terminated as of March 31, 2016.

Notes Payable

The Loan and Security Agreement provided for the borrowing of up to $15 million. In June 2013, we entered into an amendment to the Loan and Security Agreement, or the First Amendment, to extend the draw down date for the final tranche of $5.0 million from June 2013 to May 2014, and to require us to draw that amount, which we did in May 2014. In connection with the First Amendment, we issued a warrant to purchase up to 6,193 shares of our common stock with an exercise price of $96.88 per share. The warrant expires on the tenth anniversary of its issuance date and had an initial fair value of $130,000, which represents financing fees, and is included in other assets in the accompanying Consolidated Balance Sheets and was being amortized as non-cash Interest expense over the remaining term of the Loan and Security Agreement using the effective interest method. We estimated the fair value of this warrant 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.

In November 2015, we elected to exercise our prepayment right to repay the loan in full and paid MidCap Financial $6.6 million in full settlement of the remaining outstanding principal balance, accrued interest, an exit fee and a reduced prepayment fee of 1%. The prepayment resulted in a gain on extinguishment of debt of $61,000 in the fourth quarter of 2015. Refer to Note 7 to the consolidated financial statements included elsewhere in this Annual Report on Form 10-K for additional details regarding the Loan and Security Agreement, including our classification of the notes payable as current as of December 31, 2014, and the decision to record a financing derivative liability resulting from an embedded derivative related to the prepayment feature of the Loan and Security Agreement.

Contracts

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.

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

Information requested by this Item is not applicable as we are electing scaled disclosure requirements available to Smaller Reporting Companies with respect to this Item.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our Consolidated Financial Statements and The Reports of Independent Registered Public Accounting Firms are included in this Annual Report on Form 10-K on pages F-1 through F-31.

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 Interim Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2015. 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 Interim Chief Financial Officer, to allow timely decisions regarding required disclosure. Based on this evaluation, and in light of the weaknesses in our internal control over financial reporting described below, our Chief Executive Officer and Interim Chief Financial Officer concluded that our disclosure controls and procedures were not effective as of December 31, 2015.

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 Exchange Act). Our Chief Executive Officer and Interim Chief Financial Officer assessed the effectiveness of our internal control over financial reporting as of December 31, 2015. In making this assessment, our Chief Executive Officer and Interim Chief Financial Officer used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO", in *Internal Control—Integrated Framework*. Based on that assessment and using the COSO criteria, our Chief Executive Officer and Interim Chief Financial Officer have concluded that, as of December 31, 2015, our internal control over financial reporting was not effective because of the material weaknesses described below.

A material weakness is defined as "a deficiency, or a combination of deficiencies in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis."

The ineffectiveness of our internal control over financial reporting was due to the following material weaknesses which each reflect our limited number of accounting and financial reporting personnel and high levels of turnover in our personnel responsible for performing activities related to our internal control over financial reporting: (i) an inability to complete our financial statement close process in a timely and accurate manner; (ii) an insufficient degree of segregation of duties amongst our accounting and financial reporting personnel; and (iii) a lack of technical competency in review and approval of financial reporting processes.

During 2016, our management intends to work to remediate the material weaknesses identified above, which could include the addition of accounting and financial reporting personnel and/or the engagement of accounting and personnel consultants on a limited-time basis until we add a sufficient number of personnel.

Despite the existence of the material weaknesses above, we believe that our Consolidated Financial Statements contained in this Form 10-K fairly present our financial position, results of operations and cash flows as of and for the periods presented in all material respects.

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

Other than as described above, there has been no change in our internal control over financial reporting during the quarter ended December 31, 2015, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations of Controls

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

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Directors

The following table sets forth the names, ages and current positions of members of the Board of Directors, or the Board, of KaloBios Pharmaceuticals, Inc., or the Company or us. Following the table is biographical information for each director, including information on specific experiences, qualifications and skills that support the conclusion that the director should currently serve on the Board.

Name	Age	Principal Occupation	Director Since
Cameron Durrant, M.D.	56	Chairman and Chief Executive Officer, KaloBios Pharmaceuticals, Inc.	2016
Ronald Barliant, JD	71	Of Counsel, Goldberg Kohn, Ltd.	2016
Dale Chappell, M.D.	46	Managing Member, Black Horse Capital Management LLC	2016
Timothy Morris	54	Chief Financial Officer, AcelRx Pharmaceuticals, Inc.	2016
Ezra Friedberg	46	General Partner, Multiplier Capital	2016

Cameron Durrant, M.D., has served as a member and Chairman of our Board since January 2016, and as our Chief Executive Officer since March 2016. From May 2014 to January 2016, Dr. Durrant served as Founder and Director of Taran Pharma Limited, a private semi-virtual specialty pharma company developing and registering treatments in Europe for orphan conditions. Dr. Durrant served as President and Chief Executive Officer of ECR Pharmaceuticals Co., Inc., a subsidiary of Hi-Tech Pharmacal Co., Inc., from September 2012 to April 2014. From January 2010 to September 2012, Dr. Durrant served as a consultant to several biopharma companies, as the Founder, CEO, CFO and director of PediatRx, Inc. and on the boards of several privately-held healthcare companies. He previously served as CEO of PediaMed Pharmaceuticals and has been a senior executive at Johnson and Johnson, Pharmacia Corporation, GSK and Merck. Dr. Durrant has been a director of Immune Pharmaceuticals Inc. since July 2014 and serves on the boards of directors of several privately held healthcare companies. Dr. Durrant earned his medical degree from the Welsh National School of Medicine, Cardiff, UK, his DRCOG from the Royal College of Obstetricians and Gynecologists, London, UK, his MRCGP from the Royal College of General Practitioners, London, UK, his DipCH from the Melbourne Academy, Australia and his MBA from Henley Management College, Oxford, UK. Dr. Durrant brings to the Board extensive experience as a pharma/biotech entrepreneur, operating executive and board member, as well as his day to day operating experience as our Chief Executive Officer.

Ronald Barliant, JD, has served as a member of our Board since January 2016. Mr. Barliant has been Of Counsel to Goldberg Kohn, Ltd. since January 2016, and immediately prior to that had served as a principal in Goldberg Kohn's Bankruptcy & Creditors' Rights Group since September 2002. He previously served as U.S. bankruptcy judge for the Northern District of Illinois from 1988 to 2002. Mr. Barliant has represented debtors and creditors in complex bankruptcy cases, and counseled major financial institutions, business firms and boards of directors in connection with workouts. He is a member of the board of directors of a closely held information technology company and the board of the estate representative supervising the liquidation of assets in the Global Crossing case. Mr. Barliant brings to the Board valuable experience gained from a distinguished career as a counselor to numerous boards, considered judgment and experience with bankruptcy in the bankruptcy setting, which continues to be relevant as we address the finalization of matters related to our emergence from bankruptcy.

Dale Chappell, M.D., has served as a member of our Board since June 2016. Dale Chappell is the managing member of Black Horse Capital Management LLC, a private investment manager that specializes in biopharmaceuticals with a particular focus on distressed and turn-around situations, a position he has held since 2002. Dr. Chappell has served as CEO, President and CFO of L'Isola US Holdings Inc., a private investment company with holdings in the hospitality industry, since April 2015 and also serves on the boards of directors of several private companies. Prior to his current position, Dr. Chappell was an associate with Chilton Investment Company, covering healthcare. Previously, Dr. Chappell was an analyst at W.P. Carey & Company, and before moving into the business sector, he was a Howard Hughes Medical Institute fellow at the National Cancer Institute where he studied tumor immunology. Dr. Chappell received his MD from Dartmouth Medical School and his MBA from Harvard Business School. Dr. Chappell brings to the Board his extensive experience in dealing with companies facing challenging situations in the biopharmaceuticals industry, as well as the perspective of a significant shareholder in the Company.

Timothy Morris has served as a member of our Board since June 2016. Mr. Morris has served as the Chief Financial Officer of AcelRx Pharmaceuticals, Inc. since March 2014. In April 2015, he also assumed the role of Head of Business Development for AcelRx. From November 2004 to December 2013, Mr. Morris served as Senior Vice President Finance and Global Corporate Development, Chief Financial Officer of VIVUS, Inc. a biopharmaceutical company. From September 2001 to November 2004, Mr. Morris was CFO, SVP Finance, Manufacturing and Administration for Questcor Pharmaceuticals, Inc., a specialty pharmaceutical company. He was a member of the Office of the President at Questcor from August 2004 to November 2004. Mr. Morris served as a non-executive director of PAION Inc., the US subsidiary of PAION AG, a publically traded company based in Germany. Mr. Morris received his BS in Business with an emphasis in Accounting from California State University, Chico, and is a Certified Public Accountant. Mr. Morris brings to the Board valuable operational experience with public companies in the biopharmaceutical industry, particularly in the areas of finance and corporate development.

Ezra Friedberg has served as a member of our Board since June 2016. Since 2012, Mr. Friedberg has served as general partner of Multiplier Capital, a fund he founded that focuses on lending opportunities to sponsor-backed growth companies, and is a member of the fund's credit committee. Separately, Mr. Friedberg owns and operates other financial services businesses. Since 2003, Mr. Friedberg has been the founder and manager of Key Recovery Group, a private equity investment firm, and the PUN Companies, a buyer of distressed debt. Mr. Friedberg received his Bachelor of Talmudic Law from Ner Israel Rabbinical College and his Masters of Administrative Science from Johns Hopkins University. Mr. Friedberg brings to the Board his experience and perspective as a seasoned investor with over twenty years of investing experience across public and private companies, with entities in the United States, Canada and a variety of other jurisdictions.

Upon the emergence from our bankruptcy on June 30, 2016, each of the above directors was designated (in the case of Dr. Durrant and Mr. Barliant) or appointed (in the case of each of the other directors) to serve on our Board pursuant to the terms of the Stock Purchase Agreement discussed in Item 13 below. Accordingly, Dr. Durrant continued to serve on the Board as a joint designee of Black Horse Capital Master Fund Ltd., or BHCMF, Black Horse Capital LP, or BHC, Cheval Holdings, Ltd., or Cheval (together with BHCMF and BHC, the Black Horse Entities), and Nomis Bay LTD, or Nomis, and Mr. Barliant was designated by the Black Horse Entities. Dr. Chappell was appointed by the Black Horse Entities, and Mr. Morris and Mr. Friedberg were appointed by Nomis.

Executive Officers

The following table sets forth the names, ages and current positions of each of our executive officers. Following the table is biographical information for each director, including information on specific experiences, qualifications and skills that support the conclusion that the director should currently serve on the Board.

Name	Age	Position
Cameron Durrant, M.D.	56	Chief Executive Officer
Dean (Kip) Witter III	69	Interim Chief Financial Officer
Morgan Lam	52	Chief Scientific Officer

Cameron Durrant, M.D has served as our Chief Executive Officer since March 2016. See "–Directors" for Dr. Durrant's biographical information.

Dean (Kip) Witter III has served as our interim Chief Financial Officer since January 2016. Mr. Witter is also Senior Consultant with The Brenner Group, LLC, a financial consultancy firm, a position he has held since January 2009. Through The Brenner Group, he has held a variety of positions with other companies, including Interim Chief Financial Officer, Secretary, and Principal Accounting Officer of Unwired Planet, Inc., from March 2015 to November 2015 and Chief Financial Officer of a number of privately held companies since 2009. Mr. Witter also serves on the boards of directors of several privately-held companies.

Mr. Witter is serving as interim Chief Financial Officer pursuant to an engagement letter agreement between The Brenner Group, LLC and us, or the Engagement Agreement. Under the Engagement Agreement, we have agreed to pay the Brenner Group for Mr. Witter's services a fee of $24,000 per month and reimburse the Brenner Group for all travel and out of pocket expenses incurred in connection therewith. The Engagement Agreement may be terminated by us or by the Brenner Group at any time upon 30 days written notice.

Morgan Lam has served as our Chief Operating Officer since February 2016. Mr. Lam previously served as our Head of Clinical Operations from May 2015 through January 2016. Mr. Lam served as Executive Director, Medical Affairs of Geron Corporation, a biopharmaceutical company, from May 2010 to May 2015 and as Clinical Program Leader at Genentech, Inc. from September 2005 through May 2010.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, requires our directors, executive officers and 10% stockholders to file reports of ownership of our equity securities. To our knowledge, based solely on review of the copies of such reports furnished to us related to the year ended December 31, 2015, all such reports were made on a timely basis except for one report for former Chief Financial Officer Herb C. Cross and two reports for former Executive Chairman and Director Ronald A. Martell.

Code of Ethics

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

Audit Committee Matters

We have established an audit committee of the Board, which is currently comprised of Mr. Morris, as chair of the Committee, and Dr. Chappell and Mr. Friedberg. The Board has determined that Mr. Morris is an audit committee financial expert. Because we are not listed on a national securities exchange and there are no listing standards applicable to us, the Board makes determinations as to director independence based on the definition under the NASDAQ rules. Consistent with the discussion in Item 13 below regarding director independence, the Board has determined that each member of the Audit Committee is currently independent.

ITEM 11. EXECUTIVE COMPENSATION

Summary Compensation Table

The following summary compensation table shows, for the fiscal years ended December 31, 2015 and December 31, 2014, information regarding the compensation awarded to, earned by or paid to our two most highly compensated executive officers and all individuals serving as our principal executive officer during the fiscal year ended December 31, 2015. We refer to these officers as our "named executive officers."

Name and Principal Position	Year	Salary ($)	Bonus ($)	Option Awards ($)(6)	Non-Equity Incentive Plan Compensation ($)(7)	All Other Compensation ($)(8)	Total ($)
David W. Pritchard (1)	2015	11,308	-	-	-	781,496	792,804
Former President & Chief Executive Officer	2014	490,000	-	862,075	151,900	-	1,503,975
Herb C. Cross (2)	2015	430,946	-	124,800	-	650,320	1,206,066
Former Interim President, Chief Executive Officer and Chief Financial Officer	2014	340,000	-	-	95,540	-	435,540
Martin Shkreli (3)	2015	-	-	-	-	-	-
Former Chief Executive Officer							
Donald R. Joseph (4)	2015	268,896	-	85,498	-	585,450	939,844
Former Chief Legal Officer	2014	302,000	-	139,222	84,862		526,084
Geoffrey Yarranton, Ph.D. (5)	2015	262,500	-	85,498	-	381,179	729,176
Former Chief Scientific Officer	2014	300,000	-	261,066	84,300	-	645,366

(1) Resigned January 8, 2015.
(2) Appointed as Chief Financial Officer in October 2013 and as interim Chief Executive Officer on January 8, 2015. Terminated on November 19, 2015.
(3) Appointed as Chief Executive Officer on November 19, 2015 and terminated on December 17, 2015.
(4) Terminated on November 19, 2015.
(5) Terminated on November 13, 2015.
(6) The amounts in this column represent the aggregate grant date fair value of option awards granted to each named executive officer, computed in accordance with FASB ASC Topic 718. See Note 11of the notes to our Consolidated Financial Statements for a discussion of all assumptions made by us in determining the grant date fair value of our equity awards.
(7) Amounts reflected in this column for fiscal year 2014 relate to a cash incentive bonus program that paid with respect to a performance period that covered the full fiscal (calendar) year 2014. Payments under that program were made in February 2015. See "Narrative to Summary Compensation Tables/Cash Incentive Compensation Plan" below for further information regarding the 2014 cash incentive bonus program.
(8) Amounts reflected in this column for fiscal year 2015 relate to severance benefits paid in connection with resignations and terminations during the year. See "Narrative to Summary Compensation Tables/All Other Compensation" below for further information regarding these amounts.

Narrative to Summary Compensation Table

Stock Options

We offer stock options to our employees, including our named executive officers, as the long-term incentive component of our compensation program. Our stock options allow our employees to purchase shares of our common stock at a price equal to the fair market value of our common stock on the date of grant. In 2014 and 2015, the only forms of equity compensation granted to our named executive officers were stock options. Mr. Cross, Mr. Joseph and Dr. Yarranton were granted options in 2015, which depending on the grant were scheduled to vest either ratably over 12 months of continuous service or one quarter on each six-month anniversary of continuous service after the date of the grant. However, the vesting of all of the stock option awards granted to our named executive officers in 2015 was accelerated and all such options were fully vested in connection with their terminations in November. In addition, the exercisability period of vested options was extended to one year post termination.

Cash Incentive Plan Compensation

Our 2014 annual cash incentive bonus program for our named executive officers incorporated corporate and individual performance objectives that applied to the full fiscal year 2014. For the 2014 period, Mr. Pritchard received a bonus of $151,900, Mr. Cross received a bonus of $95,540, Mr. Joseph received a bonus of $84,862 and Dr. Yarranton received a bonus of $84,300. Target annual bonus amounts are established as a percentage of the officer's base salary, with Mr. Pritchard's target bonus for each performance period set at 50% of his base salary, Mr. Cross, Mr. Joseph and Dr. Yarranton each set at 40% of their respective base salaries. The 2014 performance objectives that applied to Mr. Pritchard's cash incentive bonuses related 100% to corporate-level objectives, whereas Mr. Cross's and Dr. Yarranton's cash incentive bonuses related 75% to corporate-level objectives and 25% to individual objectives in achievement of certain clinical development milestones and Mr. Joseph's cash incentive bonus related 75% to corporate-level objectives and 25% to individual objectives in achievement of certain legal and administrative milestones. In February 2015, our compensation committee and our Board determined that for 2014, the corporate-level performance objectives had been achieved at the 62% level and that the applicable individual-level objectives had been achieved at the 95% level for each of Mr. Cross, Mr. Joseph and Dr. Yarranton. Accordingly, for fiscal 2014, our named executive officers received the amounts under our annual cash incentive bonus program reflected for that year in the column titled "Non-Equity Incentive Plan Compensation" in the table above. The corporate-level performance metrics that applied January 2014 through December 2014 included achievement of certain clinical development milestones. Our executive officers were entitled to participate in our annual cash incentive bonus program in 2015, but were terminated before any payments were determined. See discussion under "All Other Compensation" below for pro-rated incentive amounts paid as severance.

All Other Compensation

During fiscal 2014, we entered into amended and restated employment agreements with certain executive officers, including Messers. Pritchard, Cross, Joseph and Dr. Yarranton. These agreements required as a condition to receipt of severance benefits that the officer provide us with a general release of claims.

Each amended and restated employment agreement provided that if employment was terminated by us without cause (as defined in the agreements) or if the applicable employment agreement was not renewed by us at the end of its term, then the terminated named executive officer would become eligible to receive the following severance benefits for a period of nine months (twelve months in Mr. Pritchard's case): (i) salary continuation, (ii) an amount equal to the cost of the officer's COBRA coverage (less the active rate for such coverage) for the applicable period, payable as a lump sum, (iii) a pro-rated incentive bonus, and (iv) vesting credit under any then-unvested equity awards. In connection with the retirement of Mr. Pritchard in January 2015, these severance provisions were implemented.

The amended and restated employment agreements also provided that if, in connection with or within one year following a change in control, employment is terminated by us without cause or by the executive for good reason, then the terminated executive will become eligible to receive the following severance benefits: (i) fifteen months (eighteen months for Mr. Pritchard) of salary continuation; (ii) an amount equal to the cost of fifteen months (eighteen months for Mr. Pritchard) of COBRA coverage less the active rate for such coverage, payable as a lump sum; (iii) 125% (150% for Mr. Pritchard) of the target incentive bonus; and (iv) full vesting of all then-unvested equity awards.

The amounts in the All Other Compensation column in the Summary Compensation Table above reflect include the following amounts paid to Mr. Pritchard, Mr. Cross, Mr. Joseph and Dr. Yarranton pursuant to their amended and restated employment agreements in connection with the termination of their employment by us without cause, plus amounts paid for accrued vacation as of the date of termination of employment:

- Mr. Pritchard: Salary Continuation of $469,584; COBRA coverage of $21,026, pro-rated incentive bonus of $245,000; and accrued vacation of $45,886.
- Mr. Cross: Severance salary of $425,000; COBRA coverage of $51,015; pro-rated incentive bonus of $170,000; and accrued vacation of $4,305.
- Mr. Joseph: Severance salary of $377,000, Bonus of $151,000, COBRA coverage of $45,980 and accrued vacation of $11,470.

- Dr. Yarranton: Severance salary of $90.000; COBRA coverage of $38,054; pro-rated incentive bonus of $225,000; and accrued vacation of $28,125.

Outstanding Equity Awards at 2015 Fiscal Year End

The following table shows certain information regarding outstanding equity awards held by our named executive officers as of December 31, 2015.

	Option Awards				Stock Awards	
Name	Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Options Unexercisable	Option Exercise Price ($)	Option Expiration Date	Number of Shares of Stock That Have Not Yet Vested	Market Value of Shares of Stock That Have Not Yet Vested ($)
David W. Pritchard	8,774	-	$ 9.68	1/8/2018		
	16,665	-	$ 48.00	1/8/2018		
	15,624	-	$ 42.88	1/8/2018		
Herb C. Cross	18,749	-	$ 33.20	11/19/2016		
	1,875	-	$ 3.52	11/19/2016		
	1,875	-	$ 3.36	11/19/2016		
	37,500	-	$ 3.60	11/19/2016		
	1,875	-	$ 4.48	11/19/2016		
	1,875	-	$ 3.76	11/19/2016		
	1,875	-	$ 4.00	11/19/2016		
	1,875	-	$ 4.58	11/19/2016		
	1,875	-	$ 3.92	11/19/2016		
	1,875	-	$ 2.05	11/19/2016		
	1,875	-	$ 3.45	11/19/2016		
	1,875	-	$ 2.31	11/19/2016		
	1,875	-	$ 0.95	11/19/2016		
Martin Shkreli	-	-	N/A	N/A		
Donald R. Joseph	15,625	-	$ 46.00	11/19/2016		
	4,999	-	$ 43.28	11/19/2016		
	37,499	-	$ 3.60	11/19/2016		
Geoffrey Yarranton, Ph.D.	3,509		$ 4.24	11/13/2016		
	1,754	-	$ 9.68	11/13/2016		
	1,754		$ 11.68	11/13/2016		
	868	-	$ 17.36	11/13/2016		
	8,985	-	$ 48.00	11/13/2016		
	8,104	-	$ 43.28	11/13/2016		
	30,468	-	$ 3.60	11/13/2016		

Retirement Benefits

We have established a 401(k) tax-deferred savings plan, which permits participants, including our named executive officers, to make contributions by salary deduction pursuant to Section 401(k) of the Internal Revenue Code. We are responsible for administrative costs of the 401(k) plan. We may, in our discretion, make matching contributions to the 401(k) plan. No employer contributions have been made to date.

Director Compensation

In connection with our initial public offering in 2013, our compensation committee engaged Radford, an Aon Hewitt Company, to, among other things, conduct a review of our Board of Directors compensation program. Radford recommended that certain changes be made to our Board of Directors compensation program to align with the 50th percentile when compared to our peer group as determined by Radford, or the Director Compensation Program. The Director Compensation Program was recommended to and approved by our Board of Directors and became effective during the second quarter of fiscal year 2013 and was effective through December 31, 2015. Our Board of Directors has the authority to amend the compensation program for its members at any time.

Pursuant to the Director Compensation Program, each member of our Board of Directors during 2015 who was not our employee was eligible to receive an annual cash retainer and annual equity compensation. The annual cash retainer amounts payable to our eligible directors during 2015 were as follows:

- Board of Directors member: $40,000;
- Non-employee chair of our Board of Directors: $25,000;
- Audit committee member: $10,000;
- Audit committee chair: $20,000;
- Compensation committee member: $6,000;
- Compensation committee chair: $12,000;
- Nominating and corporate governance committee member: $4,000; and
- Nominating and corporate governance committee chair: $8,000.

The equity compensation component of our Directors Compensation Program during 2015 provided that newly appointed directors would be granted an initial option to purchase 20,000 shares of our common stock and continuing directors are eligible to receive an annual option to purchase 10,000 shares of our common stock. Initial Stock Option Grants are granted as soon as reasonably practicable following appointment to the Board and vest ratably over 36 months of continuous service following the date on which the director is appointed to our Board of Directors. The following table shows for the fiscal year ended December 31, 2015 certain information with respect to the compensation of our non-employee directors and by Mr. Martell:

The following table shows for the fiscal year ended December 31, 2015 certain information with respect to the compensation of all of our non-employee directors:

Name	Fees Earned or Paid in Cash ($)(1)	Option Awards ($)(2)	Stock Awards ($)(3)	All Other Compensation ($)(4)	Total ($)
Robert A. Baffi	31,484	10,700	-	-	42,184
Denise Gilbert	45,000	10,700	-	-	55,700
Ted W. Love	56,250	10,700	-	-	66,950
Gary Lyons	46,500	10,700	-	-	57,200
Ron Martell	3,956	9,750	9,750	289,267	312,723
Laurie Smaldone Alsup	37,500	10,700	-	-	48,200
Raymond M. Withy	40,500	10,700	-	-	51,200
Thomas Fernandez	-	-	-	-	-
Michael Harrison	-	-	-	-	-

-

(1) The amounts of cash retainers paid reflect payment of retainers under the Board of Directors Compensation Program for fiscal year 2015, except with respect to Mr. Martell, Mr. Moradi and Mr. Harrison, for whom the amounts reflect pro-rated amounts, given their limited time of service.

(2) The amounts in this column represent the aggregate grant date fair value of option awards granted to each named executive officer, computed in accordance with FASB ASC Topic 718. See Note 11 of the notes to our Consolidated Financial Statements for a discussion of all assumptions made by us in determining the grant date fair value of our equity awards.

(3) The amount in this column represents the aggregate grant date fair value of 3,750 restricted stock units granted to Mr. Martell, computed in accordance with FASB ASC Topic 718.

(4) The amount in this column represents the aggregate grant date fair value of 18,750 option awards granted to Mr. Martell for his service as executive chairman, computed in accordance with FASB ASC Topic 718. These awards were cancelled upon his termination in 2015. In addition, the amount includes base salary of $240,707 paid to Mr. Martell for his service as executive chairman, as well as accrued vacation of $15,625 and COBRA benefits in the amount of $2,935, upon his termination in November 2015.

As of December 31, 2015, Dr. Baffi held outstanding options to purchase 10,000 shares of our common stock, Dr. Gilbert held outstanding options to purchase 12,004 shares of common stock, Dr. Love held outstanding options to purchase 13,321 shares of common stock, Mr. Lyons held outstanding options to purchase 10,690 shares of common stock, Mr. Martell held outstanding options to purchase 3,750 shares of our common stock, Dr. Alsup held outstanding options to purchase 10,000 shares of common stock, Dr. Withy held outstanding options to purchase 13,760 shares of common stock, and Mr. Moradi and Mr. Harrison held no options to purchase shares of common stock.

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

Security Ownership Information

The following table presents information regarding beneficial ownership of our common stock as of August 30, 2016 by:

- each stockholder or group of stockholders known by us to be the beneficial owner of more than 5% of our common stock;
- each of our directors;
- each of our named executive officers; and
- all of our current directors and executive officers as a group.

Beneficial ownership is determined in accordance with the rules of the SEC, and thus represents voting or investment power with respect to our securities. Unless otherwise indicated below, to our knowledge, the persons and entities named in the table have sole voting and sole investment power with respect to all shares beneficially owned, subject to community property laws where applicable.

Percentage ownership of our common stock is based on 14,897,993 shares of our common stock outstanding as of August 30, 2016.

Shares of our common stock subject to options that are currently exercisable or exercisable within 60 days of August 30, 2016 are deemed to be outstanding and to be beneficially owned by the person holding the options but are not deemed to be outstanding for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, the address of each of the individuals and entities named below is c/o KaloBios Pharmaceuticals, Inc., 1000 Marina Boulevard, Suite 250, Brisbane, CA 94005.

Name and Address of Beneficial Owner	Shares of Common Stock Beneficially Owned	Percentage of Shares Beneficially Owned
5% Stockholders		
Entities affiliated with Black Horse Capital LP(1)	4,948,758	33.2%
Nomis Bay LTD(2)	3,719,006	25.0%
Nantahala Capital Management, LLC (3)	1,450,000	9.7%
Cortleigh Limited(4)	949,752	6.4%
Named Executive Officers and Directors		
David W. Pritchard(5)	41,063	*
Herb C. Cross(6)	76,874	*
Martin Shkreli(7)	-	*
Donald R. Joseph(8)	58,123	*
Geoffrey Yarranton, Ph.D.(9)	88,140	*
Cameron Durrant, M.D.	135,583	*
Ronald Barliant	93,786	*
Dale Chappell, M.D.(1)(10)	4,948,758	33.2%
Timothy Morris	-	*
Ezra Friedberg	-	*
All current executive officers and directors as a group (7 persons)(11)	5,179,897	34.8%

(1) Number of shares based solely on information reported on the Schedule 13G filed with the SEC on July 11, 2016, reporting beneficial ownership as of June 30, 2016, by BHC, BHCMF, Cheval, Black Horse Capital Management LLC, or BH Management, and Dale Chappell. According to the report, BHC has shared voting and dispositive power with respect to 872,977 shares, BHCMF has shared voting and dispositive power with respect to 2,040,463 shares, Cheval has shared voting and dispositive power with respect to 2,035,318 shares, BH Management has shared voting and dispositive power with respect to 2,908,295 shares and Dr. Chappell has shared voting and dispositive power with respect to 4,948,758 shares. The business address of each of BHC, BHCMF, BH Management and Dr. Chappell is c/o Opus Equum, Inc. P.O. Box 788, Dolores, Colorado 81323. The business address of Cheval is P.O Box 309G, Ugland House, Georgetown, Grand Cayman, Cayman Islands KY1-1104.

(2) Number of shares based solely on information reported on the Schedule 13G filed with the SEC on July 13, 2016, reporting beneficial ownership as of July 7, 2016, by Nomis. Nomis has sole voting and dispositive power over all 3,719,006 shares. The business address of Nomis is Penboss Building 50 Parliament St., Hamilton, Bermuda HM12.

(3) Number of shares based on information provided by Nantahala Capital Management, LLC ("Nantahala"). Nantahala and its managing members, Wilmot B. Harkey and Daniel Mack, share voting and dispositive power with respect to the shares. The business address of each of Nantahala, Mr. Harkey and Mr. Mack is 19 Old Kings Highway South, Suite 200, Darien, Connecticut 06820.

(4) Number of shares based solely on information reported on the Schedule 13G filed with the SEC on August 16, 2016, reporting beneficial ownership as of June 30, 2016 by Kapil Dhar, Sable Fiduciary Limited, or Sable, and Cortleigh Limited, or Cortleigh. Mr. Dhar, Sable and Cortleigh have shared voting and dispositive power with respect to the shares. The business address of each of Mr. Dhar, Sable and Cortleigh is 4th Floor, Rodus Building, Road Reef, Road Town, Tortola, British Virgin Islands.

(5) Includes options to purchase 41,063 shares of common stock that may be exercised within 60 days of August 30, 2016.

(6) Includes options to purchase 76,874 shares of common stock that may be exercised within 60 days of August 30, 2016.

(7) The address of Mr. Shkreli is 245 East 40th Street, 18H, New York, New York 10016.

(8) Includes options to purchase 58,123 shares of common stock that may be exercised within 60 days of August 30, 2016.

(9) Includes options to purchase 55,442 shares of common stock that may be exercised within 60 days of August 30, 2016.

(10) Dr. Chappell is the managing member of BH Management, which is the managing member of BHC, and the controlling person of BHCMF. By virtue of these relationships, each of BH Management and Dr. Chappell may be deemed to beneficially own the Shares owned directly by each of BHC and Cheval and Dr. Chappell may be deemed to beneficially own the Shares owned directly by BHCMF.

(11) Includes options to purchase 1,770 shares of common stock that may be exercised within 60 days of August 30, 2016.

The following table sets forth information as of December 31, 2015 with respect to shares of common stock that may be issued under our existing equity compensation plans.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights (a)	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights (b)	Number of Securities Remaining Available for Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a)) (c)
Equity compensation plans approved by security holders(1)	469,151	$ 19.29	404,279
Equity compensation plans not approved by security holders	-	-	-
Total	469,151	$ 19.29	404,279

(1) Represents shares reserved for issuance under the 2001 Stock Plan, the 2012 Equity Incentive Plan, as amended and restated, and the 2012 Employee Stock Purchase Plan.

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

Related Party Transactions

December 2015 Private Placement

On December 3, 2015, we entered into a Securities Purchase Agreement, which was subsequently amended, for a private placement by the Company of shares of our common stock. The purchasers in the private placement identified in the table below were at the time of the private placement directors of the Company and they purchased the number of shares set forth opposite their names for the dollar amounts indicated.

Name	Number of Shares	Aggregate Dollar Amount at $29.32 per share
David Moradi *as beneficial owner through* Anthion Partners II LLC	3,410	$ 100,000
Marek Biestek	10,000	$ 293,200
Michael Harrison	1,705	$ 50,000
Thomas Fernandez	6,821	$ 200,000

Services Arrangement

On December 3, 2015, we entered into a Services Agreement, or the Services Agreement, with Turing Pharmaceuticals LLC, or Turing, a life sciences company. Our then Chairman and Chief Executive Officer, Martin Shkreli, was also the chief executive officer and a member of the board of directors of Turing. Pursuant to the Services Agreement, Turing was to provide certain employees to us, to utilize on a part-time basis, including Christopher Thorn, who was appointed as our interim chief financial officer on December 3, 2015. The Services Agreement provided that Turing would charge us for Mr. Thorn's services an hourly rate of $151.92 per hour, and Mr. Thorn would remain employed and compensated by Turing during the term of the Services Agreement. No amounts were paid by us to Turing, and Mr. Thorn resigned on December 21, 2015.

Bankruptcy Related Financing Transactions

As a result of challenges facing us at the time, on December 29, 2015, we filed a voluntary petition for bankruptcy protection under Chapter 11 of Title 11 of the U.S. Bankruptcy Code. On June 30, 2016, or the Effective Date, our plan of reorganization, or the Plan, became effective, and we emerged from Chapter 11 bankruptcy proceedings.

During the pendency of our bankruptcy proceedings, we entered into a Debtor-in-Possession Credit and Security Agreement, or the Credit Agreement, and a Securities Purchase Agreement, or the SPA, with the Black Horse Entities and Nomis, or the Lenders. As described further below, as a result of the issuance of shares of common stock on the Effective Date pursuant to the terms of the Credit Agreement and the SPA, each of the Lenders became a holder of greater than 5% of the outstanding common stock. In addition, pursuant to the terms of the SPA, Dr. Chappell, who is the managing member of the managing general partner of BHC, the controlling person of BHCMF, and a director of Cheval, was appointed to the Board on the Effective Date. Dr. Chappell and his wife Mary Chappell are the sole owners of Cheval.

Credit Agreement

On April 1, 2016, we entered into the Credit Agreement with the Lenders and BHCMF, as administrative agent and lender, or Agent. The Credit Agreement provided for a debtor-in-possession credit facility in the original principal amount of $3,000,000, or the Term Loan, that bore interest at a rate per annum equal to 12.00%. The Credit Agreement provided that the Term Loan was made by the Lenders with a fee equal to $191,000, or the Upfront Fee, required the payment by us to the Lenders of a commitment fee equal to $150,000, or the Commitment Fee. In accordance with the terms of the Credit Agreement, we used the proceeds of the Term Loan for working capital, bankruptcy-related costs, costs related to our plan of reorganization, the payment of certain fees and expenses owed to the Agent and the Lenders in connection with the Credit Agreement and other costs incurred in the ordinary course of business. In accordance with the bidding procedures order entered by the Bankruptcy Court, the Term Loan and the SPA were together subject to competing, higher and better offers.

Our obligations under the Credit Agreement were represented by promissory notes and were secured, in connection with which the parties also entered into an Intellectual Property Security Agreement.

The Credit Agreement provided that the outstanding principal balance of the Term Loan, plus accrued and unpaid interest, plus the Upfront Fee, plus the Commitment Fee and all other non-contingent obligations would mature on the earlier of an event of default under the Credit Agreement or the effective date of our plan of reorganization. The maturity date was deemed to occur simultaneously with the Effective Date and, accordingly, on June 30, 2016, 2,350,480 shares of Common Stock were issued to the Lenders in repayment of our debt obligations under the Credit Agreement, including 201,436 shares to BHC, 470,096 shares to BHCMF, 503,708 shares to Cheval, 940,192 shares to Nomis and 235,048 shares to Cortleigh Limited, or Cortleigh. Pursuant to the terms of the Credit Agreement, we also paid $405,145 to BHC in payment of its fees and expenses and $283,132 to Nomis in payment of its fees and expenses.

Securities Purchase Agreement

On April 1, 2016, we entered into the SPA with the Lenders. The SPA provided for the sale to the Lenders on the closing date of an aggregate of 5,885,000 shares of our common stock, subject to adjustment as provided in the SPA, in respect of exit financing in the amount of $11,000,000, or the Exit Financing, plus an exit financing commitment fee of $770,000 payable by us to the Lenders, plus payment to the Lenders of their fees and expenses incurred in connection with the Exit Financing and the SPA. Nomis subsequently assigned twenty percent (20%) of its interest in the shares of Common Stock to be purchased by Nomis under the Credit Agreement and the SPA to Cortleigh, or collectively with the Lenders, the Purchasers.

The consummation of the transactions contemplated by the SPA were contingent upon, among other things, our Board, upon the effectiveness of the confirmed plan of reorganization, consisting of (i) one director to be designated by Nomis; (ii) one director to be jointly designated by BHC, BHCF, and Cheval; (iii) our Chief Executive Officer to be designated jointly and unanimously by the Lenders; and (iv) two independent directors to be designated jointly and unanimously by the Lenders.

The issuance of the shares contemplated by the SPA was consummated on the Effective Date, and we issued to the purchasers an aggregate of 7,147,035 shares of our common stock for an aggregate purchase price of $11,000,000, including 612,501 shares to BHC, 1,429,407 shares to BHCMF, 1,531,610 shares to Cheval, 2,858,814 shares to Nomis and 714,703 shares to Cortleigh. Pursuant to the terms of the SPA, we paid $427,383 to BHC in payment of its fees and expenses and $240,773 to Nomis in payment of its fees and expenses.

The terms of the SPA require us to file and seek to have declared effective a registration statement registering the resale of the shares acquired pursuant to the SPA.

Governance Agreement

On the Effective Date, we entered into a Corporate Governance Agreement with Mr. Shkreli, or the Governance Agreement, which provides for certain terms and conditions regarding the acquisition, disposition, holding and voting of our securities by Mr. Shkreli. The Governance Agreement applies to all of our common stock owned by Mr. Shkreli or affiliates he controls.

Under the terms of the Governance Agreement, for 180 days following the Effective Date, Mr. Shkreli could not sell his shares at a price per share that was less than the greater of (x) $2.50 and (y) a 10% discount to the prior two week volume-weighted average price, or the Market Discount Price. In addition, for 180 days following the 61st day after the Effective Date, we had a right to purchase any or all of Mr. Shkreli's shares at a purchase price per share equal to the Market Discount Price. For a limited time, we also had a right of first refusal to purchase shares that Mr. Shkreli proposed to sell. Mr. Shkreli was also prohibited from transferring any shares to his affiliates or associates unless such transferee agreed to be subject to the terms of the Governance Agreement. Transfers of shares by Mr. Shkreli not made in compliance with the Governance Agreement would be null and void.

Under the terms of the Governance Agreement, Mr. Shkreli will not have any right to nominate directors to the Board and agrees in connection with any shareholder vote to vote his shares in proportion to the votes of our public stockholders. The Governance Agreement also prohibits Mr. Shkreli or his affiliates for a period of 24 months after the date of the Governance Agreement, from, among other things: purchasing any of our stock or assets; participating in any proposal for any merger, tender offer or other business combination, or similar extraordinary transaction involving us or any of our subsidiaries; seeking to control or influence the management, our Board or our policies; or submitting any proposal to be considered by our stockholders.

In addition, any material transaction between Mr. Shkreli or his associates and us, or relating to the Governance Agreement, cannot be taken without the prior approval of our Board.

The Governance Agreement provides for a mutual release between us and Mr. Shkreli of all claims and liabilities existing as of the date of execution.

On August 25 and August 26, Mr. Shkreli sold all of his shares of the Company to third party investors in private transactions.

Director Independence

We are not currently a listed issuer. However, we use the definition of "independent" set forth in NASDAQ Marketplace rules in determining whether a director is independent in the capacity of director. Consistent with NASDAQ's independence criteria, our Board has affirmatively determined that each of our directors other than Dr. Chappell and Dr. Durrant, our Chief Executive Officer, is independent. Additionally, among those persons who served as a director during any part of our last completed fiscal year, only Mr. Shkreli and Mr. Martell were not independent. NASDAQ's independence criteria include a series of objective tests, such as that the director is not an employee of the Company and has not engaged in various types of business dealings with us. In addition, as further required by NASDAQ rules, our Board has subjectively determined as to each independent director and nominee for director that no relationship exists that, in the opinion of the board of directors, would interfere with each such person's exercising independent judgment in carrying out his or her responsibilities as a director. In making these determinations on the independence of our directors, our Board considered the relationships that each such director has with us and all other facts and circumstances the board deemed relevant in determining independence, including the beneficial ownership of our capital stock by each such person.

We have established an audit committee, a compensation committee and a nominating and corporate governance committee. Dr. Durrant, who our Board has determined is not independent, was a member of each committee during portions of 2016.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Independent Registered Public Accounting Firm's Fees

The following table represents aggregate fees billed to us for the year ended December 31, 2015 by our independent registered accounting firm, HORNE LLP.

	Year ended December 31, 2015
Annual audit fees(1)	$ 223,037
Audit-related fees	-
Tax fees	-
All other fees	-
Total fees	$ 223,037

(1) Audit fees in 2015 include fees billed or incurred by HORNE LLP for professional services rendered in connection with the annual audit of our Consolidated Financial Statements for the year ending December 31, 2015 and the review of our quarterly reports on Form 10-Q.

The following table represents aggregate fees billed to us for the years ended December 31, 2015, and 2014, by our former independent registered accounting firm, Ernst & Young LLP, or E&Y.

	Year ended December 31,	
	2015	2014
Annual audit fees(1)	$ 424,075	$ 621,309
Audit-related fees	-	-
Tax fees (2)	20,000	20,000
All other fees	1,820	-
Total fees	$ 445,895	$ 641,309

(1) Audit fees in 2015 include fees billed or incurred by E&Y for professional services rendered in connection with the review of our 2015 quarterly reports on Form 10-Q and a progress payment towards a 2015 audit, not completed before E&Y's resignation. Audit fees in 2014 include fees billed or incurred by E&Y for professional services rendered in connection with the annual audit of our Consolidated Financial Statements for the year ending December 31, 2014 and the review of our quarterly reports on Form 10-Q and other procedures related to a registration statement on Form S-8 as well as other procedures related to a registration statement on Form S-3.

(2) Tax fees related to Internal Revenue Code Section 382 analysis.

On December 8, 2015, we were notified by E&Y that it had resigned as our independent registered public accounting firm not due to any reason related to our reporting or accounting operations, policies or procedures. Between December 8, 2015 and December 21, 2015, Marcum LLP served as our independent registered public accounting firm. Marcum's resignation was not due to any reason related to our reporting or accounting operations, policies or procedures. We paid Marcum a retainer of $45,000 as an advance for work related to the 2015 audit.

All fees described above were pre-approved by the audit committee in accordance with the requirements of Regulation S-X under the Exchange Act.

Pre-Approval Policies and Procedures

The audit committee's policy is to pre-approve all audit and permissible non-audit services rendered by our independent registered public accounting firm. The audit committee can pre-approve specified services in defined categories of audit services, audit-related services and tax services up to specified amounts, as part of the audit committee's approval of the scope of the engagement of our independent registered public accounting firm or on an individual case-by-case basis before our independent registered public accounting firm is engaged to provide a service. The audit committee has determined that the rendering of tax-related services by our independent registered public accounting firm is compatible with maintaining the principal accountant's independence for audit purposes. Our independent registered public accounting firm has not been engaged to perform any non-audit services other than tax-related services and as indicated above.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

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

(1) Financial Statements—See Index to Consolidated Financial Statements at Part I, Item 8 on page F-1 of this Annual Report on Form 10-K.

(2) All financial statement schedules have been omitted because they are not applicable or not required or because the information is included elsewhere in the financial statements or the Notes thereto.

(3) See the accompanying Index to Exhibits filed as a part of this Annual Report, which list is incorporated by reference in this Item.

(b) See the accompanying Index to Exhibits filed as a part of this Annual Report.

(c) Other schedules are not applicable.

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/ Cameron Durrant, M.D.
Cameron Durrant, M.D.
Chief Executive Officer and Chairman of the Board of Directors

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

Signature	Title	Date
/s/ Cameron Durrant, M.D. Cameron Durrant, M.D.	Chairman of the Board of Directors and Chief Executive Officer (Principal Executive Officer)	September 1, 2016
/s/ Dean (Kip) Witter III Dean (Kip) Witter III	Interim Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	September 1, 2016
/s/ Ronald Barliant Ronald Barliant	Director	September 1, 2016
/s/ Dale Chappell, M.D. Dale Chappell, M.D.	Director	September 1, 2016
/s/ Timothy Morris Timothy Morris	Director	September 1, 2016
/s/ Ezra Friedberg Ezra Friedberg	Director	September 1, 2016

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders
KaloBios Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheet of KaloBios Pharmaceuticals, Inc. (the "Company") as of December 31, 2015, and the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for the year then ended. 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 audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2015, and the consolidated results of its operations and its cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America.

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/ HORNE LLP
Ridgeland, Mississippi
September 1, 2016

Report of Independent Registered Public Accounting Firm

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

We have audited the accompanying consolidated balance sheet of KaloBios Pharmaceuticals, Inc. as of December 31, 2014, and the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for year then ended. 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 audit.

We conducted our audit 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 audit 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 audit provides 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 the consolidated results of its operations and its cash flows for the year then ended, in conformity with U.S. generally accepted accounting principles**.**

/s/ Ernst & Young LLP

Redwood City, California
March 16, 2015

KaloBios Pharmaceuticals, Inc. (Debtor-In-Possession)
Consolidated Balance Sheets
(in thousands, except share and per share data)

	December 31, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$ 8,431	$ 10,923
Marketable securities	-	29,790
Prepaid expenses and other current assets	1,963	1,532
Total current assets	10,394	42,245
Property and equipment, net	288	414
Restricted cash	193	193
Other assets	271	125
Total assets	$ 11,146	$ 42,977
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ -	$ 1,822
Accrued compensation	-	1,400
Deferred rent, short-term	-	16
Accrued research and clinical liabilities	-	3,470
Notes payable, net of discount	-	10,928
Financing derivative	-	89
Other accrued liabilities	-	328
Total current liabilities	-	18,053
Deferred rent, long-term	-	311
Liabilities subject to compromise	5,414	-
Total liabilities	5,414	18,364
Commitments and contingencies	-	-
Stockholders' equity:		
Common stock, $0.001 par value: 85,000,000 shares and 85,000,000 shares authorized at December 31, 2015 and December 31, 2014 respectively; 4,450,994 and 4,124,004 shares issued and outstanding at December 31, 2015 and December 31, 2014, respectively	4	4
Additional paid-in capital	219,319	202,830
Accumulated other comprehensive loss	-	(8)
Accumulated deficit	(213,591)	(178,213)
Total stockholders' equity	5,732	24,613
Total liabilities and stockholders' equity	$ 11,146	$ 42,977

See accompanying notes.

KaloBios Pharmaceuticals, Inc. (Debtor-In-Possession)
Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)

	Year Ended December 31,	
	2015	**2014**
Operating expenses:		
Research and development	$ 16,721	$ 26,573
General and administrative	14,296	10,145
Litigation accrual expense	3,335	-
Total operating expenses	34,352	36,718
Loss from operations	(34,352)	(36,718)
Other (expense) income:		
Interest expense	(842)	(1,214)
Interest income	29	88
Other expense, net	(213)	(154)
Net loss	(35,378)	(37,998)
Other comprehensive income (loss):		
Net unrealized gain (loss) on marketable securities	8	(11)
Comprehensive loss	$ (35,370)	$ (38,009)
Basic and diluted net loss per common share	$ (8.57)	$ (9.22)
Weighted average common shares outstanding used to calculate basic and diluted net loss per common share	4,125,009	4,122,395

See accompanying notes.

KaloBios Pharmaceuticals, Inc. (Debtor-In-Possession)
Consolidated Statements of Stockholders' Equity
(in thousands, except share and per share data)

(in thousands, except share information)	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
Balances at December 31, 2013	4,116,373	$ 4	$ 200,744	$ 3	$ (140,215)	$ 60,536
Issuance of common stock upon exercise of stock options	7,048	-	66	-	-	66
Issuance of common stock upon ESPP conversion	583	-	7	-	-	7
Stock-based compensation expense	-	-	2,013	-	-	2,013
Comprehensive loss	-	-	-	(11)	(37,998)	(38,009)
Balances at December 31, 2014	4,124,004	4	202,830	(8)	(178,213)	24,613
Issuance of common stock, net of issuance costs	326,698	-	8,218	-	-	8,218
Issuance of common stock upon ESPP conversion	750	-	1	-	-	1
Obligation to issue common stock in settlement of litigation	-	-	2,835	-	-	2,835
Issuance of warrants in exchange for services	-	-	2,507	-	-	2,507
Stock-based compensation expense	-	-	1,971	-	-	1,971
Modification of stock options related to executive retirement	-	-	479	-	-	479
Modification of stock options related to restructuring activities	-	-	480	-	-	480
Settlement of fractional shares upon reverse split	(458)	-	(2)	-	-	(2)
Comprehensive loss	-	-	-	8	(35,378)	(35,370)
Balances at December 31, 2015	4,450,994	$ 4	$ 219,319	$ -	$ (213,591)	$ 5,732

See accompanying notes.

KaloBios Pharmaceuticals, Inc. (Debtor-In-Possession)
Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31,	
	2015	**2014**
Operating activities:		
Net loss	$ (35,378)	$ (37,998)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	197	310
Noncash interest expense	190	217
Financing derivative	252	89
Amortization of premium on marketable securities	130	495
Stock based compensation expense	1,971	2,013
Gain on extinguishment of long-term debt	(61)	-
Gain on sale of property and equipment	(56)	-
Issuance of warrants in exchange for services	2,507	-
Obligation to issue common stock in settlement of litigation	2,835	-
Modification of stock options related to executive retirement	479	-
Modification of stock options related to restructuring activities	480	-
Changes in operating assets and liabilities:		
Contract receivables	-	44
Prepaid expenses and other assets	(674)	(257)
Accounts payable	2,465	(1,375)
Accrued compensation	(1,368)	309
Accrued research and clinical liabilities	(3,387)	161
Other liabilities	371	(114)
Deferred rent	(16)	167
Net cash used in operating activities	(29,063)	(35,939)
Investing activities:		
Purchase of marketable securities	(3,703)	(54,163)
Proceeds from maturities of marketable securities	33,371	46,379
Purchases of property and equipment	(136)	(448)
Proceeds from sale of property and equipment	121	-
Changes in restricted cash	444	12
Net cash provided by (used in) investing activities	30,097	(8,220)
Financing activities:		
Increase in restricted cash for notes payable	(8,291)	-
Proceeds from issuance of notes payable	-	5,000
Proceeds from issuance of common stock	8,219	73
Principal payments under notes payable	(3,452)	(4,211)
Settlement of fractional shares upon reverse stock split	(2)	-
Net cash (used in) provided by financing activities	(3,526)	862
Net decrease in cash and cash equivalents	(2,492)	(43,297)
Cash and cash equivalents, beginning of period	10,923	54,220
Cash and cash equivalents, end of period	$ 8,431	$ 10,923
Supplemental cash flow disclosure:		
Cash paid for interest	$ 685	$ 990
Supplemental disclosure of non-cash financing activities:		
Principal payments under notes payable from restricted cash	$ 7,337	$ -
Obligation to issue common stock in settlement of litigation	$ 2,835	$ -
Issuance of warrants in exchange for services	$ 2,507	$ -

See accompanying notes.

KaloBios Pharmaceuticals, Inc. (Debtor-In-Possession)
Notes to Consolidated Financial Statements

1. Organization and Description of Business

KaloBios Pharmaceuticals, Inc. (the "Company") is a biopharmaceutical company focused on developing medicines for patients with neglected and rare diseases, with an ancillary focus on pediatric conditions, and on executing its Responsible Pricing Model in the commercialization of the Company's product candidates that may be approved. The Company's lead product candidate is benznidazole for the treatment of Chagas disease, a parasitic illness that can lead to long-term heart, intestinal and neurological problems. As more fully described in Note 16, the Company acquired certain worldwide rights to benznidazole on June 30, 2016. The Company is developing one of its proprietary monoclonal antibodies, lenzilumab (formerly known as KB003), for the treatment of chronic myelomonocytic leukemia, and potentially for the treatment of juvenile myelomonocytic leukemia both of which are rare hematologic cancers with high unmet medical need. The Company is exploring development of another of its proprietary monoclonal antibodies, ifabotuzumab (formerly known as KB004), for the treatment of certain rare solid and hematologic cancers. With a focus on neglected, rare and orphan diseases, the Company believes that it has the opportunity to benefit from various regulatory incentives, such as orphan drug exclusivity, breakthrough therapy designation, fast track designation, accelerated approval, priority review and priority review vouchers, where available, that provide for certain periods of exclusivity, expedited review and/or other benefits.

The Company has undergone a significant transformation in the last year. As a result of challenges facing it at the time, on December 29, 2015, the Company filed a voluntary petition for bankruptcy protection under Chapter 11 of Title 11 of the U.S. Bankruptcy Code. On June 30, 2016, the Company's Second Amended Plan of Reorganization, dated May 9, 2016, as amended (the "Plan"), became effective and the Company emerged from its Chapter 11 bankruptcy proceedings. Refer to Note 2 for additional details regarding the Company's bankruptcy proceedings.

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 $213.6 million as of December 31, 2015. The Company has financed its operations primarily through the sale of equity securities, debt financings, interest income earned on cash and cash equivalents, grants and the payments received under its agreements with Novartis Pharma AG 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 are not available on acceptable terms 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. These conditions raise substantial doubt about the Company's ability to continue as a going concern.

The Consolidated Financial Statements for the year ended December 31, 2015 were prepared on the basis of a going concern, which contemplates that the Company will be able to realize assets and discharge liabilities in the normal course of business. The ability of the Company to meet its total liabilities of $5.4 million at December 31, 2015, and to continue as a going concern is dependent upon the availability of future funding. The financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

On January 13, 2016, the Company's common stock was suspended from the Nasdaq Global Market and began trading on the over-the-counter market under the KBIOQ symbol. On January 26, 2016, NASDAQ filed a Form 25 with the Securities and Exchange Commission to complete the delisting of the common stock, and the delisting was effective on February 5, 2016.

KaloBios Pharmaceuticals, Inc. (Debtor-In-Possession)
Notes to Consolidated Financial Statements

2. Chapter 11 Filing

On December 29, 2015, the Company filed a voluntary petition for bankruptcy protection under Chapter 11 of the U.S. Bankruptcy Code. The filing was made in the United States Bankruptcy Court for the District of Delaware (the "Bankruptcy Court") (Case No. 15-12628 (LSS)).

In connection with financing efforts in connection with the Company's bankruptcy proceedings, on April 1, 2016, the Company entered into a Debtor-in-Possession Credit and Security Agreement (the "Credit Agreement") with a group of lenders (the "DIP Lenders"), pursuant to which the Company received $3 million in funds for working capital, bankruptcy-related costs, costs related to its plan of reorganization, payment of certain fees to the DIP Lenders and other costs associated with the ordinary course of business. Funds received under the Credit Agreement bore interest at a rate of 12% and were due and payable upon the Effective Date of the Plan, as defined below. Payment due under the Credit Agreement was convertible into shares of the Company's common stock, with share amounts subject to calculation as provided in the Credit agreement.

On April 1, 2016, the Company also entered into a Securities Purchase Agreement (the "SPA") with the DIP Lenders. The SPA provided for the sale of the Company's common stock, with share amounts subject to calculation as provided in the SPA, in respect of exit financing in the amount of $11,000,000 to be received upon the Effective Date of the Plan, as defined below.

Refer to Note 16 for additional information on the Credit Agreement and the SPA.

Plan of Reorganization

On May 9, 2016, the Company filed with the Bankruptcy Court the Plan and related amended disclosure statement pursuant to Chapter 11 of the Bankruptcy Code. On June 16, 2016, the Bankruptcy Court entered an order confirming the Plan.

The Plan became effective on June 30, 2016 (the "Effective Date") and the Company emerged from its Chapter 11 bankruptcy proceedings. In connection with such emergence, as further described in Note 16, the Company consummated the transactions and other items described below.

- Pursuant to the SPA and in repayment of its obligations under the Credit Agreement, the Company issued an aggregate of 9,497,515 shares of its common stock to the DIP Lenders.
- The Company became obligated to issue 327,608 shares of common stock to the plaintiffs in litigation related to the Company's 2015 private financing transaction in accordance with the settlement stipulation discussed in Note 16 below. The Company has recorded an obligation to issue the related shares in stockholders' equity and recorded the related expense of approximately $1.5 million as of December 31, 2015.
- The Company reserved 300,000 shares of common stock for issuance to the plaintiffs in class action litigation related to the events surrounding the Company's former Chairman and Chief Executive Officer. The Company recorded an obligation to issue the related shares in stockholders' equity and recorded the related expense of approximately $1.3 million as of December 31, 2015.
- The Company became obligated to issue 3,750 shares of common stock to a former director in satisfaction of claims against the Company. The Company recorded an obligation to issue the related shares in stockholders' equity and recorded the related expense of approximately $16,000 as of December 31, 2015.
- The Company reserved for the issuance of shares of common stock in connection with certain other claims and interests as set forth in the Plan in an amount as yet to be determined.
- The Company issued promissory notes in an aggregate principal amount of approximately $1.3 million to certain claimants in accordance with the Plan. The notes bear interest at 10% per annum and will be due and payable in full, including principal and accrued interest on June 30, 2019.

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Pre-Petition Claims

On February 29, 2016, the Company filed its schedules of assets and liabilities and statement of financial affairs (the "Schedules") with the Bankruptcy Court. The Bankruptcy Court entered an order setting April 1, 2016 as the deadline for filing proofs of claim (the "Bar Date"). The Bar Date is the date by which non-government claims against the Company relating to the period prior to the commencement of the Company's Chapter 11 case must be filed if such claims are not listed in liquidated, non-contingent and undisputed amounts in the Schedules, or if the claimant disagrees with the amount, characterization or classification of its claim as reflected in the Schedules. Claims that are subject to the Bar Date and that are not filed on or prior to the Bar Date may be barred from participating in any distribution that may be made under a plan of reorganization in the Company's Chapter 11 case.

As of the Effective Date, approximately 195 proofs of claim were outstanding (including claims that were previously identified on the Schedules) totaling approximately $32 million. Prior to the Bar Date, certain investors filed a class action claim in the amount of $20 million in connection with events surrounding the Company's former Chairman and Chief Executive Officer. On June 16, 2016, a settlement stipulation related to the class action suit was approved under order of the Bankruptcy Court. The settlement stipulation required the Company to issue 300,000 shares of common stock and submit a payment of $250,000 to the claimants. See Note 15 for additional information on this matter and settlement. Separately, a claim was filed by certain investors in the Company's 2015 private financing transaction totaling approximately $6.9 million. On May 9, 2016, a settlement stipulation related to this suit was approved under order of the Bankruptcy Court. The settlement stipulation required the Company to issue 327,608 shares of common stock and submit a payment of $250,000 to the claimants. See Note 15 for additional information on this matter and settlement. As of December 31, 2015, the Company recorded an obligation to issue the related shares in stockholders' equity totaling approximately $2.8 million and recorded the cash liability of $500,000 in liabilities subject to compromise in the accompanying Consolidated Balance Sheets. Excluding these stipulated claims, all other proofs of claim amount to approximately $5.1 million. As of December 31, 2015, the Company recorded a liability of approximately $4.5 million, which represents its estimate of the amount of the $5.1 million expected to be allowed by the Bankruptcy Court, in liabilities subject to compromise in the accompanying consolidated balance sheets. In addition, the Company also has liabilities related to accrued compensation and deferred rent, totaling approximately $0.4 million, included in liabilities subject to compromise in the accompanying Consolidated Balance Sheets, as of December 31, 2015.

The Company will ask the Bankruptcy Court to disallow claims that the Company believes are duplicative, have been later amended or superseded, are without merit, are overstated, have already been paid, or should be disallowed for other reasons. In addition, as a result of this process, the Company may identify additional liabilities that will need to be recorded or reclassified to liabilities subject to compromise. The resolution of such claims could result in material adjustments to the Company's financial statements.

Financial Reporting in Reorganization

The Company applied Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 852, *Reorganizations*, which is applicable to companies under bankruptcy protection, and requires amendments to the presentation of key financial statement line items. It requires that the financial statements for periods subsequent to the Chapter 11 filing distinguish transactions and events that are directly associated with the reorganization from the ongoing operations of the business. Revenues, expenses, realized gains and losses, and provisions for losses that can be directly associated with the reorganization and restructuring of the business must be reported separately as reorganization items in the Consolidated Statements of Operations and Comprehensive Loss. The balance sheet must distinguish pre-petition liabilities subject to compromise from both those pre-petition liabilities that are not subject to compromise and from post-petition liabilities. Liabilities that may be subject to a plan of reorganization must be reported at the amounts expected to be allowed in the Company's Chapter 11 case, even if they may be settled for lesser amounts as a result of the plan of reorganization or negotiations with creditors. In addition, cash used by reorganization items are disclosed separately in the Consolidated Statements of Cash Flow. As of December 31, 2015, the Company had not incurred or paid significant amounts related to its reorganization, other than the litigation accrual expense outlined above.

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3. 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 that 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 Consolidated Financial Statements and accompanying notes. Actual results could differ materially from those estimates. The Company believes judgment is involved in determining the valuation of the financing derivative, the fair value-based measurement of stock-based compensation, accruals, liabilities subject to compromise 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.

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 and cash equivalents 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.

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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 the financing derivative) 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, 2015			
(in thousands)	**Level 1**	**Level 2**	**Level 3**	**Total**
Investments:				
Money market funds	$ 196	$ —	$ —	$ 196
Total assets measured at fair value	$ 196	$ —	—	$ 196

	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

The Company's Level 2 investments as of December 31, 2014 included 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. There were no transfers between Level 1 and Level 2 during the periods presented.

In 2014, the Company recorded a financing derivative liability resulting from an embedded derivative related to the prepayment feature of the Company's loan and security agreement with MidCap Financial SBIC LP, which was entered into by the Company in September 2012 and subsequently amended (the "Loan and Security Agreement"). 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. 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 was based on management's judgment. Refer to Note 7 for additional details regarding the Loan and Security Agreement.

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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, 2013	$ —
Financing derivative	89
Balance at December 31, 2014	89
Financing derivative	252
Financing derivative – loan payoff	(341)
Balance at December 31, 2015	$ —

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 Sheets. There were no notes payable outstanding as of December 31, 2015.

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.

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 expense, net in the Consolidated Statements of Operations and 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 recognized a net gain from the sale of marketable securities of $8,000 for the year ended December 31, 2015. The Company had no realized gains or losses from the sale of marketable securities for the year ended December 31, 2014.

Restricted Cash

Restricted cash at December 31, 2015 and December 31, 2014 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 non-cancelable term of the related lease. Maintenance and repair costs are charged as expense in the Statements of Operations and Comprehensive Loss as incurred.

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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.

Research and Development Expenses

Development costs incurred in the research and development of new product candidates 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. During the year ended December 31, 2015, accrued liabilities were reduced by $312,000 related to research-related manufacturing expenses incorrectly recorded in 2014. The Company analyzed and assessed the effect of this adjustment on the previously reported annual and interim periods in 2014 as well as the impact of the benefit from the reversal of these expenses to the results of the annual and interim periods in 2015. Following this analysis and taking into account both quantitative and qualitative factors, the Company believes that the uncorrected out-of-period costs are not material to the respective periods in which the errors occurred.

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.

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.

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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 Accounting Standards Update ("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 that 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.

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.

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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 Operations and 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, stock options, restricted stock units and common 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 stock options, restricted stock units and warrants have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per common share and be antidilutive. Therefore, the denominator used to calculate both basic and diluted net loss per common share is the same in all periods presented.

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

	Year Ended December 31,	
	2015	2014
Options to purchase common stock	465,401	334,686
Warrants to purchase common stock	131,193	11,067
Restricted stock units	3,750	—
	600,344	345,753

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 operates in only one segment, which is related to the development of pharmaceutical products.

Recent Accounting Pronouncements Not Yet Effective

The Company qualifies as an "emerging growth company" ("EGC") pursuant to the provisions of the JOBS Act and has elected to take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act which permits EGCs to defer compliance with new or revised accounting standards (the "EGC extension") until non-issuers are required to comply with such standards. Accordingly, so long as the Company continues to qualify as an EGC, the Company will not have to adopt or comply with new accounting standards until non-issuers are required to comply with such standards.

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In May 2014, the FASB issued ASU 2014-09, "Revenue from Contracts with Customers (Topic 606)." ASU 2014-09 completes the joint effort by the FASB and International Accounting Standards Board to improve financial reporting by creating common revenue recognition guidance for U.S. GAAP and International Financial Reporting Standards. ASU 2014-09 applies to all companies that enter into contracts with customers to transfer goods or services. ASU 2014-09 is effective for public entities for interim and annual reporting periods beginning after December 15, 2017. EGCs that have elected the EGC extension, including the Company, and non-public entities will be required to comply with the guidance for annual reporting periods beginning after December 15, 2018. Early application is not permitted and entities have the choice to apply ASU 2014-09 either retrospectively to each reporting period presented or by recognizing the cumulative effect of applying ASU 2014-09 at the date of initial application and not adjusting comparative information. The Company is currently evaluating the requirements of ASU 2014-09 and has not yet determined its impact on the Company's Consolidated Financial Statements.

In August 2014, the FASB issued ASU 2014-15, “Presentation of Financial Statements - Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern”, which defines management’s responsibility to evaluate, at each annual and interim reporting period, whether there are conditions or events that raise substantial doubt about an entity’s ability to continue as a going concern within one year after the date the financial statements are issued and to provide related footnote disclosures in certain circumstances. In connection with each annual and interim period, management must assess if there is substantial doubt about the company’s ability to continue as a going concern within one year after the issuance date. Disclosures are required if conditions give rise to substantial doubt. This standard is effective for all companies in the first annual period ending after December 15, 2016, and interim periods thereafter, with early adoption permitted. The Company is currently evaluating the requirements of ASU 2014-15 and has not yet determined its impact on the Company's Consolidated Financial Statements.

In February 2016, the FASB issued ASU 2016-02, “Leases (Topic 842)”, which requires lessees to recognize on the balance sheet a right-of use asset, representing its right to use the underlying asset for the lease term, and a lease liability for all leases with terms greater than 12 months. The guidance also requires qualitative and quantitative disclosures designed to assess the amount, timing, and uncertainty of cash flows arising from leases. The standard requires the use of a modified retrospective transition approach, which includes a number of optional practical expedients that entities may elect to apply. EGCs that have elected the EGC extension, including the Company, and non-public entities will be required to comply with the guidance in 2019, and interim periods within that year. Early application is permitted. The Company is currently evaluating the requirements of ASU 2016-02 and has not yet determined its impact on the Company's Consolidated Financial Statements.

4. Investments

At December 31, 2015, 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	$ 196	$ —	$ —	$ 196
Total investments	$ 196	$ —	$ —	$ 196
Reported as:				
Cash and cash equivalents				$ 3
Restricted cash				193
Total investments				$ 196

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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

5. Property and Equipment

Property and equipment consists of the following:

	December 31,	
(In thousands)	2015	2014
Laboratory equipment	$ —	$ 552
Computer equipment and software	330	519
Leasehold improvements, furniture and fixtures	189	277
	519	1,348
Accumulated depreciation and amortization	(231)	(934)
Property and equipment, net	$ 288	$ 414

Depreciation and amortization expense for the years ended December 31, 2015 and December 31, 2014 was $197,000 and $310,000, respectively.

6. Research and Development Collaboration and License Agreement

Sanofi

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 biologic (the "Sanofi Agreement"). Sanofi was solely responsible for conducting, at its cost, the research, development, manufacture, and commercialization of licensed products for the diagnosis, treatment and/or prevention of all human diseases and conditions caused by *Pseudomonas aeruginosa* ("*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.

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, the Company 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 the Company 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.

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In January 2015, the Company announced that KB001-A had failed to meet its primary endpoint in a Phase 2 trial in CF patients with *Pa* lung infections. Thereafter, the Company discontinued development of KB001-A. The Company is currently actively seeking out-licensing or other partnership opportunities to help fund KB001-A's further clinical development. However, as a result of the Phase 2 trial's outcome and discontinued development of KB001-A and a shift in operating focus, the Company elected to terminate certain committed manufacturing activities with external contract manufacturing organizations on certain of its programs. In connection with 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.

7. Notes Payable

Loan and Security Agreement

In September 2012, the Company entered into the Loan and Security Agreement, which provided for the borrowing of up to $15 million. The MidCap Agreement originally provided 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 First Amendment described below, the final tranche of $5 million was available to be drawn at the option of the Company by no later than June 2013. The loan had 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%. Interest on amounts outstanding were payable monthly in arrears. An interest only period to December 31, 2013 was followed by straight-line principal payments over thirty-six months until December 31, 2016. Under the terms of the Loan and Security Agreement, at the time of final payment, the Company was required to pay an exit fee of 3% of the drawn amount. If the Company chose to prepay the loan, or if the loan was determined to be in default and early repayment was required, the Company would also have had to pay a fee ranging from 1% to 2% of the outstanding loan balance at the date of default. Pursuant to the Loan and Security Agreement, the Company also provided a first priority security interest in all existing and after-acquired assets, excluding intellectual property.

Events of default under the terms of the Loan and Security Agreement included, but were not limited to, an occurrence such as a payment default, a material adverse change, insolvency, a change of control, or a lender determination that the Company's ability to repay the loan was at risk. Any failure to raise capital could have been deemed a material adverse change under the Loan and Security Agreement and that could have resulted 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 classified notes payable as current as of December 31, 2014.

In connection with the Loan and Security Agreement and draws in 2012, the Company issued a warrant, which subsequently expired on the Company's IPO, to MidCap Financial to purchase shares of the Company's Series E convertible preferred stock. 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 have been accreted using the interest method. Other debt issuance costs for legal fees are included in other assets in the accompanying Consolidated Balance Sheets and have been 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 Operations and Comprehensive Loss.

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In June 2013, the Company entered into an amendment to the Loan and Security Agreement ("the First Amendment") to extend the draw down date for the final tranche of $5.0 million from June 2013 to May 2014, and to require the Company to draw that amount, which it did in May 2014. In connection with the First Amendment, the Company issued a warrant to purchase up to 6,193 shares of the Company's common stock with an exercise price of $96.88 per share. The warrant expires on the tenth anniversary of its issuance date and had an initial fair value of $130,000, which represents financing fees, and is included in other assets in the accompanying Consolidated Balance Sheets and was being amortized as non-cash Interest expense over the remaining term of the Loan and Security Agreement using the effective interest method. The Company estimated the fair value of this warrant 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.

The Company recorded interest expense related to the borrowings of $842,000 and $1.2 million for the years ended December 31, 2015 and 2014. 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 years ended December 31, 2015 and 2014, the effective interest rate on the amounts borrowed under the Loan and Security Agreement, including the accretion of the debt discount and the accretion of the final payment, was 10%.

In August 2015, the Company entered into Amendment No. 2 to the Loan and Security Agreement, whereby the Company agreed to maintain, in a separate account with a financial institution (held in the Company's name), an amount equal to the aggregate of the remaining future principal, interest and exit fee due under the Loan and Security Agreement, equating to $8.3 million as of the date of Amendment No. 2. Under the terms of the Loan and Security Agreement, as amended, MidCap Financial was permitted to draw payments from this account as they become due, and upon such draws, there would be a corresponding reduction in the amount owed to MidCap Financial by the Company. MidCap Financial had exclusive control to withdraw funds from that account at any time. The account was to be maintained either until the debt has been repaid in full, or until MidCap Financial determined that the Company satisfied certain capital requirements related to the Company's future operating plans.

In November 2015, the Company elected to exercise its prepayment right to repay the loan in full and paid MidCap Financial $6.6 million in full settlement of the remaining outstanding principal balance, accrued interest, the exit fee and a reduced prepayment fee of 1%. The prepayment resulted in a gain on extinguishment of debt of $61,000 in the fourth quarter of 2015, which is included in Other expense, net in the accompanying Consolidated Statements of Operations and Comprehensive Loss.

8. Warrants to Purchase Common Stock

On June 19, 2013, in connection with the First Amendment, the Company issued a warrant to MidCap Financial. See Note 7 for more information on this warrant and its treatment in the Consolidated Financial Statements.

On December 4, 2015, the Company issued a warrant to purchase up to an aggregate of 125,000 shares of common stock at an exercise price of $29.32 per share. The warrant expires on the fifth anniversary of its issuance and had an initial fair value of approximately $2.5 million which is included in General and administrative expenses in the accompanying Consolidated Statements of Operations and Comprehensive Loss. The warrant provides that if the Company declares a dividend, or makes any other distribution of its assets, to holders of common stock, then the warrant holder shall be entitled to participate in such dividend or distribution to the same extent that the holder would have participated had it held the number of shares of common stock acquirable upon complete exercise of the warrant. The Company estimated the fair value of this warrant 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. The warrant was issued in connection with a November 18, 2015 financing the Company elected not to pursue.

On October 31, 2015, warrants issued in 2005 to purchase an aggregate of 4,874 shares of common stock at $41.04 per share expired.

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9. Related Party Transactions

On December 3, 2015, the Company entered into a Services Agreement (the "Services Agreement") with Turing Pharmaceuticals LLC ("Turing"), a life sciences company. The Company's then Chairman and Chief Executive Officer, Martin Shkreli, was also the chief executive officer and a member of the board of directors of Turing. Pursuant to the Services Agreement, Turing was to provide certain employees to the Company, to utilize on a part-time basis, including Christopher Thorn, who was appointed as the Company's interim chief financial officer on December 3, 2015. The Services Agreement provided that Turing would charge the Company for Mr. Thorn's services an hourly rate of $151.92 per hour, and Mr. Thorn would remain employed and compensated by Turing during the term of the Services Agreement. No amounts have been, or will be, paid by the Company to Turing, and Mr. Thorn resigned on December 21, 2015.

On December 3, 2015, the Company entered into the Securities Purchase Agreement, as defined in Note 11, for the private placement (the "Private Placement") by the Company of shares of the Company's common stock. At the time of the Private Placement, certain participants were serving as directors of the Company. These participants purchased a total of 21,936 shares of the Company's common stock at a per share price of $29.32 for a total of $643,200.

10. Commitments and Contingencies

Operating Leases

The Company's non-cancelable operating lease for its former facilities in South San Francisco, California expired in June 2014. In connection with the lease, the Company 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 the accompanying Consolidated Balance Sheets and was being amortized over the term of the lease, on a straight-line basis. Rent expense was recognized on a straight-line basis over the term of the lease.

In January 2009, the Company entered into a sublease agreement with a third party to sublease a portion of the Company's former facility in South San Francisco, California. The sublease had a 29 month term that began February 1, 2009 and ended June 2011, which was thereafter renewed for a term ending June 2014. In 2011, the sublease was amended to include additional space. In March 2012, the Company entered into a second sublease agreement with another third party to sublease another portion of the Company's former facility. 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.

In December 2013, the Company entered into a lease agreement for a facility in South San Francisco, California. The lease commenced in July 2014 and was set to 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. Deferred rent applicable to this lease totaled $311,000 and $327,000 at December 31, 2015 and 2014, respectively. Deferred rent at December 31, 2015 is included in Liabilities subject to compromise in the accompanying Consolidated Balance Sheet. In March 2016, the Company entered into a termination agreement (the "Lease Termination Agreement") related to the lease of this facility. The Lease Termination Agreement, approved by order of the Bankruptcy Court issued March 15, 2016, waived all damages related to early termination of the lease, relieved the Company of March rental expenses and set an effective termination date of March 31, 2016. Concurrent with the termination of its prior lease, the Company entered into a lease agreement for a new facility in Brisbane, California. The new lease commenced in April 2016 and will expire in March 2017. At the end of the one-year term of the new lease, the Company has the option to extend its term for an additional one year at the then current fair market value rental rate determined in accordance with the terms of the lease. The minimum lease payments presented in the table below include payments due under the new lease and the 2016 payments under the prior lease terminated as of March 31, 2016.

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As of December 31, 2015, future minimum lease payments due under the Company's lease are as follows:

(in thousands)		
2016	$	327
2017		64
Total	$	391

Rent expense, net of sublease income, was $0.7 million and $0.4 million for the years ended December 31, 2015 and 2014, respectively. Sublease income was $0.6 million for the year ended December 31, 2014.

Indemnification

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.

11. Stockholders' Equity

Common Stock Offering

On December 3, 2015, the Company entered into a Securities Purchase Agreement (the "Securities Purchase Agreement") with certain investors (the "Purchasers") relating to a private placement of up to an aggregate 511,596 shares of common stock at a purchase price of $29.32 per share, or up to $15 million (the "Private Placement"). On December 15, 2015 the Securities Purchase Agreement was amended resetting the share price for all Purchasers other than those Purchasers who were directors, officers, employees or consultants of the Company to $24.86. Upon closing of the Private Placement, the Company issued to the Purchasers 326,698 shares of common stock for an aggregate of $8.2 million.

Common Stock

In June 2014, the Company amended and restated its certificate of incorporation to increase the authorized common stock to 85,000,000 shares.

On July 13, 2015, the Company effected a one-for-eight reverse stock split of its outstanding common stock pursuant to an amendment to the Company's certificate of incorporation. As a result of the reverse stock split, each eight shares of the Company's common stock were combined into one share of common stock. The reverse stock split was effective with respect to stockholders of record at the close of business on July 13, 2015, and trading of the Company's common stock on the Nasdaq Global Market began on a split-adjusted basis on July 14, 2015. Holders of common stock who would have otherwise received fractional shares of the Company's common stock pursuant to the reverse stock split received cash in lieu of the fractional share. The reverse stock split reduced the total number of shares of the Company's common stock outstanding from approximately 33.0 million shares to approximately 4.1 million shares. In addition, the number of shares of common stock subject to outstanding options, restricted stock units and warrants issued by the Company and the number of shares reserved for future issuance under the Company's stock plans were reduced by a factor of eight to proportionately reflect the reverse stock split, and per share exercise prices were increased by a factor of eight. The reverse stock split was accounted for retroactively and is reflected in the Company's common stock, warrant, stock option and restricted stock activity as of and for the years ended December 31, 2015 and 2014. Unless stated otherwise, all share data in the financial statements and accompanying notes have been adjusted, as appropriate, to reflect the reverse stock split.

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The Company had reserved the following shares of common stock for issuance as of December 31, 2015:

Warrants to purchase common stock	131,193
Restricted stock units	3,750
Options:	
Outstanding under the 2012 Equity Incentive Plan	402,470
Outstanding under the 2001 Equity Incentive Plan	62,931
Available for future grants under the 2012 Equity Incentive Plan	404,279
Total common stock reserved for future issuance	1,004,623

2012 Equity Incentive Plan

In July 2012, the Company's board of directors adopted the 2012 Equity Incentive Plan (the "2012 Plan"). Under the 2012 Plan, the aggregate number of common shares issued shall not exceed the sum of (a) 140,391 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 133,371 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 were increased automatically on the first business day of each fiscal year of the Company, starting with fiscal year 2013 and ending in 2015, 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) 105,293 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. Accordingly, effective the first business day of 2013, 2014 and 2015, the number of shares authorized for issuance under the 2012 Equity Incentive Plan was increased by 13,650 shares, 105,293 shares, and 105,293 shares, respectively. On July 7, 2015, the Company's stockholders approved an amendment to the 2012 Equity Incentive Plan to, among other things, increase the number of shares reserved for issuance thereunder by 312,500 shares and to eliminate the provisions that provided for the automatic increases in 2013, 2014 and 2015. As of December 31, 2015, there were 404,279 shares available for grant under the 2012 Equity Incentive Plan.

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 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 426,030 shares of common stock to employees, directors, consultants, and other service providers. In connection with the 2012 Plan taking effect, the 2001 Plan was terminated in August 2012. However, the awards under the 2001 Plan outstanding as of the termination of the 2001 Plan continued to be governed by their existing terms. As of December 31, 2015, there were no shares available for grant under the 2001 Plan.

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2012 Employee Stock Purchase Plan

The Employee Stock Purchase Plan (the "ESPP") provided 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 of the offering period, or the fair market value on the purchase date. The ESPP was 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 was not subject to the provisions of the Employee Retirement Income Security Act of 1974. There were 21,058 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 ended on April 30, 2015. Offerings subsequent to the second offering commence on May 1 and November 1 and end on April 30 and October 31 each year. As of December 31, 2015, there were 19,725 shares available for grant under the ESPP. On May 3, 2016, the ESPP was terminated.

Stock Option Activity

The following table summarizes stock option activity for the year ended December 31, 2015:

	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, 2014	334,686	$ 34.00		
Options granted	321,020	3.46		
Options forfeited	(176,764)	17.58		
Options expired	(13,541)	24.32		
Options exercised	—	—		
Balances at December 31, 2015	465,401	19.29	1.14	$ 5,343
As of December 31, 2015:				
Options vested and expected to vest(3)	462,941	19.37	1.14	$ 5,294
Exercisable	445,879	19.97	0.85	$ 4,953

(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 the Company's common stock for in-the-money options at December 31, 2015.

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(3) The stock options outstanding and exercisable by exercise price at December 31, 2015 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
$0.95 - $3.52	21,810	5.05	$ 2.30	11,510	$ $2.62
$3.60 - $3.60	155,927	0.82	3.60	154,989	$3.60
$3.68 - $4.56	47,346	0.85	3.87	44,846	$3.86
$4.58 - $14.80	46,561	1.84	9.37	40,922	$9.86
$14.96 - $37.92	63,562	0.63	28.19	63,560	$28.19
$42.00 - $42.88	17,498	1.86	42.79	17,498	$42.79
$43.28 - $43.28	38,483	0.62	43.28	38,385	$43.28
$46.00 - $46.06	15,625	0.88	46.00	15,625	$46.00
$48.00 - $48.00	56,012	1.02	48.00	55,967	$48.00
$51.36 - $51.36	2,577	0.12	51.36	2,577	$51.36
	465,401	1.14	$ 19.29	445,879	$ $19.97

The total fair value of options vested for the years ended December 31, 2015 and 2014 was $2.9 million and $3.2 million, respectively.

Stock Option Modifications

During the year ended December 31, 2015, the Company's Board of Directors approved modifications to certain stock options in connection with the Company's restructuring activities. The modifications included both the acceleration of the vesting of options in connection with terminations of certain employees, as well as the extension of the exercise period post termination from the standard 90 day period to one year. The Company accounted for the option modification under ASC Topic 718, *Compensation – Stock Compensation*, and as a result, recognized $959,000 in incremental compensation expense during the year ended December 31, 2015.

In addition, the vesting on certain options was accelerated upon termination based upon terms of the employment agreements with certain individuals.

Stock-Based Compensation

The Company's 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 the Company's publicly listed peers over a period equal to the expected terms of the options as the Company does not have a sufficient trading history to use the volatility of its own common stock. To estimate the expected term, the Company has 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, the Company is required to estimate the expected forfeiture rate and only recognize expense for those shares expected to vest. The Company estimates the forfeiture rate based on historical experience and its 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, 2015 and 2014 was $2.15 and $21.84 per share, respectively. The fair 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:

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	Year Ended December 31,	
	2015	2014
Expected term	5-6 years	6 years
Expected volatility	67 - 78%	68 - 76%
Risk-free interest rate	1.5 - 1.8%	1.8 - 1.9%
Expected dividend yield	0%	0%

Total stock-based compensation expense recognized was as follows:

	Year Ended December 31,	
(In thousands)	**2015**	**2014**
General and administrative	$ 1,134	$ 1,026
Research and development	837	987
	$ 1,971	$ 2,013

At December 31, 2015, the Company had $36,000 of total unrecognized compensation expense, net of estimated forfeitures, related to outstanding stock options that will be recognized over a weighted-average period of 3.4 years.

12. Restructuring Charges

Restructuring charges incurred during the nine months ended September 30, 2015 primarily consist of severance and other post-termination benefit costs resulting from the cost reduction program implemented by the Company in January 2015. These activities primarily consisted of 20% reduction of the Company's workforce. Restructuring charges incurred during the three months ended December 31, 2015 primarily relates to a board-approved restructuring plan announced in November 2015 to reduce costs and extend the cash runway in order to allow the Company to evaluate strategic alternatives for the products and the Company. As part of the restructuring plan, the Company elected to exercise its right to prepay the Loan and Security Agreement and paid MidCap Financial $6.6 million in full settlement of the remaining outstanding principal balance, accrued interest, the exit fee and a reduced prepayment fee of 1%. In addition, the Company undertook a reduction in force that eliminated the positions of 17 employees or more than 60% of the Company's workforce.

Per ASC 420-10-05-1, Exit or Disposal Cost Obligations, include, but are not limited to, involuntary termination benefits provided to employees under the terms of a one-time benefit arrangement that, in substance, is not an ongoing benefit arrangement or a deferred compensation contract, and certain contract termination costs. Restructuring costs are expensed during the period in which the Company determines it will incur those costs and all requirements of accrual are met.

A summary of the activity is presented below:

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(in thousands)	Contract termination costs - R&D	Salaries and benefits - R&D	Salaries and benefits - G&A	Total
Balance as of December 31, 2014	$ 1,185	$ —	$ —	$ 1,185
Accrued	—	522	82	604
Paid	(479)	(257)	—	(736)
Balance as of March 31, 2015	706	265	82	1,053
Accrued	—	57	122	179
Paid	(135)	(142)	—	(277)
Balance as of June 30, 2015	571	180	204	955
Accrued	—	—	—	—
Adjustments	(78)	—	—	(78)
Paid	(493)	(148)	(136)	(777)
Balance as of September 30, 2015	—	32	68	100
Accrued	—	588	807	1,395
Paid	—	(620)	(864)	(1,484)
Balance as of December 31, 2015	$ —	$ —	$ 11	$ 11

As disclosed in Note 11, in addition to the restructuring charges in the table above, the Company recorded stock based compensation expense of $959,000 during the twelve months ended December 31, 2015 related to the fair value of stock options of former employees which were modified such that they did not expire upon termination. The Company classified $542,000 and $417,000 as general and administrative expenses and research and development expenses, respectively.

As of December 31, 2014, the Company accrued certain contract termination costs of $1.2 million as a restructuring charge relating to manufacturing activity that no longer had identifiable future benefit to the Company.

13. Income Taxes

No provision for federal income taxes has been recorded for the years ended December 31, 2015 and 2014 due to net losses and the valuation allowance established.

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, 2015	December 31, 2014
Deferred tax assets:		
Net operating losses	$ 49,145	$ 37,715
Research & other credits	1,977	1,527
Accrued bankruptcy settlement	1,328	—
Other	1,270	2,172
Total deferred tax assets	53,720	41,414
Valuation allowance	(53,720)	(41,414)
Net deferred tax assets	$ —	$ —

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A reconciliation of the statutory tax rates and the effective tax rates for the years ended December 2015 and 2014 is as follows:

	Year Ended December 31,	
	2015	2014
Statutory rate	34.0%	34.0%
Valuation Allowance	-31.1%	-33.3%
Nondeductible Stock Compensation	-2.9%	-0.7%
Effective tax rate	0.0%	0.0%

Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by $12.3 million during 2015 and decreased by $15.4 million during 2014.

At December 31, 2015, the Company had federal net operating loss carryforwards of approximately $123.4 million, which expire in the years 2025 through 2035, and state net operating loss carryforwards of approximately $123.2.0 million, which expire in the years 2016 through 2035.

At December 31, 2015, the Company had federal research and development credit carryforwards of approximately $3.3 million, which expire in the years 2022 through 2035 and state research and development credit carryforwards of approximately $2.2 million. The state research and development credit carryforwards can be carried forward indefinitely.

During 2013, 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. An ownership change may have occurred during 2015. As a result, tax attributes such as net operating losses and research and development credits may be subject to further limitation.

The Company adopted FASB 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.

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

Balance at December 31, 2013	$ 1,196
Additions based on tax positions related to prior year	-
Additions based on tax positions related to current year	297
Balance at December 31, 2014	1,493
Additions based on tax positions related to prior year	-
Additions based on tax positions related to current year	212
Balance at December 31, 2015	$ 1,705

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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. Federal and California corporation income tax returns beginning with the 2000 tax year remain subject to examination by the Internal Revenue Service and the California Franchise Tax Board, respectively.

14. 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.

15. Litigation

Bankruptcy Proceeding

The Company filed for protection under Chapter 11 of Title 11 of the United States Bankruptcy Code on December 29, 2015. See Note 2 and Note 16 for additional information related to the bankruptcy.

Securities Class Action Litigation

On December 18, 2015, a putative class action lawsuit (captioned *Li v. KaloBios Pharmaceuticals, Inc. et al*., 5:15-cv-05841-EJD) was filed against the Company in the United States District Court for the Northern District of California (the "Class Action Court"), alleging violations of the federal securities laws by Martin Shkreli, the Company's former Chairman and Chief Executive Officer. On December 23, 2015, a putative class action lawsuit was filed against the Company in the Class Action Court (captioned *Sciabacucchi v. KaloBios Pharmaceuticals, Inc. et al*., 3:15-cv-05992-CRB), similarly alleging violations of the federal securities laws by Mr. Shkreli. On December 31, 2015, a putative class action lawsuit was filed against the Company in the Class Action Court (captioned *Isensee v. KaloBios Pharmaceuticals, Inc. et al*., Case No. 15-cv-06331-EJD) also alleging violation of the federal securities laws by Mr. Shkreli. On April 28, 2016, the Class Action Court consolidated these cases (the "Securities Class Action Litigation") and appointed certain plaintiffs as the lead plaintiffs. The lead plaintiffs in the Securities Class Action Litigation were seeking damages of $20.0 million on behalf of all the affected members of the class represented in the Securities Class Action Litigation, (the "Securities Class Action Members").

On June 15, 2016, a settlement stipulation (the "Securities Class Action Settlement"), was approved by the Bankruptcy Court. Subject to the approval of the Class Action Court, the Securities Class Action Settlement required us to issue 300,000 shares of common stock and submit a payment of $250,000 the Securities Class Action Members and advance insurance proceeds of $1.25 million to the Securities Class Action Members (collectively, the consideration is the "Securities Class Action Settlement Consideration"). Subject to the final approval of the Securities Class Action Settlement, any Securities Class Action Member is entitled to share in the Securities Class Action Settlement Consideration. The Securities Class Action Settlement provides for releases and related injunctions to be granted for the benefit of, among others, the Company, Ronald Martell, Herb Cross and all of the Company's past, present and future directors, officers and employees, excluding Mr. Shkreli. Alternatively, Securities Class Action Members may exclude themselves from the Securities Class Action Settlement and are thereby not bound by the terms of the Securities Class Action Settlement nor entitled to receive any amount of the Securities Class Acton Settlement Consideration. Such individuals remain free to assert claims against the Company and such claims were subordinated to the level of the Company's common stock and otherwise remain subject to the Company's objection. The Company's agreement to the Securities Class Action Settlement was not in any way an admission of the Company's wrongdoing or liability.

KaloBios Pharmaceuticals, Inc. (Debtor-In-Possession)
Notes to Consolidated Financial Statements

PIPE Litigation

On January 7, 2016, certain investors (the "PIPE Claimants"), commenced an adversary proceeding (captioned *Gregory Rea, et al. v. KaloBios Pharmaceuticals, Inc.*, Adv. Pro. No. 16-50001 (LSS)) in the Bankruptcy Court against the Company alleging implied trust theories, breach of contract, fraud and violations of the federal securities laws in connection with the PIPE Claimants' purchase of the Company's common stock in the Private Placement (the "PIPE Litigation"). The PIPE Claimants also raised certain other objections to the Company's bankruptcy proceeding. The PIPE Claimants sought an aggregate total of approximately $6.9 million in damages.

On May 9, 2016, the Bankruptcy Court entered an order approving a settlement stipulation between the Company and the PIPE Claimants (the "Settlement Stipulation"). Under the Settlement Stipulation, in connection with the effectiveness of the Plan, and per the terms of the Settlement Stipulation, the Company became obligated to issue 327,608 shares to the PIPE Claimants and make a payment of $250,000 to the PIPE Claimants for the purpose of satisfying expenses related to the PIPE Settlement.

Claim by Marek Bistek

Marek Biestek was a director who, while not a plaintiff in the above described PIPE Litigation, filed a proof of claim alleging damages from the PIPE transaction and filed an objection to the confirmation of our Plan. To resolve his objection to the Plan, we settled with him individually by issuing him 3,750 additional shares of common stock. Mr. Biestek, as a former director of the company, was excluded from the Securities Class Action Members and therefore received nothing from the Securities Class Action Litigation.

As of December 31, 2015, the Company recorded an obligation to issue the shares related to the above claims in stockholders' equity totaling approximately $2.8 million and recorded the cash liability of $500,000 in liabilities subject to compromise in the accompanying Consolidated Balance Sheet.

16. Subsequent Events

Bankruptcy Related Financing Arrangements

On April 1, 2016, as described in Note 2, the Company entered into a Debtor in Possession Credit and Security Agreement (the "Credit Agreement") with the DIP Lenders, which were Black Horse Capital Master Fund Ltd., as administrative agent and lender ("BHCMF" or "Agent"), Black Horse Capital LP, as a lender ("BHC"), Cheval Holdings, Ltd., as a lender ("Cheval") and Nomis Bay LTD, as a lender ("Nomis" and, together with BHCMF, BHC and Cheval, the "DIP Lenders"). The Credit Agreement provided for a debtor-in-possession credit facility in the original principal amount of $3,000,000 (the "Term Loan"). The Credit Agreement provided that the Term Loan will be made by the Lenders at an original discount to $191,000 (the "Upfront Fee") and required the payment by the Company to the Lenders of a commitment fee equal to $150,000 (the "Commitment Fee"). In accordance with the terms of the Credit Agreement, the Company used the proceeds of the Term Loan for working capital, bankruptcy-related costs, costs related to the Company's plan of reorganization, the payment of certain fees and expenses owed to the Agent and the Lenders in connection with the Credit Agreement and other costs incurred in the ordinary course of business.

Pursuant to the terms of the Credit Agreement, the Term Loan bore interest at a rate per annum equal to 12.00%. In accordance with the bidding procedures order entered by the Bankruptcy Court, the Term Loan and the SPA (defined below) were together subject to competing, higher and better offers. The Company's obligations under the Credit Agreement were secured pursuant to an Intellectual Property Security Agreement.

In connection with the Credit Agreement, the Company executed in favor of Agent an Intellectual Property Security Agreement, dated as of April 1, 2016 (the "IP Security Agreement"). Under the terms of the IP Security Agreement, the Company pledged to Agent for the ratable benefit of the Lenders, as collateral for its obligations under the Credit Agreement, all of its intellectual property.

KaloBios Pharmaceuticals, Inc. (Debtor-In-Possession)
Notes to Consolidated Financial Statements

The Credit Agreement provided that the outstanding principal balance of the Term Loan, plus accrued and unpaid interest, plus the Upfront Fee, plus the Commitment Fee and all other non-contingent obligations would mature on the earlier of an event of default under the Credit Agreement or the effective date of the Company's plan of reorganization. The Maturity Date was deemed to occur simultaneously with the Effective Date and, accordingly, on June 30, 2016, 2,350,480 shares of common stock were issued to the Lenders in repayment of the Company's debt obligations under the Credit Agreement, including 201,436 shares to BHC, 470,096 shares to BHCMF, 503,708 shares to Cheval, 940,192 shares to Nomis and 235,048 shares to Cortleigh Limited ("Cortleigh"). Pursuant to the terms of the Credit Agreement, the Company also paid $405,145 to BHC in payment of its fees and expenses and $283,132 to Nomis in payment of its fees and expenses.

On April 1, 2016, as described in Note 2, the Company also entered into a Securities Purchase Agreement (the "SPA") with the Lenders. The SPA provides for the sale to the Lenders on the closing date of an aggregate of 5,885,000 shares of the common stock, subject to adjustment as provided in the SPA, in respect of exit financing in the amount of $11,000,000 (the "Exit Financing") plus an exit financing commitment fee of $770,000 payable by the Company to the Lenders, plus payment to the Lenders of their fees and expenses incurred in connection with the Exit Financing and the SPA. Nomis subsequently assigned twenty percent (20%) of its interest in the shares of common stock to be distributed to Nomis under the Credit Agreement and the SPA to Cortleigh (collectively with the Lenders, the "Purchasers").

The consummation of the transactions contemplated by the SPA were contingent on, among other things, the funding of the Term Loan, the approval of the Bankruptcy Court of the Company's plan of reorganization, and the simultaneous closing of the Company's transaction with Savant, as described below. In addition, the closing of the transactions under the SPA were contingent upon the board of directors of the Company, upon the effectiveness of the confirmed plan of reorganization, consisting of (i) one director to be designated by Nomis; (ii) one director to be jointly designated by BHC, BHCF, and Cheval; (iii) the Chief Executive Officer of the Company to be designated jointly and unanimously by the Lenders; and (iv) two independent directors to be designated jointly and unanimously by the Lenders.

The issuance of the shares contemplated by the SPA was consummated on the Effective Date, and the Company issued to the Purchasers an aggregate of 7,147,035 shares of common stock for an aggregate purchase price of $11,000,000, including 612,501 shares to BHC, 1,429,407 shares to BHCMF, 1,531,610 shares to Cheval, 2,858,814 shares to Nomis and 714,703 shares to Cortleigh. Pursuant to the terms of the SPA, the Company paid $427,383 to BHC in payment of its fees and expenses and $240,773 to Nomis in payment of its fees and expenses.

Emergence from Bankruptcy

On May 9, 2016, the Company filed with the Bankruptcy Court the Plan and related amended disclosure statement pursuant to Chapter 11 of the Bankruptcy Code. On June 16, 2016, the Bankruptcy Court entered an order confirming the Plan (the "Confirmation Order"). On May 9, 2016, the Bankruptcy Court entered an order (the "Order") approving the Settlement Stipulation entered into between (i) Gregory Rea, RTAT LLC, Nancy Retzlaff, Armistice Capital Master Fund, Ltd. Andrew Pizzo and Sabine Gritti and (ii) the Company (the "Settlement Stipulation"). The Settlement Stipulation provides for the resolution among the parties of the PIPE Litigation described in Note 15. Pursuant to the terms of the Settlement Stipulation, the plaintiffs in the PIPE Litigation received 327,608 shares of the common stock of the Company as reorganized pursuant to the Plan, in addition to certain other consideration.

On the Effective Date, the Plan became effective and the Company emerged from its Chapter 11 bankruptcy proceedings.

On the Effective Date, in accordance with the terms of the Plan, in addition to shares issued to the Lenders and the Purchasers under the Credit Agreement and SPA, respectively, and shares issued in connection with the Settlement Stipulation, the Company reserved for issuance 300,000 shares to the plaintiffs in a class action lawsuit related to the events surrounding the Company's former Chairman and Chief Executive Officer, and the Company became obligated to issue 3,750 shares to Marek Biestek, a former director, in satisfaction of claims by Mr. Biestek against the Company. In addition, on the Effective Date, the Company reserved for issuance shares of common stock in connection with certain other claims and interests as set forth in the Plan in an amount as yet to be determined.

KaloBios Pharmaceuticals, Inc. (Debtor-In-Possession)
Notes to Consolidated Financial Statements

In accordance with the Plan, on the Effective Date, the Company became obligated to issue promissory notes (the "Notes") in the aggregate principal amount of approximately $1.3 million to certain holders of allowed general unsecured claims in the Company's bankruptcy proceedings. The Notes are unsecured, bear interest at a rate of 10% per annum and mature on June 30, 2019.

Savant Arrangements

On February 29, 2016, the Company entered into a binding letter of intent (the "LOI") with Savant Neglected Diseases, LLC ("Savant"). The LOI provided that the Company would acquire certain worldwide rights relating to benznidazole (the "Compound") from Savant. Under the LOI, the Company made a non-refundable deposit to Savant of $500,000, which was credited towards the Initial Payment (as defined below), and agreed to make monthly payments to Savant equal to $87,500 for development services performed by Savant relating to the Compound.

The LOI provided that in consideration for the assets to be acquired, the Company would provide consideration to Savant, including:

- $3,000,000 (the "Initial Payment") payable as soon as practicable but in no event later than the Company emerging from its Chapter 11 bankruptcy pursuant to a plan of reorganization (the "Bankruptcy Exit");
- a five-year warrant from the date of the Bankruptcy Exit to purchase up to 200,000 shares of the Company's common stock at a per share price of $2.25, exercisable for 25% of the shares immediately and exercisable for the remaining shares upon reaching certain milestones related to regulatory approval of the Compound; and
- certain additional payments to be further specified in the definitive agreements.

On the Effective Date, as authorized by the Plan and the Confirmation Order, the Company and Savant entered into an Agreement for the Manufacture, Development and Commercialization of Benznidazole for Human Use (the "MDC Agreement"), pursuant to which the Company acquired certain worldwide rights relating to benznidazole (the "Compound"). The MDC Agreement consummates the transactions contemplated by the LOI.

Under the terms of the MDC Agreement, the Company acquired certain regulatory and non-intellectual property assets relating to the Compound and any product containing the Compound and an exclusive license of certain intellectual property assets related to the Compound. Savant will retain the right to use the licensed intellectual property for veterinary uses. The MDC Agreement provides that the Company and Savant will jointly conduct research and development activities with respect to the Compound, while the Company will be solely responsible for commercializing the Compound. The Company will fund the development program for the Compound and will reimburse Savant for its development program costs.

As required by the MDC Agreement, on the Effective Date, the Company made payments to Savant totaling $2,687,500, consisting of the remaining portion of the Initial Payment less the deposit in the amount of $2,500,000, an initial monthly Joint Development Program Cost payment of $87,500, and reimbursement of Savant's legal fees capped at $100,000. The MDC Agreement provides for regulatory and other milestone payments of up to $21 million and certain other contingent payments. Additionally, the Company will pay Savant royalties on any net sales of the Compound, which royalty would increase if a priority review voucher is granted subsequent to regulatory approval of the Compound. The MDC Agreement also provides that Savant is entitled to a portion of the amount the Company receives upon the sale, if any, of a priority review voucher regarding the Compound.

KaloBios Pharmaceuticals, Inc. (Debtor-In-Possession)
Notes to Consolidated Financial Statements

In addition, on the Effective Date the Company and Savant also entered into a Security Agreement (the "Security Agreement"), pursuant to which the Company granted Savant a continuing senior security interest in the assets and rights acquired by the Company pursuant to the MDC Agreement and certain future assets developed from those acquired assets.

On the Effective Date, the Company issued to Savant a five year warrant (the "Warrant") to purchase 200,000 shares of common stock, at an exercise price of $2.25 per share, subject to adjustment. The Warrant is exercisable for 25% of the shares immediately and exercisable for the remaining shares upon reaching certain milestones related to regulatory approval of the Compound. In addition, pursuant to the MDC Agreement, the Company has granted Savant certain "piggyback" registration rights for the shares issuable under the Warrant.

Governance Arrangements

On the Effective Date, the Company and Martin Shkreli, the Company's former chief executive officer, former chairman and former controlling stockholder, entered into a Corporate Governance Agreement (the "Governance Agreement"), which provides for certain terms and conditions regarding the acquisition, disposition, holding and voting of securities of the Company by Mr. Shkreli. The Governance Agreement applies to all common stock owned by Mr. Shkreli or affiliates he controls.

Under the terms of the Governance Agreement, for 180 days following the Effective Date, Mr. Shkreli could not sell his shares of common stock at a price per share that was less than the greater of (x) $2.50 and (y) a 10% discount to the prior two week volume-weighted average price (the "Market Discount Price"). In addition, for 180 days following the 61st day after the Effective Date, the Company had a right to purchase any or all of Mr. Shkreli's shares at a purchase price per share equal to the Market Discount Price. For a limited time, the Company also had a right of first refusal to purchase shares that Mr. Shkreli proposed to sell. Mr. Shkreli was also prohibited from transferring any shares to his affiliates or associates unless such transferee agreed to be subject to the terms of the Governance Agreement. Transfers of shares by Mr. Shkreli not made in compliance with the Governance Agreement would be null and void.

Under the terms of the Governance Agreement, Mr. Shkreli will not have any right to nominate directors to the board of directors of the Company and agrees in connection with any stockholder vote to vote his shares in proportion to the votes of the Company's public stockholders. The Governance Agreement also prohibits Mr. Shkreli or his affiliates for a period of 24 months after the date of the Governance Agreement, from, among other things:

- purchasing any stock or assets of the Company;
- participating in any proposal for any merger, tender offer or other business combination, or similar extraordinary transaction involving the Company or any of its subsidiaries;
- seeking to control or influence the management, the Company's Board or the policies of the Company; or
- submitting any proposal to be considered by the stockholders of the Company.

In addition, any material transaction between Mr. Shkreli or his associates and the Company, or relating to the Governance Agreement, cannot be taken without the prior approval of the Company's Board.

The Governance Agreement provides for a mutual release between the Company and Mr. Shkreli of all claims and liabilities existing as of the date of execution.

On August 25 and August 26, 2016, Mr. Shkreli sold all of his shares of the Company to third party investors in private transactions.

Stock Issuance

On May 24, 2016, the board of directors approved a one-time equity award (the "Equity Award") to each of Cameron Durrant, Ronald Barliant and David Moradi. On the Effective Date, in accordance with the Plan, the Company became obligated to issue an aggregate 323,155 shares of common stock under the Equity Award.

KaloBios Pharmaceuticals, Inc. (Debtor-In-Possession)
Notes to Consolidated Financial Statements

Board Changes

On the Effective Date, in accordance with the Plan and pursuant to the terms of the SPA, Cameron Durrant, current Chief Executive Officer of the Company, as joint designee of BHCMF, BHC and Cheval (the "Black Horse Entities") and Nomis, continued as a director, Ronald Barliant, current member of the Board, continued as a director as the designee of the Black Horse Entities, Dale Chappell became a director as a designee of Nomis, and Timothy Morris and Ezra Friedberg became directors as joint designees of the Black Horse Entities and Nomis.

EXHIBIT INDEX

Exhibit	Description
3.1	Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's Registration Statement on Form S-1 (File No. 333-184299) filed on January 15, 2013).
3.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-35798) filed on August 10, 2015).
3.3	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.4 to the Registrant's Registration Statement on Form S-1 (File No. 333-184299) filed on January 15, 2013).
3.4	Amendment to Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K (File No. 001-35798) filed on December 28, 2015).
4.1	Specimen of Stock Certificate evidencing shares of Common Stock (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-184299) filed on January 15, 2013).
4.2	Warrant to Purchase Stock, by and between the Registrant and MidCap Financial SBIC, LP, dated as of June 19, 2013 (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K (File No. 001-35798) filed on June 24, 2013).
4.3	Registration Rights Agreement, dated December 3, 2015, between the Registrant and each of the several purchasers signatory thereto (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K (File No. 001-35798) filed on December 9, 2015).
4.4	Common Stock Purchase Warrant, by and between the Registrant and Armistice Capital Fund, dated as December 4, 2015 (incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K (File No. 001-35798) filed on December 9, 2015).
10.1*	2012 Equity Incentive Plan, as amended and restated (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-35798) filed on August 10, 2015).
10.2*	Form of Notice of Grant and Stock Option Agreement under the 2012 Equity Incentive Plan (incorporated by reference to Exhibit 10.8 to the Registrant's Registration Statement on Form 10-12G (File No. 000-54735) filed on June 12, 2012).
10.3*	Form of Notice of Grant and Stock Option Agreement under the 2012 Equity Incentive Plan (Outside Directors) (incorporated by reference to Exhibit 10.37 to the Registrant's Annual Report on Form 10-K (File No. 001-35798) filed on March 13, 2014).
10.4*	Form of Notice of Stock Unit Award under the 2012 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-35798) filed on April 24, 2015).
10.5*	Form of Director and Officer Indemnification Agreement (incorporated by reference to Exhibit 10.11 to the Registrant's Registration Statement on Form 10-12G (File No. 000-54735) filed on June 12, 2012).

10.6*	Development, Commercialization, Collaboration and License Agreement, dated January 8, 2010, by and between the Registrant and Sanofi Pasteur S.A. (incorporated by reference to Exhibit 10.12 to the Registrant's Registration Statement on Form 10-12G/A (File No. 000-54735) filed on September 12, 2012).
10.7*	Development and License Agreement, dated May 11, 2004, by and between the Registrant and the Ludwig Institute for Cancer Research (incorporated by reference to Exhibit 10.13 to the Registrant's Registration Statement on Form 10-12G/A (File No. 000-54735) filed on August 7, 2012).
10.8*	License Agreement, dated April 7, 2006, by and between the Registrant and the Ludwig Institute for Cancer Research (incorporated by reference to Exhibit 10.14 to the Registrant's Registration Statement on Form 10-12G/A (File No. 000-54735) filed on August 7, 2012).
10.9*	Amendment to License Agreement, dated October 9, 2008, by and between the Registrant and the Ludwig Institute for Cancer Research (incorporated by reference to Exhibit 10.8 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-35798) filed on May 8, 2014).
10.10*	Amendment to License Agreement, dated June 8, 2011, by and between the Registrant and the Ludwig Institute for Cancer Research (incorporated by reference to Exhibit 10.9 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-35798) filed on May 8, 2014).
10.11	Exclusive License Agreement, dated April 6, 2004, by and between the Registrant and The Regents of the University of California (incorporated by reference to Exhibit 10.15 to the Registrant's Registration Statement on Form 10-12G/A (File No. 000-54735) filed on August 7, 2012).
10.12†	Non-Exclusive License Agreement, dated October 15, 2010, by and between the Registrant, BioWa, Inc. and Lonza Sales AG (incorporated by reference to Exhibit 10.6 to the Registrant's Registration Statement on Form 10-12G/A (File No. 000-54735) filed on September 12, 2012).
10.13†	License Agreement, dated March 16, 2007, by and between the Registrant and Novartis International Pharmaceutical Ltd. (incorporated by reference to Exhibit 10.17 to the Registrant's Registration Statement on Form 10-12G/A (File No. 000-54735) filed on August 7, 2012).
10.14†	Incentive Bonus Plan (incorporated by reference to Exhibit 10.38 to the Registrant's Annual Report on Form 10-K (File No. 001-35798) filed on March 13, 2014).
10.15	Termination Agreement, by and between the Registrant and Sanofi Pasteur S.A., dated as of July 24, 2014 (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-35798) filed on November 6, 2014).
10.16	Amendment to Termination Agreement, by and between the Registrant and Sanofi Pasteur S.A., dated as of July 24, 2014 (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-35798) filed on May 11, 2015).
10.17†	Securities Purchase Agreement, dated as of December 3, 2015, between the Registrant and each purchaser identified on the signature pages thereto (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-35798) filed on December 9, 2015).
10.18†	Amendment No. 1 to Securities Purchase Agreement, dated as of December 15, 2015, between the Registrant and each purchaser identified on the signature pages thereto (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-35798) filed on December 16, 2015).

10.19†	Services Agreement, dated December 3, 2015, by and between Turing Pharmaceuticals, LLC and the Registrant (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K (File No. 001-35798) filed on December 9, 2015).
10.20*	Employment Offer Letter, dated May 28, 2015, by and between the Registrant and Ronald A. Martell (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-35798) filed on August 10, 2015).
23.1	Consent of Ernst & Young LLP.
23.2	Consent of HORNE LLP.
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as amended.
31.2	Certification of Interim Chief Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as amended.
32.1**	Certification of Chief Executive Officer pursuant to 18 U.S.C. §1350.
32.2**	Certification of Interim Chief Financial Officer pursuant to 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 of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

*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 Annual Report on Form 10-K, irrespective of any general incorporation language contained in such filing.

EXHIBIT 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements

(1) Registration Statement (Form S-8 No. 333-183725) pertaining to the 2001 Stock Plan and 2012 Equity Incentive Plan of KaloBios Pharmaceuticals, Inc.,
(2) Registration Statement (Form S-8 No. 333-194597) pertaining to the 2012 Equity Incentive Plan of KaloBios Pharmaceuticals, Inc.,
(3) Registration Statement (Form S-8 No. 333-202934) pertaining to the 2012 Equity Incentive Plan of KaloBios Pharmaceuticals, Inc.,
(4) Registration Statement (Form S-8 No. 333-206321) pertaining to the 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. for the year ended December 31 2014, included in this Annual Report (Form 10-K) of KaloBios Pharmaceuticals, Inc. for the year ended December 31, 2015.

/s/ Ernst & Young LLP

Redwood City, California
September 1, 2016

EXHIBIT 23.2

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statements (Nos. 333-183725, 333-194597, 333-202934 and 333-206321) on Form S-8 of KaloBios Pharmaceuticals, Inc. of our report dated September 1, 2016, relating to the consolidated financial statements of KaloBios Pharmaceuticals, Inc., appearing in this Annual Report on Form 10-K of KaloBios Pharmaceuticals, Inc. for the year ended December 31, 2015.

/s/ HORNE LLP

Ridgeland, Mississippi
September 1, 2016

EXHIBIT 31.1

CERTIFICATION PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

CERTIFICATIONS

I, Cameron Durrant, 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

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.

Date: September 1, 2016

/s/ Cameron Durrant

Cameron Durrant, Chief Executive Officer (Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

CERTIFICATIONS

I, Dean Witter, III, 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.

Date: September 1, 2016

/s/ Dean Witter, III
Dean Witter, III, Interim Chief Financial Officer (Principal Financial and Accounting Officer)

EXHIBIT 32.1

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

I, Cameron Durrant, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report of KaloBios Pharmaceuticals, Inc. on Form 10-K for the year ended December 31, 2015 fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act and that information contained in such Annual Report of KaloBios Pharmaceuticals, Inc. on Form 10-K fairly presents, in all material respects, the financial condition and results of operations of KaloBios Pharmaceuticals, Inc..

By: /s/ Cameron Durrant

Name:Cameron Durrant
Title: Chief Executive Officer (Principal Executive Officer)
Date: September 1, 2016

EXHIBIT 32.2

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

I, Dean Witter, III, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report of KaloBios Pharmaceuticals, Inc. on Form 10-K for the year ended December 31, 2015 fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act and that information contained in such Annual Report of KaloBios Pharmaceuticals, Inc. on Form 10-K fairly presents, in all material respects, the financial condition and results of operations of KaloBios Pharmaceuticals, Inc.

By: /s/ Dean Witter, III

Name:Dean Witter, III
Title: Interim Chief Financial Officer (Principal Financial and Accounting Officer)
Date: September 1, 2016