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**

For the transition period from to

Commission file number 001-36845

Bellerophon Therapeutics, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**47-3116175**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
184 Liberty Corner Road, Suite 302 Warren, New Jersey	**07059**
(Address of Principal Executive Offices)	(Zip Code)

Registrant's telephone number, including area code: **(908) 574-4770**

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

Title of each class	Name of each exchange on which registered
Common Stock, $0.01 par value per share	**The NASDAQ Global Market**

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. ☐ Yes ☒ No

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) 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 (§229.405) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

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

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

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

As of June 30, 2015, the aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was approximately $39.1 million, based upon the closing price on the NASDAQ Global Market reported for such date. Shares of common stock held by each officer and director and by each person who is known to own 10% or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates of the registrant. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

The number of shares outstanding of the registrant's common stock, as of March 10, 2016: 13,477,296

TABLE OF CONTENTS

REFERENCES TO BELLEROPHON

In this Annual Report on Form 10-K, unless otherwise stated or the context otherwise requires:

- references to the "Company," "Bellerophon," "we," "us" and "our" following the date of the Corporate Conversion refer to Bellerophon Therapeutics, Inc. and its consolidated subsidiaries;
- references to the "Company," "Bellerophon," "we," "us" and "our" prior to the date of the Corporate Conversion refer to Bellerophon Therapeutics LLC and its consolidated subsidiaries; and
- references to the "Corporate Conversion" or "corporate conversion" refer to all of the transactions related to the conversion of Bellerophon Therapeutics LLC into Bellerophon Therapeutics, Inc., including the conversion of all of the outstanding units of Bellerophon Therapeutics LLC into shares of common stock of Bellerophon Therapeutics, Inc.

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Annual Report on Form 10-K, including statements regarding our future results of operations and financial position, business strategy and plans and objectives of management for future operations, are forward-looking statements. The words "may," "will," "should," "expects," "plans," "anticipates," "could," "intends," "target," "projects," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

The forward-looking statements in this Annual Report on Form 10-K include, among other things, statements about:

- the timing of the ongoing and expected clinical trials of our product candidates, including statements regarding the timing of completion of the trials and the respective periods during which the results of the trials will become available;
- the timing of and our ability to obtain marketing approval of our product candidates, and the ability of our product candidates to meet existing or future regulatory standards;
- our ability to comply with government laws and regulations;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our estimates regarding the potential market opportunity for our product candidates;
- the timing of or our ability to enter into partnerships to market and commercialize our product candidates;
- the rate and degree of market acceptance of any product candidate for which we receive marketing approval;
- our intellectual property position;
- our expectations related to the use of proceeds from our initial public offering in February 2015;
- our estimates regarding expenses, future revenues, capital requirements and needs for additional funding and our ability to obtain additional funding;
- the success of competing treatments;
- our competitive position; and
- our expectations regarding the time during which we will be an "emerging growth company" under the Jumpstart Our Business Startups Act of 2012.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Annual Report on Form 10-K, particularly in the "Risk Factors" section, that could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

You should read this Annual Report on Form 10-K and the documents that we have filed as exhibits to this Annual Report on Form 10-K completely and with the understanding that our actual future results may be materially different from what we expect. We do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

This Annual Report on Form 10-K includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third-party research,

surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information.

PART I

Item 1. Business

Overview

We are a clinical-stage therapeutics company focused on developing innovative products at the intersection of drugs and devices that address significant unmet medical needs in the treatment of cardiopulmonary diseases. The focus of our clinical program is the continued development of our nitric oxide therapy for patients with pulmonary hypertension, or PH, using our proprietary delivery system, INOpulse, with pulmonary arterial hypertension, or PAH, as the lead indication.

Our Development Program

The following table summarizes key information about our primary development product, INOpulse, and indications for which we have worldwide commercialization rights.

Product	Indication	Stage of Development
INOpulse®	**Indications under development**	
	Pulmonary arterial hypertension	Phase 3
	PH associated with chronic obstructive pulmonary disease	Phase 2
	PH associated with idiopathic pulmonary fibrosis	Phase 2
	Additional indications:	
	Chronic thromboembolic PH	
	PH associated with sarcoidosis	
	PH associated with pulmonary edema from altitude sickness	

From the inception of our business through December 31, 2015, $228.0 million was invested in our development programs. Prior to our February 2015 initial public offering, or IPO, our sole source of funding was investments in us by our former parent company, Ikaria, Inc. (a subsidiary of Mallinckrodt plc), or Ikaria. As used herein, unless the context otherwise requires, references to "Ikaria" refer to Ikaria, Inc. and its subsidiaries and any successor entity.

INOpulse

Our INOpulse program is an extension of the technology used in hospitals to deliver continuous-flow inhaled nitric oxide. Use of inhaled nitric oxide is approved by the U.S. Food and Drug Administration, or the FDA, and certain other regulatory authorities to treat persistent PH of the newborn. Ikaria has marketed continuous-flow inhaled nitric oxide as INOmax for hospital use in this indication since FDA approval in 1999. In October 2013, Ikaria transferred to us exclusive worldwide, royalty-free rights to develop and commercialize pulsed nitric oxide in PAH, PH associated with chronic obstructive pulmonary disease, or PH-COPD, and PH associated with idiopathic pulmonary fibrosis, or PH-IPF. In July 2015, we expanded the scope of our license to allow us to develop our INOpulse program for the treatment of chronic thromboembolic PH, or CTEPH, PH associated with sarcoidosis and PH associated with pulmonary edema from high altitude sickness with a royalty equal to 5% of net sales of any commercial products for these three additional indications. In November 2015, we entered into an amendment to our exclusive cross-license, technology transfer and regulatory matters agreement with Ikaria that included a royalty equal to 3% of net sales of any commercial products for PAH. Our INOpulse program is built on scientific and technical expertise developed for the therapeutic delivery of inhaled nitric oxide. In 2010 and 2012, respectively, Ikaria submitted investigational new drug applications, or INDs, for INOpulse for the treatment of patients with PAH and PH-COPD. PAH is a form of PH that is closely related to persistent PH of the newborn. These INDs were included in the assets that were transferred to us by Ikaria.

Nitric oxide is naturally produced and released by the lining of the blood vessels and results in vascular smooth muscle relaxation, an important factor in regulating blood pressure. Relaxation of the muscles of the blood vessels allow the heart to increase blood flow to tissues and organs of the body, including the lung. When administered through inhalation, nitric oxide acts to selectively reduce pulmonary arterial pressure in the lung with minimal effects on blood pressure outside of the lungs, an important safety consideration.

Inhaled nitric oxide is widely used in the hospital setting for the treatment of a variety of conditions and, as reported by Ikaria, over 600,000 patients have been treated with inhaled nitric oxide worldwide since its first such use. However, chronic outpatient use of this therapy has previously been limited by a lack of a safe and compact delivery system for outpatient use. We have designed our INOpulse device, which is the means by which inhaled nitric oxide is delivered to the patient, to be

portable, which enables use by ambulatory patients on a daily basis inside or outside their homes. Our INOpulse device has a proprietary mechanism that delivers brief, targeted pulses of nitric oxide timed to occur at the beginning of a breath for delivery to the well-ventilated alveoli of the lungs, which minimizes the amount of drug required for treatment. We estimate this, and the higher concentration of nitric oxide we use, reduces the volume of drug delivered to approximately 5% of the volume required for equivalent alveolar absorption using standard continuous flow delivery systems, and also reduces the amount of nitric oxide, as well as its by-product nitrogen dioxide, that is exhaled and released into the patient's environment. INOpulse is designed to automatically adjust nitric oxide delivery based on a patient's breathing pattern to deliver a constant and appropriate dose of the inhaled nitric oxide over time, independent of the patient's activity level, thus ensuring more consistent dosing of the nitric oxide to the alveoli of the lungs.

In our recently completed INOpulse clinical trials, we used the first generation INOpulse device, which we refer to as the INOpulse DS device. Beginning with our Phase 3 trial of INOpulse for PAH in the first half of 2016, we will begin using our second generation device, which we refer to as the INOpulse device. The INOpulse device has approximately the same dimensions as a paperback book and weighs approximately 2.5 pounds. The INOpulse device has a simple and intuitive user interface and a battery life of approximately 16 hours when recharged, which takes approximately four hours and can be done while the patient sleeps. Based on the doses we have evaluated in our clinical trials, we expect that most patients will use two cartridges a day. The INOpulse device incorporates our proprietary triple-lumen nasal cannula, safety systems and proprietary software algorithms. The triple-lumen nasal cannula enables more accurate dosing of nitric oxide and minimizes infiltration of oxygen, which can react with nitric oxide to form nitrogen dioxide. Our triple-lumen nasal cannula consists of a thin, plastic tube that is divided into three channels from end-to-end, including at the prongs that are placed in the patient's nostrils, with one channel delivering inhaled nitric oxide, a second for breath detection and a third available for oxygen delivery. INOpulse is configured to be highly portable and compatible with long-term oxygen therapy, or LTOT, systems via nasal cannula delivery.

The INOpulse device has been well received by patients in the usability research we have conducted. In addition to the baseline testing on the original INOpulse DS device, we have conducted two rounds of testing with COPD and PAH patients to evaluate the user interface, loading mechanism, size, carrying bag and other features. In the usability research we have conducted, all eight patients with experience with the INOpulse DS device responded positively to the INOpulse device, and several of these patients indicated that the ability to take the INOpulse device outside the home would likely reduce concerns with maintaining compliance.

Our technology is based on patents we have exclusively licensed from Ikaria for the treatment of PAH, PH-COPD, PH-IPF, CTEPH, PH associated with sarcoidosis and PH associated with pulmonary edema from altitude sickness which, collectively, we refer to as the Bellerophon indications. These include patents with respect to the pulsed delivery of nitric oxide to ensure a consistent dose over time, which expire as late as 2027 in the United States and as late as 2026 in certain other countries, as well as with respect to the special triple-lumen cannula that allows for safer and more accurate dosing of pulsed nitric oxide, which expires in 2033 in the United States and abroad. We have also licensed several other patent applications from Ikaria for certain of the innovations included in the INOpulse device and certain of the resulting patents, if issued, would expire as late as 2030 in the United States.

During January 2016, the European Patent Office issued a Notice of Intention to Grant a European Patent that provides protection for our INOpulse program. The patent, entitled "System of Administering a Pharmaceutical Gas to a Patient," covers the ability to provide a known amount of pharmaceutical gas to a patient regardless of the patient inspiration rate or volume and distinguishes the INOpulse® delivery system from others on the market. Upon grant by the European Patent Office, the patent can be officially validated in up to 38 European countries. Also during January 2016, we received EC Certification for our proprietary new, INOpulse® drug-device delivery system. This European Conformity, or ECc Certification grants CE marking on the INOpulse product, which confirms INOpulse compliance with the essential requirements of the relevant European health, safety and environment protection legislation of the European Union. This certification covers the design, development and manufacture of inhaled pulsatile nitric oxide drug delivery systems including our triple-lumen cannula and application software.

INOpulse for PAH

We are developing INOpulse for the treatment of PAH to address a significant and unmet medical need in an orphan disease, which is a disease that affects fewer than 200,000 individuals in the United States. This program represents a potential first-in-class therapy for this indication. In 2011, the FDA granted orphan drug designation to our nitric oxide program for the treatment of PAH. If a product with an orphan drug designation is the first to receive FDA approval, the FDA will not approve another product for the same indication that uses the same active ingredient for seven years, except in a limited number of specific situations such as another product being shown to be clinically superior.

PAH is characterized by abnormal constriction of the arteries in the lung that increases the blood pressure in the lungs which, in turn, results in abnormal strain on the heart's right ventricle, eventually leading to heart failure. While prevalence data varies widely, we estimate that there are a total of at least 35,000 patients currently diagnosed with and being treated for PAH in the United States and European Union. Moreover, because PAH is rare and causes varied symptoms, we believe there is significant under-diagnosis of the condition at its early stages. There are several approved therapies for PAH, and we estimate, based on public product sales data, that 2014 combined global sales for these therapies were over $4.6 billion. Most PAH patients are treated with multiple medications and many are on supportive therapy. We believe that 40 to 60% of PAH patients are on LTOT. Despite the availability of multiple therapies for this condition, PAH continues to be a life-threatening, progressive disorder. A French registry initiated in 2002 and a U.S. registry initiated in 2006 estimate that the median survival of patients with PAH is three and five years from initial diagnosis, respectively.

We completed a randomized, placebo-controlled, double-blind Phase 2 clinical trial of INOpulse for PAH in October 2014, which was Part 1 of the trial. In February 2016, we announced positive data from the final analysis of Part 2 of our Phase 2 clinical trial of INOpulse for PAH. The data reinforces the results from October 2014 and indicates a sustainability of benefit to PAH patients who received INOpulse therapy at the 75 mcg dose for an average of greater than 12 hours per day and were also treated with LTOT. After reaching agreement with the FDA, and the European Medicines Agency, or EMA, on our Phase 3 protocol, we are moving forward with Phase 3 development. In September 2015, the FDA issued a Special Protocol Assessment, or SPA, for our Phase 3 PAH program for INOpulse, which will include two confirmatory clinical trials, undertaken either sequentially or in parallel, with the first patient expected to be enrolled in the first half of 2016.

INOpulse for PH-COPD

We are also developing INOpulse for the treatment of PH-COPD. COPD is a disease characterized by progressive and persistent airflow limitations. Patients with more severe COPD frequently have hypoxemia, or an abnormally low level of oxygen in the blood, and may be treated with LTOT. Despite treatment with oxygen, hypoxemia can progress and contribute to PH. In 2010, Datamonitor estimated that over 1.4 million COPD patients in the United States were being treated with LTOT. Based on academic studies, we estimate that 50% of COPD patients on LTOT have PH. PH-COPD patients have a lower median life expectancy and a higher rate of hospitalization than COPD patients with similar respiratory disease but without PH. Currently, there are no approved therapies for treating PH-COPD, and the only generally accepted treatments are LTOT, pulmonary rehabilitation and lung transplant.

The data from an initial three-month, open-label chronic-use Phase 2 trial conducted by a third party, which we in-licensed, showed that pulsed inhaled nitric oxide significantly reduced pulmonary arterial pressures in PH-COPD patients on LTOT and did so without causing hypoxemia, which is a significant concern for these patients. The FDA asked us to confirm the dose range and the safety related to hypoxemia in PH-COPD patients using the INOpulse device, prior to proceeding to large scale trials. Following this guidance, we conducted a Phase 2 acute dose ranging randomized placebo-controlled trial in 159 patients with the INOpulse DS device, with doses ranging from 3 mcg to 75 mcg. This trial, which we completed in July 2014, identified a dose range that showed similar reduction in pulmonary arterial pressure versus baseline when compared to the initial acute effects of pulsed inhaled nitric oxide in the original chronic-use trial. In addition, in our confirmatory trial, none of the INOpulse doses tested had an adverse effect on hypoxemia relative to placebo. While the reduction in pulmonary arterial pressure did not reach statistical significance versus placebo in this acute setting, which was the primary endpoint of the trial, we believe that the results have confirmed a dose range for this therapy that delivers a significant reduction in pulmonary arterial pressure versus baseline and does not cause hypoxemia in patients with PH-COPD. In September 2015, an oral presentation of late-breaking data from a clinical trial sponsored by us was presented at the European Respiratory Society International Congress 2015 in Amsterdam. The data showed that INOpulse improved vasodilation in patients with PH-COPD. We plan to build upon this and other work we have done over recent quarters. We are planning further Phase 2 development and plan to perform testing to demonstrate the potential benefit on exercise capacity in 2016.

BCM

Our Bioabsorbable Cardiac Matrix, or BCM, is a medical device intended to prevent congestive heart failure following an ST segment elevation myocardial infarction, or STEMI, which is a type of severe heart attack. Patients who suffer a STEMI are at an increased risk for congestive heart failure due to potential cardiac remodeling, which is a structural change in the size and shape of the heart that affects its ability to function normally.

We have an exclusive worldwide license to BCM from BioLineRx Ltd. and its subsidiary, or BioLine, including with respect to issued composition of matter patents on BCM that expire as late as 2029 in the United States, with a possible patent term extension to 2032 to 2034 depending on the timing of marketing approval and other factors, and 2024 in certain other countries. We licensed this product candidate in 2009, following completion of a 27-patient pilot clinical trial conducted by

We initiated a clinical trial of BCM in December 2011, which we call our PRESERVATION I trial, and enrolled the first patient in April 2012. We completed enrollment of this trial in December 2014, with 303 patients having completed the treatment procedure at almost 90 clinical sites in Europe, Australia, North America and Israel. Top-line results from the randomized, double-blind, placebo-controlled clinical trial were announced in July 2015. From a safety perspective, we observed no significant difference in adverse events rates between patients in the BCM and placebo treatment groups. However, the data showed no statistically significant treatment differences between patients treated with BCM and patients treated with placebo for both the primary and secondary endpoints in the trial. We presented detailed results from the PRESERVATION I trial for our BCM program at the European Society of Cardiology meeting in London on September 1, 2015. Following the results, further exploratory work is under consideration but we do not intend to proceed with further clinical development of BCM at this point until and unless we can determine an alternative path forward.

Our Strategy

Our goal is to become a leader in developing and commercializing innovative products at the intersection of drugs and devices that address significant unmet medical needs in the treatment of cardiopulmonary diseases. The key elements of our strategy to achieve this goal include:

- *Advance the clinical development of INOpulse.* One of our lead indications for our product candidate is INOpulse for PAH. We plan to initiate a Phase 3 clinical trial in the first half of 2016. In addition, we believe that the results of the PH-COPD clinical trials support continued Phase 2 development and we plan to perform further testing to demonstrate the potential benefit on exercise capacity in 2016. We also plan to initiate our Phase 2 studies in PH-IPF in 2016 consisting of an exploratory acute hemodynamic study followed by exercise capacity.

- *Leverage our historical core competencies to expand our pipeline.* Our employees have years of institutional experience in the use of inhaled nitric oxide in treating PH and in the development of drug-device combination product candidates. If we successfully advance INOpulse, we expect to develop INOpulse for treatment of PH-IPF, CTEPH, PH associated with sarcoidosis and PH associated with pulmonary edema from altitude sickness and, subject to obtaining additional license rights from Ikaria, potentially other outpatient PH indications. Our longer-term vision is to identify and opportunistically in-license innovative therapies that are at the intersection of drugs and devices and to develop and commercialize these product candidates.

- *Build commercial infrastructure in select markets.* As we near completion of the development of our product candidates, we may build a commercial infrastructure to enable us to market and sell certain of our product candidates with a specialized sales force and to retain co-promotion or similar rights, when feasible, in indications requiring a larger commercial infrastructure. While we may partner with third parties to commercialize our product candidates in certain countries, we may also choose to establish commercialization capabilities in select countries outside the United States.

INOpulse

INOpulse Scientific Background

Nitric oxide is a naturally occurring molecule produced by many cells of the body. Researchers found that nitric oxide is produced and released by the lining of the blood vessels and plays a role in controlling muscle tone in blood vessels. In particular, nitric oxide results in vascular smooth muscle relaxation in blood vessels and thus is an important factor in regulating blood pressure. As the muscles of the blood vessels relax, blood flow increases, helping the heart to deliver more blood to the body. PH patients can have a deficiency in endogenous nitric oxide production in their lungs. When administered by inhalation to patients with PH, we expect inhaled nitric oxide to act in a similar manner to naturally produced nitric oxide.

The scientific journal *Science* named nitric oxide Molecule of the Year in 1992. Additionally, the three researchers who discovered the role of nitric oxide as a signaling molecule in the cardiovascular system earned the Nobel Prize for Physiology or Medicine in 1998.

In 1991, Dr. Warren Zapol and his associates at the Massachusetts General Hospital discovered that inhaling nitric oxide in gas form could reduce high blood pressure in the lungs, a condition known as PH. Nitric oxide is a rapid and potent vasodilator, which means it dilates, or widens, blood vessels. When inhaled, it quickly dilates blood vessels in the lungs, which reduces blood pressure in the lungs, strain on the right ventricle and shunting of de-oxygenated blood away from the lungs.

Because more blood can flow through the lungs, oxygen levels within blood improve. In addition, inhaled nitric oxide improves the efficiency of oxygen delivery, and because it is a gas, it goes only to the portions of the lung that are ventilated, or receiving air flow, and increases blood flow only in these areas. Thus, inhaled nitric oxide improves ventilation-perfusion matching, an important element of lung function involving the air that reaches the lungs, or ventilation, and the blood that reaches the lungs, or perfusion. Inhaled nitric oxide is quickly inactivated after contact with blood, and is selective for the lungs, meaning that it has minimal effects on blood pressure outside of the lungs, which is an important safety consideration.

In 1999, the FDA approved the use of inhaled nitric oxide for the short-term treatment of persistent PH of the newborn. Based on this approval, and similar approvals from foreign regulatory authorities, continuous-flow inhaled nitric oxide, which is administered to ventilated patients by a dedicated in-hospital device, is marketed by Ikaria and its commercialization partners worldwide as INOmax (INOflo in Japan). Inhaled nitric oxide is widely used in the hospital setting for a variety of conditions and, as reported by Ikaria, over 600,000 patients have been treated with inhaled nitric oxide worldwide since its commercial launch. However, chronic outpatient use of this therapy has previously been limited by the lack of a safe and compact delivery system for outpatient use.

Introduction to Pulmonary Hypertension

PH is a disease characterized by constriction of the blood vessels in the lung, which causes blood pressure in the lung to rise and, in turn, increases the work required for the right ventricle of the heart to pump blood. The World Health Organization, or WHO, has endorsed a consensus classification for PH that was updated most recently in 2013. The WHO classification has five broad PH groups based on similarities in pathological and hemodynamic characteristics and therapeutic approaches. We are initially focusing development of INOpulse in indications included in WHO Groups 1 and 3 due to our view of the likelihood of success and the size and commercial viability of these markets. Group 1 PH is comprised of patients with PAH. This Group combines conditions with a range of causes, all of which have a characteristic pattern of vascular remodeling. The constriction of the blood vessels and the resulting pressure on the heart is often the major reason for poor prognosis of PAH patients since they can be otherwise healthy. Most PAH-specific medications are vasodilators and work through one of the three key mechanistic pathways for vasoconstriction and vasodilation. We expect that, because inhaled nitric oxide is a vasodilator and PH patients can have a deficiency in endogenous nitric oxide production in their lungs, patients in Group 1 will benefit from INOpulse. Group 3 PH consists of PH associated with lung disease or hypoxemia, which is an abnormally low level of oxygen in the blood. This Group includes patients with PH-COPD and PH-IPF, among others.

INOpulse for Pulmonary Arterial Hypertension

We are developing INOpulse for PAH to address a significant and unmet medical need in an orphan disease. This product candidate represents the development of a potential first-in-class therapy for this indication. Although current therapy for PAH provides some therapeutic benefit, there remains no cure, and approved therapies can have significant systemic side effects, such as hypotension and liver injury. INOpulse for PAH is designed to be a selective, short-acting pulmonary vasodilator and is being tested as an add-on therapy to existing PAH medications to evaluate its efficacy and side effect profile, in particular its ability to provide clinical benefit without adding to the systemic effects of other therapies such as hypotension.

Disease Background and Market Opportunity

PAH is a life-threatening, progressive disorder characterized by abnormally high blood pressure, or hypertension, in the pulmonary artery, the blood vessel that carries blood from the heart to the lungs. PAH occurs when most of the very small arteries, or arterioles, throughout the lungs narrow in diameter, which increases the resistance to blood flow through the lungs. To overcome the increased resistance, pressure increases in the pulmonary artery and the right ventricle, which is the heart chamber that pumps blood into the pulmonary artery. In addition, PAH may cause changes to the blood vessel lining that hinder the natural production of nitric oxide. Signs and symptoms of PAH occur when this increased pressure in the right ventricle cannot fully overcome the elevated resistance.

There are a number of drugs approved for the treatment of PAH that work primarily by reducing pulmonary vascular resistance, which is the primary problem for these patients. However, despite the availability of multiple therapies for this condition, the mortality rate for PAH remains high, with estimates of median survival ranging from three to five years. Patients with PAH also report severe impairment of health-related quality of life, including poor general and emotional health and impaired physical functioning. The most common symptoms of PAH are shortness of breath during exertion and syncope, or fainting spells. People with PAH may experience additional symptoms, particularly as the condition worsens, including dizziness, swelling of the ankles or legs, chest pain and a racing pulse. These impairments to health-related quality of life are comparable and sometimes more severe than those reported in patients with severely debilitating conditions such as spinal cord injury.

Since PAH is an orphan condition with poor diagnosis rates, published prevalence estimates for PAH vary widely. Based on epidemiological studies and current treatment rates, we estimate that there are a total of at least 35,000 patients currently diagnosed and treated for PAH in the United States and European Union. The average age of PAH patients at diagnosis is approximately 50 years, and approximately 80% of PAH patients are female. PAH is often diagnosed late in the disease progression with approximately 73% of these patients already having progressed to WHO functional Class III or IV at the time of diagnosis.

PAH is characterized by abnormal constriction of the arteries in the lung. PAH patients are generally treated with one or more of the four major classes of approved medications, which are prostacyclin and prostacyclin analogs, phosphodiesterase type-5 inhibitors, endothelin receptor antagonists and a soluble guanylate cyclase stimulator, all of which potentially result in vasodilatory systemic effects and, therefore, hypotension. Current guidelines recommend treatment with multiple medications in Class III and IV patients with progressive disease but suggest treatment be carefully managed by experienced physicians. Approximately 45% of PAH patients are treated with more than one class of medication at a given time. In addition, since hypoxemia can be a problem in these patients, it is often treated with LTOT in accordance with broadly supported treatment guidelines in the United States and European Union.

We are testing INOpulse for PAH as an add-on therapy for use in patients whose disease is progressing and who use additional medications. If it is approved, we expect INOpulse will provide the greatest benefit to patients who require pulmonary arterial pressure reductions beyond the reductions achieved with the medication they are already using. Because of its localized effect and short-half life, we do not expect INOpulse will add to systemic blood pressure reductions of other PAH drugs. We believe that INOpulse is also likely to be preferentially prescribed for patients already on LTOT. Data from the REVEAL registry, a registry study of PAH based in the United States, indicate that approximately 40% of patients are treated with oxygen at diagnosis for hypoxemia. Approximately 60% of the patients from Part 1 of our Phase 2 clinical trial completed in October 2014 were on LTOT. We believe that, as compared to patients who are not using a nasal cannula, patients who are accustomed to using a nasal cannula for delivery of oxygen are more likely to be prescribed and are more likely to be compliant with the use of INOpulse.

A 2013 report by CVS Caremark Specialty Analytics provided examples of PAH medications with annual prices ranging from approximately $100,000 to $150,000 per patient per year in the United States. We expect that, if approved, the price of INOpulse will be in the range of other established PAH medications.

Scientific Rationale for Use of INOpulse for PAH

Since the discovery of the significant role of nitric oxide in vasodilation, there has been an expectation in the scientific community that inhaled nitric oxide could be an effective therapy for PAH. According to the Cleveland Clinic Center for Continuing Education section on Pulmonary Hypertension, exogenous administration of nitric oxide by inhalation is probably the most effective and specific therapy for PAH, but cost and technical complexity of delivering inhaled nitric oxide have limited its use to the hospital. Although not approved for the treatment of PAH, data from an in-hospital survey conducted by Ikaria showed an estimated 1,000 to 2,000 INOmax uses in PAH patients in the United States each year, indicating that physicians already use nitric oxide in some PAH patients. The difficulty in delivering inhaled nitric oxide outside of the hospital results from the size of the device and cylinder and the need for a specialized delivery system with built-in safety systems.

We are developing nitric oxide for treatment of PAH because nitric oxide is a proven vasodilator, and PAH is primarily a disease of high pulmonary vascular resistance. PAH is associated with impaired release of nitric oxide and thus we believe chronic administration of inhaled nitric oxide may be viewed as an adjunctive or replacement therapy in patients with PAH. The use of inhaled nitric oxide in PAH has been proposed since the role of nitric oxide in this disease was identified. This drug has been tested in limited investigational studies conducted at academic institutions.

One clinical trial conducted by a third party at an academic center in Spain in 11 patients, seven of whom had severe PAH and four of whom had severe chronic thromboembolic PH, or CTEPH, evaluated the use of pulsed inhaled nitric oxide in an ambulatory setting. In this open-label, single-arm trial with no placebo control, patients were given ambulatory pulsed inhaled nitric oxide therapy via a nasal cannula for up to one year, after being withdrawn from PAH-specific therapy. The nitric oxide pulse was delivered to the patient at the beginning of each inspiration at a flow rate that was individualized for such patient. The goal of this trial was to evaluate the efficacy and safety of long-term treatment with inhaled nitric oxide outside the hospital setting.

At the start of this trial, patients were evaluated for various measures including the distance they were able to walk in six minutes and their WHO functional class status. At baseline, most of these patients had significant impairment of six-minute

walk distance, or 6MWD, with the ability to walk an average of 125 meters, and poor WHO functional class status, with nine patients in Class IV and two patients in Class III. After one month of therapy, overall, patients improved based on WHO functional class, with six patients in Class III and five in Class II, and had improvements in 6MWD of 128 meters on average. After six months of treatment, patients did not worsen clinically, however, between months six and 12, seven patients were given a phosphodiesterase type-5 inhibitor due to clinical worsening. One patient who initially did well with the added phosphodiesterase type-5 inhibitor therapy developed severe right heart failure at month eight and died, and another patient received a lung transplant at month nine. The remaining nine patients all had clinical status at month 12 similar to their one month evaluation, and improvements in functional class and 6MWD for the group persisted over time.

We do not expect INOpulse to have systemic effects beyond the pulmonary vasculature because of the short half-life of nitric oxide combined with its targeted delivery to the alveoli. When nitric oxide is delivered as a pulse at the beginning of inhalation, it travels to the alveoli where it diffuses rapidly across the alveolar capillary membrane into the adjacent vascular smooth muscle of pulmonary vessels. This transport is similar to the natural transport of endogenous nitric oxide from the endothelial cells, where it is produced, to the vascular smooth muscle cells where it relaxes the muscle and causes vasodilation of the pulmonary arteries. We believe this makes INOpulse unlikely to have intolerable side effects, such as systemic hypotension or drug-drug interactions. Given the need for PAH patients to be treated with multiple therapies and the potential for increased hypotension from each of the currently approved PAH therapies, we are developing INOpulse as an add-on or adjunctive therapy for PAH, where we believe it has the highest commercial potential.

Clinical Development Program

INOpulse for PAH is designated as a drug-device combination by the FDA and is subject to review by the Division of Cardiovascular and Renal Products within the Center for Drug Evaluation and Research with consultation from the Center for Devices and Radiological Health. Based upon our IND for PAH, the FDA has agreed that no further preclinical studies are required for clinical development of INOpulse for PAH.

Phase 2 Clinical Trial

In October 2014, we completed Part 1 of our ongoing Phase 2 clinical trial of INOpulse for PAH in the United States and Canada. Our key inclusion criteria for patients in this trial were that they be diagnosed with PH WHO Group 1, be on at least one other PAH medication for at least 12 weeks prior to treatment with INOpulse; and demonstrate being able to walk between 100 and 450 meters within six minutes. In addition, this trial excluded patients with evidence of significant left ventricular dysfunction.

The trial was a randomized, placebo-controlled, double-blind clinical trial with patients randomized 1:1:1 to placebo or to one of two active doses, either 25 or 75 mcg/kg ideal body weight/hour, or mcg, for 16 weeks. The primary endpoint in this trial was a change in pulmonary vascular resistance from baseline to 16 weeks, which was the end of Part 1. The target change in pulmonary vascular resistance was 190 dynes sec. cm-5, and the trial was powered for statistical significance at 130 dynes sec. cm-5. The main secondary endpoint was change in 6MWD over the same period. A clinically meaningful change in 6MWD is typically considered to be an increase of at least 30 to 35 meters.

We randomized 80 patients for Part 1 of the Phase 2 clinical trial. The majority of the patients were female (79%), white (89%) and had idiopathic PAH (74%). The results from Part 1 of this trial, showed a trend toward lower pulmonary vascular resistance in both the active arms compared to placebo and a trend toward increased 6MWD in the higher dose group. However, neither result was statistically significant.

However, among LTOT users, there was a clinically meaningful and statistically significant improvement versus placebo in both pulmonary vascular resistance and 6MWD in patients at the 75 mcg dose who received INOpulse therapy for an average of greater than 12 hours per day.

INOpulse was relatively well-tolerated in Part 1 of this trial. Our Independent Data Safety Monitoring Board evaluated the safety analysis from Part 1 of the trial in November 2014 and recommended proceeding with Part 2 of the trial. Possibly drug-related serious adverse events, or SAEs, occurred in no patients in the placebo group and one subject in each of the 25 mcg and 75 mcg groups.

One patient in the placebo arm died during Part 1 of the trial due to worsening PAH. SAEs were reported for four patients in the placebo arm, including one each of: pneumonia/worsening PAH, catheter-related infection, ascites and left hip sciatica. Each of these was assessed by the investigator for the trial as unrelated. Four patients in the 25 mcg low-dose active treatment arm experienced SAEs, including bacteremia, myelodysplastic syndrome, increased shortness of breath and dyspnea,

one of which was assessed as possibly related to trial therapy. The 75 mcg high-dose active treatment arm had nine patients with SAEs. The most common SAEs reported in the 75 mcg group were syncope and bronchitis/tracheobronchitis, one of which was assessed as possibly related to trial therapy. Discontinuation of trial therapy due to adverse events, or AEs, occurred for two patients in the 75 mcg arm and one subject in each of the 25 mcg and placebo arms.

In February 2016, we announced positive data from the final analysis of our Phase 2 long-term extension clinical trial of INOpulse for PAH, which is Part 2 of our Phase 2 clinical trial of INOpulse for PAH. The data reinforces the results from October 2014 and indicates a sustainability of benefit to PAH patients who received INOpulse 75mcg dose therapy for an average of greater than 12 hours per day and were also treated with LTOT.

Following 16 weeks of blinded therapy in Part 1 of the trial, in Part 2 of the trial, 65 patients were randomized to receive INOpulse doses of either 25 or 75 mcg/kg ideal body weight per hour (iNO 25 or iNO 75). The long-term extension analysis was performed after patients had completed between 16 and 32 months of INOpulse treatment, and data from the long-term extension analysis was compared to baseline measurements taken at the beginning of Part 1 of the trial. All patients in the trial were on at least one approved PAH therapy, and most were on two or three PAH therapies.

The long-term extension analysis showed the following:

- Patients on LTOT in the iNO 75 dose treatment arm who remained on INOpulse therapy for at least 12 hours a day had a mean improvement of 55.2 meters as compared to baseline (n=7).
- Patients on LTOT in the iNO 75 dose treatment arm who remained on INOpulse therapy for less than 12 hours a day showed a mean decrease of 18.0 meters as compared to baseline (n=6).
- Patients in the iNO 25 dose treatment arm, including those on LTOT, had a mean decrease of 43.7 meters from baseline (n=12).

For patients in the long-term extension study, no significant safety issues have been found with no reports of methemoglobin elevation and no adjudicated cases of pulmonary rebound. Only two SAEs have been reported as possibly related, with these subjects continuing on iNO therapy.

Pivotal Phase 3 Clinical Trials

After reaching agreement with the FDA and EMA on our Phase 3 protocol, we are moving forward with our Phase 3 development program. In September 2015, the FDA issued a SPA for our Phase 3 PAH program for INOpulse, which will include two confirmatory clinical trials, undertaken either sequentially or in parallel, with the first patient expected to be enrolled during the first half of 2016.

The key elements of the planned U.S. and European Union Phase 3 development program are:

- The Phase 3 program will consist of two clinical trials totaling approximately 450 patients; one trial with two treatment arms (iNO 75 and placebo) and one with three treatment arms (iNO 75, iNO 50 and placebo). Each treatment arm will consist of approximately 90 patients.
- All patients in the trials will be on LTOT.
- The primary endpoint is improvement in 6MWD compared to placebo after 16 weeks.
- The secondary endpoint is Time to Clinical Worsening (TTCW), with analysis pooled across both trials. Patients will stay on therapy until the last patient visit measuring 6MWD.
- Each trial will have a run-in period of two weeks to ensure compliance. Patients who do not stay on the therapy for at least 16 hours a day during this period will be replaced.

INOpulse for PH-COPD

We are developing INOpulse for PH-COPD to address a significant unmet medical need that we believe is often overlooked in everyday clinical practice because of the lack of available therapy. PH is more prevalent among those COPD patients who have advanced loss of respiratory function and low peripheral blood oxygen levels requiring treatment with LTOT. The co-morbidity of PH in these patients leads to cardiovascular complications from the added strain on the right ventricle of the heart. Current drug therapies for COPD are targeted to relieve the symptoms and complications of the respiratory component of the disease. Unlike these therapies, INOpulse is directed at treating the cardiovascular complications of PH-COPD. We believe PH-COPD patients on LTOT who are at risk for cardiovascular complications could benefit from use of INOpulse in addition to any respiratory benefits that result from their existing treatments.

Disease Background and Market Opportunity

COPD is a progressive disease caused by chronic inflammation and destruction of the airways and lung tissue. While COPD is primarily a respiratory disease, over time, as the disease progresses, the chronic pulmonary restrictions and resulting deprivation of adequate oxygen, or hypoxia, can contribute to vasoconstriction in the pulmonary arterial bed. In addition, COPD patients can have deficiency in endogenous nitric oxide production in their lungs, which can worsen vasoconstriction. This pulmonary vasoconstriction puts pressure on the right side of the heart, making it less able to cope with stressors and potentially leading to progressive cardiac dilation, heart failure and death. This cardiovascular component of COPD is, we believe, often overlooked despite pulmonologists' general awareness of the problem, in part because there are no specific therapies for the condition in these patients. While it is widely believed that the cardiovascular complications of COPD occur only in the advanced stage of the disease as a consequence of chronic hypoxemia, recent findings demonstrate an earlier involvement of the cardiovascular system in this disease.

In 2010, Datamonitor estimated that approximately 12 million patients in the United States were being treated for COPD and that over 1.4 million of these patients were being treated with LTOT. Based on academic studies, we estimate that 50% of COPD patients on LTOT in the United States have PH. Even though the degree of PH in these patients is milder than in PAH patients, data published in literature suggests that even small elevations in mean pulmonary artery pressure in patients with advanced COPD can impact hospitalization, patient-assessed functional outcomes and mortality. PH is a well-known predictor of increased morbidity and mortality in COPD patients and is associated with poor quality of life, worse clinical outcomes and shorter survival time. Based on a long-term study completed in 1992 and published in 1995, PH-COPD patients had a four-year survival rate of approximately 50%. By contrast, in this same long-term study, COPD patients with similar pulmonary functions, but without PH, had a four-year survival rate of 80%.

We expect INOpulse for PH-COPD, if approved, would be a treated as a specialty drug. Specialty drugs are typically high-cost medications, often ranging in price in the United States from approximately $15,000 to $50,000 per patient per year, used to treat rare or complex conditions, requiring close clinical management, special handling and distribution through specialty pharmacies.

Scientific Rationale for Use of INOpulse for PH-COPD

The mechanism of action of inhaled nitric oxide in vasodilation at the alveolar smooth muscle in PH-COPD is similar to its action in PAH. Like endogenous pulmonary nitric oxide, inhaled nitric oxide works by selectively relaxing lung vascular smooth muscles, causing dilation of pulmonary blood vessels and consequently increased pulmonary blood flow. This reduces the elevated pulmonary artery pressure in patients with PH-COPD.

PH-COPD patients generally have hypoxemia as a result of deteriorating lung function, which can be treated with supplemental oxygen therapy. However, these patients are not treated with currently approved PAH-specific drugs because these drugs can worsen hypoxemia. This worsening can occur when these drugs, which are systemically bioavailable, cause indiscriminate pulmonary vasodilation, even in poorly ventilated alveoli, resulting in lower average blood oxygenation levels. We believe that inhaled nitric oxide, as a locally active selective pulmonary vasodilator with minimal systemic effects, can drop pulmonary arterial pressures, and when delivered with INOpulse as a targeted pulse to the well-ventilated alveoli, avoid this indiscriminate vasodilation and the consequent lowering of blood oxygen levels.

The targeted delivery of inhaled nitric oxide to specific alveoli is important because early trials with continuous-flow inhaled nitric oxide reduced pulmonary arterial pressure in PH-COPD patients but also resulted in lowering of blood oxygen levels. It was postulated that this unwanted effect might be avoided by administering nitric oxide as a brief pulse at the beginning of each breath because well-ventilated alveoli open faster, and a brief early pulse would only reach these alveoli. As early as 1997, this concept was demonstrated by testing inhaled nitric oxide in PH-COPD patients during exercise, which allowed the dose to mimic pulse dosing. Recently, data from a computational fluid-flow modeling study we conducted, using high resolution computed tomography scans and computer simulations, supported this hypothesis that early pulsed delivery of nitric oxide could be directed specifically to the well-ventilated alveoli.

Clinical Development Program

INOpulse for PH-COPD is designated as a drug-device combination by the FDA and is being reviewed by the Division of Cardiovascular and Renal Products in the Center for Drug Evaluation and Research with consultation from the Division of Pulmonary, Allergy, and Rheumatology Products and the Center for Devices and Radiological Health. In our IND for PH-COPD, we referenced all of the information in our IND for PAH. The data referenced in our IND, as well as the years of use of the marketed product, demonstrate that nitric oxide is well tolerated. The FDA has agreed that the IND package is adequate for

supporting Phase 2 clinical development of INOpulse for PH-COPD. The FDA also agreed that no additional pre-clinical studies are needed to support product approval.

We completed a randomized, placebo-controlled, double-blind, dose-confirmation Phase 2 clinical trial of INOpulse for PH-COPD in July 2014. We have received results from this trial, and we are planning further Phase 2 testing to demonstrate the potential benefit on exercise capacity. In September 2015, an oral presentation of late-breaking data from a clinical trial sponsored by us was presented at the European Respiratory Society International Congress 2015 in Amsterdam. The data showed that INOpulse improved vasodilation in patients with PH-COPD. We plan to build upon this and other work we have done over recent quarters. We are planning further Phase 2 development and plan to perform testing to demonstrate the potential benefit on exercise capacity in 2016.

INOpulse for Other Pulmonary Hypertension Conditions

PH disease is often classified according to the WHO classification system which groups patients with PH according to the underlying etiologies, or causes, of the PH. In this system, PAH is defined as Group 1 and PH-COPD is classified under Group 3, PH due to lung disease and/or hypoxemia. We believe the mechanism of action of inhaled nitric oxide as a pulmonary vasodilator, and thus INOpulse, can be effective in treating PH related to other conditions, including PH associated with IPF, CTEPH, PH associated with sarcoidosis and PH associated with pulmonary edema from high altitude sickness.

While there are two recently approved treatments for IPF, there are currently no approved therapies for PH-IPF. In 2013, riociguat (Adempas) was the first drug therapy approved for treating CTEPH, although other PAH medications are sometimes used to treat this condition. Patients with sarcoidosis are often treated with steroids or other anti-inflammatory medications, however, there are no therapies approved to treat the PH associated with this disease. Pulmonary edema from high altitude sickness is typically treated with oxygen therapy, however, there are no current treatments for PH associated with this disease.

Our current license from Ikaria covers the development of the Bellerophon indications as noted above.

BCM for Prevention of Cardiac Remodeling Following a STEMI

We were developing BCM as a medical device to prevent congestive heart failure following a STEMI. Patients who suffer a STEMI are at increased risk for congestive heart failure due to potential cardiac remodeling, which is a structural change in the size and shape of the heart that affects its ability to function normally. We have an exclusive worldwide license to BCM under a license agreement we entered into with BioLine in August 2009.

Relationship with Ikaria after the Spin-Out

The development of our programs was initiated under the leadership of our scientific and development team while at Ikaria. Ikaria's lead product, INOmax, is an inhaled nitric oxide product used for treatment of persistent PH of the newborn. Our understanding of the medical applications of nitric oxide and associated delivery devices, as well as our innovative approach to the pulsed delivery of nitric oxide, originated at Ikaria, and we in-licensed BCM while we were a part of Ikaria.

In October 2013, Ikaria completed an internal reorganization of certain assets and subsidiaries, in which it transferred to us exclusive worldwide royalty-free rights to develop and commercialize pulsed nitric oxide in PAH, PH-COPD and PH-IPF. In November 2015, we entered into an amendment to our exclusive cross-license, technology transfer and regulatory matters agreement with Ikaria that included a royalty equal to 3% of net sales of any commercial products for PAH. Following the internal reorganization, in February 2014, Ikaria distributed all of our then outstanding units to its stockholders through the payment of a special dividend on a pro rata basis based on each stockholder's ownership of Ikaria capital stock. We refer to Ikaria's distribution of our then outstanding units to its stockholders as the Spin-Out.

Shortly after the Spin-Out, Ikaria was acquired by entities affiliated with Madison Dearborn Partners. On April 16, 2015, Mallinckrodt plc, or Mallinckrodt, announced that it had completed its acquisition of Ikaria.

In connection with the Spin-Out, we entered into several agreements with Ikaria providing for, among other things, the provision of transition services, the cross license of certain intellectual property, commitments not to compete, the manufacture and supply of the INOpulse drug and device and certain employee matters.

Transition Services Agreement and 2015 Services Agreement

In February 2014 and July 2015, we entered into a transition services agreement and an amendment to the transition services agreement, respectively, with Ikaria, which we refer to as the TSA. Pursuant to the terms and conditions of the TSA, Ikaria had agreed to use commercially reasonable efforts to provide certain services to us until February 2016. In exchange for the services provided by Ikaria pursuant to the TSA, we paid to Ikaria a service fee in the amount of $772,000 per month and reimbursed Ikaria for any out of pocket expenses, any taxes imposed on Ikaria in connection with the provision of services under the TSA. The termination of these services was accelerated to September 30, 2015 as part of the amendment to the agreement entered in July 2015.

Under our additional services agreement with Ikaria, or the 2015 Services Agreement, which became effective on January 1, 2015, Ikaria provided to us certain information technology and device servicing services. In exchange for the services provided by Ikaria pursuant to the 2015 Services Agreement, we paid to Ikaria fees that totaled, in the aggregate, approximately $0.2 million. We also received payments of $1.7 million from Ikaria in connection with the 2015 Services Agreement for using commercially reasonable efforts to provide certain services to Ikaria, including services related to regulatory matters, drug and device safety, clinical operations, biometrics and scientific affairs. In July 2015, we entered into an amendment to the 2015 Services Agreement advancing the termination date from February 8, 2016 to September 30, 2015.

Exclusive Cross-License, Technology Transfer and Regulatory Matters Agreement

In February 2014, we entered into an exclusive cross-license, technology transfer and regulatory matters agreement with Ikaria. Pursuant to the terms of the license agreement, Ikaria granted to us a fully paid-up, non-royalty bearing, exclusive license under specified intellectual property rights controlled by Ikaria to engage in the development, manufacture and commercialization of nitric oxide, devices to deliver nitric oxide and related services for or in connection with out-patient, chronic treatment of patients with PAH, PH-COPD or PH-IPF. On July 27, 2015, we entered into an amendment to the license agreement to expand the scope of our license to allow us to develop our INOpulse program for the treatment of three additional indications: CTEPH, PH associated with sarcoidosis and PH associated with pulmonary edema from high altitude sickness. Subject to the terms set forth therein, the amendment to the license agreement also provides that the Company will pay Ikaria a royalty equal to 5% of net sales of any commercialized products for the three additional indications. In November 2015, we entered into an amendment to our exclusive cross-license, technology transfer and regulatory matters agreement with Ikaria that included a royalty equal to 3% of net sales of any commercial products for PAH.

We have granted to Ikaria a fully paid-up, non-royalty-bearing, exclusive license under specified intellectual property rights that we control to engage in the development, manufacture and commercialization of products and services for or used in connection with the diagnosis, prevention or treatment, whether in- or out-patient, of certain conditions and diseases other than the Bellerophon indications and for the use of nitric oxide to treat or prevent conditions that are primarily managed in the hospital, which we refer to collectively as the Ikaria nitric oxide business.

We have agreed that, during the term of the license agreement, we will not, without the prior written consent of Ikaria, grant a sublicense under any of the intellectual property licensed to us under the license agreement to any of our affiliates or any third party, in either case that directly or indirectly competes with the Ikaria nitric oxide business. We have also agreed that we will include certain restrictions in our agreements with customers of our products to ensure that such products will only be used for the Bellerophon indications.

The license agreement will expire on a product-by-product basis for products for a specific Bellerophon indication at such time as we are no longer developing or commercializing any product for such indication. The license agreement may be terminated by either party in the event an act or order of a court or governmental authority prohibits either party from substantially performing under the license agreement. Either party may also terminate the license agreement in the event of an uncured material breach by the other party or in the event the other party is insolvent or in bankruptcy proceedings. Ikaria may also terminate the license agreement if we or any of our affiliates breach the agreements not to compete described below, or if we or any successor to our rights under the license agreement markets a generic nitric oxide product that is competitive with INOmax. Under certain circumstances, if the license agreement is terminated, the licenses granted to Ikaria by us will survive such termination.

Ikaria retains the right to develop and commercialize inhaled nitric oxide products, including pulsed products, in all indications other than the Bellerophon indications.

Agreements Not to Compete

In September 2013, October 2013 and February 2014, we and each of our subsidiaries entered into an agreement not to compete with Ikaria, each of which was amended in July 2015. We refer to these agreements collectively as the agreements not

to compete. Pursuant to the agreements not to compete, as amended, we and each of our subsidiaries agreed not to engage, anywhere in the world, in any manner, directly or indirectly, until the earlier of five years after the effective date of such agreement not to compete, as amended, or the date on which Ikaria and all of its subsidiaries are no longer engaged in such business, in:

- the development, manufacture, commercialization, promotion, sale, import, export, servicing, repair, training, storage, distribution, transportation, licensing or other handling or disposition of any product or service (including, without limitation, any product or service that utilizes, contains or includes nitric oxide for inhalation, a device intended to deliver nitric oxide or a service that delivers or supports the delivery of nitric oxide), bundled or unbundled, for or used in connection with (a) the diagnosis, prevention or treatment, in both adult and/or pediatric populations, and whether in- or out-patient, of: (i) hypoxic respiratory failure associated with pulmonary hypertension, (ii) pulmonary hypertensive episodes and right heart failure associated with cardiovascular surgery, (iii) bronchopulmonary dysplasia, (iv) the management of ventilation-perfusion mismatch in acute lung injury, (v) the management of ventilation-perfusion mismatch in acute respiratory distress syndrome, (vi) the management of pulmonary hypertension episodes and right heart failure in congestive heart failure, (vii) the management of pulmonary hypertension episodes and right heart failure in pulmonary or cardiac surgery, (viii) the management of pulmonary hypertension episodes and right heart failure in organ transplant, (ix) sickle cell vaso-occlusive crisis, (x) hypoxia associated with pneumonia or (xi) ischemia-reperfusion injury or (b) the use of nitric oxide to treat or prevent conditions that are primarily managed in the hospital; or

- any and all development, manufacture, commercialization, promotion, sale, import, export, storage, distribution, transportation, licensing, or other handling or disposition of any terlipressin or any other product within the pressin family, (a) intended to treat (i) hepatorenal syndrome in any form, (ii) bleeding esophageal varices or (iii) septic shock or (b) for or in connection with the management of low blood pressure.

The agreements not to compete expressly exclude the Bellerophon indications.

In February 2014, we also entered into drug and device clinical supply agreements and an employee matters agreement with Ikaria. In November 2015, we entered into an amendment to the drug supply agreement. See “Manufacturing” below for a description of the drug and device clinical supply agreements and “Certain Relationships and Related Person Transactions-Relationship with Ikaria” for a description of the employee matters agreement.

BioLine License Agreement

In August 2009, we entered into a license agreement with BioLineRx Ltd. and BioLine Innovations Jerusalem L.P., collectively BioLine, under which we obtained an exclusive worldwide license to BCM. Under the license agreement, we are obligated to use commercially reasonable efforts to develop and commercialize at least one product containing BCM. We have established a joint development committee with BioLine to oversee the development of BCM.

We currently do not intend to proceed with further clinical development of BCM until and unless we can determine an alternative path forward. Consequently, any future milestones payments to BioLine would depend on finding a path forward for future clinical development. Under the terms of the license agreement, if we achieve certain clinical and regulatory events specified in the license agreement, we will be obligated to pay milestone payments to BioLine, which could total, in the aggregate, up to $115.5 million, and if we achieve certain commercialization targets specified in the license agreement, we will be obligated to pay additional milestone payments to BioLine, which could total, in the aggregate, up to $150.0 million. In addition, we will be obligated to pay BioLine a specified percentage of any upfront consideration we receive for sublicensing BCM, as well as royalties on net sales, if any, at a percentage ranging from 11% to 15%, depending on net sales level, of any approved product containing BCM, subject to offsets for specified payments to third parties made in connection with BCM. We reimbursed BioLine for certain legal fees in the amount of $250,000 following completion of our IPO.

Except under specified circumstances, neither we, nor any other person that controls, is controlled by, or is under common control with us, may directly or indirectly acquire more than a specified percentage of the equity or debt securities of BioLine, or urge, induce, entice or solicit any other party to acquire such securities, without BioLine’s consent.

We and BioLine have the right to terminate the license agreement for an uncured material breach by the other party. In addition, we have the right to terminate the license agreement if at any time we determine that further development of products containing BCM is not warranted.

Manufacturing

INOpulse Drug Product

In February 2014, we and a subsidiary of Ikaria entered into a drug supply agreement which was subsequently amended in November 2015. Under this agreement, Ikaria has agreed to use commercially reasonable efforts to supply inhaled nitric oxide for us in our clinical trials, and we have agreed to purchase our clinical supply of inhaled nitric oxide from Ikaria. We have also granted Ikaria a right of first negotiation in the event that we desire to enter into a commercial supply agreement with a third party for supply of nitric oxide for inhalation. The drug supply agreement will expire on a product-by-product basis on the date we discontinue clinical development of such product. In addition, either party may terminate the drug supply agreement in the event of an uncured material breach by the other party.

Ikaria manufactures pharmaceutical-grade nitric oxide at its facility in Port Allen, Louisiana. This facility, which we believe is operated in compliance with current Good Manufacturing Practices, or cGMP, is the only FDA-approved site for manufacturing medical nitric oxide in the world.

To support business outside of the United States, the Port Allen manufacturing facility has also successfully passed inspections by the EMA, Health Canada; the Pharmaceutical and Medical Devices Agency, or PMDA, of Japan, and the Korean FDA, or KFDA. The EMA, the Health Protection Branch of Health Canada, PMDA and KFDA operate in a similar fashion to the FDA in that each requires submission of a dossier containing substantial evidence of safety and effectiveness prior to approval. These agencies' monitoring of safety in a post-marketing setting also is similar to that of the FDA.

The operations that Ikaria currently performs to manufacture the minicylinder used for the INOpulse DS consists of two steps. The first step is to manufacture the concentrated drug product, which Ikaria conducts using the same processes that it uses to manufacture its own drug product. The second step is the filling operation in which the pre-mix product is mixed to the appropriate concentration and filled into the final minicylinders that we use with INOpulse DS and DS-C. As we have reduced the size and weight of INOpulse, we have also developed a smaller drug cartridge for INOpulse. The filling process has been developed by Ikaria as a high-throughput batch fill process that leverages several technologies that Ikaria has developed, and we have licensed, to fill smaller containers at a higher pressure and purity and at a significantly higher production rate than prior technology. The process eliminates the need for the pre-mix and directly dilutes into a receiving vessel prior to filling the cartridges.

This manufacturing system is designed to be modular and can be expanded as needed. The current installed capacity within the Port Allen plant is sufficient to support our INOpulse clinical program as currently planned. In addition, the plant has the capacity to expand to meet additional demand. We have a license from Ikaria to use this fill process technology to work with additional companies, as needed, to produce the final cartridge. Commercial supply manufacturing can be supported with additional units installed at the Port Allen site or other regional locations, by Ikaria or other manufacturers, as determined by distribution requirements. For our clinical trials, Ikaria can supply and ship product from the Port Allen site and the current cartridges are expected to have a shelf life of at least one year. We are testing the finished product to potentially establish a shelf life of up to two years.

INOpulse Drug Delivery Systems

In February 2015, we entered into an agreement with Flextronics Medical Sales and Marketing Ltd., a subsidiary of Flextronics International Ltd., or Flextronics, to manufacture and service the INOpulse device that we will use in future clinical trials of INOpulse for PAH and INOpulse for PH-COPD and PH-IPF.

PAH patients have the potential for rebound PH, which is a sudden and serious increase in pulmonary arterial pressure that results from therapy withdrawal. However, in the Phase 2 trial, all patients were tested for rebound PH and we found no adjudicated cases of rebound PH with this testing. Subjects in our PAH trials are all on at least one background specific PAH therapy, the majority being on two or more PAH therapies. These background therapies likely protect against rebound. Though the likelihood of rebound PH is very low, all patients with PAH are provided with a backup system.

BCM Product

We outsourced the manufacture of BCM for use in clinical trials. BCM was manufactured by a third-party under the terms of a manufacturing and supply agreement which expires in April 2017. BCM is composed of ultra-pure sodium alginate and calcium-D-gluconate. We purchased sodium alginate from FMC BioPolymer AS (doing business as NovaMatrix™) under the terms of a clinical supply agreement that expires in December 2018. Calcium-D-gluconate is a commodity item available from multiple suppliers. Following the results from the PRESERVATION I trial, we are not proceeding with further clinical

development and are not pursuing further manufacturing of BCM at this point until and unless we can determine an alternative path forward.

Competition

The biotechnology and pharmaceutical industries are highly competitive. There are many pharmaceutical companies, biotechnology companies, public and private universities and research organizations actively engaged in the research and development of products that may be similar to our products. In addition, other companies are increasingly looking at cardiopulmonary indications as a potential opportunity. It is possible that the number of companies seeking to develop products and therapies for the treatment of unmet needs in our target markets will increase.

Our competitors, either alone or with their strategic partners, may have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of products and the commercialization of those products. Accordingly, our competitors may be more successful than we may be in obtaining approval for therapies and achieving widespread market acceptance. We anticipate that we will face intense and increasing competition as new drugs and advanced technologies become available.

Currently, there are 13 drugs approved for the treatment of PAH, within the following categories: prostacyclin and prostacyclin analogs (including Flolan (epoprostenol), which is marketed by GlaxoSmithKline, Tyvaso (treprostinil), Orenitram (treprostinil) and Remodulin (treprostinil), which are marketed by United Therapeutics Corporation, and Ventavis (iloprost) and Veletri (epoprostenol), which are marketed by Actelion Pharmaceuticals US, Inc., or Actelion), phosphodiesterase type-5 inhibitors (including Adcirca (tadalafil), which is marketed by United Therapeutics Corporation, and Revatio (sildenafil), which is marketed by Pfizer Inc.), endothelin receptor antagonists (including Letairis (ambrisentan), which is marketed by Gilead Sciences, Inc., and Opsumit (macitentan) and Tracleer (bosentan), which are marketed by Actelion) and a soluble guanylate cyclase stimulator (Adempas (riociguat), which is marketed by Bayer HealthCare Pharmaceuticals Inc.). The most recent addition to the list is Uptravi (selexipag), a selective prostacyclin receptor agonist, which is marketed by Actelion and was approved by the FDA in December 2015.

There are also other treatments for PAH in various phases of development, including other nitric oxide generation and delivery systems such as GeNOsyl™ (being developed by GeNO LLC) and a nebulized formulation of nitrite (being developed by Mast Therapeutics) both in Phase 2 development. Further, Insmed, Inc. is developing an investigational, sustained-release, inhaled treprostinil prodrug and SteadyMed Therapeutics, Inc., or Steady Med, is developing Trevyent™ which delivers treprostinil using SteadyMed's PatchPump technology.

Currently, there are no approved therapies for treating PH-COPD, and the only generally accepted treatments are LTOT, pulmonary rehabilitation and lung transplant, and we are not aware of any therapies for PH-COPD in advanced clinical development.

Patents and Proprietary Rights

We strive to protect the proprietary technologies that we believe are important to our business, including seeking and maintaining patent protection intended to protect, for example, our product candidates, related technologies and/or other aspects of the inventions that are important to our business. Our owned and licensed patents and patent applications cover patentable subject matter from composition of matter, methods of use, manufacturing processes for BCM and method of administration, devices and device components, critical safety features and design components with respect to INOpulse. However, patent protection is not available for the composition of matter of the active pharmaceutical ingredients in INOpulse since nitric oxide is a naturally occurring molecule.

Actual protection afforded by a patent, which can vary from country to country, depends on the type of patent, the scope of its coverage and the availability of legal remedies in the country. We also rely on trade secrets and careful monitoring of our proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

We plan to continue to expand our intellectual property estate by filing patent applications directed to inventions which provide additional patent protection for our product offering, for instance, device enhancements, safety features and manufacturing processes. Our success will depend significantly on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business; defend and enforce our patents; maintain our licenses to use intellectual property owned by third parties; preserve the confidentiality of our

trade secrets; and operate without infringing the valid and enforceable patents and other proprietary rights of third parties. We also consider know-how, continuing technological innovation and in-licensing opportunities to develop, strengthen and maintain our proprietary positions.

A third party may hold intellectual property, including patent rights that are important or necessary to the development of our programs. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our product candidates, in which case we would be required to obtain a license from these third parties on commercially reasonable terms, or our business could be harmed, possibly materially. For example, if we want to expand the indications for which we could develop and commercialize pulsed nitric oxide beyond the Bellerophon indications, we will need to obtain a license from Ikaria.

The patent positions of therapeutics companies like us are generally uncertain and involve complex legal, scientific and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and patent scope can be reinterpreted by the courts after issuance. Moreover, many jurisdictions permit third parties to challenge issued patents in administrative proceedings which may result in further narrowing or even cancellation of patent claims. Consequently, we do not know whether any of our product candidates will be protectable or remain protected by enforceable patents. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors. Any patents that we own or license may be challenged, narrowed, circumvented or invalidated by third parties.

Because patent applications in the United States and certain other jurisdictions are maintained in secrecy for 18 months or potentially even longer, and since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain of the priority of inventions covered by pending patent applications. Moreover, we may have to participate in interference proceedings declared by the U.S. Patent and Trademark Office, or USPTO, to determine priority of inventions for any patent applications filed with the USPTO on or before March 15, 2013. Likewise, derivation proceedings may also be declared for any patent filings filed after March 15, 2013.

The patents and patent applications that relate to our programs are described below.

INOpulse

As of March 10, 2016, we hold exclusive licenses from Ikaria to at least 80 patents and pending patent applications in both the United States and foreign countries including Australia, Brazil, Canada, China, Europe, Hong Kong, India, Indonesia, Israel, Japan, Korea, Mexico, the Philippines, Russia and Singapore. Certain of these issued patents and patent applications, if issued, will expire as late as 2033. These patent rights have been exclusively licensed for the treatment of patients with Bellerophon indications and cover methods of delivery and the drug delivery device, as well as important safety features and the ornamental design of the drug delivery device.

A primary basis for patent exclusivity is based on pending and issued in-licensed patents directed to proprietary methods of administering pulsed inhaled nitric oxide, as well as a device for delivering the same. At least one patent has been issued in the United States as well as Australia, China, Hong Kong, Japan, and Mexico. One patent has been allowed in Europe where the PTO has issued a Notice of Intention to Grant. Patent applications are pending in Australia, Brazil, Canada, China, Europe, Hong Kong, Mexico and the United States. This patent family expires as late as 2027 in the United States and as late as 2026 in the other countries.

Another important basis for patent exclusivity is based on an in-licensed portfolio of patents, directed to novel nasal cannula features that we believe are necessary for the accurate, safe and efficacious administration of pulsed nitric oxide. The patent family consists of two issued U.S. patents and pending applications in the United States as well as Australia, Brazil, Canada, China, Russia, Europe, Israel, India, Japan, Korea and Mexico. Each of these patents and patent applications, if issued, will expire in 2033 in the United States and abroad.

Another in-licensed patent family relates to features of the drug delivery canister necessary for providing drug product for use with our proprietary pulsing drug delivery device. This patent family includes one issued U.S. patent, one issued Japanese patent, one issued Mexican patent, one issued Singaporean patent, one issued Israeli patent, one issued Chinese patent, one issued Indonesian patent, one issued Korean patent, one issued Russian patent, and three issued Australian patents, as well as 14 pending patent applications in the United States, Brazil, Canada, China, Europe, Hong Kong, India, Israel, Japan, Korea, Mexico, the Philippines, Russia and Singapore. These pending applications, if issued, as well as the non-U.S. issued patents will expire in 2029. The issued U.S. patent will expire in 2030.

Several other patent families directed to device and safety features are issued and pending. Furthermore, a design patent covering the ornamental design of the intended commercial device and clinical device has been granted.

In addition, the FDA has granted orphan drug designation to our nitric oxide program for the treatment of PAH, which could result in marketing exclusivity of seven years in the United States should this be the first NDA approved for inhaled nitric oxide in this indication. The active ingredient, nitric oxide, was previously approved by the FDA as a drug in a separate clinical application. Accordingly, any related patent rights will not be eligible for a patent term extension under relevant provisions of the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Act.

BCM

Patent protection of BCM in the United States and in Australia, Canada, China, Europe, Hong Kong, India, Israel, Japan, Korea and Mexico is provided by issued composition of matter and method of treatment patents, which we in-license from BioLine, that cover the intended commercial product. These issued patents are not limited to treatment of cardiac tissue, affording broad protection for the use of BCM in treating any damaged body tissue. We were notified by the European Patent Office in July 2014 and October 2014 that Notices of Opposition to two European patents that we licensed from BioLine, one of which covers the BCM intended commercial product described above, have been filed with the European Patent Office. A Notice of Opposition initiates a process during which the European Patent Office can decide to reconsider an issued patent and modify or revoke some or all of the patent claims. We have the right to respond to the Notices of Opposition before the European Patent Office makes a decision whether or not any or all of the patent claims are to be modified or revoked. We filed a response to the first patent opposition in December 2014 for which we have an oral proceeding schedule for July 2016, and we filed a response to the second patent opposition in March 2015, as we believe the two issued patents were properly examined and appropriately granted by the European Patent Office. Furthermore, we believe the arguments made in the Notices of Opposition misstate the facts and lack scientific merit.

BCM would be regulated as a device and therefore data exclusivity would not be available. However, under the Hatch-Waxman Act, one issued U.S. patent covering the product will be eligible for patent term extension of up to five years to recover patent term lost during clinical trials. Accordingly, if the U.S. composition of matter patent that expires in 2029 is selected for this extension and a patent term extension is granted, certain rights under the patent may not expire until 2032 to 2034, depending on the timing of marketing approval and other factors. Corresponding issued patents in other countries will expire in 2024 and may also be eligible for patent term extensions. We do not expect to be granted a patent term extension for composition of matter patents in Europe, but patent term extensions may be available in other countries such as Japan and Israel.

Method of manufacturing patents that we have in-licensed have been issued in the United States, Australia, China, Europe, India, Israel, Korea, Mexico and Canada. The U.S. issued patent expires in 2025 and the non-U.S. issued patents expire in 2024. The method of manufacturing patent applications we developed and own, issued in the United States and pending in Canada and Europe, will expire in 2032, not including any applicable patent term adjustment.

Further, there is no abbreviated clinical trial pathway, such as an abbreviated new drug application, or ANDA, or a 505(b)(2) new drug application, for a device product approved via a PMA pathway.

Patent Term

The base term of a U.S. patent is 20 years from the filing date of the earliest-filed non-provisional patent application from which the patent claims priority. The term of a U.S. patent can be lengthened by patent term adjustment, which compensates the owner of the patent for administrative delays at the USPTO. In some cases, the term of a U.S. patent is shortened by a terminal disclaimer that reduces its term to that of an earlier-expiring patent.

The term of a U.S. patent may be eligible for patent term extension under the Hatch-Waxman Act to account for at least some of the time the drug or device is under development and regulatory review after the patent is granted. With regard to a drug or device for which FDA approval is the first permitted marketing of the active ingredient, the Hatch-Waxman Act allows for extension of the term of one U.S. patent. Thus, patent term extension is not available for INOpulse since the active moiety is nitric oxide, which is already subject to an approved NDA. The extended patent term cannot exceed the shorter of five years beyond the non-extended expiration of the patent or 14 years from the date of the FDA approval of the drug or device. Some foreign jurisdictions have analogous patent term extension provisions that allow for extension of the term of a patent that covers a device approved by the applicable foreign regulatory agency.

Trade Secrets

In addition to patents, we rely on trade secrets and know-how to develop and maintain our competitive position. We typically rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. For example, elements of the manufacture of our products are based on trade secrets and know-how that are not publicly disclosed. We protect trade secrets and know-how by establishing confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors and commercial partners. These agreements provide that all confidential information developed or made known during the course of an individual or entity's relationship with us must be kept confidential during and after the relationship. These agreements also provide that all inventions resulting from work performed for us or relating to our business and conceived or completed during the period of employment or assignment, as applicable, shall be our exclusive property. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary technology by third parties.

Trademarks

We also seek trademark protection where available and when appropriate. The symbol ™ indicates a common law trademark. Other service marks, trademarks and trade names appearing in this Annual Report on Form 10-K are the property of their respective owners.

Government Regulation

Government authorities in the United States, at the federal, state and local level, and in other countries and jurisdictions, including the European Union, extensively regulate, among other things, the research, development, testing, manufacture, quality control, clearance, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of pharmaceutical products and medical devices. The processes for obtaining marketing approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

Review and Approval of Drugs in the United States

In the United States, the FDA regulates drugs under the Food, Drug, and Cosmetic Act, or FDCA, and implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval may subject an applicant and/or sponsor to a variety of administrative or judicial sanctions, including refusal by the FDA to approve pending applications, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters and other types of letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits, or civil or criminal investigations and penalties brought by the FDA and the Department of Justice or other governmental entities.

Our product candidates must be approved by the FDA before they may be legally marketed in the United States. An applicant seeking approval to market and distribute a new drug product in the United States must typically undertake the following:

- completion of pre-clinical laboratory tests, animal studies and formulation studies in compliance with applicable FDA's good laboratory practice, or GLP, regulations;
- submission to the FDA of an investigational new drug application, or IND, which must take effect before human clinical trials may begin;
- approval by an independent institutional review board, or IRB, at each clinical site before a clinical trial may be initiated at that site;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practices, or GCP, to establish the safety and efficacy of the proposed drug product for each indication;
- preparation and submission to the FDA of a new drug application, or NDA;

- review of the product by an FDA advisory committee, where appropriate or if applicable;

- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities at which the product, or components thereof, are produced to assess compliance with cGMP requirements and to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;

- payment of user fees and securing FDA approval of the NDA; and

- compliance with any post-approval requirements, including Risk Evaluation and Mitigation Strategies, or REMS, and post-approval studies required by the FDA.

Pre-Clinical Studies

Pre-clinical studies include laboratory evaluation of the purity and stability of the manufactured drug substance or active pharmaceutical ingredient and the formulated drug or drug product, as well as *in vitro* and animal studies to assess the toxicity, safety and activity of the drug for initial testing in humans and to establish a rationale for therapeutic use. The conduct of pre-clinical and other non-clinical studies is subject to federal regulations and requirements, including GLP regulations. The results of the pre-clinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical trials, among other things, are submitted to the FDA as part of an IND.

Companies usually must complete some long-term pre-clinical testing, such as animal tests of reproductive adverse events and carcinogenicity, and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the drug in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

Human Clinical Studies in Support of an NDA

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include, among other things, the requirement that all research subjects provide their informed consent in writing before their participation in any clinical trial. Clinical trials are conducted under written protocols detailing, among other things, the objectives of the clinical trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to a proposed clinical trial and places the trial on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Accordingly, submission of an IND may or may not result in the FDA allowing clinical trials to commence.

In addition, an IRB representing each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must conduct continuing review at least annually. The IRB must review and approve, among other things, the study protocol and informed consent information to be provided to study subjects. An IRB must operate in compliance with FDA regulations.

A sponsor who wishes to conduct a clinical trial outside the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to the FDA in support of an NDA or IND so long as the clinical trial is conducted in compliance with GCP, and the FDA is able to validate the data from the trial through an onsite inspection if the agency deems it necessary.

Human clinical trials are typically conducted in three sequential phases, which may overlap or be combined:

- Phase 1: The drug is initially introduced into a small number of healthy human subjects or patients with the target disease (e.g., cancer) or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness and to determine optimal dosage.

- Phase 2: The drug is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.

- Phase 3: Phase 3 clinical trials are commonly referred to as "pivotal" studies, which typically denotes a clinical trial which is intended to present the data that the FDA or other relevant regulatory agency will use to determine whether or not to approve a drug. In Phase 3 clinical trials, the drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product, and to provide adequate information for the labeling of the product.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if SAEs occur. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. The FDA will typically inspect one or more clinical sites to assure compliance with GCP and the integrity of the clinical data submitted. In addition, the sponsor of a clinical trial must register with the National Institutes of Health, or NIH, and list information about the trial on NIH's clinicaltrials.gov website.

Section 505(b)(2) NDAs

NDAs for most new drug products are based on two full clinical trials that must contain substantial evidence of the safety and efficacy of the proposed new product. These applications are submitted under Section 505(b)(1) of the FDCA. The FDA is, however, authorized to approve an alternative type of NDA under Section 505(b)(2) of the FDCA. This type of application allows the applicant to rely, in part, on the FDA's previous findings of safety and efficacy for a similar product, or published literature. Specifically, Section 505(b)(2) applies to NDAs for a drug for which the investigations made to show whether or not the drug is safe for use and effective in use and relied upon by the applicant for approval of the application "were 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."

Thus, Section 505(b)(2) authorizes the FDA to approve an NDA based on safety and effectiveness data that were not developed by the applicant. NDAs filed under Section 505(b)(2) may provide an alternate and potentially more expeditious pathway to FDA approval for new or improved formulations or new uses of previously approved products. If the 505(b)(2) applicant can establish that reliance on the FDA's previous approval is scientifically appropriate, the applicant may eliminate the need to conduct certain pre-clinical or clinical studies of the new product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new drug candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

Submission of an NDA to the FDA

Assuming successful completion of required clinical trials and other requirements, the results of the non-clinical studies and clinical trials, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the drug product for one or more indications. Under federal law, the submission of most NDAs is additionally subject to an application user fee, currently exceeding $2.1 million, and the sponsor of an approved NDA is also subject to annual product and establishment fees, currently exceeding $104,000 per product and $554,000 per establishment. These fees are typically increased annually.

The FDA conducts a preliminary review of an NDA within 60 days of its receipt and informs the sponsor by the 74th day after the FDA's receipt of the submission whether the application is sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA has agreed to specified performance goals in the review process of NDAs. Most such applications are meant to be reviewed within ten months from the date of filing, and most applications for "priority review" products are meant to be reviewed within six months of filing. The review process may be extended by the FDA for various reasons, including for three additional months to consider new information or clarification provided by the applicant to address an outstanding deficiency identified by the FDA following the original submission.

Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is or will be

manufactured. These pre-approval inspections may cover all facilities associated with an NDA submission, including drug component manufacturing (such as Active Pharmaceutical Ingredients), finished drug product manufacturing, and control testing laboratories. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will often inspect one or more clinical sites to assure compliance with GCP.

The FDA may refer an application for a novel drug to an advisory committee or explain why such referral was not made. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Special Protocol Assessment

A sponsor of an IND may request that the FDA evaluate within 45 days certain protocols and issues relating to the protocols to assess whether they are adequate to meet scientific and regulatory requirements identified by the sponsor. Such special protocol assessments, or SPAs, may be requested for clinical protocols for Phase 3 trials whose data will form the primary basis for an efficacy claim if the trials had been the subject of discussion at an end-of-Phase 2/pre-Phase 3 meeting with the FDA. If the sponsor and the FDA reach a written agreement regarding the protocol, the SPAs will be considered binding on the FDA and will not be changed unless the sponsor fails to follow the agreed-upon protocol, data supporting the request are found to be false or incomplete, or the FDA determines that a substantial scientific issue essential to determining the safety or effectiveness of the drug was identified after the testing began. Even if a SPA is agreed to, approval of the NDA is not guaranteed since a final determination that an agreed-upon protocol satisfies a specific objective, such as the demonstration of efficacy, or supports an approval decision, will be based on a complete review of all the data in the NDA.

Accelerated Approval Pathway

The FDA may grant accelerated approval to a drug for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the drug has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a condition when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, or IMM, and that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. Drugs granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a drug, such as an effect on IMM. The FDA has limited experience with accelerated approvals based on intermediate clinical endpoints, but has indicated that such endpoints generally may support accelerated approval where the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate clinical benefit of a drug.

The accelerated approval pathway is most often used in settings in which the course of a disease is long and an extended period of time is required to measure the intended clinical benefit of a drug, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. As a result, 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 confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the drug from the market on an expedited basis. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA.

The FDA's Decision on an NDA

On the basis of the FDA's evaluation of the NDA and accompanying information, including the results of the inspection

of the manufacturing facilities, the FDA may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

If the FDA approves a product, it may limit the approved indications for use for the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess the drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions which can materially affect the potential market and profitability of the product. In addition, as a condition of approval, the FDA may require an applicant to develop a REMS. REMS use risk minimization strategies beyond the professional labeling to ensure that the benefits of the product outweigh the potential risks. To determine whether a REMS is needed, the FDA will consider the size of the population likely to use the product, seriousness of the disease, expected benefit of the product, expected duration of treatment, seriousness of known or potential adverse events, and whether the product is a new molecular entity. REMS can include medication guides, physician communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU may include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The FDA may require a REMS before approval or post-approval if it becomes aware of a serious risk associated with use of the product. The requirement for a REMS can materially affect the potential market and profitability of a product.

The FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs. After approval, many types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Post-Approval Requirements

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP and other requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product license approvals;

- product seizure or detention, or refusal to permit the import or export of products; or

- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, or PDMA, which regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution.

Abbreviated New Drug Applications for Generic Drugs

In 1984, with passage of the Hatch-Waxman Amendments to the FDCA, Congress authorized the FDA to approve generic drugs that are the same as drugs previously approved by the FDA under the NDA provisions of the statute. To obtain approval of a generic drug, an applicant must submit an abbreviated new drug application, or ANDA, to the agency. In support of such applications, a generic manufacturer may rely on the pre-clinical and clinical testing previously conducted for a drug product previously approved under an NDA, known as the reference listed drug, or RLD.

Specifically, in order for an ANDA to be approved, the FDA must find that the generic version is identical to the RLD with respect to the active ingredients, the route of administration, the dosage form, and the strength of the drug. At the same time, the FDA must also determine that the generic drug is "bioequivalent" to the innovator drug. Under the statute, a generic drug is bioequivalent to a RLD if the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug.

Upon approval of an ANDA, the FDA indicates whether the generic product is "therapeutically equivalent" to the RLD in its publication "Approved Drug Products with Therapeutic Equivalence Evaluations," also referred to as the "Orange Book." Physicians and pharmacists consider a therapeutic equivalent generic drug to be fully substitutable for the RLD. In addition, by operation of certain state laws and numerous health insurance programs, the FDA's designation of therapeutic equivalence often results in substitution of the generic drug without the knowledge or consent of either the prescribing physician or patient.

Under the Hatch-Waxman Amendments, the FDA may not approve an ANDA until any applicable period of non-patent exclusivity for the RLD has expired. The FDCA provides a period of five years of non-patent data exclusivity for a new drug containing a new chemical entity. In cases where such exclusivity has been granted, an ANDA may not be submitted to the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification, in which case the applicant may submit its application four years following the original product approval. The FDCA also provides for a period of three years of exclusivity if the NDA includes reports of one or more new clinical investigations, other than bioavailability or bioequivalence studies, that were conducted by or for the applicant and are essential to the approval of the application. This three-year exclusivity period often protects changes to a previously approved drug product, such as a new dosage form, route of administration, combination or indication.

Hatch-Waxman Patent Certification and the 30-Month Stay

Upon approval of an NDA or a supplement thereto, NDA sponsors are required to list with the FDA each patent with claims that cover the applicant's product or an approved method of using the product. Each of the patents listed by the NDA sponsor is published in the Orange Book. When an ANDA applicant submits its application to the FDA, the applicant is required to certify to the FDA concerning any patents listed for the reference product in the Orange Book, except for patents covering methods of use for which the ANDA applicant is not seeking approval. To the extent that the Section 505(b)(2) applicant is relying on studies conducted for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would.

Specifically, the applicant must certify with respect to each patent that:

- the required patent information has not been filed;

- the listed patent has expired;

- the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or

- the listed patent is invalid, unenforceable or will not be infringed by the new product.

A certification that the new product will not infringe the already approved product's listed patents or that such patents are invalid or unenforceable is called a Paragraph IV certification. If the applicant does not challenge the listed patents or indicate that it is not seeking approval of a patented method of use, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired.

If the ANDA applicant or 505(b)(2) applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days after the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months after the receipt of the Paragraph IV notice, expiration of the patent, or a decision in the infringement case that is favorable to the ANDA applicant.

Orphan Designation and Exclusivity

Under the Orphan Drug Act, FDA may designate a drug product as an "orphan drug" if it is intended to treat a rare disease or condition (generally meaning that it affects fewer than 200,000 individuals in the United States, or more in cases in which there is no reasonable expectation that the cost of developing and making a drug product available in the United States for treatment of the disease or condition will be recovered from sales of the product). A company must request orphan product designation before submitting a NDA. If the request is granted, FDA will disclose the identity of the therapeutic agent and its potential use. Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product with orphan status receives the first FDA approval for the disease or condition for which it has such designation, the product will be entitled to orphan product exclusivity. Orphan product exclusivity means that FDA may not approve any other applications for the same product for the same indication for seven years, except in certain limited circumstances. Competitors may receive approval of different products for the indication for which the orphan product has exclusivity and may obtain approval for the same product but for a different indication. If a drug or drug product designated as an orphan product ultimately receives marketing approval for an indication broader than what was designated in its orphan product application, it may not be entitled to exclusivity.

Pediatric Studies and Exclusivity

Under the Pediatric Research Equity Act of 2003, a NDA or supplement thereto must contain data that are adequate to assess the safety and effectiveness of the drug product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. With enactment of the Food and Drug Administration Safety and Innovation Act, or FDASIA, in 2012, sponsors must also submit pediatric study plans prior to the assessment data. Those plans must contain an outline of the proposed pediatric study or studies the applicant plans to conduct, including study objectives and design, any deferral or waiver requests, and other information required by regulation. The applicant, the FDA, and the FDA's internal review committee must then review the information submitted, consult with each other, and agree upon a final plan. The FDA or the applicant may request an amendment to the plan at any time.

The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. Additional requirements and procedures relating to deferral requests and requests for extension of deferrals are contained in FDASIA.

Pediatric exclusivity is another type of non-patent marketing exclusivity in the United States and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity, including the non-patent exclusivity. This six-month exclusivity may be granted if an NDA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection cover the product are extended by six

months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application.

Patent Term Restoration and Extension

A patent claiming a new drug product or medical device may be eligible for a limited patent term extension under the Hatch-Waxman Act, which permits a patent restoration of up to five years for patent term lost during product development and the FDA regulatory review. The restoration period granted on a patent covering a new drug product is typically one-half the time between the date a clinical investigation on human beings is begun and the submission date of an application for premarket approval of the product, plus the time between the submission date of an application for approval of the product and the ultimate approval date. Patent term restoration cannot be used to extend the remaining term of a patent past a total of 14 years from the product's approval date. Only one patent applicable to an approved drug product is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent in question. A patent that covers multiple drugs for which approval is sought can only be extended in connection with one of the approvals. The USPTO reviews and approves the application for any patent term extension or restoration in consultation with the FDA.

Review and Approval of Medical Devices in the United States

Medical devices in the United States are strictly regulated by the FDA. Under the FDCA a medical device is defined as an instrument, apparatus, implement, machine, contrivance, implant, *in vitro* reagent, or other similar or related article, including a component, part or accessory which is, among other things: intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals; or intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes. This definition provides a clear distinction between a medical device and other FDA regulated products such as drugs. If the primary intended use of the product is achieved through chemical action or by being metabolized by the body, the product is usually a drug. If not, it is generally a medical device.

Unless an exemption applies, a new medical device may not be marketed in the United States unless and until it has been cleared through the 510(k) premarket notification process, or 510(k), or approved by the FDA pursuant to a premarket approval application, or PMA. The information that must be submitted to the FDA in order to obtain clearance or approval to market a new medical device varies depending on how the medical device is classified by the FDA. Medical devices are classified into one of three classes on the basis of the controls deemed by the FDA to be necessary to reasonably ensure their safety and effectiveness.

Class I devices are those low risk devices for which reasonable assurance of safety and effectiveness can be provided by adherence to the FDA's general controls for medical devices, which include applicable portions of the FDA's Quality System Regulation, or QSR, facility registration and product listing, reporting of adverse medical events and malfunctions and appropriate, truthful and non-misleading labeling, advertising and promotional materials. Many Class I devices are exempt from premarket regulation; however, some Class I devices require premarket clearance by the FDA through the 510(k) premarket notification process.

Class II devices are moderate risk devices and are subject to the FDA's general controls, and any other special controls, such as performance standards, post-market surveillance, and FDA guidelines, deemed necessary by the FDA to provide reasonable assurance of the devices' safety and effectiveness. Premarket review and clearance by the FDA for Class II devices are accomplished through the 510(k) premarket notification procedure, although some Class II devices are exempt from the 510(k) requirements. Premarket notifications are subject to user fees, unless a specific exemption applies.

Class III devices are deemed by the FDA to pose the greatest risk, such as those for which reasonable assurance of the device's safety and effectiveness cannot be assured solely by the general controls and special controls described above and that are life-sustaining or life-supporting. A PMA application must provide valid scientific evidence, typically extensive pre-clinical and clinical trial data and information about the device and its components regarding, among other things, device design, manufacturing and labeling. PMA applications (and supplemental PMA applications) are subject to significantly higher user fees than are 510(k) premarket notifications.

Post-Marketing Restrictions and Enforcement

After a device is placed on the market, numerous regulatory requirements apply. These include, but are not limited to:

- submitting and updating establishment registration and device listings with the FDA;
- compliance with the QSR, which requires manufacturers to follow stringent design, testing, control, documentation, record maintenance, including maintenance of complaint and related investigation files, and other quality assurance controls during the manufacturing process;
- unannounced routine or for-cause device inspections by the FDA, which may include our suppliers' facilities; and
- labeling regulations, which prohibit the promotion of products for uncleared or unapproved or "off-label" uses and impose other restrictions on labeling; post-approval restrictions or conditions, including requirements to conduct post-market surveillance studies to establish continued safety data or tracking products through the chain of distribution to the patient level.

Under the FDA medical device reporting, or MDR, regulations, medical device manufacturers are required to report to the FDA information that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to death or serious injury if the malfunction of the device or a similar device of such manufacturer were to recur. The decision to file an MDR involves a judgment by the manufacturer. If the FDA disagrees with the manufacturer's determination, the FDA can take enforcement action.

Additionally, the FDA has the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture. The authority to require a recall must be based on an FDA finding that there is reasonable probability that the device would cause serious adverse health consequences or death. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. The FDA requires that certain classifications of recalls be reported to the FDA within ten working days after the recall is initiated.

The failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions:

- warning letters, fines, injunctions or civil penalties;
- recalls, detentions or seizures of products;
- operating restrictions;
- delays in the introduction of products into the market;
- total or partial suspension of production;
- delay or refusal of the FDA or other regulators to grant 510(k) clearance or PMA approvals of new products;
- withdrawals of 510(k) clearance or PMA approvals; or
- in the most serious cases, criminal prosecution.

To ensure compliance with regulatory requirements, medical device manufacturers are subject to market surveillance and periodic, pre-scheduled and unannounced inspections by the FDA, and these inspections may include the manufacturing facilities of subcontractors.

Review and Approval of Combination Products in the United States

Certain products may be comprised of components that would normally be regulated under different types of regulatory authorities, and frequently by different Centers at the FDA. These products are known as combination products. Specifically, under regulations issued by the FDA, a combination product may be:

- a product comprised of two or more regulated components that are physically, chemically, or otherwise combined or mixed and produced as a single entity;
- two or more separate products packaged together in a single package or as a unit and comprised of drug and device

products;

- a drug or device packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug or device where both are required to achieve the intended use, indication, or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed, e.g., to reflect a change in intended use, dosage form, strength, route of administration, or significant change in dose; or

- any investigational drug or device packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device, or biological product where both are required to achieve the intended use, indication, or effect.

Under the FDCA, the FDA assigns primary jurisdiction to a lead center at the FDA for review of a combination product. That determination is based on the "primary mode of action" of the combination product. Thus, if the primary mode of action of a device-drug combination product is attributable to the drug product, the Center for Drug Evaluation and Research would have primary jurisdiction for the combination product. The FDA's Office of Combination Products addresses issues related to combination products and is intended to provide more certainty to the regulatory review process. That office serves as a focal point for combination product issues for agency reviewers and industry. It is also responsible for developing guidance and regulations to clarify the regulation of combination products, and for assignment of the FDA center that has primary jurisdiction for review of combination products where the jurisdiction is unclear or in dispute.

Review and Approval of Drug Products in the European Union

In order to market any product outside of the United States, a company must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of drug products. Whether or not it obtains FDA approval for a product, the company will have to obtain the necessary approvals by the comparable foreign regulatory authorities before it can commence clinical trials or marketing of the product in those countries or jurisdictions. The approval process ultimately varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

Pursuant to the European Clinical Trials Directive, a system for the approval of clinical trials in the European Union has been implemented through national legislation of the member states. Under this system, an applicant must submit a clinical trial authorization, or CTA, and obtain approval from the competent national authority of a European Union member state in which the clinical trial is to be conducted. Furthermore, the applicant may only start a clinical trial after a competent ethics committee has issued a favorable opinion. A CTA must be accompanied by an investigational medicinal product dossier with supporting information prescribed by the European Clinical Trials Directive and corresponding national laws of the member states and further detailed in applicable guidance documents.

To obtain marketing approval of a drug under European Union regulatory systems, an applicant must submit a marketing authorization application, or MAA, either under a centralized or decentralized procedure.

The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid for all European Union member states. The centralized procedure is compulsory for specific products, including for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy products and products with a new active substance indicated for the treatment of certain diseases. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, the centralized procedure may be optional.

Under the centralized procedure, the Committee for Medicinal Products for Human Use, or the CHMP, established at the EMA, is responsible for conducting the initial assessment of a drug. The CHMP is also responsible for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing marketing authorization. Under the centralized procedure in the European Union, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops, when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP. Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is of major interest from the point of view of public health and in particular from the viewpoint of

therapeutic innovation. In this circumstance, the EMA ensures that the opinion of the CHMP is given within 150 days.

The decentralized procedure is available to applicants who wish to market a product in various European Union member states where such product has not received marketing approval in any European Union member states before. The decentralized procedure provides for approval by one or more other, or concerned, member states of an assessment of an application performed by one member state designated by the applicant, known as the reference member state. Under this procedure, an applicant submits an application based on identical dossiers and related materials, including a draft summary of product characteristics, and draft labeling and package leaflet, to the reference member state and concerned member states. The reference member state prepares a draft assessment report and drafts of the related materials within 210 days after receipt of a valid application. Within 90 days of receiving the reference member state's assessment report and related materials, each concerned member state must decide whether to approve the assessment report and related materials.

If a member state cannot approve the assessment report and related materials on the grounds of potential serious risk to public health, the disputed points are subject to a dispute resolution mechanism and may eventually be referred to the European Commission, whose decision is binding on all member states.

Review and Approval of Medical Devices in the European Union

The European Union has adopted numerous directives and standards regulating, among other things, the design, manufacture, clinical trials, labeling, approval and adverse event reporting for medical devices. In the European Union, medical devices must comply with the Essential Requirements in Annex I to the EU Medical Devices Directive (Council Directive 93/42/EEC), or the Essential Requirements. Compliance with these requirements is a prerequisite to be able to affix the CE mark of conformity to medical devices, without which they cannot be marketed or sold in the European Economic Area, or EEA, comprised of the European Union member states plus Norway, Iceland, and Liechtenstein. Actual implementation of these directives, however, may vary on a country-by-country basis.

To demonstrate compliance with the Essential Requirements a manufacturer must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. Except for low risk medical devices, where the manufacturer can issue a CE Declaration of Conformity based on a self-assessment of the conformity of its products with the Essential Requirements, a conformity assessment procedure requires the intervention of a third-party organization designated by competent authorities of a European Union country to conduct conformity assessments, or a Notified Body. Notified Bodies are independent testing houses, laboratories, or product certifiers typically based within the European Union and authorized by the European member states to perform the required conformity assessment tasks, such as quality system audits and device compliance testing. The Notified Body would typically audit and examine the product's Technical File and the quality system for the manufacture, design and final inspection of the product before issuing a CE Certificate of Conformity demonstrating compliance with the relevant Essential Requirements.

Medical device manufacturers must carry out a clinical evaluation of their medical devices to demonstrate conformity with the relevant Essential Requirements. This clinical evaluation is part of the product's Technical File. A clinical evaluation includes an assessment of whether a medical device's performance is in accordance with its intended use, and that the known and foreseeable risks linked to the use of the device under normal conditions are minimized and acceptable when weighed against the benefits of its intended purpose. The clinical evaluation conducted by the manufacturer must also address any clinical claims, the adequacy of the device labeling and information (particularly claims, contraindications, precautions and warnings) and the suitability of related Instructions for Use. This assessment must be based on clinical data, which can be obtained from clinical studies conducted on the devices being assessed, scientific literature from similar devices whose equivalence with the assessed device can be demonstrated or both clinical studies and scientific literature.

With respect to implantable devices or devices classified as Class III in the European Union, the manufacturer must conduct clinical studies to obtain the required clinical data, unless relying on existing clinical data from similar devices can be justified. As part of the conformity assessment process, depending on the type of devices, the Notified Body will review the manufacturer's clinical evaluation process, assess the clinical evaluation data of a representative sample of the device's subcategory or generic group, or assess all the clinical evaluation data, verify the manufacturer's assessment of that data and assess the validity of the clinical evaluation report and the conclusions drawn by the manufacturer.

Even after a manufacturer receives a CE Certificate of Conformity enabling the CE mark on it products and the right to sell the products in the EEA countries, a Notified Body or a competent authority may require post-marketing studies of the products. Failure to comply with such requirements in a timely manner could result in the withdrawal of the CE Certificate of Conformity and the recall or withdrawal of the subject product from the European market.

A manufacturer must inform the Notified Body that carried out the conformity assessment of the medical devices of any planned substantial changes to the devices which could affect compliance with the Essential Requirements or the devices' intended purpose. The Notified Body will then assess the changes and verify whether they affect the product's conformity with the Essential Requirements or the conditions for the use of the devices. If the assessment is favorable, the Notified Body will issue a new CE Certificate of Conformity or an addendum to the existing CE Certificate of Conformity attesting compliance with the Essential Requirements. If it is not, the manufacturer may not be able to continue to market and sell the product in the EEA.

In the European Union, medical devices may be promoted only for the intended purpose for which the devices have been CE marked. Failure to comply with this requirement could lead to the imposition of penalties by the competent authorities of the European Union Member States. The penalties could include warnings, orders to discontinue the promotion of the medical device, seizure of the promotional materials and fines. Promotional materials must also comply with various laws and codes of conduct developed by medical device industry bodies in the European Union governing promotional claims, comparative advertising, advertising of medical devices reimbursed by the national health insurance systems and advertising to the general public.

Additionally, all manufacturers placing medical devices in the market in the European Union are legally bound to report any serious or potentially serious incidents involving devices they produce or sell to the competent authority in whose jurisdiction the incident occurred. In the European Union, manufacturers must comply with the EU Medical Device Vigilance System. Under this system, incidents must be reported to the relevant authorities of the European Union countries, and manufacturers are required to take Field Safety Corrective Actions, or FSCAs, to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market. An incident is defined as any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labeling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient or user or of other persons or to a serious deterioration in their state of health. An FSCA may include the recall, modification, exchange, destruction or retrofitting of the device. FSCAs must be communicated by the manufacturer or its European Authorized Representative to its customers and to the end users of the device through Field Safety Notices. In September 2012, the European Commission adopted a proposal for a regulation which, if adopted, will change the way that most medical devices are regulated in the European Union, and may subject products to additional requirements.

Pharmaceutical Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of products approved by the FDA and other government authorities. Sales of products will depend, in part, on the extent to which products are covered by third-party payors, including government health programs in the United States such as Medicare and Medicaid, commercial health insurers and managed care organizations and the amount that will be paid. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the approved products for a particular indication. Additionally, the containment of healthcare costs has become a priority of federal and state governments, and the prices of drugs have been a focus in this effort. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable regulatory approvals. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Third-party reimbursement may not be sufficient to maintain price levels high enough to realize an appropriate return on investment in product development.

In the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed to. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies. For example, the European Union provides options for its member states to restrict the range of drug products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. European Union member states may approve a specific price for a drug product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the drug product on the market. Other member states allow

companies to fix their own prices for drug products, but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert competitive pressure that may reduce pricing within a country. Any country that has price controls or reimbursement limitations for drug products may not allow favorable reimbursement and pricing arrangements.

Healthcare Law and Regulation

Healthcare providers, physicians and third-party payors play a primary role in the recommendation and prescription of drug products that are granted marketing approval. Arrangements with third-party payors and customers are subject to broadly applicable fraud and abuse and other healthcare laws and regulations. Such restrictions under applicable federal and state healthcare laws and regulations, include the following:

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

- the federal False Claims Act imposes civil penalties, and provides for civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

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

- the federal transparency requirements under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the PPACA will require applicable manufacturers of covered drugs, devices, drugs and medical supplies to report to the Department of Health and Human Services information related to payments and other transfers of value to physicians and teaching hospitals and physician ownership and investment interests; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Sales and Marketing

We do not have a sales, marketing or distribution infrastructure and have limited experience in the sale, marketing and distribution of pharmaceutical products. To achieve commercial success for any approved product, we must either develop a sales and marketing organization or outsource these functions to third parties. We expect to build a commercial infrastructure to allow us to market and sell certain of our product candidates when approved, if any, using a specialty sales force in the United States, and we may choose to establish commercialization capabilities in select countries outside the United States.

Employees

As of December 31, 2015, we had 22 full-time employees, of which 17 employees were engaged in research and development and 5 employees provided general and administrative support. Of our employees, 12 have earned advanced degrees. Our employees are not represented by a labor union or covered by a collective bargaining agreement.

Our Corporate Information

We were incorporated under the laws of the State of Delaware on October 17, 2013 under the name Ikaria Development LLC. We changed our name to Bellerophon Therapeutics LLC on January 27, 2014. On February 12, 2015, we converted from a Delaware limited liability company into a Delaware corporation and changed our name to Bellerophon Therapeutics, Inc. We currently have three wholly-owned subsidiaries: Bellerophon BCM LLC, a Delaware limited liability company; Bellerophon Pulse Technologies LLC, a Delaware limited liability company; and Bellerophon Services, Inc., a Delaware corporation. Our website address is www.bellerophon.com. The information contained on, or that can be accessed through, our website does not constitute part of this Annual Report on Form 10-K. We have included our website address in this Annual Report on Form 10-K solely as an inactive textual reference.

Our executive offices are located at 184 Liberty Corner Road, Suite 302, Warren, New Jersey 07059, and our telephone number is (908) 574-4770.

Available Information

We make available free of charge through our website our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to such reports filed or furnished pursuant to Sections 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act. We make these reports available through our website as soon as reasonably practicable after we electronically file or furnish such reports to, the Securities and Exchange Commission, or the SEC. We also make available, free of charge on our website, the reports filed with the SEC by our executive officers, directors and 10% stockholders pursuant to Section 16 under the Exchange Act as soon as reasonably practicable after copies of those filings are provided to us by those persons. The information contained on, or that can be access through, our website is not a part of or incorporated by reference in this Annual Report on Form 10-K.

Item 1A. Risk Factors

The following risk factors and other information included in this Annual Report on Form 10-K should be carefully considered. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we presently deem less significant may also impair our business operations. Please see page 2 of this Annual Report on Form 10-K for a discussion of some of the forward-looking statements that are qualified by these risk factors. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected.

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred significant losses since inception. We expect to incur losses over the next several years and may never achieve or maintain profitability.

Since inception, we have incurred significant operating losses. Our net loss was approximately $62.0 million for the year ended December 31, 2013, $59.7 million for the year ended December 31, 2014 and $46.5 million for the year ended December 31, 2015. We do not know whether or when we will become profitable. We have not generated any revenues to date from product sales. We have not completed development of any product candidate and have devoted substantially all of our financial resources and efforts to research and development, including pre-clinical studies and clinical trials. We expect to continue to incur significant expenses and operating losses over the next several years. Our net losses may fluctuate significantly from quarter to quarter and year to year. Net losses and negative cash flows have had, and will continue to have, an adverse effect on our deficit and working capital. We anticipate that our expenses will increase substantially if and as we:

- continue our research and clinical development of our product candidates;
- identify, develop and/or in-license additional product candidates;

- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- in the future, establish a manufacturing, sales, marketing and distribution infrastructure;
- maintain, expand and protect our intellectual property portfolio;
- add equipment and physical infrastructure to support our research and development;
- hire additional clinical, regulatory, quality control and scientific personnel; and
- add operational, financial and management information systems and personnel, including personnel to support our product development and any future commercialization efforts.

To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. We do not expect to generate significant revenue unless and until we are able to obtain marketing approval for, and successfully commercialize, one or more of our product candidates. This will require us to be successful in a range of challenging activities, including completing pre-clinical studies and clinical trials of our product candidates, discovering additional product candidates, obtaining regulatory approval for our product candidates, manufacturing, marketing and selling any products for which we may obtain regulatory approval, satisfying any post-marketing requirements and obtaining reimbursement for our products from private insurance or government payors. We are in the early stages of most of these activities and have not yet commenced others of these activities. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. If we are required by the FDA or the EMA to perform trials in addition to those currently expected, or if there are any delays in completing our clinical trials or the development of any of our product candidates, our expenses could increase.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings or even continue our operations. A decline in the value of our company could cause our stockholders to lose all or part of their investment in us.

In addition, our recurring losses from operations, accumulated deficit and our need to raise additional financing in order to continue to fund our operations, may raise substantial doubt about our ability to continue as a going concern. Given our planned expenditures for the next several years, including, without limitation, expenditures in connection with our clinical trials, our independent registered public accounting firm may conclude that there is substantial doubt regarding our ability to continue as a going concern.

Our very limited operating history may make it difficult for our stockholders to evaluate the success of our business to date and to assess our future viability.

We were formed as a wholly-owned subsidiary of Ikaria in October 2013 and became a stand-alone company in February 2014 following the Spin-Out and, as such, have a limited independent operating history.

Our operations to date have been limited to organizing and staffing our company, developing and securing our technology, and undertaking pre-clinical studies and clinical trials of our product candidates. We have not yet demonstrated the ability to complete development of any product candidates, obtain marketing approvals, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, any predictions our stockholders make about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing products.

Assuming we obtain marketing approval for any of our product candidates, we will need to transition from a company with a research and development focus to a company capable of supporting commercial activities or we will need to enter into strategic partnerships. We may encounter unforeseen expenses, difficulties, complications and delays and may not be successful in such a transition.

We will need substantial additional funding. If we are unable to raise capital when needed, we could be forced to delay,

reduce or eliminate our product development programs or commercialization efforts.

We expect our expenses to increase in connection with our ongoing activities, particularly as we continue research and development and initiate additional clinical trials of our product candidates and seek regulatory approval for these and potentially other product candidates. In addition, if we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. In particular, the costs that may be required for the manufacture of any product candidate that receives marketing approval may be substantial. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

We plan to use our current cash and cash equivalents and marketable securities primarily to fund our ongoing research and development efforts. We will be required to expend significant funds in order to advance development of our product candidates and any other potential product candidates. Our existing cash and cash equivalents and marketable securities will not be sufficient to fund all of the efforts that we plan to undertake or the completion of clinical development or commercialization of any of our product candidates, such as the two INOpulse for PAH Phase 3 trials. Accordingly, we will be required to obtain further funding through public or private equity offerings, debt financings, collaborations or licensing arrangements or other sources. Adequate additional funding may not be available to us on acceptable terms or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy.

We believe that our existing cash and cash equivalents and marketable securities as of December 31, 2015 will be sufficient to satisfy our operating cash needs for at least the next 12 months. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including:

- the timing, progress, and results of our ongoing and planned clinical trials of our product candidates;
- our ability to manufacture sufficient clinical supply of our products candidates and the costs thereof;
- discussions with regulatory agencies regarding the design and conduct of our clinical trials and the costs, timing and outcome of regulatory review of our product candidates;
- the cost and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the costs of any other product candidates or technologies we pursue;
- our ability to establish and maintain strategic partnerships, licensing or other arrangements and the financial terms of such agreements;
- the revenue, if any, received from commercial sales of any product candidates for which we receive marketing approval; and
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims.

Identifying potential product candidates and conducting clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for several years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. See “Certain Relationships and Related Person Transactions—Corporate Conversion” for restrictions on issuing shares and incurring indebtedness that are part of our Stockholders Agreement.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to technologies or product candidates.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of public or private equity offerings, debt financings and/or license and development agreements with collaboration partners. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our stockholders may be materially diluted, and the terms of such securities could include liquidation or other preferences or other rights such as anti-dilution rights that adversely affect the rights of our stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include restrictive covenants that limit our ability to take specified actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. If we raise funds through collaborations, strategic partnerships or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us.

Risks Related to Our Business and Industry

Our historical financial information is not necessarily representative of the results we would have achieved as a stand-alone company and may not be a reliable indicator of our future results.

The historical financial information for the years ended December 31, 2013 and 2014 included in this annual report may not reflect what our results of operations, financial position and cash flows would have been had we been a stand-alone company during the periods presented. This is primarily because our historical financial information for the years ended December 31, 2013 and 2014 reflect allocations for services historically provided to us by Ikaria, does not reflect changes that occurred as a result of our separation from Ikaria and excludes additional costs associated with being a public company. Therefore, our historical financial information for 2013 and 2014 may not be indicative of our future performance as a public company.

For additional information about our past financial performance and the basis of presentation of our financial statements, please see "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and the notes thereto included elsewhere in this Annual Report on Form 10-K.

We face substantial competition from other pharmaceutical, biotechnology and medical device companies and our operating results may suffer if we fail to compete effectively.

The pharmaceutical, biotechnology and medical device industries are highly competitive. There are many pharmaceutical, biotechnology and medical device companies, public and private universities and research organizations actively engaged in the research and development of products that may be similar to our product candidates. In addition, other companies are increasingly looking at the cardiopulmonary disease market as a potential opportunity. Currently, there are 13 drugs approved for the treatment of PAH and there are also other potential therapies in Phase 1, 2 and 3 clinical development, including other nitric oxide generation and delivery systems.

Many of our competitors, either alone or through their strategic partners, have substantially greater name recognition and financial, technical, manufacturing, marketing and human resources than we do and significantly greater experience and infrastructure in the research and clinical development of medical products, obtaining FDA and other regulatory approvals of those products, and commercializing those products around the world. Additional mergers and acquisitions in the pharmaceutical, biotechnology and medical device industries may result in even more resources being concentrated in our competitors. Large pharmaceutical and medical device companies in particular have extensive expertise in pre-clinical and clinical testing and in obtaining regulatory approvals for medical products. In addition, academic institutions, government agencies and other public and private organizations conducting research may seek patent protection with respect to potentially competitive products or technologies. These organizations may also establish exclusive collaborative or licensing relationships with our competitors. Accordingly, our competitors may be more successful than we may be in obtaining approval for inhaled nitric oxide products and achieving widespread market acceptance. We anticipate that we will face intense and increasing competition as new products and technologies become available.

We will not be able to compete effectively unless we successfully:

- design, develop and commercialize products that are competitive in the market;

- attract qualified scientific, medical, sales and marketing, engineering and commercial personnel;
- obtain patent and/or other proprietary protection for our processes and product candidates; and
- obtain required regulatory approvals.

It is also possible that Ikaria will seek to develop and commercialize inhaled nitric oxide products or product candidates in the Bellerophon indications. While a subsidiary of Ikaria has granted to us an exclusive license to develop and commercialize pulsed nitric oxide in the Bellerophon indications and the scope of that license includes certain technology developed or acquired by that subsidiary after the date of the license agreement, the license does not include technology developed or acquired by other subsidiaries or affiliates of Ikaria including Mallinckrodt's other subsidiaries. Because Ikaria, Mallinckrodt and its other subsidiaries and affiliates are not subject to any non-competition obligations in our favor, it is possible that these other subsidiaries or affiliates of Ikaria or Mallinckrodt may seek to develop or commercialize inhaled nitric oxide or other products or product candidates, using technology not exclusively licensed to us that are competitive with our products or product candidates.

Risks Related to the Discovery, Development and Commercialization of Our Product Candidates

We are dependent on the success of our INOpulse product candidates and our ability to develop, obtain marketing approval for and successfully commercialize these product candidates. If we are unable to develop, obtain marketing approval for or successfully commercialize our product candidates, either alone or through a collaboration, or experience significant delays in doing so, our business could be materially harmed.

We currently have no products approved for sale and have invested a significant portion of our efforts and financial resources in the development of our INOpulse for PAH, INOpulse for PH-COPD and BCM product candidates. Our prospects are substantially dependent on our ability to develop, obtain marketing approval for and successfully commercialize these product candidates.

In July 2015, we announced top-line results of our 303-patient, randomized, double-blind, placebo-controlled clinical trial of BCM, which showed no statistically significant treatment differences between patients treated with BCM and patients treated with placebo for both the primary and secondary endpoints. Following these results, we are considering further exploratory work but we do not intend to proceed with further clinical development of BCM at this point until and unless we can determine an alternative path forward. As a result, we have become even more dependent on the success of our INOpulse product candidates and our ability to develop, obtain marketing approval for and successfully commercialize our INOpulse product candidates.

The success of our product candidates will depend on, among other things, our ability to successfully complete clinical trials of each product candidate. The clinical trial process is uncertain, and failure of one or more clinical trials can occur at any stage of testing. For example, although we believe our Phase 2 clinical trials of INOpulse for PAH and INOpulse for PH-COPD support advancement into a Phase 3 clinical trial and further Phase 2 testing, respectively, the primary endpoints for both INOpulse for PAH and INOpulse for PH-COPD were not statistically significant for any of the doses tested.

In addition to the successful completion of clinical trials, the success of our product candidates will also depend on several other factors, including the following:

- receipt of marketing approvals from the FDA or other applicable regulatory authorities;
- establishment of supply arrangements with third-party raw materials suppliers and manufacturers;
- establishment of arrangements with third-party manufacturers to obtain finished drug products that are appropriately packaged for sale;
- the performance of our future collaborators for one or more of our product candidates, if any;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- obtaining and maintaining patent, trade secret protection and regulatory exclusivity, both in the United States and internationally;

- protection of our rights in our intellectual property portfolio;
- launch of commercial sales if and when our product candidates are approved;
- a continued acceptable safety profile of our product candidates following any marketing approval;
- commercial acceptance, if and when approved, by patients, the medical community and third-party payors;
- establishing and maintaining pricing sufficient to realize a meaningful return on our investment; and
- competition with other products.

If we are unable to develop, obtain marketing approval for or successfully commercialize our INOpulse product candidates, either alone or through a collaboration, or experience significant delays in doing so, our business could be materially harmed.

Clinical trials involve a lengthy and expensive process with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

The risk of failure of all of our product candidates is high. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans or will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. The clinical development of our product candidates is susceptible to the risk of failure inherent at any stage of development, including failure to demonstrate efficacy in a clinical trial or across a broad population of patients, the occurrence of severe or medically or commercially unacceptable adverse events, failure to comply with protocols or applicable regulatory requirements and determination by the FDA or any comparable non-U.S. regulatory authority that a drug product is not approvable.

It is possible that even if one or more of our product candidates has a beneficial effect, that effect will not be detected during clinical evaluation as a result of one or more of a variety of factors, including the size, duration, design, measurements, conduct or analysis of our clinical trials. Conversely, as a result of the same factors, our clinical trials may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any. Similarly, in our clinical trials we may fail to detect toxicity of or intolerability caused by our product candidates, or mistakenly believe that our product candidates are toxic or not well tolerated when that is not in fact the case. Also, the exclusion criteria we define may not sufficiently rule out patients who are at a higher risk of being harmed by the treatment. For example, our exclusion criteria for pre-existing left heart dysfunction in our Phase 2 INOpulse clinical trials completed in 2014 may not rule out patients who may experience an adverse event related to left ventricular function due to exposure to nitric oxide. In addition, patients who are not excluded for reactive pulmonary vasculature when exposed to nitric oxide may still experience PH.

The outcome of pre-clinical studies and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results, particularly when earlier trials are small, open-label or non-placebo-controlled trials and in trials that have different endpoints than earlier trials. For example, for BCM, we were using the results of the 27-patient pilot trial conducted by BioLineRx Ltd. that used anatomical changes to measure efficacy and did not have a control group as support for our larger ongoing clinical trial, which did not achieve the same results as the BioLineRx Ltd. trial. Many companies in the biotechnology, pharmaceutical and medical device industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in earlier development, and we cannot be certain that we will not face such setbacks.

The design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced or completed. We have limited experience in designing clinical trials and may be unable to design and execute a clinical trial to support marketing approval. In addition, pre-clinical and clinical data are often susceptible to varying interpretations and analyses. Many companies that believed their product candidates performed satisfactorily in pre-clinical studies and clinical trials have nonetheless failed to obtain marketing approval for the product candidates. Even if we believe that the results of clinical trials for our product candidates warrant marketing approval, the FDA or comparable non-U.S. regulatory authorities may disagree and may not grant marketing approval of our product candidates.

In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants. Any Phase 3 or other clinical trials that we may conduct may not demonstrate the efficacy and safety necessary to obtain regulatory approval to market our product candidates.

INOpulse is a sophisticated electro-mechanical device comprised of components that may fail or deteriorate over time or with improper use. If we experience problems with, failure of, or delays in obtaining any INOpulse components, our business could be materially adversely harmed.

Because INOpulse is a sophisticated electro-mechanical device, the parts which comprise the device are subject to sudden failure or to wear and tear, which may result in decreased function or failure of those parts over time. Although we perform scheduled, preventive maintenance on our drug delivery system to limit device failures, and additional maintenance as needed whenever a user reports a device malfunction, components of our devices may fail. In addition, although we have designed INOpulse to be simple and easy to use and will provide user manuals and other training materials, users of INOpulse may use the devices improperly, which could cause the devices to fail or otherwise not work properly.

There are several components in INOpulse that are custom designed or assembled for us. We are dependent on a single company to supply us with some of these components. While we believe there are alternative suppliers from which we could purchase most of these components, there is a risk that a single-source supplier could fail to deliver adequate supply, or could suffer a business interruption that could affect our supply of these components.

We obtain some of the components for INOpulse through individual purchase orders executed on an as needed basis rather than pursuant to long-term supply agreements. Our business, financial condition or results of operations could be adversely affected if any of our principal third-party suppliers or manufacturers experience production problems, lack of capacity or transportation disruptions or otherwise cease producing such components.

We intend to conduct, and may in the future conduct, clinical trials for certain of our product candidates at sites outside the United States, and the FDA may not accept data from trials conducted in such locations.

We have conducted, and may in the future choose to conduct, one or more of our clinical trials outside the United States. For example, our first of two Phase 3 clinical trials of INOpulse for PAH will include sites outside of the United States, including Canada.

Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of this data is subject to certain conditions imposed by the FDA. For example, the clinical trial must be well designed and conducted and performed by qualified investigators in accordance with GCP in the case of drug trials, or the Declaration of Helsinki or the laws and regulations of the country in which the research is conducted, whichever affords greater protection to the human subjects, in the case of device trials. The trial population must also adequately represent the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. Generally, the patient population for any clinical trials conducted outside of the United States must be representative of the population for whom we intend to seek approval in the United States. In addition, while these clinical trials are subject to the applicable local laws, FDA acceptance of the data will be dependent upon its determination that the trials also complied with all applicable U.S. laws and regulations. There can be no assurance that the FDA will accept data from trials conducted outside of the United States. If the FDA does not accept the data from our first of two Phase 3 clinical trials of INOpulse for PAH outside of the United States or any future trial that we conduct outside the United States, it would likely result in the need for additional trials, which would be costly and time-consuming and delay or permanently halt our development of INOpulse for PAH or any future product candidates.

In addition, the conduct of clinical trials outside the United States could have a significant impact on us. Risks inherent in conducting international clinical trials include:

- foreign regulatory requirements that could restrict or limit our ability to conduct our clinical trials;
- administrative burdens of conducting clinical trials under multiple foreign regulatory schema;
- foreign exchange fluctuations; and

- diminished protection of intellectual property in some countries.

If clinical trials of our product candidates fail to demonstrate safety and efficacy of our product candidates to the satisfaction of the FDA and comparable non-U.S. regulators, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of these product candidates.

We are not permitted to commercialize, market, promote or sell any product candidate in the United States without obtaining marketing approval from the FDA. Comparable non-U.S. regulatory authorities, such as the EMA, impose similar restrictions. We may never receive such approvals. We must complete extensive pre-clinical studies and clinical trials to demonstrate the safety and efficacy of our product candidates in humans before we will be able to obtain these approvals.

Any inability to successfully complete pre-clinical and clinical development could result in additional costs to us and impair our ability to generate revenues from product sales. In addition, if (1) we are required to conduct additional clinical trials or other testing of our product candidates beyond the trials and testing that we contemplate, (2) we are unable to successfully complete clinical trials of our product candidates or other testing, (3) the results of these trials or tests are unfavorable, uncertain or are only modestly favorable, such as in our Phase 2 clinical trials of INOpulse for PAH and INOpulse for PH-COPD, or (4) there are unacceptable safety concerns associated with our product candidates, we, in addition to incurring additional costs, may:

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as we intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or significant safety warnings, including boxed warnings;
- be subject to additional post-marketing testing or other requirements; or
- be required to remove the product from the market after obtaining marketing approval.

If the FDA or other regulatory authority requires us to conduct additional testing or determines that an unacceptable amount of nitrogen dioxide is formed through the use of INOpulse, we may be required to alter the design of INOpulse, which may not be possible, and the clinical development timeline for INOpulse may be delayed or prove to be more costly than we currently anticipate.

If we experience any of a number of possible unforeseen events in connection with clinical trials of our product candidates, potential marketing approval or commercialization of our product candidates could be delayed or prevented.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent marketing approval of our product candidates, including:

- clinical trials of our product candidates may produce unfavorable or inconclusive results;
- we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, patient enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors, including those manufacturing our product candidates or components or ingredients thereof or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner or at all;
- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;

- we may experience delays in reaching or fail to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- patients who enroll in a clinical trial may misrepresent their eligibility to do so or may otherwise not comply with the clinical trial protocol, resulting in the need to withdraw such patients from the clinical trial, increase the needed enrollment size for the clinical trial or extend the clinical trial's duration;
- regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or their respective standards of conduct, a finding that the participants are being exposed to unacceptable health risks, undesirable side effects or other unexpected characteristics of the product candidate or findings of undesirable effects caused by a chemically or mechanistically similar drug or drug candidate;
- the FDA or comparable non-U.S. regulatory authorities may disagree with our clinical trial design or our interpretation of data from pre-clinical studies and clinical trials;
- the FDA or comparable non-U.S. regulatory authorities may find regulatory non-compliance with the manufacturing processes or facilities of third-party manufacturers with which we enter into agreements for clinical and commercial supplies;
- the supply or quality of raw materials or manufactured product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply; and
- the approval policies or regulations of the FDA or comparable non-U.S. regulatory authorities may significantly change in a manner rendering our clinical data insufficient to obtain marketing approval.

Product development costs for us will increase if we experience delays in testing or pursuing marketing approvals and we may be required to obtain additional funds to complete clinical trials and prepare for possible commercialization of our product candidates. We do not know whether any pre-clinical studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. For example, although we recently completed a Phase 2 clinical trial for INOpulse for PH-COPD, we are currently evaluating our options for further Phase 2 development in this indication. Significant pre-clinical study or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates and may harm our business and results of operations. In addition, many of the factors that cause, or lead to, clinical trial delays may ultimately lead to the denial of marketing approval of any of our product candidates.

If we experience delays or difficulties in the enrollment of patients in clinical trials, we may not achieve our clinical development on our anticipated timeline, or at all, and our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for our INOpulse product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in clinical trials. Patient enrollment is a significant factor in the timing of clinical trials, and is affected by many factors, including:

- the size and nature of the patient population;
- the severity of the disease under investigation;
- the proximity of patients to clinical sites;
- the eligibility criteria for the trial;
- the design of the clinical trial;
- limitations placed on enrollment by regulatory authorities;

- efforts to facilitate timely enrollment;
- competing clinical trials; and
- clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new product candidates that may be approved for the indications we are investigating.

For example, we may experience difficulty enrolling our clinical trials, including, but not limited to, any future clinical trials of INOpulse for PAH, which is an orphan disease due to the small number of patients who suffer from PAH, or any future clinical trials of INOpulse for PH-COPD because such trials may require that patients meet the restrictive enrollment criteria, such as having been diagnosed with both COPD and PH, be undergoing treatment with LTOT and not having significant left ventricular dysfunction.

Our inability to enroll a sufficient number of patients for our clinical trials could result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, delay or halt the development of and approval processes for our product candidates and jeopardize our ability to achieve our clinical development timeline and goals, including the dates by which we will commence, complete and receive results from clinical trials. Enrollment delays may also delay or jeopardize our ability to commence sales and generate revenues from our product candidates. Any of the foregoing could cause the value of our company to decline and limit our ability to obtain additional financing, if needed.

We may not obtain orphan drug exclusivity for all of our product candidates and indications, or we may not receive the full benefit of orphan drug exclusivity even if we obtain such exclusivity.

Regulatory authorities in some jurisdictions, including the United States and European Union, may designate drugs and biologics intended for the treatment of relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug or biologic intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States who have been diagnosed as having the disease or condition at the time of the submission of the request for orphan drug designation. The FDA has granted orphan drug designation to our nitric oxide program for the treatment of PAH. Accordingly, the first company to receive FDA approval for nitric oxide for the treatment of PAH will obtain seven years of marketing exclusivity, during which time the FDA may not approve another product containing nitric oxide as its active ingredient for the treatment of PAH, unless such product is shown to be clinically superior. We have not yet applied for orphan drug designation in any jurisdictions outside of the United States.

Even though we have obtained orphan drug designation for our nitric oxide program to treat PAH in the United States, and even if we obtain orphan drug designation for our product candidates in other indications, for our future product candidates or in other jurisdictions, due to the uncertainties associated with developing pharmaceutical products, we may not be the first to obtain marketing approval for any particular orphan indication, or we may not obtain approval for an indication for which we have obtained orphan drug designation. Further, even if we obtain orphan drug exclusivity for a product candidate, that exclusivity may not protect the product effectively from competition because different drugs can be approved for the same condition. For example, even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is safer, more effective or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a drug, nor gives the drug any advantage in the regulatory review or approval process. Orphan drug exclusivity may be lost if the FDA, or the equivalent regulatory authority in jurisdictions outside of the United States, determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of patients with the rare disease or condition.

SAEs or undesirable side effects or other unexpected properties of our product candidates may be identified during development that could delay or prevent the product candidate's marketing approval.

SAEs or undesirable side effects caused by, or other unexpected properties of, our product candidates could cause us, an institutional review board or regulatory authorities to interrupt, delay or halt clinical trials of one or more of our product candidates and could result in a more restrictive label or the delay or denial of marketing approval by the FDA or comparable non-U.S. regulatory authorities. If any of our product candidates is associated with SAEs or undesirable side effects or has properties that are unexpected, we may need to abandon development or limit development of that product candidate to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more

acceptable from a risk-benefit perspective. Many drugs or devices that initially showed promise in clinical or earlier stage testing have later been found to cause undesirable or unexpected side effects that prevented further development of the drug or device.

For example, in our Phase 2 clinical trial for INOpulse for PAH completed in October 2014, SAEs were reported for four patients in the 25 mcg/kg ideal body weight/hour, or mcg, low-dose active treatment arm, including bacteremia, myelodysplastic syndrome, increased shortness of breath, and dyspnea, one of which was assessed as possibly related to trial therapy. In the 75 mcg high-dose active treatment arm, nine patients had SAEs. The most common SAEs reported were syncope and bronchitis/tracheobronchitis, one of which was assessed as possibly related to trial therapy. Discontinuation of trial therapy due to adverse events occurred for two patients in the 75 mcg arm and one subject in the 25 mcg arm. Additional or more SAEs, undesirable side effects or other unexpected properties of INOpulse for PAH or our other product candidates could arise or become known during further clinical development. If such an event occurs during development, clinical trials for our product candidates could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us or our collaborators to cease further development, require us to conduct additional clinical trials or other tests or studies or deny approval of the applicable product candidate. Further, pending discussions with regulatory authorities, we may be required to conduct a drug-drug interaction study of INOpulse for PH-COPD. We expect the FDA to require us primarily to study interactions with long-acting beta agonists, which is the only class of COPD drug that has been identified as having potential adverse cardiac side effects, to confirm that pulsed inhaled nitric oxide does not increase systemic bio-availability of inhaled beta agonists. If the results of such a study indicate increased bioavailability that we are not able to address to the satisfaction of the FDA, marketing approval of INOpulse for PH-COPD, if any, may be limited to patients who do not use long-acting beta agonists.

Additionally, INOpulse is an extension of the technology that is used in hospitals to deliver inhaled nitric oxide to neonates with a form of PH called persistent PH of the newborn. Persistent PH is an FDA-approved use of inhaled nitric oxide, which is currently marketed by Ikaria as INOmax. Because INOpulse draws on the established efficacy and safety of INOmax, if any SAEs or undesirable side effects or other unexpected properties of INOmax or other inhaled nitric oxide delivery systems developed by Ikaria are identified, INOpulse may be adversely affected and we may be required to interrupt, delay or halt our INOpulse clinical trials.

We may not be successful in our efforts to identify or discover additional potential product candidates.

A significant portion of the research that we are conducting involves the development of innovative approaches to the pulsed delivery of nitric oxide. Our drug-device discovery efforts may not be successful in creating drugs or devices that have commercial value or therapeutic utility. Our research programs may initially show promise in creating potential product candidates, yet fail to yield viable product candidates for clinical development for a number of reasons, including that potential product candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be product candidates that will receive marketing approval and achieve market acceptance.

Our research programs to identify new product candidates will require substantial technical, financial and human resources. In addition, we may focus our efforts and resources on one or more potential product candidates that ultimately prove to be unsuccessful.

Pursuant to the terms of our license agreement with Ikaria, we only have the right to develop and commercialize pulsed nitric oxide for the Bellerophon indications; Ikaria retains the right to develop and commercialize inhaled nitric oxide products, including pulsed products, for all other indications. Additionally, we are limited in the scope of potential product candidates that we can identify or discover due to non-competition agreements that we entered into with Ikaria, which agreements were amended in July 2015. See "Certain Relationships and Related Person Transactions-Relationship with Ikaria" in Part III for a summary of our agreements not to compete with Ikaria. In the event that we or one of our subsidiaries materially breach the provisions of the non-competition agreements and do not cure such breach within 30 days after receiving written notice thereof from Ikaria, Ikaria will have the right to terminate the license agreement.

If we are unable to identify suitable additional compounds for pre-clinical and clinical development, or at all, our ability to develop product candidates and obtain product revenues in future periods could be compromised, which could result in significant harm to our financial position and adversely impact our stock price.

If any of our product candidates receives marketing approval and we, or others, later discover that the product is less effective than previously believed or causes undesirable side effects that were not previously identified, our ability to market the product could be compromised.

Clinical trials of our product candidates are conducted in carefully defined subsets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects. If, following approval of a product candidate, we, or others, discover that the drug is less effective than previously believed or causes undesirable side effects that were not previously identified, any of the following undesirable events could occur:

- regulatory authorities may withdraw their approval of the product or seize the product;
- we may be required to recall the product or change the way the product is administered;
- additional restrictions may be imposed on the marketing of, or the manufacturing processes for, the particular product;
- we may be subject to fines, injunctions or the imposition of civil or criminal penalties;
- regulatory authorities may require the addition of labeling statements, such as a "black box" warning or a contraindication;
- we may be required to create a handout, sometimes referred to as a Medication Guide, outlining the risks of the previously unidentified side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may suffer.

Any of these events could have a material and adverse effect on our operations and business and could adversely impact our stock price.

Even if one of our product candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success, and the market opportunity for the product candidate may be smaller than we estimate.

We have never commercialized a product. Even if one of our product candidates is approved by the appropriate regulatory authorities for marketing and sale, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. For example, physicians are often reluctant to switch their patients from existing therapies even when new and potentially more effective or convenient treatments enter the market. Further, patients often acclimate to the therapy that they are currently taking and do not want to switch unless their physicians recommend switching products or they are required to switch therapies due to lack of reimbursement for existing therapies.

Efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may not be successful. If any of our product candidates is approved but does not achieve an adequate level of market acceptance, we may not generate significant revenues and we may not become profitable. The degree of market acceptance of, and potential market opportunity for, our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and safety of the product;
- the potential advantages of the product compared to alternative treatments;
- the prevalence and severity of any side effects;
- the clinical indications for which the product is approved;
- whether the product is designated under physician treatment guidelines as a first-line therapy or as a second- or third-line therapy;
- limitations or warnings, including distribution or use restrictions, contained in the product's approved labeling;

- our ability to offer the product for sale at competitive prices;
- our ability to establish and maintain pricing sufficient to realize a meaningful return on our investment;
- our ability to prevent use of our INOpulse for PH-COPD device by PAH patients due to expected pricing differences;
- the product's convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try, and of physicians to prescribe, the product;
- the strength of sales, marketing and distribution support;
- the approval of other new products for the same indications;
- changes in the standard of care for the targeted indications for the product;
- the timing of market introduction of our approved products as well as competitive products and other therapies;
- availability and amount of reimbursement from government payors, managed care plans, private health coverage insurers and other third-party payors;
- adverse publicity about the product or favorable publicity about competitive products; and
- potential product liability claims.

The potential market opportunities for our product candidates are difficult to estimate precisely. Our estimates of the potential market opportunities, including our estimates with respect to pricing and reimbursement, are predicated on many assumptions, including industry knowledge and publications, third-party research reports and other surveys. While we believe that our internal assumptions are reasonable, these assumptions involve the exercise of significant judgment on the part of our management, are inherently uncertain and the reasonableness of these assumptions has not been assessed by an independent source. If any of the assumptions proves to be inaccurate, the actual markets for our product candidates could be smaller than our estimates of the potential market opportunities.

If we are unable to establish sales, marketing and distribution capabilities or enter into acceptable sales, marketing and distribution arrangements with third parties, we may not be successful in commercializing any product candidates that we develop, if and when those product candidates are approved.

We do not have a sales, marketing or distribution infrastructure and have limited experience in the sale, marketing and distribution of pharmaceutical products. To achieve commercial success for any approved product, we must either develop a sales and marketing organization or outsource these functions to third parties. We expect to build a commercial infrastructure to allow us to market and sell certain of our product candidates when approved, if any, using a specialty sales force in the United States, and we may choose to establish commercialization capabilities in select countries outside the United States. The development of sales, marketing and distribution capabilities will require substantial resources, will be time-consuming and could delay any product launch. We expect that we will commence the development of these capabilities prior to receiving approval of any of our product candidates. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing and distribution capabilities is delayed or does not occur for any reason, we could have prematurely or unnecessarily incurred these commercialization costs. Such a delay may be costly, and our investment could be lost if we cannot retain or reposition our sales and marketing personnel. In addition, we may not be able to hire or retain a sales force in the United States that is sufficient in size or has adequate expertise in the medical markets that we plan to target. If we are unable to establish or retain a sales force and marketing and distribution capabilities, our operating results may be adversely affected.

If a potential partner has development or commercialization expertise or financial resources that we believe is particularly relevant to one of our product candidates, then we may seek to collaborate with that potential partner even if we believe we could otherwise develop and commercialize the product independently. We may partner with third parties to commercialize our product candidates in certain countries outside the United States. As a result of entering into arrangements with third parties to perform sales, marketing and distribution services, our product revenues or the profitability of these product revenues may be lower, perhaps substantially lower, than if we were to directly market and sell products in those

markets. Furthermore, we may be unsuccessful in entering into the necessary arrangements with third parties or may be unable to do so on terms that are favorable to us. In addition, we may have little or no control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our product candidates effectively.

If we do not establish sales and marketing capabilities, either on our own or in collaboration with third parties, we will not be successful in commercializing any of our product candidates that receive marketing approval.

Even if we are able to commercialize any product candidate that we develop, the product may become subject to unfavorable pricing regulations, third-party payor reimbursement practices or healthcare reform initiatives that could harm our business.

The commercial success of our product candidates will depend substantially, both in the United States and abroad, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish and maintain pricing sufficient to realize a meaningful return on our investment.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved drugs and devices. Marketing approvals, pricing and reimbursement for new drug and device products vary widely from country to country. Some countries require approval of the sale price of a drug or device before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some non-U.S. markets, pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay commercial launch of the product, possibly for lengthy time periods, which may negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval.

Our ability to commercialize our product candidates will depend in part on the extent to which coverage and reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will cover and establish reimbursement levels. The healthcare industry is acutely focused on cost containment, both in the United States and elsewhere. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications, which could affect our ability to sell our product candidates profitably. These payors may not view our products, if any, as cost-effective, and coverage and reimbursement may not be available to our customers, or may not be sufficient to allow our products, if any, to be marketed on a competitive basis. Cost-control initiatives could cause us to decrease the price we might establish for products, which could result in lower than anticipated product revenues. If the prices for our products, if any, decrease or if governmental and other third-party payors do not provide adequate coverage or reimbursement, our prospects for revenue and profitability will suffer. Approval of a product does not guarantee sufficient reimbursement to achieve commercial success.

There may also be delays in obtaining coverage and reimbursement for newly approved products, and coverage may be more limited than the indications for which the product is approved by the FDA or comparable non-U.S. regulatory authorities. Moreover, eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Reimbursement rates may vary, by way of example, according to the use of the product and the clinical setting in which it is used. Reimbursement rates may also be based on reimbursement levels already set for lower cost products or may be incorporated into existing payments for other services.

In addition, increasingly, third-party payors are requiring higher levels of evidence of the benefits and clinical outcomes of new technologies and are challenging the prices charged. We cannot be sure that coverage will be available for any product candidate that we commercialize and, if available, that the reimbursement rates will be adequate. Further, the net reimbursement for drug products may be subject to additional reductions if there are changes to laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. An inability to promptly obtain coverage and adequate payment rates from both government-funded and private payors for any our product candidates for which we obtain marketing approval could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

If the FDA or comparable non-U.S. regulatory authorities approve generic versions of any of our products that receive marketing approval, or such authorities do not grant our products appropriate periods of data exclusivity before approving generic versions of our products, the sales of our products could be adversely affected.

Once an NDA is approved, the product covered thereby becomes a "reference listed drug" in the FDA's publication, "Approved Drug Products with Therapeutic Equivalence Evaluations." Manufacturers may seek approval of generic versions of reference listed drugs through submission of ANDAs in the United States, or through a similar process in foreign jurisdictions. In support of an ANDA, a generic manufacturer need not conduct clinical studies. Rather, the applicant generally must show that its product has the same active ingredient(s), dosage form, strength, route of administration and conditions of use or labeling as the reference listed drug and that the generic version is bioequivalent to the reference listed drug, meaning it is absorbed in the body at the same rate and to the same extent. Generic products may be significantly less costly to bring to market than the reference listed drug and companies that produce generic products are generally able to offer them at lower prices. Thus, following the introduction of a generic drug, a significant percentage of the sales of any branded product or reference listed drug may be typically lost to the generic product.

The FDA may not approve an ANDA for a generic product until any applicable period of non-patent exclusivity for the reference listed drug has expired. Manufacturers may seek to launch these generic products following the expiration of the applicable marketing exclusivity period, even if we still have patent protection for our product.

Competition that our products may face from generic versions of our products could materially and adversely impact our future revenue, profitability and cash flows and substantially limit our ability to obtain a return on the investments we have made in those product candidates.

Product liability lawsuits against us could divert our resources, cause us to incur substantial liabilities and limit commercialization of any products that we may develop.

We face an inherent risk of product liability claims as a result of the clinical testing of our product candidates despite obtaining appropriate informed consents from our clinical trial participants. We will face an even greater risk if we commercially sell any product that we may develop. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. For example:

- improper use or failure of INOpulse may result in rebound PH, which can be fatal in some patients;
- rebound PH may also occur if both the primary and back-up devices fail before we can replace them, if the built-in back-up with a device does not work properly or if the patient does not carry or have access to his or her back-up device; and
- rebound PH can also occur in patients who were not previously considered at risk for this reaction and who may not have been provided an adequate back-up device.

Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend resulting litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue;
- reduced resources of our management to pursue our business strategy; and

- the inability to commercialize any products that we may develop.

Although we maintain general liability insurance of $1.0 million in the aggregate, umbrella insurance in the amount of $10.0 million in the aggregate and clinical trial liability insurance of $20.0 million in the aggregate, this insurance may not fully cover potential liabilities that we may incur. The cost of any product liability litigation or other proceeding, even if resolved in our favor, could be substantial. We will need to increase our insurance coverage if and when we begin the commercial sale of any product candidate that receives marketing approval. In addition, insurance coverage is becoming increasingly expensive. If we are unable to obtain or maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product liability claims, it could prevent or inhibit the development and commercial production and sale of our product candidates, which could adversely affect our business, financial condition, results of operations and prospects.

Our INOpulse devices use lithium-ion battery cells, which have been observed to catch fire or vent smoke and flame, and these events may raise concerns about the batteries we use.

The battery pack used in our INOpulse devices makes use of lithium-ion cells. On rare occasions, lithium-ion cells can rapidly release the energy they contain by venting smoke and flames in a manner that can ignite nearby materials. Highly publicized incidents of laptop computers and cell phones bursting into flames have focused consumer attention on the safety of these cells. There can be no assurance that the battery packs we use would not fail, which could lead to property damage, personal injury or death, and may subject us to lawsuits. We may also have to recall our products, if any, which would be time consuming and expensive. Also, negative perceptions in the healthcare and patient communities regarding the suitability of lithium-ion cells for medical applications or any future incident involving lithium-ion cells could seriously harm our business, even in the absence of an incident involving us.

Risks Related to Our Dependence on Third Parties

The intellectual property underlying INOpulse is exclusively licensed from Ikaria. If Ikaria terminates the license agreement, or fails to prosecute, maintain or enforce the underlying patents, our business will be materially harmed.

We have licensed the intellectual property underlying INOpulse from Ikaria. The license agreement prohibits us from sublicensing to any competitor of Ikaria any intellectual property licensed to us by Ikaria. In addition, we are required to ensure that all of our products candidates are used solely for the chronic treatment of the Bellerophon indications and to enter into written agreements with any customers that contain restrictions on the use of our products and termination rights in the event such restrictions are violated.

Ikaria has the initial right, but not the obligation, to prosecute and maintain all patents that are licensed to us pursuant to the license agreement. While we have certain step-in rights to assume control if Ikaria declines to file, prosecute or maintain certain licensed patents that are core to our business, in the event Ikaria reasonably determines that our actions could materially impair its business operations or intellectual property rights, Ikaria may prohibit us from taking such actions. In addition, Ikaria has the initial right, but not the obligation, to initiate a legal action against a third party with respect to any actual or suspected infringement of patent rights licensed to us pursuant to the license agreement. We have the right to initiate legal action against a third-party infringer of licensed patents that are core to our business in the event Ikaria declines to take action with respect to such infringement, however, if Ikaria determines that our pursuit of any such action could materially impair its business operations or intellectual property rights, Ikaria may prohibit us from taking any such action.

The license agreement terminates, on an INOpulse product-by-INOpulse product basis, at such time as we are no longer actively and continuously engaged in the development or commercialization of such product. In addition, Ikaria may terminate the license agreement if, among other things, (1) we breach or fail to comply with any material term or condition required to be performed or complied with by us and do not cure such breach or failure within 30 days after receiving written notice of such breach from Ikaria, (2) we or any of our affiliates breaches any of our agreements not to compete with Ikaria, (3) we or any of our affiliates challenges the validity or enforceability of the licensed patents or (4) we or any person that is a successor to our license rights markets a generic nitric oxide product that is competitive with Ikaria's INOmax product. Upon termination of the license agreement with respect to any INOpulse product candidate, we will lose our ability to market such INOpulse product candidate, and upon, Ikaria's written request, be required to transfer any and all regulatory approvals relating to such INOpulse product candidate to Ikaria.

We rely, and expect to continue to rely, on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.

We currently rely on third-party clinical research organizations, or CROs, to conduct our clinical trials. We expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct our clinical trials. Our agreements with these third parties generally allow the third party to terminate the agreement at any time. If we are required to enter into alternative arrangements because of any such termination, the introduction of our product candidates to market could be delayed.

Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we design our clinical trials and will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with GCPs for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

We also expect to rely on other third parties to store and distribute drug and device supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our product candidates or commercialization of our products, producing additional losses and depriving us of potential product revenue.

We rely on Ikaria, as our single source supplier, for our supply of nitric oxide for the clinical trials of INOpulse. Ikaria's inability to continue manufacturing adequate supplies of nitric oxide, or its refusal to supply us with commercial quantities of nitric oxide on commercially reasonable terms, or at all, could result in a disruption in the supply of, or impair our ability to market, INOpulse.

We have entered into a drug clinical supply agreement with Ikaria, pursuant to which Ikaria will manufacture and supply our requirements for nitric oxide for inhalation and corresponding placebo for use in clinical trials of INOpulse. Ikaria manufactures pharmaceutical-grade nitric oxide at its facility in Port Allen, Louisiana, which is the only FDA-inspected site for manufacturing pharmaceutical-grade nitric oxide in the world. Ikaria's Port Allen facility is subject to the risks of a natural disaster or other business disruption. We maintain under controlled storage conditions a two- to three-month supply of clinical trial drug product, but there can be no assurance that we would be able to meet our requirements for INOpulse if there were a catastrophic event or failure of Ikaria's manufacturing system. Because Ikaria's Port Allen facility is the only FDA-inspected site that can manufacture INOpulse and because the manufacture of a pharmaceutical gas requires specialized equipment and expertise, there are few, if any, third-party manufacturers to which we could contract this work in a short period of time. Therefore, any disruption in Ikaria's Port Allen facility, or the failure by Ikaria for any other reason to provide us with nitric oxide, could materially and adversely affect supplies of INOpulse and our ongoing and planned clinical trials. Any such disruption would force us to seek nitric oxide from an alternative source, which may not be available on commercially reasonable terms, or at all. In addition, we do not currently have any arrangements with Ikaria to provide us with commercial quantities of nitric oxide. If we are unable to arrange for Ikaria to provide such quantities on commercially reasonable terms, or at all, we may not be able to successfully produce and market INOpulse or may be delayed in doing so.

We rely on third-party suppliers and manufacturers to produce and deliver clinical devices and supplies as well as for the servicing of these devices for our INOpulse product candidates, and may also do so for other product candidates. Any failure by a third-party supplier or manufacturer to produce or deliver supplies for us or to provide necessary servicing may delay or impair our ability to complete our clinical trials or commercialize our product candidates.

We currently rely, and expect to continue to rely, on third parties for supply of the device, cannula and certain other supplies for our INOpulse product candidates. These suppliers are, and any future third-party suppliers with whom we enter into agreements may be, our sole suppliers of these devices or any of our other current or future devices used in the INOpulse program. These suppliers are commonly referred to as single-source suppliers. If our suppliers fail to deliver materials and provide services needed for the production of the INOpulse device and related supplies or for our other product candidates in a timely and sufficient manner, if they fail to comply with applicable regulations, or if we do not qualify alternate suppliers,

clinical development or regulatory approval of our product candidates or commercialization of our products could be delayed, increasing our costs to complete clinical development and to obtain regulatory approval, which could deprive us of potential additional product revenue.

If one or more of our product candidates are approved by the FDA or comparable regulatory authorities in other countries for commercial sale, we will need to manufacture such product candidate in larger quantities. We do not currently have any arrangements with Ikaria or any other third-party manufacturer to provide commercial quantities of our product candidates. If we are unable to arrange for such a third-party manufacturing source, or fail to do so on commercially reasonable terms, we may not be able to successfully produce and market our product candidates or may be delayed in doing so.

Our product candidates currently in development are exclusively licensed from third parties, and we may enter into additional agreements to in-license technology from third parties. If current or future licensors terminate the applicable license, or fail to maintain or enforce the underlying patents, our competitive position and market share will be harmed.

We have an exclusive worldwide license for our BCM product candidate, subject to certain retained rights of the licensor, from BioLine. Under the terms of the license agreement, we are obligated to use commercially reasonable efforts to develop and commercialize at least one product containing BCM. BioLine has the right to terminate its license agreement with us for an uncured material breach by us, upon which our exclusive license for BCM will terminate.

We have also exclusively licensed INOpulse, for certain indications and settings, and subject to certain retained rights of the licensor, from Ikaria. See "Certain Relationships and Related Person Transactions-Relationship with Ikaria" for a summary of our exclusive cross-license, technology transfer and regulatory matters agreement with Ikaria.

We may enter into additional license agreements as part of the development of our business in the future. Such licensors, if any, may be responsible for prosecution of certain patent applications and maintenance of certain patents. Such licensors may not successfully prosecute such patent applications or maintain such patents, which we have licensed and on which our business depends. Our licensors may fail to pursue litigation against third-party infringers, may fail to prove infringement, or may fail to defend against counterclaims of patent invalidity or unenforceability. If these in-licenses are terminated, or if the underlying patents fail to provide the intended market exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products identical to ours. This could have a material adverse effect on our competitive business position and our business prospects.

Third parties may seek to hold us responsible for liabilities of Ikaria that we did not assume in our agreements.

In connection with our separation from Ikaria, Ikaria has generally agreed to retain all liabilities that did not historically arise from our business. Third parties may seek to hold us responsible for Ikaria's retained liabilities. Under our agreements with Ikaria, Ikaria has agreed to indemnify us for claims and losses relating to these retained liabilities. However, if those liabilities are significant and we are ultimately liable for them, we cannot assure our stockholders that we will be able to recover the full amount of our losses from Ikaria.

Any disputes that arise between us and Ikaria with respect to our past and ongoing relationships could harm our business operations.

Disputes may arise between Ikaria and us in a number of areas relating to our past and ongoing relationships, including:

- intellectual property, technology and business matters, including failure to make required technology transfers and failure to comply with non-compete provisions applicable to Ikaria and us;
- labor, tax, employee benefit, indemnification and other matters arising from our separation from Ikaria;
- distribution and supply obligations;
- employee retention and recruiting;
- business combinations involving us;
- the nature, quality and pricing of transitional services Ikaria has agreed to provide us; and
- business opportunities that may be attractive to both Ikaria and us.

We may not be able to resolve any potential conflicts, and even if we do, the resolution may be less favorable than if we were dealing with an unaffiliated party.

We may seek to enter into collaborations with third parties for the development and commercialization of our product candidates. If we fail to enter into such collaborations, or such collaborations are not successful, we may not be able to capitalize on the market potential of our product candidates.

We may seek third-party collaborators for development and commercialization of our product candidates. Our likely collaborators for any marketing, distribution, development, licensing or broader collaboration arrangements include large and mid-size pharmaceutical and medical device companies, regional and national biotechnology companies and pharmaceutical companies. We are not currently party to any such arrangement. However, if we do enter into any such arrangements with any third parties in the future, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements.

Collaborations involving our product candidates would pose certain risks to us, including:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- collaborators with marketing and distribution rights to one or more of our products may not commit sufficient resources to the marketing and distribution of such product or products;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our products or product candidates or that result in costly litigation or arbitration that diverts management attention and resources; and
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates.

Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If a collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program could be delayed, diminished or terminated.

If we are not able to establish collaborations, we may have to alter our development and commercialization plans.

Our drug and device development programs and the potential commercialization of our product candidates will require

substantial additional cash to fund expenses. For some of our product candidates, we may decide to collaborate with biotechnology and pharmaceutical companies for the development and potential commercialization of those product candidates.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. The terms of our current or future license agreements may restrict our ability to enter into agreements on certain terms with future collaborators. For example, our license agreement with Ikaria prohibits us from granting a sublicense under any of the intellectual property licensed to us under such license agreement to any of our affiliates or any third party, in each case, that directly or indirectly competes with the Ikaria nitric oxide business, and any future license agreements may contain similar restrictions. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent protection for our technology and products or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and products may be impaired.

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our proprietary technology and products. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our technologies and product candidates. The patents we have licensed from Ikaria relating to INOpulse's feature of providing delivery of nitric oxide to ensure a consistent dose over time expire as late as 2027 in the United States and as late as 2026 in certain other countries, as well as a patent with respect to the triple-lumen cannula that allows for safer and more accurate dosing of pulsed inhaled nitric oxide, which expires in 2033. The patents we have licensed from BioLine relating to our BCM product candidate expire as late as 2029 in the United States, with a possible patent term extension to 2032 to 2034, and 2024 in certain other countries.

The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, pursuant to our license agreement with Ikaria, we do not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering the INOpulse technology that we license from Ikaria, except in the event that Ikaria declines to prosecute or maintain certain licensed patents that are core to our business, elects to allow any of such patents to lapse or elects to abandon any such patents, in which case we would have step-in rights to assume control of the prosecution and/or maintenance of such patents, subject to Ikaria's right to prohibit us from taking such actions if it reasonably determines that such actions could materially impair its business, operations or intellectual property rights. Similarly, under the terms of any future agreements that we may enter into with other third parties, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering the technology that is licensed to us under such agreements. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the laws of non-U.S.

countries may not protect our rights to the same extent as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than U.S. law does. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, and in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not issue as patents that protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our owned or licensed issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. The Leahy-Smith Act includes provisions that affect the way patent applications are prosecuted and affect patent litigation. The USPTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act. Many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our owned or licensed patent applications and the enforcement or defense of our owned or licensed issued patents, all of which could have a material adverse effect on our business and financial condition.

Moreover, we may be subject to third-party preissuance submissions of prior art to the USPTO, or become involved in opposition, derivation, reexamination, *inter partes* review, post-grant review or interference proceedings challenging our owned or licensed patent rights or the patent rights of others. For example, Notices of Opposition to two European patents covering BCM that we licensed from BioLine have been filed with the European Patent Office. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Even if our owned and licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us, or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner. We may not receive patent term extension under the Hatch-Waxman Act that we expect or our rights during the extension period may be more limited than the full scope of the patent, making it easier for our competitors to develop and market non-infringing technologies or products.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate, or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our owned or licensed patents or other intellectual property. To counter infringement or unauthorized use, we may be required to file or participate in infringement claims, which can be expensive and time consuming. Any claims we or our licensors assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents. In addition, in a patent infringement proceeding, a court may decide that a patent of ours or our licensor is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our owned or licensed patents at risk of

being invalidated or interpreted narrowly.

Under the terms of our license agreement with Ikaria, in the event a third party is suspected of infringing any patent rights licensed to us by Ikaria, Ikaria has the initial right, but not the obligation, to initiate a legal action against such third party. In the event that Ikaria declines to take any action with respect to an alleged infringement of certain licensed patents that are core to our business, we have the right, in certain circumstances, to initiate a legal action against such third party, provided that, if Ikaria reasonably determines that our pursuit of any action with respect to infringement of any of such core patents could materially impair Ikaria's business operations or intellectual property rights, Ikaria may require us to not undertake or to cease any such action. Our inability to initiate a legal action against a third party suspected of infringing intellectual property rights important to our business may have a material adverse effect on our competitive business position and our business prospects.

If we fail to comply with our obligations under license agreements, we could lose rights that are important to our business.

Under our license agreement with Ikaria, we have granted Ikaria a sole and exclusive worldwide license to any intellectual property rights that we control for use in Ikaria's nitric oxide business, are required to ensure that all of our products, if any, are used solely for the chronic treatment of Bellerophon indications and to enter into written agreements with any customers that contain restrictions on the use of our products and termination rights in the event such restrictions are violated, and have agreed to pay 100% of the reasonable and documented costs incurred by Ikaria for the prosecution and maintenance of certain licensed patents that are core to our business and 10% of such costs incurred by Ikaria for all other licensed patents. If we fail to comply with our obligations under current or future license agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market any product that is covered by the agreement or face other penalties under the agreement. Such an occurrence could materially adversely affect the value of the product candidate being developed under any such agreement. We are also party to a license agreement with BioLine relating to our BCM product candidate that imposes, and we may enter into additional license agreements that may impose, various diligence, milestone payment, royalty and other obligations on us. Under our existing license agreement with BioLine, we are obligated to pay royalties on the net sales of product candidates or related technologies to the extent they are covered by the agreement. We also have diligence and development obligations under this agreement.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Our commercial success depends upon our ability to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. There is considerable intellectual property litigation in the pharmaceutical, biotechnology and medical device industries. We may become party to, or be threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products and technology, including interference or derivation proceedings before the USPTO. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future.

If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

We may be subject to claims by third parties asserting that we or our employees have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our employees were previously employed at other pharmaceutical, biotechnology or medical device companies, including our competitors or potential competitors. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. Litigation may be necessary to defend against these claims.

In addition, while it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in timely

obtaining such an agreement with each party who in fact develops intellectual property that we regard as our own. Even if timely obtained, such agreements may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

If we fail in prosecuting or defending any such claims, we may lose valuable intellectual property rights or personnel, in addition to paying monetary damages. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs.

Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for some of our technology and product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. Even if we are successful in prosecuting such claims, any remedy awarded may be insufficient to fully compensate us for the improper disclosure or misappropriation. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- Others may be able to develop and commercialize treatments that are similar to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed.
- We or our licensors might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed.
- We or our licensors might not have been the first to file patent applications covering certain of our inventions.
- Others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights.
- It is possible that our pending patent applications will not lead to issued patents.
- Issued patents that we own or have exclusively licensed may not provide us with any competitive advantages, or

may be held invalid or unenforceable, as a result of legal challenges by our competitors.

- Our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets.

- We may not develop additional proprietary technologies that are patentable.

- The patents of others may have an adverse effect on our business.

- Another party may be granted orphan drug exclusivity for an indication that we are seeking before us or may be granted orphan drug exclusivity for one of our products for another indication.

Risks Related to Regulatory Approval of Our Product Candidates and Other Legal Compliance Matters

Even if we complete the necessary clinical trials, the marketing approval process is expensive, time consuming and uncertain and may prevent us from obtaining approvals for the commercialization of some or all of our product candidates. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize our product candidates, and our ability to generate revenue will be materially impaired.

Our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by the EMA and similar regulatory authorities outside the United States. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. Our product candidates are in the early stages of development and are subject to the risks of failure inherent in drug and device development. We have not received approval to market any of our product candidates from regulatory authorities in any jurisdiction. We have only limited experience in conducting and managing the clinical trials, and in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party CROs to assist us in this process. Securing marketing approval requires the submission of extensive pre-clinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional pre-clinical, clinical or other studies. In addition, varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable. If we experience delays in obtaining approval or if we fail to obtain approval of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenues will be materially impaired.

Even though we have obtained orphan drug designation from the FDA for the treatment of pulmonary arterial hypertension the designation-related marketing exclusivity periods may be challenged by others or may prove to be of no practical benefit. In addition, even though we have reached agreement on a Special Protocol Assessment, or SPA, with the FDA with respect to our Phase 3 PAH program for INOpulse, the FDA is not obligated to approve INOpulse for PAH as a result of the SPA if we fail to meet all the conditions of the SPA agreement or if safety or efficacy issues become evident after the trial begins. Therefore, we cannot provide assurance that positive results in the clinical trial will be sufficient for FDA approval.

Our failure to obtain marketing approval in foreign jurisdictions would prevent our product candidates from being marketed abroad, and any approval we are granted for our product candidates in the United States would not assure approval of product candidates in foreign jurisdictions.

In order to market and sell our products in the European Union and many other jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any market.

Even if we obtain marketing approval for our product candidates, the terms of approvals and ongoing regulation of our products may limit how we manufacture and market our products and compliance with such requirements may involve substantial resources, which could materially impair our ability to generate revenue.

Even if marketing approval of a product candidate is granted, an approved product and its manufacturer and marketer are subject to ongoing review and extensive regulation, including the requirement to implement a risk evaluation and mitigation strategy or to conduct costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product. We must also comply with requirements concerning advertising and promotion for any of our product candidates for which we obtain marketing approval. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved labeling. Thus, we will not be able to promote any products we develop for indications or uses for which they are not approved. In addition, manufacturers of approved products and those manufacturers' facilities are required to ensure that quality control and manufacturing procedures conform to cGMP, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. We and our contract manufacturers could be subject to periodic unannounced inspections by the FDA and other regulatory authorities to monitor and ensure compliance with cGMP.

Accordingly, assuming we receive marketing approval for one or more of our product candidates, we and our contract manufacturers will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control. If we are not able to comply with post-approval regulatory requirements, we could have the marketing approvals for our products withdrawn by regulatory authorities and our ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. Thus, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

Any product candidate for which we obtain marketing approval will be subject to strict enforcement of post-marketing requirements and we could be subject to substantial penalties, including withdrawal of our product from the market, if we fail to comply with all regulatory requirements or if we experience unanticipated problems with our products, when and if any of them are approved.

Any product candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include, but are not limited to, restrictions governing promotion of an approved product, submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, and requirements regarding the distribution of samples to physicians and recordkeeping.

The FDA and other federal and state agencies, including the Department of Justice, closely regulate compliance with all requirements governing prescription drug and device products, including requirements pertaining to marketing and promotion of drugs and devices in accordance with the provisions of the approved labeling and manufacturing of products in accordance with cGMP requirements. Violations of such requirements may lead to investigations alleging violations of the Food, Drug, and Cosmetic Act and other statutes, including the False Claims Act and other federal and state health care fraud and abuse laws as well as state consumer protection laws. Our failure to comply with all regulatory requirements, and later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, may yield various results, including:

- litigation involving patients taking our products;

- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- untitled or warning letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- damage to relationships with any potential collaborators;
- unfavorable press coverage and damage to our reputation;
- refusal to permit the import or export of our products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

Non-compliance by us or any future collaborator with regulatory requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, can also result in significant financial penalties. Similarly, failure to comply with regulatory requirements regarding the protection of personal information could also lead to significant penalties and sanctions.

Our relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;
- the federal False Claims Act imposes criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented false or fraudulent claims for payment by a federal government program, or making a false statement or record material to payment of a false claim or avoiding, decreasing or concealing an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also imposes obligations, including mandatory contractual

terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

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

- the federal transparency requirements under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the PPACA, requires applicable manufacturers of covered drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to payments and other transfers of value to physicians and teaching hospitals and physician ownership and investment interests; and

- analogous state laws and regulations such as state anti-kickback and false claims laws and analogous non-U.S. fraud and abuse laws and regulations, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. State and non-U.S. laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of products from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Laws and regulations governing any international operations we may have in the future may preclude us from developing, manufacturing and selling certain product candidates and products outside of the United States and require us to develop and implement costly compliance programs.

If we expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The Foreign Corrupt Practices Act, or the FCPA, prohibits any U.S. individual or business from paying, offering, authorizing payment or offering anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of such third party in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the company, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the medical device industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the United States, it will require us to dedicate

additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing or selling certain product candidates and products outside of the United States, which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

Currently, we do not operate any research and development or production facilities, including laboratory, development or manufacturing facilities. However, if we decided to operate our own research and development and production facilities, we would be subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Such operations may involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations may also produce hazardous waste products. Even if we contract with third parties for the disposal of these materials and wastes, we would not be able to eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use or disposal of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

Although we would increase our level of workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not expect to maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our possible future storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Risks Related to Employee Matters and Managing Growth

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

We are dependent on the scientific, business development and clinical expertise of our management team. Leadership transitions can be inherently difficult to manage and may cause some disruptions in our business.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. Any of our employees may terminate their employment with us at any time. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. We do not maintain "key person" insurance for any of our executives or other employees. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical, biotechnology and medical device companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

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

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with federal and state

healthcare fraud and abuse laws and regulations, to report financial information or data accurately, to disclose unauthorized activities to us or to comply with our code of business conduct and ethics. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, false claims, inappropriate promotion, 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 information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. 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, including the imposition of significant fines or other sanctions.

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

Our staff reduction plan may not result in anticipated savings, could result in total costs and expenses that are greater than expected and could disrupt our business.

In September 2015, we announced a staff reduction plan pursuant to which we reduced our workforce by approximately 20 people, or the Restructuring. We took these actions in order to reduce operating expenses and conserve cash resources. The Restructuring was completed by the end of 2015.

Our restructuring plan may be disruptive to our operations. For example, cost savings measures may distract management from our core business, harm our reputation, yield unanticipated consequences, such as attrition beyond planned staff reductions, or increase difficulties in our day-to-day operations, and may adversely affect employee morale. Our staff reductions could also harm our ability to attract and retain qualified management, scientific, clinical, manufacturing and sales and marketing personnel who are critical to our business. Any failure to attract or retain qualified personnel could prevent us from successfully developing and commercializing our product candidates in the future.

Risks Related to Ownership of Our Common Stock

Our principal stockholders have substantial control over us, which could limit ability of our stockholders to influence the outcome of key transactions, including any change of control.

Our executive officers, directors and stockholders who are known by us to beneficially own more than 5% of our common stock, in the aggregate, beneficially owned 77.5% of our outstanding common stock as of March 10, 2016. As a result, if these stockholders were to choose to act together, they would be able to exert a significant degree of influence over matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, could delay, defer or prevent a change in control; entrench our management or board of directors; or impede a merger, consolidation, takeover or other business combination involving us that other stockholders may desire.

In addition, as of March 10, 2016, our largest stockholder, investment funds affiliated with New Mountain Capital, or the New Mountain Entities, owned, in the aggregate, approximately 36.1% of our outstanding common stock. Pursuant to the terms of a stockholders agreement, the New Mountain Entities are entitled to designate one director for nomination to our board of directors and to designate one director to the board of directors (or equivalent governing body) of each of our subsidiaries and to appoint the lead director of our board of directors, in each case, for so long as the New Mountain Entities or certain of their respective assignees beneficially own (i) 50% or more of the sum of (a) the aggregate number of shares of our common stock that they collectively owned immediately prior to the closing of our IPO and (b) the number of shares of our common stock, if any, acquired following the closing of our IPO and (ii) 15% or more of our common stock outstanding (as set forth on the cover of our then most recently filed annual report on Form 10-K or quarterly report on Form 10-Q).

The New Mountain Entities also have certain other rights conferred by the stockholders agreement. The New Mountain

Entities may exert significant influence over matters requiring board approval. In addition, their consent is required for certain matters requiring approval by our stockholders, including the compensation and hiring and firing of our chief executive officer, business combinations, issuance of shares of our capital stock and incurrence of debt. These stockholder approval rights will terminate as outlined in "Certain Relationships and Related Person Transactions-Stockholders Agreements" in Part III-Item 13.

Our second largest stockholder, Linde North America, Inc., an indirect wholly-owned subsidiary of Linde AG, or Linde, owned approximately 12.1% of our outstanding common stock, as of March 10, 2016. Pursuant to the terms of a stockholders agreement, Linde is entitled to designate one director to our board of directors and to designate one director to the board of directors (or equivalent governing body) of each of our subsidiaries if continuing ownership requirements are met as outlined in "Certain Relationships and Related Person Transactions-Stockholders Agreements" in Part III-Item 13.

The New Mountain Entities and Linde may have interests that differ from the interests of our other stockholders, and they may vote in ways with which our other stockholders disagree and that may be adverse to interests of our other stockholders. The concentration of ownership of our capital stock may have the effect of delaying, preventing or deterring a change of control of our company, could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company and may adversely affect the market price of our common stock.

A significant portion of our total outstanding shares are subject to volume limitations as to sale, but have registration rights that could allow them to be sold into the market without such restrictions, which could cause the market price of our common stock to drop significantly, even if our business is performing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time, subject to certain restrictions described below. These sales, or the perception in the market that holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. As of March 10, 2016, holders of an aggregate of approximately 8,733,628 shares of our common stock have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. Many of these shares could be freely sold without registration subject to the volume limitations applicable to affiliates under Rule 144. As of March 10, 2016, we had unvested restricted share awards of 432,289 and outstanding options to purchase an aggregate of 958,512 shares of our common stock, of which options to purchase approximately 317,744 were vested. These shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates.

If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our stock, the price or trading volume of our stock could decline.

The trading market for our common stock relies, in part, on the research and reports that industry or financial analysts publish about us or our business. If no, or few, analysts commence coverage of us, the trading price of our stock would likely decrease. Even if we do obtain analyst coverage, if one or more of the analysts covering our business do not publish favorable reports or downgrade their evaluations of our stock, the price of our stock could decline. If one or more analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price or trading volume to decline.

The price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for our stockholders.

Our stock price may be volatile. The stock market in general, and the market for pharmaceutical companies in particular, has experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their shares of common stock at or above the price they paid for their shares. The market price for our common stock may be influenced by many factors, including:

- actual or anticipated results from and any delays in our clinical trials, including our expected and ongoing clinical trials of our INOpulse product candidates, as well as results of regulatory input on our clinical trial programs and regulatory reviews relating to the approval of our product candidates;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or products;
- failure or discontinuation of any of our clinical development programs;
- the level of expenses related to any of our product candidates or clinical development programs;

- commencement or termination of any collaboration or licensing arrangement;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures and capital commitments;
- additions or departures of key scientific or management personnel;
- variations in our financial results or those of companies that are perceived to be similar to us;
- new products, product candidates or new uses for existing products introduced or announced by our competitors, and the timing of these introductions or announcements;
- results of clinical trials of product candidates of our competitors;
- general economic and market conditions and other factors that may be unrelated to our operating performance or the operating performance of our competitors, including changes in market valuations of similar companies;
- regulatory or legal developments in the United States and other countries;
- changes in the structure of healthcare payment systems;
- conditions or trends in the pharmaceutical, biotechnology and medical device industries;
- actual or anticipated changes in earnings estimates, development timelines or recommendations by securities analysts;
- announcement or expectation of additional financing efforts;
- sales of common stock by us or our stockholders in the future, as well as the overall trading volume of our common stock; and
- the other factors described in this "Risk Factors" section.

If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

In the past, following periods of volatility in the market price of a company's securities, securities class-action litigation often has been instituted against that company. Such litigation, if instituted against us, could cause us to incur substantial costs to defend such claims and divert management's attention and resources, which could seriously harm our business, financial condition, results of operations and prospects.

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

Our shares of common stock began trading on the NASDAQ Global Market on February 13, 2015. Given the limited trading history of our common stock, there is a risk that an active trading market for our shares may not continue to develop or be sustained. If an active market for our common stock does not continue to develop or is not sustained, it may be difficult for investors to sell shares without depressing the market price for the shares, or at all.

We have broad discretion in the use of our cash and cash equivalents and may not use them effectively.

Our management has broad discretion in the application of our cash and cash equivalents and could spend these funds in ways that do not improve our results of operations or enhance the value of our common stock. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause

the price of our common stock to decline and delay the development of our product candidates. Pending their use, we may invest our cash and cash equivalents in a manner that does not produce income or that loses value.

We are an "emerging growth company," and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. We will remain an emerging growth company until the earlier of: (i) the last day of the fiscal year in which we have total annual gross revenues of $1 billion or more; (ii) December 31, 2020; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC, which means the first day of the year following the first year in which the market value of our common stock that is held by non-affiliates exceeds $700 million as of June 30. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002;
- not being required to comply with 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;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We may choose to take advantage of some, but not all, of the available exemptions. We have taken advantage of reduced reporting burdens in this Annual Report on Form 10-K. In particular, we have not included all of the executive compensation information that would be required if we were not an emerging growth company. We cannot predict whether investors will find our common stock less attractive if we rely on certain or all of these exemptions. 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, the JOBS Act provides that an emerging growth company may take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we are subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

We are currently incurring and expect to continue to incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

We completed our IPO in February 2015. As a public company, we incur and expect to continue to incur significant legal, accounting and other expenses. We expect that our expenses will further increase after we are no longer an "emerging growth company." We expect that we will need to hire additional accounting, finance and other personnel to comply with the requirements of being a public company, and our management and other personnel will need to devote a substantial amount of time towards maintaining compliance with these requirements. In addition, the Sarbanes-Oxley Act of 2002 and rules subsequently implemented by the SEC and NASDAQ have imposed various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we will be required to furnish a report by our management on our internal control over financial reporting, including an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. Many of the internal controls over financial reporting have not been tested. To

achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that neither we nor our independent registered public accounting firm will be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

Our certificate of incorporation provides that the doctrine of "corporate opportunity" will not apply to any of our stockholders or directors, except in limited circumstances, which may adversely affect our business or prospects.

Our certificate of incorporation provides that the doctrine of "corporate opportunity" will not apply to any of our stockholders or directors, other than any stockholder or director that is an employee of ours. The doctrine of corporate opportunity generally provides that a corporate fiduciary may not develop an opportunity using corporate resources, acquire an interest adverse to that of the corporation or acquire property that is reasonably incident to the present or prospective business of the corporation or in which the corporation has a present or expectancy interest, unless that opportunity is first presented to the corporation and the corporation chooses not to pursue that opportunity. The doctrine of corporate opportunity is intended to preclude officers or directors from personally benefiting from opportunities that belong to the corporation. We have renounced any prospective corporate opportunity so that our stockholders and directors (other than those that are employees of ours) and their respective representatives have no duty to communicate or present corporate opportunities to us, including any opportunity that becomes known to Ikaria and its directors, and have the right to either hold any corporate opportunity for its (and its representatives') own account and benefit or to recommend, assign or otherwise transfer such corporate opportunity to persons other than us, including to Ikaria. As a result, our stockholders, directors and their respective affiliates will not be prohibited from investing in competing businesses or doing business with our customers. Therefore, we may be in competition with our stockholders, directors or their respective affiliates, and we may not have knowledge of, or be able to pursue, a transaction that could potentially be beneficial to us. Accordingly, we may lose a corporate opportunity or suffer competitive harm, which could negatively impact our business or prospects.

Our certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our certificate of incorporation or our bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine. This provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find this provision in our certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

Provisions in our certificate of incorporation, our bylaws or Delaware law might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the trading price of our common stock.

Provisions of our certificate of incorporation, our bylaws or Delaware law may discourage, delay or prevent a merger, acquisition or other change in control that stockholders may consider favorable, including transactions in which our stockholders might otherwise receive a premium for their shares. These provisions may also prevent or frustrate attempts by our stockholders to change the composition of our board of directors or to replace or remove our management. These provisions include:

- limitations on the removal of directors;
- a classified board of directors so that not all members of our board are elected at one time;
- advance notice requirements for stockholder proposals and nominations;

- limitations on the ability of stockholders to call and bring business before special meetings and to take action by written consent in lieu of a meeting;
- limitations on the liability of, and the provision of indemnification to, our director and officers; and
- the ability of our board of directors to authorize the issuance of blank check preferred stock, which could be issued with voting, liquidation, dividend and other rights superior to our common stock.

In addition, we are subject to Section 203 of the Delaware General Corporation Law, which prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner.

The existence of the foregoing provisions and anti-takeover measures could limit the price that investors might be willing to pay in the future for shares of our common stock. They could also deter potential acquirers of our company, thereby reducing the likelihood that investors could receive a premium for their shares of our common stock in an acquisition.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be the sole source of gain for our stockholders.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for our stockholders for the foreseeable future.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our principal facilities consist of approximately 22,000 square feet of office space at our headquarters located in Warren, New Jersey and approximately 1,600 square feet of office space and research lab facilities at the Commercialization Center for Innovative Technologies located in North Brunswick, New Jersey. We lease the space in Warren, New Jersey under a lease that expires in 2023.We lease the space in North Brunswick, New Jersey under a month-to-month lease. We believe that we have adequate space for our anticipated needs and that suitable additional space will be available at commercially reasonably terms as needed.

Item 3. Legal Proceedings

We are not presently a party to any material litigation or regulatory proceeding, and we are not aware of any pending or threatened litigation or regulatory proceeding against us that could have a material adverse effect on our business, operating results, financial condition or cash flows.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Our common stock has been publicly traded on the NASDAQ Global Market under the symbol "BLPH" since February 13, 2015. Prior to that time, there was no public market for our common stock. As a result, we have not set forth quarterly information with respect to the high and low sales prices for our common stock for the time periods prior to when our stock began to be publicly traded. The following table sets forth the high and low sales prices per share for our common stock on the NASDAQ Global Market starting from February 13, 2015, our first day of trading on NASDAQ:

2015	High	Low
First Quarter (February 13, 2015 through March 25, 2015)	$ 12.92	$ 8.01
Second Quarter	10.88	7.32
Third Quarter	8.54	2.75
Fourth Quarter	5.09	2.47

Stockholders

As of March 10, 2016, there were approximately 269 holders of record of our common stock. This number does not include beneficial owners whose shares are held by nominees in street name.

Dividend Policy

We have not declared or paid any cash dividends on our common stock since our inception. We intend to retain future earnings, if any, to finance the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future.

Information About Our Equity Compensation Plans

Information regarding our equity compensation plans is incorporated by reference to Item 12, "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters-Equity Compensation Plan Information" of Part III of this Annual Report on Form 10-K.

Recent Sales of Unregistered Securities

Set forth below is information regarding securities sold or granted by us during the fiscal year ended December 31, 2015 that were not registered under the Securities Act of 1933, as amended, or the Securities Act and is the consideration, if any, we received for such securities and information relating to the section of the Securities Act or rule of the SEC under which exemption from registration was claimed.

In February 2015, prior to our IPO, we issued and sold 67 non-voting units to Mr. Peacock, our president and chief executive officer, at a price per unit of $15.03 for an aggregate purchase price of $1,007.

Prior to our IPO, we converted from a Delaware limited liability company into a Delaware corporation. In connection with the conversion, all of our outstanding voting units and non-voting units converted into shares of voting common stock and non-voting common stock, respectively, and options to purchase our non-voting units became options to purchase non-voting shares of our common stock. Pursuant to their terms, upon the consummation of our IPO, the non-voting common stock converted into voting common stock and options to purchase non-voting common stock became options to purchase voting common stock.

In December 2015, we issued 8,000 shares to Global Corporate Finance as consideration under a letter agreement as consideration for services to be provided at a price per share of $2.95 for an aggregate value of $23,600.

Each of the foregoing issuances was made by us in a transaction not involving a public offering pursuant to an exemption from the registration requirements of the Securities Act in reliance upon Section 4(a)(2) of the Securities Act or

Rule 701 promulgated under Section 3(b) of the Securities Act. We did not pay or give, directly or indirectly, any commission or other remuneration, including underwriting discounts or commissions, in connection with any of the issuances of securities listed above, and no underwriters were involved in the foregoing issuances of securities. All recipients either received adequate information about the registrant or had access, through employment or other relationships, to such information.

Use of Proceeds

We effected the IPO of our common stock pursuant to a Registration Statement on Form S-1 (File No. 333-201474) that was declared effective by the SEC on February 13, 2015. On February 19, 2015, we completed the sale of 5,000,000 shares of common stock in our IPO at a price to the public of $12.00 per share, resulting in net proceeds to us of $51.9 million, after deducting underwriting discounts and commissions of $4.2 million and offering costs of $3.9 million. In addition, we granted the underwriters a 30-day option, which expired unexercised, to purchase up to 750,000 additional shares of common stock at the IPO price to cover over allotments, if any. The offering commenced on February 13, 2015 and terminated before the sale of all of the securities registered in the offering. None of the underwriting discounts and commissions or other offering expenses were paid to directors or officers of ours or their associates or to persons owning 10% or more of our common stock or to any affiliates of ours. Leerink Partners LLC and Cowen and Company, LLC acted as joint book-running managers of the offering and as representatives of the underwriters. SunTrust Robinson Humphrey, Inc. and FBR Capital Markets & Co. acted as co-managers for the offering. There were no selling stockholders in the offering.

None of the net proceeds were paid directly or indirectly to directors or officers of ours or their associates or to persons owning 10% or more of our common stock or to any affiliates of ours, other than payments in the ordinary course of business to officers for salaries and to non-employee directors as compensation for board or board committee service. As of December 31, 2015, we have used approximately $27.8 million of the net proceeds of our IPO to fund our Phase 3 clinical development of INOpulse for PAH and for working capital and other general corporate purposes. As of December 31, 2015, we have invested the balance of the net proceeds from the offering in a variety of capital preservation investments, including demand deposits with U.S. banking institutions, federally insured certificates of deposit and corporate or agency bonds rated A or better. There has been no material change in our planned use of the balance of the net proceeds from the offering as described in our final prospectus filed with the SEC pursuant to Rule 424(b) under the Securities Act of 1933, as amended.

Issuer Purchases of Equity Securities

We did not purchase any of our registered equity securities during the period covered by this Annual Report on Form 10-K.

Item 6. Selected Financial Data

The following selected financial data should be read together with our financial statements and the related notes appearing elsewhere in this Annual Report on Form 10-K and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section of this Annual Report on Form 10-K. We have derived the statements of operations data for the years ended December 31, 2015, 2014 and 2013 and the balance sheet data as of December 31, 2015 and 2014 from our audited financial statements included elsewhere in this Annual Report on Form 10-K, which have been audited by KPMG LLP, an independent registered public accounting firm. The balance sheet data as of December 31, 2013 are from our audited financial statements that are not included in this Annual Report on Form 10-K. Our historical results for any prior period are not necessarily indicative of results to be expected in any future period.

(in thousands, except per share/unit data)	Year Ended December 31, 2015	2014	2013
Statement of Operations Information			
Operating expenses:			
Research and development	$ 33,365	$ 45,978	$ 52,985
General and administrative	14,870	13,775	9,013
Other operating expense	—	—	—
Total operating expenses	48,235	59,753	61,998
Other operating income	1,667	—	—
Loss from operations	(46,568)	(59,753)	(61,998)
Interest income	109	79	—
Net loss	$ (46,459)	$ (59,674)	$ (61,998)
Net loss per share/unit:			
Basic and diluted (1)	$ (3.79)	$ (7.56)	

(in thousands)	As of December 31, 2015	2014	2013
Balance Sheet Information			
Cash and cash equivalents	$ 6,260	$ 16,815	$ —
Restricted cash, current	—	9,264	—
Restricted cash, non-current	457	1,548	—
Marketable securities	17,807	—	—
Working capital (deficit)	21,379	17,227	(12,440)
Total assets	38,409	33,391	3,636
Total long term liabilities	—	—	5,381
Investment by Ikaria, Inc.	—	—	160,778
Common stock	131	—	—
Additional paid-in capital	130,902	—	—
Members' capital	—	77,156	—
Accumulated deficit	(100,678)	(54,219)	(176,515)
Stockholders'/Members' equity / invested (deficit)	$ 30,336	$ 22,937	$ (15,737)

(1) The weighted average shares and units outstanding for basic and diluted net loss per unit for the years ended December 31, 2015 and 2014 is 12,267,693 and 7,898,289, respectively. No net loss per unit information is presented for periods prior to the Spin-Out.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read together with our financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties and should be read together with the "Risk Factors" section of this Annual Report on Form 10-K for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

Business

We are a clinical-stage therapeutics company focused on developing innovative products at the intersection of drugs and devices that address significant unmet medical needs in the treatment of cardiopulmonary diseases. The focus of our clinical program is the continued development of our nitric oxide therapy for patients with pulmonary hypertension, or PH, using our proprietary delivery system, INOpulse, with pulmonary arterial hypertension, or PAH, representing the lead indication. Our INOpulse program is based on our proprietary pulsatile nitric oxide delivery device.

We completed a randomized, placebo-controlled, double-blind Phase 2 clinical trial of INOpulse for PAH in October 2014, which is Part 1 of the trial. In February 2016, we announced positive data from the final analysis of our Phase 2 long-term extension clinical trial of INOpulse for PAH, which is Part 2 of our Phase 2 clinical trial of INOpulse for PAH. The data reinforces the results from October 2014 and indicates a sustainability of benefit to PAH patients who received INOpulse therapy. After reaching agreement with the U.S. Food and Drug Administration, or FDA, and the European Medicines Agency, or EMA, on our Phase 3 protocol, we are moving forward with Phase 3 development. In September 2015, the FDA issued a Special Protocol Assessment, or SPA, for our Phase 3 PAH program for INOpulse, which will include two confirmatory clinical trials, undertaken either sequentially or in parallel, with the first patient expected to be enrolled during the first half of 2016.

We completed a randomized, placebo-controlled, double-blind, dose-confirmation Phase 2 clinical trial of INOpulse for PH-COPD in July 2014. We have received results from this trial, and we are planning further Phase 2 testing to demonstrate the potential benefit on exercise capacity. In September 2015, an oral presentation of late-breaking data from a clinical trial sponsored by us was presented at the European Respiratory Society International Congress 2015 in Amsterdam. The data showed that INOpulse improved vasodilation in patients with PH-COPD. We plan to build upon this and other work we have done over recent quarters to continue Phase 2 testing for the use of the INOpulse device for PH-COPD patients.

We are planning to undertake clinical testing of the INOpulse therapy to treat PH associated with idiopathic pulmonary fibrosis, or PH-IPF, based on feedback from the medical community and the large unmet medical need for this condition. In addition, other opportunities for the application of our INOpulse program include the following indications: chronic thromboembolic PH, or CTEPH, PH associated with sarcoidosis and PH associated with pulmonary edema from high altitude sickness.

We presented detailed results from the PRESERVATION I trial for our Bioabsorbable Cardiac Matrix, or BCM, program at the European Society of Cardiology meeting in London on September 1, 2015. Following the results, we are considering further exploratory work but we do not intend to proceed with further clinical development of BCM at this point until and unless we can determine an alternative path forward.

We have devoted all of our resources to our therapeutic discovery and development efforts, including conducting clinical trials for our product candidates, protecting our intellectual property and the general and administrative support of these operations. We have devoted significant time and resources to developing and optimizing our drug delivery system, INOpulse, which operates through the administration of nitric oxide as brief, controlled pulses that are timed to occur at the beginning of a breath. In addition, in prior quarters, we had incurred significant costs to scale up manufacturing of BCM to support our clinical trials.

To date, we have generated no revenue from product sales. We expect that it will be several years before we commercialize a product candidate, if ever.

Restructuring

Following the results of our PRESERVATION I clinical trial for BCM, on September 11, 2015, our Board of Directors approved a staff reduction plan in order to reduce operating expenses and conserve cash resources, which we refer to as the Restructuring. The Restructuring included a workforce reduction of approximately 20 people completed in 2015. We offered severance benefits to the affected employees, including cash severance payments. Each affected employee's eligibility for the severance benefits was contingent upon such employee's execution (and non-revocation) of a separation agreement, which included a general release of claims against us. We recorded pre-tax charges of $1.4 million associated with the Restructuring, primarily consisting of the cash severance payments specified above. These charges were incurred largely in the third quarter of 2015 and are anticipated to be paid out in cash by March 2017.

Separation and Spin-Out from Ikaria

Prior to February 2014, we were a wholly-owned subsidiary of Ikaria, Inc. (a subsidiary of Mallinckrodt plc), or Ikaria. As part of an internal reorganization of Ikaria in October 2013, Ikaria transferred to us exclusive worldwide rights, with no royalty obligations, to develop and commercialize pulsed nitric oxide in PAH, PH-COPD and PH-IPF. In November 2015, we entered into an amendment to our exclusive cross-license, technology transfer and regulatory matters agreement with Ikaria that included a royalty equal to 3% of net sales of any commercial products for PAH. Following the internal reorganization, in February 2014, Ikaria distributed all of our then outstanding units to its stockholders through the payment of a special dividend on a pro rata basis based on each stockholder's ownership of Ikaria capital stock, which we refer to as the Spin-Out, and as a result we became a stand-alone company.

Our inception date is August 26, 2009, which is the date that BCM was licensed to us by BioLineRx Ltd. and BioLine Innovations Jerusalem L.P., which we refer to collectively as BioLine. Our operations since that date have included organization and staffing, business planning, in-licensing technology, developing product candidates in clinical programs, evaluating potential future product candidates, as well as undertaking pre-clinical studies and clinical trials of our product candidates.

In February 2014 and July 2015, we entered into a transition services agreement and an amendment to the transition services agreement, respectively, with Ikaria, which we refer to as the TSA. Pursuant to the terms and conditions of the TSA, Ikaria agreed to use commercially reasonable efforts to provide certain services to us until February 2016, the termination of which was accelerated to September 30, 2015 as part of the amendment, subject to the terms of the TSA. In exchange for the services provided by Ikaria pursuant to the TSA, we paid to Ikaria a service fee in the amount of $772,000 per month and reimbursed Ikaria for any out of pocket expenses, any taxes imposed on Ikaria in connection with the provision of services under the TSA.

Under our additional services agreement with Ikaria, or the 2015 Services Agreement, which became effective on January 1, 2015, Ikaria provided to us certain information technology and device maintenance services. In exchange for the services provided by Ikaria pursuant to the 2015 Services Agreement, we paid to Ikaria fees that totaled, in the aggregate, approximately $200,000. In July 2015, we entered into an amendment to the 2015 Services Agreement advancing the termination date from February 8, 2016 to September 30, 2015. Additionally, pursuant to the 2015 Services Agreement, we agreed to use commercially reasonable efforts to provide certain services to Ikaria, including services related to regulatory matters, drug and device safety, clinical operations, biometrics and scientific affairs. We also received payments of $1.7 million from Ikaria in connection with the 2015 Services Agreement.

Accounting for the Separation and Spin-Out

Our historical financial statements for periods prior to February 12, 2014, the date of the Spin-Out, discussed in this Management's Discussion and Analysis of Financial Condition and Results of Operations were derived from the audited historical financial statements and accounting records of Ikaria and include allocations for direct costs and indirect costs attributable to the research and development segment of Ikaria. In particular, for the period January 1, 2014 to February 11, 2014, our financial statements include expense allocations for (1) certain corporate functions historically provided by Ikaria, including finance, audit, legal, information technology and human resources services, (2) research and development expenses and (3) stock-based compensation. These allocations are based on either specific identification or allocation methods such as time and wage studies, headcount or other measures determined by us. Management believes that the statements of operations and comprehensive loss for the period of time prior to the Spin-Out includes a reasonable allocation of costs and expenses incurred by Ikaria from which we benefited. See Notes 1 and 2 to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K.

Due to this presentation, the financial information for the years ended December 31, 2014 and 2013 included in this Annual Report on Form 10-K does not reflect what our financial position, results of operations and cash flows will be in the future or what our financial position, results of operations and cash flows would have been in the past had we been a public, stand-alone company throughout the periods presented.

Financial Operations Overview

Revenue

To date, we have not generated any revenue from product sales and may not generate any revenue from product sales for the next several years, if ever. In the future, we may generate revenue from a combination of product sales, license fees and milestone payments in connection with strategic partnerships, and royalties from the sale of products developed under licenses of our intellectual property. Our ability to generate revenue and become profitable depends primarily on our ability to successfully develop and commercialize or partner our product candidates as well as any product candidates we may advance in the future. We expect that any revenue we may generate will fluctuate from quarter to quarter as a result of the timing and amount of any payments we may receive under future partnerships, if any, and from sales of any products we successfully develop and commercialize, if any. If we fail to complete the development of any of our product candidates currently in clinical development or any future product candidates in a timely manner, or to obtain regulatory approval for such product candidates, our ability to generate future revenue, and our business, results of operations, financial condition and cash flows and future prospects would be materially adversely affected.

Research and Development Expenses

Research and development expenses consist of costs incurred in connection with the development of our product candidates, including upfront and development milestone payments, related to in-licensed product candidates and technologies.

In order to fairly present our historical information for periods prior to the Spin-Out, certain departmental expenses from Ikaria have been allocated to us. The allocations were applied to us for the purpose of presenting our company as a stand-alone entity. Direct and indirect costs for periods prior to the Spin-Out related to the INOpulse and BCM clinical programs have been allocated to us. All allocations were based on actual costs incurred. For purposes of allocating non-project specific expenses, each Ikaria department head provided information as to the percentage of employee time incurred on our behalf.

Research and development expenses primarily consist of:

- employee-related expenses, including salary, benefits and stock-based compensation expense;
- expenses incurred under agreements with contract research organizations, investigative sites that conduct our clinical trials and consultants that conduct a portion of our pre-clinical studies;
- expenses relating to vendors in connection with research and development activities;
- the cost of acquiring and manufacturing clinical trial materials;
- facilities, depreciation of fixed assets and allocated expenses;
- lab supplies, reagents, active pharmaceutical ingredients and other direct and indirect costs in support of our pre-clinical and clinical activities;
- device development and drug manufacturing engineering;
- license fees related to in-licensed products and technology; and
- costs associated with non-clinical activities and regulatory approvals.

We expense research and development costs as incurred.

Conducting a significant amount of research and development is central to our business model. Product candidates in late stages of clinical development generally have higher development costs than those in earlier stages of clinical development primarily due to the increased size and duration of late-stage clinical trials. Subject to the availability of requisite financing, we

plan to increase our research and development expenses for ongoing clinical programs for the foreseeable future as we seek to continue multiple clinical trials for our product candidates, including to potentially advance INOpulse for PH-IPF, and seek to identify additional early-stage product candidates.

We track external research and development expenses and personnel expenses on a program-by-program basis. We use our employee and infrastructure resources, including regulatory, quality, clinical development and clinical operations, across our clinical development programs and have included these expenses in research and development infrastructure. Research and development laboratory expenses are also not allocated to a specific program and are included in research and development infrastructure. Engineering activities related to INOpulse and the manufacture of cylinders related to INOpulse are included in INOpulse engineering.

INOpulse for PAH

We completed a randomized, placebo-controlled, double-blind Phase 2 clinical trial of INOpulse for PAH in October 2014. The goal of the trial was to determine the safety, tolerability and efficacy of two different doses of INOpulse for PAH. In February 2016, we performed the final analysis of our Phase 2 long-term extension clinical trial of INOpulse for PAH, which is Part 2 of our Phase 2 clinical trial of INOpulse for PAH, which reinforced the results from Part 1 of our Phase 2 clinical trial of INOpulse for PAH. After reaching agreement with the FDA and the EMA on our Phase 3 protocol, we are moving forward with Phase 3 development.

INOpulse for PH-COPD

We completed a randomized, placebo-controlled, double-blind, dose-confirmation Phase 2 clinical trial of INOpulse for PH-COPD in July 2014. We have received results from this trial, and we are planning further Phase 2 testing in 2016 to demonstrate the potential benefit of INOpulse on exercise capacity.

INOpulse for PH-IPF

We also plan to initiate our Phase 2 studies in PH-IPF in 2016 consisting of an exploratory acute hemodynamic study followed by exercise capacity.

BCM

We initiated a clinical trial of BCM, which we refer to as our PRESERVATION I trial, in December 2011, enrolled the first patient in April 2012 and completed enrollment in December 2014. Top-line results from the randomized, double-blind, placebo-controlled clinical trial were announced in July 2015. From a safety perspective we observed no significant difference in adverse events rates between patients in the BCM and placebo treatment groups. However, the data showed no statistically significant treatment differences between patients treated with BCM and patients treated with placebo for both the primary and secondary endpoints in the trial. We presented detailed results from the PRESERVATION I trial for our BCM program at the European Society of Cardiology meeting in London on September 1, 2015. Following the results, we are considering further exploratory work but we do not intend to proceed with further clinical development of BCM at this point until and unless we can determine an alternative path forward.

Research and Development Infrastructure

We invest in regulatory, quality, clinical development and clinical operations activities, which are expensed as incurred. These activities primarily support our clinical development programs.

INOpulse Engineering

We have invested a significant amount of funds in INOpulse, which is configured to be highly portable and compatible with available modes of long-term oxygen therapy via nasal cannula delivery. Our Phase 2 clinical trials of INOpulse for PAH and INOpulse for PH-COPD utilized the first generation INOpulse DS device. We believe our second generation INOpulse device, as well as a custom triple-lumen cannula, will significantly improve several characteristics of our INOpulse delivery system. We have also invested in design and engineering technology, through Ikaria, for the manufacture of our drug cartridges. In February 2015, we entered into an agreement with Flextronics Medical Sales and Marketing Ltd., a subsidiary of Flextronics International Ltd., or Flextronics, to manufacture and service the INOpulse devices that we will use in future clinical trials of INOpulse for PAH and INOpulse for PH-COPD and PH-IPF.

It is difficult to determine with certainty the duration and completion costs of our current or any future pre-clinical programs and any of our current or future clinical trials and any future product candidates we may advance, or if, when or to what extent we will generate revenue from the commercialization and sale of any of our product candidates that obtain regulatory approval. We may never succeed in achieving regulatory approval for any of our product candidates. The duration, costs and timing of clinical trials and development of our product candidates will depend on a variety of factors, including the uncertainties of any future clinical trials and pre-clinical studies, uncertainties in clinical trial enrollment rate and significant and changing government regulation. In addition, the probability of success for each product candidate will depend on numerous factors, including competition, manufacturing capability and commercial viability. A change in the outcome of any of these variables with respect to the development of a product candidate could change significantly the costs and timing associated with the development of that product candidate. For example, if the FDA or other regulatory authority were to require us to conduct clinical trials beyond those that we currently anticipate will be required for the completion of clinical development of a product candidate, or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time with respect to the development of that product candidate. We will determine which programs to pursue and how much to fund each program in response to the scientific and clinical success of each product candidate, as well as an assessment of each product candidate's commercial potential, including the likelihood of regulatory approval on a timely basis.

General and Administrative Expenses

General and administrative expenses consist principally of salaries and costs related to executive, finance, business development, marketing, legal and human resources functions, either through direct expenses or the TSA. Other general and administrative expenses include patent filing, patent prosecution, professional fees for legal, insurance, consulting, information technology and auditing and tax services not otherwise included in research and development expenses.

We believe that the following factors, among others, will affect the amount of our general and administrative expenses in the future:

- we expect to incur reduced general and administrative expenses following the completion of the Restructuring;
- we expect to incur reduced general and administrative expenses previously paid to Ikaria following the expiration of the TSA and the 2015 Services Agreement, in each case on September 30, 2015; and
- we expect to incur additional general and administrative expenses to replace services previously provided to us by Ikaria under the TSA such as accounting and financial management support, human resources support, drug and device safety services, biometrics support, information technology services and manufacturing and device servicing support.

Results of Operations

Comparison of Years Ended December 31, 2015 and 2014

The following table summarizes our results of operations for the years ended December 31, 2015 and 2014, together with the changes in these items in dollars and as a percentage.

(Dollar amounts in thousands)	Year Ended December 31, 2015	2014	$ Change	% Change
Research and development expenses:				
BCM	$ 8,154	$ 13,660	$ (5,506)	(40)%
PAH	10,678	11,319	(641)	(6)%
PH-COPD	(28)	3,026	(3,054)	(100)%
Clinical programs	18,804	28,005	(9,201)	(33)%
Research and development infrastructure	8,564	11,675	(3,111)	(27)%
INOpulse engineering	5,997	6,298	(301)	(5)%
Total research and development expenses	33,365	45,978	(12,613)	(27)%
General and administrative	14,870	13,775	1,095	8 %
Total operating expenses	48,235	59,753	(11,518)	(19)%
Other operating income	(1,667)	—	(1,667)	n.a.
Loss from operations	(46,568)	(59,753)	13,185	(22)%
Interest income	(109)	(79)	(30)	38 %
Net loss and comprehensive loss	$ (46,459)	$ (59,674)	$ 13,215	(22)%

Total Operating Expenses. Total operating expenses for the year ended December 31, 2015 were $48.2 million compared to $59.8 million for the year ended December 31, 2014, a decrease of $11.6 million, or 19%. This decrease was primarily due to reductions in research and development expenses pertaining to our BCM and INOpulse for PH-COPD programs and to a decrease in research and development infrastructure expenses.

Research and Development Expenses. Total research and development expenses for the year ended December 31, 2015 were $33.4 million compared to $46.0 million for the year ended December 31, 2014, a decrease of $12.6 million, or 27%. Total research and development expenses consisted of the following:

- BCM research and development expenses for the year ended December 31, 2015 were $8.2 million compared to $13.7 million for the year ended December 31, 2014, a decrease of $5.5 million, or 40%. The decrease was primarily due to us ceasing further clinical development of BCM following the PRESERVATION I results.

- PAH research and development expenses for the year ended December 31, 2015 were $10.7 million compared to $11.3 million for the year ended December 31, 2014, a decrease of $0.6 million, or 6%. The decrease was primarily due to the completion of the Phase 2 clinical trial in late-2014 and a reversal of an accrual in the year ended December 31, 2015 partially offset by increased costs in anticipation of the start of the Phase 3 clinical trials.

- PH-COPD research and development expenses for the year ended December 31, 2015 were $0.0 million compared to $3.0 million for the year ended December 31, 2014, a decrease of $3.0 million, or 100%. The decrease primarily resulted from the completion of the Phase 2a clinical trial in mid-2014.

- Research and development infrastructure expenses for the year ended December 31, 2015 were $8.6 million compared to $11.7 million for the year ended December 31, 2014, a decrease of $3.1 million, or 27%. The decrease was due to reductions in infrastructure spending to support our INOpulse and BCM clinical programs and the discontinuance of cash bonuses. In September 2015, we decided to pay 2015 bonuses by granting employees restricted stock awards which will vest over a one-year period from the date of grant. Accordingly, the related cost will be recognized over such period.

- INOpulse engineering expenses for the year ended December 31, 2015 were $6.0 million compared to $6.3 million for the year ended December 31, 2014, a decrease of $0.3 million, or 5%.

General and Administrative Expenses. General and administrative expenses for the year ended December 31, 2015 were $14.9 million compared to $13.8 million for the year ended December 31, 2014, an increase of $1.1 million, or 8%. The increase was primarily due to restructuring charges of $1.1 million and additional costs of operating as a public company, including expenses related to transition services from Ikaria and other professional services offset, in part, by the discontinuance of cash bonuses. In September 2015, we decided to pay 2015 bonuses by granting employees restricted stock awards which will vest over a one-year period from the date of grant. Accordingly, the related cost will be recognized over such period.

Other Operating Income. Other operating income for the year ended December 31, 2015 was $1.7 million, and we had no operating income for the year ended December 31, 2014. The increase resulted from payments received from Ikaria in connection with entering into the 2015 Services Agreement.

Comparison of Years Ended December 31, 2014 and 2013

The following table summarizes our results of operations for the years ended December 31, 2014 and 2013, together with the changes in these items in dollars and as a percentage.

	Year Ended December 31,			
(Dollar amounts in thousands)	**2014**	**2013**	**$ Change**	**% Change**
Research and development expenses:				
BCM	$ 13,660	$ 17,266	$ (3,606)	(21)%
PAH	11,319	8,099	3,220	40
PH-COPD	3,026	8,420	(5,394)	(64)
Clinical programs	28,005	33,785	(5,780)	(17)
Research and development infrastructure	11,675	14,000	(2,325)	(17)
INOpulse engineering	6,298	5,200	1,098	21
Total research and development expenses	45,978	52,985	(7,007)	(13)
General and administrative	13,775	9,013	4,762	53
Total operating expenses	59,753	61,998	(2,245)	(4)
Interest income	$ (79)	$ —	(79)	n.a.
Net loss and comprehensive loss	$ (59,674)	$ (61,998)	$ 2,324	(4)%

Total Operating Expenses. Total operating expenses for the year ended December 31, 2014 were $59.8 million compared to $62.0 million for the year ended December 31, 2013, a decrease of $2.2 million, or 4%. This decrease was primarily due to reductions in research and development expenses pertaining to our BCM and INOpulse for PH-COPD programs and to decreased research and development infrastructure expenses, partially offset by increases in general and administrative expenses, research and development expenses pertaining to INOpulse for PAH and INOpulse engineering expenses.

Research and Development Expenses. Total research and development expenses for the year ended December 31, 2014 were $46.0 million compared to $53.0 million for the year ended December 31, 2013, a decrease of $7.0 million, or 13%. Total research and development expenses consisted of the following:

- BCM research and development expenses for the year ended December 31, 2014 were $13.7 million compared to $17.3 million for the year ended December 31, 2013, a decrease of $3.6 million, or 21%. The decrease primarily resulted from the effect of certain non-recurring manufacturing costs in the 2013 period, as well as a decrease in the pre-clinical activities that we conducted with respect to BCM during the year ended December 31, 2014. This decrease was partially offset by an increase in clinical trial costs as a result of an increase in patient enrollments in the year ended December 31, 2014 as compared to the prior year period.

- PAH research and development expenses for the year ended December 31, 2014 were $11.3 million compared to $8.1 million for the year ended December 31, 2013, an increase of $3.2 million, or 40%. The increase was primarily due to higher clinical trial expenses in the year ended December 31, 2014, driven by higher patient enrollment costs as compared to the prior year period, as well as increased spending in respect of development of the INOpulse device in preparation for our anticipated Phase 3 clinical trial.

- PH-COPD research and development expenses for the year ended December 31, 2014 were $3.0 million compared to $8.4 million for the year ended December 31, 2013, a decrease of $5.4 million, or 64%. The decrease primarily resulted from lower dosing trial costs as a result of the completion of our Phase 2 clinical trial.

- Research and development infrastructure expenses for the year ended December 31, 2014 were $11.7 million compared to $14.0 million for the year ended December 31, 2013, a decrease of $2.3 million, or 17%. The decrease was primarily the result of reductions in headcount in connection with managing staffing needs to support our INOpulse and BCM clinical programs.

- INOpulse engineering expenses for the year ended December 31, 2014 were $6.3 million compared to $5.2 million for the year ended December 31, 2013, an increase of $1.1 million, or 21%. The increase was primarily due to increases in development costs as we transitioned from the INOpulse DS device to the newer INOpulse device.

General and Administrative Expenses. General and administrative expenses for the year ended December 31, 2014 were $13.8 million compared to $9.0 million for the year ended December 31, 2013, an increase of $4.8 million, or 53%. The increase was primarily due to the incremental costs of operating as a stand-alone entity, including professional service fees, executive search costs, the payment of certain retention bonuses and information technology expenditures.

Liquidity and Capital Resources

In the course of our development activities, we have sustained operating losses and expect such losses to continue over the next several years.

We had cash and cash equivalents of $6.3 million and marketable securities of $17.8 million as of December 31, 2015. We received net proceeds of $51.9 million in February 2015 as a result of the IPO, after deducting underwriting discounts and commissions of $4.2 million and offering costs of $3.9 million.

We expect to continue to incur significant expenses and operating losses for the foreseeable future as we continue the development and clinical trials of, and seek regulatory approval for, our product candidates. Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, third-party clinical research and development services, contract manufacturing services, laboratory and related supplies, clinical costs, legal and other regulatory expenses and general overhead costs.

If we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses. We do not currently have the infrastructure for the sale, marketing, manufacture or distribution of any products. To develop a commercial infrastructure, we will have to invest financial and management resources, some of which would have to be deployed prior to having any certainty of marketing approval.

Our existing cash and cash equivalents and marketable securities of $24.1 million as of December 31, 2015 will be used primarily to fund the first of two INOpulse for PAH Phase 3 trials, in which we expect to enroll the first patient in the first half of 2016. In addition, as of December 31, 2015, we had $11.3 million prepayments of research and development expenses related to our amended drug supply agreement with Ikaria and the clinical research organization we have partnered with for the first of the two Phase 3 clinical trials for INOpulse for PAH. We believe, as of December 31, 2015, we have sufficient funds to satisfy our operating cash needs for at least the next 12 months due in part to the Restructuring and other cost saving initiatives.

We expect these funds, combined with additional funding anticipated from Global Corporate Finance, or GCF, will be sufficient to complete the first of two PAH Phase 3 trials. During December 2015, we entered into a letter agreement with GCF. In accordance with the terms of the letter agreement, we have agreed to place with GCF up $20 million of our common stock subject to the execution of a definitive share purchase agreement and registration rights agreement. We may not draw down amounts that would result in GCF owning more than 19.9% of our outstanding shares. The first two draw downs under this letter agreement may not exceed $2 million. Thereafter, the draw down amounts will depend on the average daily trading volume of our shares.

We have based our estimates on assumptions that may prove to be wrong, and we may exhaust our capital resources sooner than we expect. In addition, the process of testing product candidates in clinical trials is costly, and the timing of progress in clinical trials is uncertain. Because our product candidates are in clinical development and the outcome of these efforts is uncertain, we cannot estimate the actual amounts that will be necessary to successfully complete the development and commercialization of our product candidates or whether, or when, we may achieve profitability. Our future capital requirements will depend on many factors, including:

- the timing, progress and results of our ongoing and planned clinical trials of INOpulse for PAH, PH-COPD and PH-IPF;
- our ability to manufacture sufficient supply of our product candidates and the costs thereof;
- discussions with regulatory agencies regarding the design and conduct of our clinical trials and the costs, timing and outcome of regulatory review of our product candidates;

- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution for any of our product candidates for which we receive marketing approval;
- the number and development requirements of any other product candidates we pursue;
- our ability to enter into collaborative agreements and achieve milestones under those agreements;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- our expenses as a stand-alone company; and
- the extent to which we acquire or in-license other products and technologies.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity and debt offerings, existing working capital and funding from potential future collaboration arrangements. To the extent that we raise additional capital through the future sale of equity or debt, the ownership interest of our existing stockholders will be diluted, and the terms of such securities may include liquidation or other preferences or rights such as anti-dilution rights that adversely affect the rights of our existing stockholders. If we raise additional funds through strategic partnerships in the future, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Cash Flows

The following table summarizes our cash flows for the years ended December 31, 2015, 2014 and 2013:

	Year Ended December 31,		
(Dollar amounts in thousands)	**2015**	**2014**	**2013**
Operating activities	$ (46,264)	$ (70,562)	$ (57,231)
Investing activities	(18,305)	—	(727)
Financing activities	54,014	87,377	57,958
Net change in cash and cash equivalents	$ (10,555)	$ 16,815	$ —

Net Cash Used in Operating Activities

Cash used in operating activities for the year ended December 31, 2015 was $46.3 million compared to $70.6 million for the year ended December 31, 2014, a decrease of $24.3 million, or 34%. The decrease in cash used in operating activities was primarily due to reduced research and development expenses and the recognition in the year ended December 31, 2014 of the $10.8 million restricted cash balance related to the escrow payment due to Ikaria, which was utilized to pay Ikaria during 2015, offset in part by a $6.6 million prepayment made to Ikaria as part of amending our drug supply agreement and an $8.0 million prepayment made to the clinical research organization we have partnered with for the first of two Phase 3 clinical trials for INOpulse for PAH.

Cash used in operating activities for the year ended December 31, 2014 was $70.6 million compared to $57.2 million for the year ended December 31, 2013, an increase of $13.4 million, or 23%. The increase in cash used in operating activities was primarily due to the deposit of escrowed cash in connection with the TSA.

Net Cash Used in Investing Activities

Cash used in investing activities for the year ended December 31, 2015 was $18.3 million, including $0.5 million for capital expenditures related to our new office space in Warren, New Jersey and $22.7 million for the purchase of marketable securities, offset by $4.9 million of proceeds from the sale of marketable securities. There were no cash flows from investing activities for the year ended December 31, 2014.

Cash used in investing activities for the year ended December 31, 2013 was $0.7 million of capital expenditures.

Net Cash Provided by Financing Activities

Cash provided by financing activities for the year ended December 31, 2015 was $54.0 million compared to $87.4 million for the year ended December 31, 2014, a decrease of $33.4 million, or 38%. The decrease resulted from the difference between the $53.8 million net proceeds from our IPO in the year ended December 31, 2015, after deducting underwriting discounts and commissions of $4.2 million and offering costs of $2.0 million paid, compared to the $89.3 million net investment by Ikaria, primarily due to a cash contribution of $80.0 million from Ikaria in the year ended December 31, 2014 in connection with the Spin-Out.

Cash provided by financing activities for the year ended December 31, 2014 was $87.4 million compared to $58.0 million for the year ended December 31, 2013, an increase of $29.4 million, or 51%. The increase was primarily due to a cash contribution of $80.0 million from Ikaria in connection with the Spin-Out.

Contractual Obligations and Commitments

The following is a summary of our long-term contractual cash obligations as of December 31, 2015 (in thousands):

	Payments Due by Period ($)				
Contractual Obligations	**Total**	**Less than 1 year**	**1 to 3 years**	**3 to 5 years**	**More than 5 years**
Operating Lease Obligations(1)	$ 4,533	$ 413	$ 1,272	$ 1,316	$ 1,532
Flextronics Agreement(2)	324	324	—	—	—
Total	$ 4,857	$ 737	$ 1,272	$ 1,316	$ 1,532

(1) Operating lease obligations include the lease agreement we entered into on August 6, 2015 for office space in Warren, New Jersey and our lease of an operating facility located in North Brunswick, New Jersey.

(2) On March 25, 2015, we entered into an agreement with Flextronics to manufacture and service the INOpulse devices that we expect to use in future clinical trials of INOpulse for PAH and INOpulse for PH-COPD. Under the agreement, we have committed to purchase devices.

Royalty payments and success-based milestones associated with our license and supply agreements with Ikaria and have not been included in the above table of contractual obligations as we cannot reasonably estimate if or when they will occur.

We do not intend to proceed with further clinical development of BCM until and unless we can determine an alternative path forward. Consequently, any future royalty and milestones payments to BioLine would depend on finding a path forward for future clinical development. Under the terms of the license agreement, if we achieve certain clinical and regulatory events specified in the license agreement, we will be obligated to pay milestone payments to BioLine, which could total, in the aggregate, up to $115.5 million, and if we achieve certain commercialization targets specified in the license agreement, we will be obligated to pay additional milestone payments to BioLine, which could total, in the aggregate, up to $150.0 million. In addition, we will be obligated to pay BioLine a specified percentage of any upfront consideration we receive for sublicensing BCM, as well as royalties on net sales, if any, at a percentage ranging from 11% to 15%, depending on net sales level, of any approved product containing BCM, subject to offsets for specified payments to third parties made in connection with BCM. We have reimbursed BioLine for certain legal fees in the amount of $250,000 following completion of our IPO.

In the course of our normal business operations, we also enter into agreements with contract service providers and others to assist in the performance of our research and development and manufacturing activities. We can elect to discontinue the work under these contracts and purchase orders at any time with notice, and such contracts and purchase orders do not contain minimum purchase obligations.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under applicable Securities and Exchange Commission rules.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to research and development expense, impairment of long-lived assets, stock-based compensation and income taxes. We base our estimates on historical experience, known trends and events and various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

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

Research and Development Expense

Research and development costs are expensed as incurred. These expenses include the costs of our proprietary research and development efforts, as well as costs incurred in connection with certain licensing arrangements. Upfront and milestone payments made to third parties in connection with research and development collaborations are expensed as incurred up to the point of regulatory approval. Payments made to third parties upon or subsequent to regulatory approval are capitalized and amortized over the remaining useful life of the related product. We also expense the cost of purchased technology and equipment in the period of purchase if we believe that the technology or equipment has not demonstrated technological feasibility and does not have an alternative future use. Nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities are deferred and are recognized as research and development expense as the related goods are delivered or the related services are performed.

As part of the process of preparing our financial statements, we are required to estimate a portion of our accrued research expenses. This process involves reviewing open contracts and purchase orders, communicating with 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. We make such estimates of our incurred research and development expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. Examples of estimated accrued research and development expenses include:

- fees paid to contract research organizations in connection with clinical trials;
- fees paid to investigative sites in connection with clinical trials; and
- fees paid to contract manufacturers in connection with the production of clinical trial materials.

We base our expenses related to research and development and clinical trials on actual costs incurred in addition to our estimates of the services received and efforts expended pursuant to contracts with multiple third parties, including research institutions and contract research organizations that conduct and manage clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing the research and development service fees, we consider the terms of each agreement, the time period over which the services will be performed and the level of effort required to complete the service. If the actual timing of the performance of the services or the level of effort varies from our estimate, we adjust the accrual accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, 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 us reporting amounts that are too high or too low in any particular period.

Stock-Based Compensation

We issue, and prior to the Spin-Out Ikaria, our former parent, issued, stock-based awards to employees and non-employees in the form of stock options, restricted stock awards, or RSAs, and restricted stock units, or RSUs. The stock-based compensation expense recorded for the periods prior to the Spin-Out presented in our audited financial statements, included elsewhere in this Annual Report on Form 10-K, represents an allocation of Ikaria's stock-based compensation expense based on the allocation percentages of our cost centers, which were determined based on specific identification or the proportionate percentage of employee time or headcount to the respective total Ikaria employee time or headcount. Because certain of these amounts relate to Ikaria stock-based awards, the amounts presented are not necessarily indicative of our future performance and do not necessarily reflect the stock-based compensation or compensation expense that we would have experienced as a stand-alone company for these periods.

We account for our stock-based compensation in accordance with Accounting Standards Codification, or ASC, 718 *Compensation- Stock Compensation*, which establishes accounting for share-based awards, including stock options and restricted stock, exchanged for services and requires companies to expense the estimated fair value of these awards over the requisite service period. We recognize stock-based compensation expense in operations based on the fair value of the award on the date of the grant. The resulting compensation expense is recognized on a straight-line basis over the requisite service period or sooner if the awards immediately vest.

Determining the appropriate fair value of stock-based awards requires the input of subjective assumptions, including the fair value of our units and, for options, the expected term of the option and expected volatility. We use the Black-Scholes-Merton option pricing model to value our stock option awards. The assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment. As a result, if factors change and management uses different assumptions, stock-based compensation expense could be materially different for future awards. The expected term of stock options is estimated using the "simplified method," as we have no historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior for our stock options grants. The simplified method is based on the average of the vesting tranches and the contractual life of each grant. For volatility, we use comparable public companies as a basis for our expected volatility to calculate the fair value of option grants due to our limited history as a public company. The risk-free interest rate is based on U.S. Treasury notes with a term approximating the expected term of the option. For restricted stock, the fair value is the closing market price per share on the grant date. The estimation of the number of stock awards that will ultimately vest requires judgment, and to the extent actual results or updated estimates differ from our current estimates, such amounts will be recorded as an adjustment in the period in which estimates are revised.

The weighted average grant-date fair value of options issued during the year ended December 31, 2015 and 2014 was $6.55 and $9.98, respectively. The following are the weighted average assumptions used in estimating the fair value of options issued during the years ended December 31, 2015 and 2014.

	Year Ended December 31, 2015	Year Ended December 31, 2014
Valuation assumptions:		
Risk-free interest rate	1.60%	1.71%
Expected volatility	79.18%	90.00%
Expected term (in years)	6.1	6.1
Dividend yield	—%	—%

For the period presented prior to the Spin-Out, the weighted average grant date fair value of stock options granted to employees and directors of Ikaria and the weighted average assumptions used by Ikaria to estimate the grant date fair value of the options using the Black-Scholes-Merton option pricing model were:

	2013
Weighted average grant date fair value	$ 1.95
Valuation assumptions:	
Risk-free interest rate	0.90%
Expected volatility	46.5%
Expected term (in years)	5.0
Expected dividend yield	—%

There were no Ikaria options issued during the period from January 1, 2014 through February 11, 2014.

Ikaria has historically granted its stock options at exercise prices not less than the fair value of its common stock. Ikaria was a private company with no active public market for its common stock. Therefore, its board of directors periodically determined for financial reporting purposes the estimated fair value of its common stock using valuations performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants Practice Aid, *Valuation of Privately Held Company Equity Securities Issued as Compensation* , also known as the Practice Aid.

The compensation expense for the RSUs was based on the grant date fair value of the RSU, which was based on the fair value of the underlying stock.

In February 2014, prior to the Spin-Out, each Ikaria stock option, other than options held by non-accredited investors who were also not employees of Ikaria, was adjusted such that it became an option to acquire the same number of shares of Ikaria non-voting common stock as were subject to the Ikaria stock option, or an Adjusted Ikaria Option, and an option to acquire the same number of our non-voting limited liability company units as the number of shares of Ikaria non-voting common stock that were subject to the Ikaria stock option, or a Bellerophon Option. There were 618,212 Bellerophon Options issued as a result of the adjustment of Ikaria stock options. The vesting of each Adjusted Ikaria Option and Bellerophon Option was fully accelerated on the date of the Spin-Out and all related compensation expense was recognized as an expense by Ikaria.

Prior to and in connection with the Spin-Out, the exercise price of each Adjusted Ikaria Option and Bellerophon Option was adjusted by allocating the relative post Spin-Out estimated fair values of Ikaria and us in a ratio of 85% and 15%, respectively, to the original Ikaria option exercise price. The expiration date of the options was not modified.

On June 20, 2014, following the Spin-Out, we granted options to purchase 514,266 of our non-voting units with an exercise price of $13.28 per non-voting unit. As we were a private company with no active public market for our equity securities at the time, the estimated fair value of one of our non-voting units as of June 20, 2014, was determined by our board of directors to be $13.28. In making this determination, our board of directors used a contemporaneous valuation based on the income approach, performed in accordance with the guidance enumerated in the Practice Aid. For the income approach, we used the discounted cash flow method to estimate the present value of the future monetary benefits expected to flow to the owners of the business. The contemporaneous valuation also considered factors enumerated in Revenue Ruling 59-60, which serves as a general guideline for the valuation of closely held securities. In addition, we considered all objective and subjective factors that we believe to be relevant to such valuation, including our best estimate of our business condition, prospects and operating performance at the valuation date. Within the contemporaneous valuation performed, a range of factors and assumptions were used. The significant factors, many of them complex and highly subjective, included:

- estimates of our future cash flows and the appropriate discount rate;
- the nature and history of our business enterprise;
- the assessment of key value drivers for our business enterprise;
- the economic outlook in general and the condition and outlook of our industry in particular;
- the financial condition of our business and the book value of our equity interests;
- the likelihood of our achieving a liquidity event; and
- prior sales of equity interests of companies engaged in the same or similar lines of business that have their stocks actively traded in a free and open market.

During the year ended December 31, 2014, we adopted the 2014 Equity Incentive Plan, or the 2014 Plan, which provides for the grant of options. Following the effectiveness of our registration statement filed in connection with our IPO, no options may be granted under the 2014 Plan. During the year ended December 31, 2015, we adopted the 2015 Equity Incentive Plan, or the 2015 Plan, which provides for the grant of options, restricted stock and other forms of equity compensation.

Since our IPO, the exercise price per share of all option grants has been set at the closing price of our common stock on the NASDAQ Global Market on the applicable date of grant.

The compensation expense for the RSAs was based on the grant date fair value of the RSA, which was based on the fair value of the underlying stock.

For the years ended December 31, 2015, 2014 and 2013, we recorded stock-based expenses as follows:

	Year Ended December 31,		
(in thousands)	**2015**	**2014**	**2013**
Research and development	$ 364	$ 271	$ 1,120
General and administrative	1,387	1,568	601
Total expense	$ 1,751	$ 1,839	$ 1,721

Recently Adopted Accounting Standards

In August 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, 2014-15, "*Presentation of Financial Statements - Going Concern: Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*". This guidance clarifies that an entity's management should evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued. The amendments in this update are effective for annual reporting periods ending after December 15, 2016, and annual and interim periods thereafter, and early application is permitted. We are assessing ASU 2014-15's impact and will adopt it when effective.

On May 28, 2014, the FASB issued ASU 2014-09, "*Revenue from Contracts with Customers*", which requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. The ASU will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective. The new standard is effective for us on January 1, 2018. The standard permits the use of either the retrospective or cumulative effect transition method. We are assessing ASU 2014-09's impact and will adopt it when effective.

In February 2016, the FASB issued ASU 2016-02, *"Leases"*, which is intended to improve financial reporting about leasing transactions. This standard requires a lessee to record on the balance sheet the assets and liabilities for the rights and obligations created by lease terms of more than 12 months. This standard will be effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. We are currently evaluating the impact the adoption of ASU 2016-02 will have on the consolidated financial position, results of operations or cash flows.

JOBS Act

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. We will remain an emerging growth company until the earlier of: (i) the last day of the fiscal year in which we have total annual gross revenues of $1 billion or more; (ii) December 31, 2020; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC, which means the first day of the year following the first year in which the market value of our common stock that is held by non-affiliates exceeds $700 million as of June 30. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002;
- not being required to comply with 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;

- reduced disclosure obligations regarding executive compensation; and

- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We may choose to take advantage of some, but not all, of the available exemptions. We have taken advantage of reduced reporting burdens in this Annual Report on Form 10-K. In particular, we have not included all of the executive compensation information that would be required if we were not an emerging growth company. We cannot predict whether investors will find our common stock less attractive if we rely on certain or all of these exemptions. 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, the JOBS Act provides that an emerging growth company may take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we are subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to market risk related to changes in interest rates. As of December 31, 2015, we had cash and cash equivalents of $6.3 million, consisting primarily of demand deposits with U.S. banking institutions and marketable securities of approximately $17.8 million. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in cash and cash equivalents, federally insured certificates of deposit and corporate or agency bonds rated A or better. Due to the nature of our deposits and the low risk profile of our investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our deposits.

Item 8. Financial Statements and Supplementary Data

Index to Financial Statements

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
Bellerophon Therapeutics, Inc.:

We have audited the accompanying consolidated balance sheets of Bellerophon Therapeutics, Inc. (formerly Bellerophon Therapeutics LLC) and subsidiaries as of December 31, 2015 and 2014, and the related consolidated statements of operations, comprehensive loss, changes in stockholders'/members' equity and invested equity (deficit) and cash flows for each of the years in the three-year period ended December 31, 2015. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Bellerophon Therapeutics, Inc. and subsidiaries as of December 31, 2015 and 2014, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2015, in conformity with U.S. generally accepted accounting principles.

/s/ KPMG LLP

Short Hills, New Jersey
March 21, 2016

BELLEROPHON THERAPEUTICS, INC.

Consolidated Balance Sheets

(Amounts in thousands, except share/unit and per share data)

	December 31, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$ 6,260	$ 16,815
Restricted cash	—	9,264
Marketable securities	17,807	—
Prepaid expenses and other current assets	5,385	1,602
Total current assets	29,452	27,681
Restricted cash, non-current	457	1,548
Deferred transaction costs	—	2,466
Other non-current assets	6,701	—
Property and equipment, net	1,799	1,696
Total assets	$ 38,409	$ 33,391
Liabilities and Stockholders' / Members' Equity		
Current liabilities:		
Accounts payable	$ 1,613	$ 376
Accrued research and development	2,825	6,666
Accrued expenses	3,487	2,751
Due to Ikaria, Inc.	148	661
Total current liabilities	8,073	10,454
Total liabilities	8,073	10,454
Commitments and contingencies (Note 9)		
Stockholders' / members' equity:		
Common stock, $0.01 par value per share; 125,000,000 shares authorized, 13,130,800 shares issued and outstanding at December 31, 2015	131	—
Preferred stock, $0.01 par value per share; 5,000,000 share authorized, zero shares issued and outstanding at December 31, 2015	—	—
Additional paid-in capital	130,902	—
Accumulated other comprehensive loss	(19)	—
Membership units, no par value per unit; 94,273,819 voting units authorized, 7,524,196 voting units issued and outstanding at December 31, 2014; 19,416,481 non-voting units authorized, 381,129 non-voting units issued and outstanding at December 31, 2014	—	77,156
Accumulated deficit	(100,678)	(54,219)
Total stockholders' / members' equity	30,336	22,937
Total liabilities and stockholders' / members' equity	$ 38,409	$ 33,391

The accompanying notes are an integral part of these consolidated financial statements.

BELLEROPHON THERAPEUTICS, INC.

Consolidated Statements of Operations

(Amounts in thousands, except share/unit and per share/unit data)

	Year Ended December 31,		
	2015	**2014**	**2013**
Operating expenses:			
Research and development	$ 33,365	$ 45,978	$ 52,985
General and administrative	14,870	13,775	9,013
Total operating expenses	48,235	59,753	61,998
Other operating income	1,667	—	—
Loss from operations	(46,568)	(59,753)	(61,998)
Interest income	109	79	—
Pre-tax loss	(46,459)	(59,674)	(61,998)
Income tax benefit (expense)	—	—	—
Net loss	$ (46,459)	$ (59,674)	$ (61,998)
Weighted average shares/units outstanding:			
Basic and diluted	12,267,693	7,898,289	
Net loss per share/unit:			
Basic and diluted	$ (3.79)	$ (7.56)	

The accompanying notes are an integral part of these consolidated financial statements.

BELLEROPHON THERAPEUTICS, INC.

Consolidated Statements of Comprehensive Loss
(in thousands)

	Year Ended December 31,		
	2015	**2014**	**2013**
Net loss	$ (46,459)	$ (59,674)	$ (61,998)
Other comprehensive loss			
Unrealized losses on available-for-sale marketable securities	$ (19)	$ —	$ —
Total other comprehensive loss	$ (19)	$ —	$ —
Comprehensive loss	$ (46,478)	$ (59,674)	$ (61,998)

The accompanying notes are an integral part of these consolidated financial statements.

BELLEROPHON THERAPEUTICS, INC.

Consolidated Statements of Changes in in Stockholders'/Members' Equity and Invested Equity (Deficit)

(Amounts in thousands except unit/share and per share data)

	Membership Units		Common Stock						Total Invested / Stockholders' / Members Equity
	Units	Amount	Shares	Amount	Additional Paid in Capital	Accumulated Other Comprehensive Loss	Investment by Ikaria, Inc.	Accumulated Deficit	
Balance December 31, 2013							$ 160,778	$ (176,515)	$ (15,737)
Net loss from January 1, 2014 through February 11, 2014, prior to Spin-Out							—	(5,455)	(5,455)
Investment by Ikaria, Inc., net prior to Spin-Out							7,547	—	7,547
Additional investment by Ikaria, Inc. for settlement of liabilities prior to Spin-Out							9,196	—	9,196
Balance February 11, 2014							$ 177,521	$ (181,970)	$ (4,449)
Contribution by Ikaria, Inc. of net assets to Bellerophon in connection with Spin-Out	7,899,251	$ 75,551					(177,521)	181,970	80,000
Net loss from February 12, 2014 through December 31, 2014	—	—					—	(54,219)	(54,219)
Stock-based compensation	—	1,568					—	—	1,568
Exercise of options	8,182	66					—	—	66
Repurchase of units	(2,108)	(29)					—	—	(29)
Balance at December 31, 2014	7,905,325	$ 77,156	—	$ —	$ —	$ —	$ —	$ (54,219)	$ 22,937
Net loss	—	—	—	—	—	—	—	(46,459)	(46,459)
Other comprehensive loss	—	—	—	—	—	(19)	—	—	(19)
Sale of membership units	67	1	—	—	—	—	—	—	1
Conversion of membership units into common stock in connection with conversion of LLC into a C-Corp.	(7,905,392)	(77,157)	7,905,392	79	77,078	—	—	—	—
Sale of common stock in initial public offering ($12.00 per share), net of underwriting discounts and commissions and offering expenses of $8,085	—	—	5,000,000	50	51,865	—	—	—	51,915
Common stock issued to Global Corporate Finance	—	—	8,000	—	24	—	—	—	24
Exercise of options	—	—	126,499	1	185	—	—	—	186
Stock-based compensation	—	—	90,909	1	1,750	—	—	—	1,751
Balance at December 31, 2015	—	$ —	13,130,800	$ 131	$ 130,902	$ (19)	$ —	$ (100,678)	$ 30,336

The accompanying notes are an integral part of these consolidated financial statements.

BELLEROPHON THERAPEUTICS, INC.

Consolidated Statements of Cash Flows

(Amounts in thousands)

	Year Ended December,		
	2015	**2014**	**2013**
Cash flows from operating activities:			
Net loss	$ (46,459)	$ (59,674)	$ (61,998)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	377	388	429
Stock-based compensation	1,751	1,839	1,721
Other items	45	—	149
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	(3,783)	(50)	94
Restricted cash held for Ikaria, Inc.	10,812	(10,812)	—
Restricted cash held as security deposit	(457)	—	—
Other non-current assets	(6,701)	—	—
Accounts payable, accrued research and development, accrued expenses and other liabilities	(1,336)	(2,914)	2,374
Amounts due to Ikaria, Inc.	(513)	661	—
Net cash used in operating activities	(46,264)	(70,562)	(57,231)
Cash flows from investing activities:			
Capital expenditures	(458)	—	(727)
Purchase of marketable securities	(22,757)	—	—
Proceeds from sale of marketable securities	4,910	—	—
Net cash used in investing activities	(18,305)	—	(727)
Cash flows from financing activities:			
Contribution from Ikaria, Inc. in connection with Spin-Out	—	80,000	—
Contributions from Ikaria, Inc., net	—	9,252	57,958
Transaction costs paid	—	(1,912)	—
Proceeds from sale of membership units	1	—	—
Proceeds received from exercise of options	186	66	—
Repurchase of units	—	(29)	—
Cash proceeds from issuance of common stock from initial public offering, net of issuance costs	53,827	—	—
Net cash provided by financing activities	54,014	87,377	57,958
Net change in cash and cash equivalents	(10,555)	16,815	—
Cash and cash equivalents at beginning of year	16,815	—	—
Cash and cash equivalents at end of year	$ 6,260	$ 16,815	$ —
Non-cash investing activities:			
Change in unrealized holding losses on marketable securities, net	$ (19)	$ —	$ —
Contribution of property, plant and equipment from Ikaria, Inc.	$ —	$ —	$ 83
Non-cash financing activities:			
Investment by Ikaria, Inc., net	$ —	$ 7,491	$ (581)

The accompanying notes are an integral part of these consolidated financial statements.

(1) Organization and Nature of the Business

Bellerophon Therapeutics, Inc., or the Company, is a clinical-stage therapeutics company focused on developing innovative products at the intersection of drugs and devices that address significant unmet medical needs in the treatment of cardiopulmonary diseases. The focus of the Company's clinical program is the continued development of its nitric oxide therapy for patients with pulmonary hypertension, or PH, using its proprietary delivery system, INOpulse, with pulmonary arterial hypertension, or PAH, representing the lead indication.

The Company's business is subject to significant risks and uncertainties, including but not limited to:

- The risk that the Company will not achieve success in its research and development efforts, including clinical trials conducted by it or its potential collaborative partners.
- The expectation that the Company will experience operating losses for the next several years.
- Decisions by regulatory authorities regarding whether and when to approve the Company's regulatory applications as well as their decisions regarding labeling and other matters which could affect the commercial potential of the Company's products or product candidates.
- The risk that the Company will fail to obtain adequate financing to meet its future operational and capital needs.
- The risk that key personnel will leave the Company and/or that the Company will be unable to recruit and retain senior level officers to manage its business.

The Company was formerly the research and development operating segment of Ikaria, Inc. (a subsidiary of Mallinckrodt plc), or Ikaria. During the third quarter of 2013 in conjunction with Ikaria's financing activities, Ikaria began reporting financial information for two operating segments: its research and development business and its commercial business. During the fourth quarter of 2013, Ikaria completed an internal reorganization of the assets and subsidiaries of its two operating segments. In connection with the internal reorganization, Ikaria formed Bellerophon Therapeutics LLC as a new wholly-owned subsidiary and transferred the research and development-related assets related to INOpulse for PAH and INOpulse for PH-COPD to the Company and/or its subsidiaries.

On December 24, 2013, Ikaria and Madison Dearborn Partners, or MDP, entered into an agreement and plan of merger, under which MDP would acquire a majority ownership position in Ikaria and existing shareholders retained a minority ownership position in Ikaria through certain merger transactions, or the Merger.

On February 12, 2014, prior to the Merger, Ikaria distributed all of the Company's outstanding units to Ikaria's stockholders in a pro rata distribution through a special dividend, which is referred to as the Spin-Out.

In the Spin-Out, each holder of Ikaria common stock received one voting limited liability company interest in the Company for each share of Ikaria common stock held.

On February 2, 2015, the Company effected a reverse unit split of its outstanding units at a ratio of one unit for every 12.5257 units previously held. All unit and per unit data included in these consolidated financial statements reflect the reverse unit split.

In February 2015, the Company converted from a limited liability company to a C-corporation. For periods prior to February 2015, references to the Company refer to Bellerophon Therapeutics, LLC.

In connection with the Spin-Out, $80.0 million of cash was distributed to the Company. At the time of the Spin-Out, $18.5 million of the $80.0 million cash held by the Company was deposited in escrow to guarantee payment of the monthly services fees payable by the Company to Ikaria in exchange for the services to be provided by Ikaria pursuant to the Company's transition services agreement with Ikaria, or the TSA, during the 24 months following the Spin-Out. See Note 8- *Related-Party Transactions*. On July 9, 2015, the Company entered into an amendment to the TSA advancing the termination date from February 9, 2016 to September 30, 2015. Pursuant to this amendment, during October 2015, the Company received from

escrow $3.3 million, which is equal to the amount it deposited to pay amounts owed to Ikaria under the TSA for the remainder of the original period.

On February 19, 2015, the Company completed the sale of 5,000,000 shares of common stock, or the IPO, at a price to the public of $12.00 per share, resulting in net proceeds to the Company of $51.9 million after deducting underwriting discounts and commissions of $4.2 million and offering costs of $3.9 million. The Company's common stock began trading on the NASDAQ Global Market under the symbol "BLPH" on February 13, 2015.

(2) Summary of Significant Accounting Policies

(a) Basis of Presentation

The financial statements have been prepared in accordance with U.S. generally accepted accounting principles or GAAP. Intercompany balances and transactions have been eliminated. For periods prior to the Spin-Out, the financial statements were carved out of the consolidated financial statements of Ikaria. Although the financial statements prior to the Spin-Out were prepared on a combined carve-out basis, the financial statements for all periods presented have been labeled "consolidated" financial statements for ease of reference since the most recent balance sheet at December 31, 2015 and 2014 are consolidated balance sheets. At the date of the Spin-Out, the historical accumulated deficit of approximately $182.0 million based on the carve-out financial statements through February 11, 2014 was eliminated in the transfer of net assets to the Company. The net loss for the period February 12, 2014 through December 31, 2014 of $54.2 million has been reflected as the accumulated deficit on the December 31, 2014 consolidated balance sheet, representing the net loss since the date of the Spin-Out. Net assets contributed to the Company in the Spin-Out were $75.6 million, including cash of $80.0 million. The results of operations and cash flows for the year ended December 31, 2015 and from February 12, 2014 through December 31, 2014 and the balance sheet as of December 31, 2015 and 2014 represent actual results and the financial position of the Company on a stand-alone basis. The Company operates in one reportable segment and solely within the United States. Accordingly, no segment or geographic information has been presented.

The preparation of financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of costs and expenses during the reporting period, including accrued research and development expenses, stock-based compensation, income taxes and valuation of long-lived assets. Actual results could differ from those estimates.

For periods prior to the Spin-Out, the financial statements were carved out of the consolidated financial statements of Ikaria. Management believes that the statements of operations for the periods prior to the Spin-Out (which include a period of forty-two days prior to the Spin-Out in the year ended December 31, 2014) include reasonable allocations of costs and expenses incurred by Ikaria which benefited the Company. However, such amounts may not be indicative of the actual level of costs and expenses that would have been incurred by the Company if it had operated as an independent stand-alone company or of the costs and expenses expected to be incurred in the future. As such, the financial information for the years ended December 31, 2014 and 2013 may not necessarily reflect the results of operations and cash flows of the Company had it been an independent stand-alone company for the period, or the results of operations and cash flows expected in the future.

Direct and indirect costs related to the Company for INOpulse for PAH, INOpulse for PH-COPD and BCM clinical programs have been allocated to the Company for periods prior to February 12, 2014. These allocations were based on either a specific identification basis or, when specific identification was not practicable, proportional cost allocation methods, such as time and wage studies, depending on the nature of the expense. All allocations were based on actual costs incurred. For purposes of allocating non-project specific expenses, each departmental head provided information as to the percentage of employee time incurred on behalf of the Company.

Allocations of general and administrative expenses by Ikaria to the Company for periods prior to February 12, 2014 include allocations of corporate management, finance, information technology, legal, human resources and other overhead expenses, based on an approximate pro-rata headcount of employees.

(b) Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity date of three months or less to be cash equivalents. All investments with maturities of greater than three months from date of purchase are classified as available-for-sale marketable securities.

(c) Restricted Cash

Restricted cash as of December 31, 2014 represents amounts previously held on deposit with a bank in relation to the TSA. The funds related to the TSA were held in an account to settle the required payment to Ikaria for services to be provided in connection with the TSA. Restricted cash as of December 31, 2015 represents amounts held on deposit with a bank as a security deposit for the lease of office space. The required deposits to be maintained in excess of one year from the balance sheet date are classified as long-term restricted cash.

(d) Property and Equipment

Property and equipment are recorded at acquisition cost, which for internally developed assets include labor, materials and overhead. Additions and improvements that increase the value or extend the life of an asset are capitalized. Repairs and maintenance costs are expensed as incurred.

Property and equipment are depreciated on a straight-line basis over the estimated useful lives (3-15 years) of the respective assets.

Leasehold improvements are capitalized and amortized over the lesser of the remaining life of the lease or the estimated useful life of the asset.

(e) Impairment of Long-Lived Assets

Long-lived assets, such as property, plant and equipment, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to estimated undiscounted expected future cash flows. If the carrying amount of an asset exceeds its estimated future cash flows, an impairment charge is recognized for the amount by which the carrying amount of the asset exceeds the fair value of the asset. Assets to be sold are no longer depreciated and are reclassified outside of property, plant and equipment at the lower of the carrying amount or fair value less costs to sell.

(f) Stock-Based Compensation

The Company accounts for its stock-based compensation in accordance with Accounting Standards Codification, or ASC, 718 *Compensation- Stock Compensation*, which establishes accounting for share-based awards, including stock options and restricted stock, exchanged for services and requires companies to expense the estimated fair value of these awards over the requisite service period. The Company recognizes stock-based compensation expense in operations based on the fair value of the award on the date of the grant. The resulting compensation expense is recognized on a straight-line basis over the requisite service period or sooner if the awards immediately vest. The Company determines the fair value of stock options issued using a Black-Scholes-Merton option pricing model. Certain assumptions used in the model include expected volatility, dividend yield, risk-free interest rate, and expected term. For restricted stock, the fair value is the closing market price per share on the grant date. See Note 7 - *Stock-Based Compensation* for a description of these assumptions.

Prior to the date of the Spin-Out, stock-based compensation expense for the Company represented an allocation of Ikaria's stock-based compensation expense based on the allocation percentages of the Company's cost centers, which were determined based on specific identification or the proportionate percentage of employee time or headcount to the respective total Ikaria employee time or headcount.

(g) Deferred Transaction Costs

Deferred transaction costs represent IPO-related costs primarily associated with third-party professional legal, accounting and printing fees associated with the IPO of the Company's shares. These IPO-related costs were deferred and charged against the gross proceeds of the offering when the public offering of equity securities was complete as a reduction of additional paid-in capital. As of December 31, 2015, the Company charged all deferred transaction costs against the gross proceeds of the offering.

(h) Income Taxes

Prior to its conversion to a Delaware corporation in February 2015, the Company was a Delaware limited liability company, or LLC, that passed through income and losses to its members for U.S. federal and state income tax purposes. As a result of its conversion to a Delaware corporation, the Company recognized deferred income taxes through income tax expense

related to temporary differences that existed as of the date of its tax status change. The Company uses the asset and liability approach to account for income taxes as required by ASC 740, *Income Taxes*, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Valuation allowances are provided when necessary to reduce deferred tax assets to the amount expected to be realized, on a more likely than not basis. The Company recognizes the benefit of an uncertain tax position that it has taken or expects to take on income tax returns it files if such tax position is more likely than not to be sustained on examination by the taxing authorities, based on the technical merits of the position. These tax benefits are measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate resolution.

As of the date of the conversion to a taxable corporation, the Company recognized approximately $17.9 million of deferred tax assets which consisted principally of excess tax-over-book basis in intangible assets and property, plant and equipment and certain accruals that were transferred from the limited liability company to the corporation. The Company also recognized a full valuation allowance since it had a cumulative loss position and no positive evidence of taxable income to support recovery of the deferred tax assets. The Company incurred transaction costs of approximately $8.1 million in connection with the IPO which were recorded as a reduction of equity. These costs are nondeductible until and if the Company liquidates or terminates, which is not expected in the foreseeable future. Therefore, the Company did not recognize a deferred tax asset for such costs.

(i) Marketable Securities

The Company's marketable securities consist of federally insured certificates of deposit classified as available-for-sale that are recorded at amortized cost, which approximates fair value, and corporate or agency bonds classified as available-for-sale that are recorded at fair value. Unrealized gains and losses are reported as accumulated other comprehensive (loss) income, except for losses from impairments which are determined to be other-than-temporary. Realized gains and losses, and declines in value judged to be other-than-temporary on available-for-sale securities are included in the determination of net loss and are included in interest income, at which time the average cost basis of these securities are adjusted to fair value. Fair values are based on quoted market prices at the reporting date. Interest on available-for-sale securities are included in interest income.

(j) Research and Development Expense

Research and development costs are expensed as incurred. These expenses include the costs of the Company's proprietary research and development efforts, as well as costs incurred in connection with certain licensing arrangements. Upfront and milestone payments made to third parties in connection with research and development collaborations are expensed as incurred up to the point of regulatory approval. Payments made to third parties upon or subsequent to regulatory approval are capitalized and amortized over the remaining useful life of the related product. The Company also expenses the cost of purchased technology and equipment in the period of purchase if it believes that the technology or equipment has not demonstrated technological feasibility and it does not have an alternative future use. Nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities are deferred and are recognized as research and development expense as the related goods are delivered or the related services are performed.

(k) Financial Instruments

The carrying amounts of cash and cash equivalents, restricted cash, prepaid expenses and other current assets and current liabilities approximate fair value due to the short-term maturity of these instruments.

(l) Reclassification

Certain prior period balances have been reclassified to conform to the current period presentation.

(m) New Accounting Pronouncements

In August 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, 2014-15, "*Presentation of Financial Statements - Going Concern: Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*". This guidance clarifies that an entity's management should evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued. The amendments in this update are effective for annual reporting periods ending after December 15, 2016, and annual and interim periods thereafter, and early application is permitted. The Company is assessing ASU 2014-15's impact and will adopt it when effective.

On May 28, 2014, the FASB issued ASU 2014-09, "*Revenue from Contracts with Customers*", which requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. The ASU will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective. The new standard is effective for the Company on January 1, 2018. The standard permits the use of either the retrospective or cumulative effect transition method. The Company is assessing ASU 2014-09's impact and will adopt it when effective.

In February 2016, the FASB issued ASU 2016-02, *"Leases"*, which is intended to improve financial reporting about leasing transactions. This standard requires a lessee to record on the balance sheet the assets and liabilities for the rights and obligations created by lease terms of more than 12 months. This standard will be effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. The Company is currently evaluating the impact the adoption of ASU 2016-02 will have on the consolidated financial position, results of operations or cash flows.

(3) Liquidity

In the course of its development activities, the Company has sustained operating losses and expects such losses to continue over the next several years.

The Company had cash and cash equivalents of $6.3 million and marketable securities of $17.8 million as of December 31, 2015. The Company received net proceeds of $51.9 million in February 2015 as a result of the IPO, after deducting underwriting discounts and commissions of $4.2 million and offering costs of $3.9 million.

The Company expects to continue to incur significant expenses and operating losses for the foreseeable future as it continues the development and clinical trials of, and seek regulatory approval for, its product candidates. The Company's primary uses of capital are, and it expects will continue to be, compensation and related expenses, third-party clinical research and development services, contract manufacturing services, laboratory and related supplies, clinical costs, legal and other regulatory expenses and general overhead costs.

The Company's existing cash and cash equivalents and marketable securities as of December 31, 2015 will be used primarily to fund the first of two INOpulse for PAH Phase 3 trials, in which the Company expects to enroll the first patient in the first half of 2016. In addition, as of December 31, 2015, the Company had $11.3 million prepayments of research and development expenses related to its amended drug supply agreement with Ikaria and the clinical research organization it has partnered with for the first of the two Phase 3 clinical trials for INOpulse for PAH. The Company believes, as of December 31, 2015, it has sufficient funds to satisfy its operating cash needs for at least the next 12 months due in part to the Restructuring and other cost saving initiatives.

The Company expects these funds, combined with additional funding anticipated from Global Corporate Finance, or GCF, will be sufficient to complete the first of two PAH Phase 3 trials. During December 2015, the Company entered into a letter agreement with GCF. In accordance with the terms of the letter agreement, the Company has agreed to place with GCF up to $20 million of its common stock subject to the execution of a definitive share purchase agreement and registration rights agreement. The Company may not draw down amounts that would result in GCF owning more than 19.9% of our outstanding shares. The first two draw downs under this letter agreement may not exceed $2 million. Thereafter, the draw down amounts will depend on the average daily trading volume of the Company's shares.

The Company's estimates and assumptions may prove to be wrong, and the Company may exhaust its capital resources sooner than expected. The process of testing product candidates in clinical trials is costly, and the timing of progress in clinical trials is uncertain. Because the Company's product candidates are in clinical development and the outcome of these efforts is uncertain, the Company cannot estimate the actual amounts that will be necessary to successfully complete the development and commercialization, if approved, of its product candidates or whether, or when, the Company may achieve profitability.

Until such time, if ever, as the Company can generate substantial product revenues, its expects to finance its cash needs through a combination of equity and debt offerings, existing working capital and funding from potential future collaboration arrangements. To the extent that the Company raises additional capital through the future sale of equity or debt, the ownership interest of its existing stockholders will be diluted, and the terms of such securities may include liquidation or other preferences or rights such as anti-dilution rights that adversely affect the rights of our existing stockholders. If the Company raises additional funds through strategic partnerships in the future, it may have to relinquish valuable rights to its technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to it. If the Company is unable to raise additional funds through equity or debt financings when needed, it may be required to delay, limit,

reduce or terminate its product development or future commercialization efforts or grant rights to develop and market product candidates that it would otherwise prefer to develop and market itself.

(4) Restructuring Charges

On July 27, 2015, the Company announced that its PRESERVATION I clinical trial for its BCM product candidate did not meet its primary or secondary endpoints. Following these results, on September 11, 2015, the Board of Directors of the Company approved a staff reduction plan in order to reduce operating expenses and conserve cash resources, or the Restructuring. The Restructuring included a workforce reduction of approximately 20 people and was completed by the end of 2015.

The Company has offered severance benefits to the affected employees, including cash severance payments. Each affected employee's eligibility for the severance benefits is contingent upon such employee's execution (and non-revocation) of a separation agreement, which includes a general release of claims against the Company.

The following table summarizes restructuring activities for the year ended December 31, 2015:

	Amounts (in thousands)
Accrual balance at December 31, 2014	$ —
Charged to research and development expense	321
Charged to general and administrative expense	1,053
Cash payments	(405)
Accrual balance at December 31, 2015[1]	$ 969

(1) Included under Accrued expenses

There were no restructuring activities in the years ended December 31, 2014 and 2013.

(5) Property and Equipment

At the date of the Spin-Out, Ikaria transferred specifically identified assets to the Company at the carrying amount of the assets as of February 12, 2014. Prior to the date of the Spin-Out, property, plant and equipment and accumulated depreciation were either specifically identified or allocated to the Company by Ikaria. Property and equipment as of December 31, 2015 and December 31, 2014 consist of the following (in thousands):

	December 31, 2015	December 31, 2014
Machinery and equipment	$ 2,943	$ 2,943
Leasehold improvements	204	—
Furniture and fixtures	276	—
Less accumulated depreciation	(1,624)	(1,247)
	$ 1,799	$ 1,696

(6) Income Taxes

The Company's tax rate for 2015 is zero because the Company expects to generate additional losses and currently has a full valuation allowance. The Company was an LLC as of December 31, 2014 and until February 12, 2015 when it converted to a C corporation. Although, the Company was not subject to income taxes in any jurisdiction while it was an LLC, one of the Company's subsidiaries was a C-corporation and subject to state and federal income taxes. This subsidiary generated an immaterial operating loss in 2014 and the short year ended February 12, 2015. Accordingly, no provision or benefit for income taxes is reflected in the Company's 2014 or 2015 consolidated financial statements. Prior to the date of the Spin-Out, the Company did not file a separate tax return as the Company was included in the tax groupings of other Ikaria entities within the respective entity's tax jurisdiction. As such, the income tax provision for 2013 was calculated using the separate return method, as if the Company filed a separate tax return in each of its respective tax jurisdictions. The income tax provisions for 2013 included in these carve out financial statements reflects Ikaria's status as a C-corporation.

A reconciliation of the statutory federal income tax rate to the Company's effective tax rate for the years ended December 31, 2015 and 2013 is as follows:

	Year Ended December 31, 2015	Year Ended December 31, 2013
U.S. federal statutory rate	34.0 %	35.0 %
State and local taxes, net of federal tax effect	5.8 %	5.3 %
Research tax credits	15.8 %	5.0 %
Valuation allowance	(55.1)%	(44.4)%
Incentive stock options	(0.5)%	(0.1)%
Other	— %	(0.8)%
	0.0 %	0.0 %

Deferred taxes as of December 31, 2015 reflect the tax effects of the differences between the amounts recorded as assets and liabilities for financial reporting purposes and the comparable amounts recorded for income tax purposes. Significant components of the deferred tax assets (liabilities) at December 31, 2015 are as follows:

	December 31, 2015	
	Assets	(Liabilities)
Net operating loss carryforwards	$ 15,459	$ —
Research tax credit carryforwards	9,753	—
Property and equipment	—	(130)
Stock based compensation	359	—
Intangible assets	12,371	—
Accrued expenses	2,521	—
Subtotal	40,463	(130)
Valuation allowance	(40,333)	—
Total deferred tax assets (liabilities)	$ 130	$ (130)
Net deferred tax assets	$ —	

There were no deferred taxes as of December 31, 2014. The increase in deferred tax assets after the corporate conversion is principally due to the year-to-date loss, adjusted for nondeductible items, including stock compensation expense related to the Company's equity incentive plan, the nondeductible portion of the orphan drug costs, and the orphan drug credits partially offset by a reduction in accrued expenses.

A valuation allowance is provided when it is more likely than not that some portion or all of the deferred tax assets will not be realized. As of December 31, 2015, management believed that it was more likely than not that the deferred tax assets would not be realized, based on future operations, consideration of tax strategies and the reversal of deferred tax liabilities. The valuation allowance is required until the Company has sufficient positive evidence of taxable income necessary to support realization of its deferred tax assets. A valuation allowance release is recognized as an income tax benefit.

Deferred taxes arising from the loss in the Company's C-corporation subsidiary as of December 31, 2014 were immaterial. No other deferred taxes existed at December 31, 2014 due to the Company's limited liability company structure.

As of December 31, 2015 and 2014, the Company had no material uncertain tax positions.

(7) Stock-Based Compensation

Determining the appropriate fair value of stock-based awards requires the input of subjective assumptions, including the fair value of the Company's units (prior to the IPO date) and for options, the expected term of the option and expected volatility. The Company uses the Black-Scholes-Merton option pricing model to value its stock option awards. The assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment. As a result, if factors change and management uses different assumptions, stock-based compensation expense could be materially different for future awards. The expected term of

stock options is estimated using the "simplified method," as the Company has no historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior for its stock options grants. The simplified method is based on the average of the vesting tranches and the contractual life of each grant. For volatility, the Company uses comparable public companies as a basis for its expected volatility to calculate the fair value of option grants due to its limited history as a public company. The risk-free interest rate is based on U.S. Treasury notes with a term approximating the expected term of the option. For restricted stock, the fair value is the closing market price per share on the grant date. The estimation of the number of stock awards that will ultimately vest requires judgment, and to the extent actual results or revised estimates differ from the Company's current estimates, such amounts will be recorded as an adjustment in the period in which estimates are revised.

Bellerophon 2015 Equity Incentive Plan

During the year ended December 31, 2015, the Company adopted the 2015 Equity Incentive Plan, or the 2015 Plan, which provides for the grant of options, restricted stock and other forms of equity compensation. As of December 31, 2015, the Company is authorized to issue equity compensation under the 2015 Plan in an amount up to an aggregate of 500,162 shares to eligible employees, directors and consultants.

As of December 31, 2015, there was approximately $3.5 million of total unrecognized compensation expense related to unvested stock awards. This expense is expected to be recognized over a weighted-average period of 2.5 years.

No tax benefit was recognized during the year end December 31, 2015 related to stock-based compensation expense since the Company incurred operating losses and has established a full valuation allowance to offset all the potential tax benefits associated with its deferred tax assets.

Options

Compensation expense is measured based on the fair value of the option on the grant date and is recognized on a straight-line basis over the requisite service period, or sooner if vesting occurs sooner than on a straight-line basis. Options are forfeited if the employee ceases to be employed by the Company prior to vesting.

During the year ended December 31, 2014, the Company adopted the 2014 Equity Incentive Plan, or the 2014 Plan, which provides for the grant of options. Following the effectiveness of the Company's registration statement filed in connection with its IPO, no options may be granted under the 2014 Plan. The awards granted under the 2014 Plan generally have a vesting period of four years, of which 25% of the awards vest on the second anniversary of grant date, 25% vest on the third anniversary and the remaining 50% vest on the fourth anniversary of the grant date. The awards granted under the 2015 Plan have a vesting period of either three or four years, of which equal annual installments vest over the vesting period either beginning on the date of grant or on the one year anniversary of the date of grant.

The weighted average grant-date fair value of options issued during the year ended December 31, 2015 and 2014 was $6.55 and $9.98, respectively. The following are the weighted average assumptions used in estimating the fair value of options issued during the years ended December 31, 2015 and 2014.

	Year Ended December 31, 2015	Year Ended December 31, 2014
Valuation assumptions:		
Risk-free interest rate	1.60%	1.71%
Expected volatility	79.18%	90.00%
Expected term (in years)	6.1	6.1
Dividend yield	—%	—%

A summary of option activity under the 2015 and 2014 Plan for the year ended December 31, 2014 and 2015 is presented below:

	Bellerophon 2015 and 2014 Equity Incentive Plans			
	Shares	Exercise Price	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)
Options outstanding as of February 12, 2014	—	—	—	
Granted	514,266	$ 13.28	$ 13.28	
Exercised	—			
Forfeited	(5,986)	$ 13.28	$ 13.28	
Options outstanding as of December 31, 2014	508,280	$ 13.28	$ 13.28	9.5
Granted	443,607	4.12 - 12.00	9.53	
Exercised	—			
Forfeited	(246,707)	8.23 - 13.28	9.95	
Options outstanding as of December 31, 2015	705,180	$ 4.12 - 13.28	$ 12.08	8.7
Options vested and exercisable as of December 31, 2015	210,723	$ 10.22 - 13.28	$ 12.97	8.6

Restricted Stock

All restricted stock awards granted under the 2015 Plan to date were in relation to 2015 incentives for employees and vest in full one year from the grant date.

A summary of restricted stock activity under the 2015 Plan for the year ended December 31, 2015 is presented below:

	Bellerophon 2015 Equity Incentive Plan			
	Shares	Weighted Average Fair Value	Aggregate Grant Date Fair Value(in millions)	Weighted Average Remaining Contractual Life (in years)
Restricted stock outstanding as of December 31, 2014	—	$ —	$ —	—
Granted	90,909	3.86	0.4	
Vested	(13,116)	(3.08)	(0.1)	
Forfeited	—			
Restricted stock outstanding as of December 31, 2015	77,793	$ 3.99	$ 0.3	0.7

Ikaria Equity Incentive Plans for Periods Prior to February 12, 2014

Options

In February 2014, prior to the Spin-Out, each Ikaria stock option, other than options held by non-accredited investors who were also not employees of Ikaria, was adjusted such that it became an option to acquire the same number of shares of Ikaria non-voting common stock as were subject to the Ikaria stock option, or an Adjusted Ikaria Option, and an option to acquire the same number of non-voting limited liability company units of the Company as the number of shares of Ikaria non-voting common stock that were subject to the Ikaria stock option, or a Bellerophon Option. There were 618,212 Bellerophon Options issued as a result of the adjustment of Ikaria stock options. The vesting of each Adjusted Ikaria Option and Bellerophon Option was fully accelerated on the date of the Spin-Out and all related compensation expense was recognized as an expense by Ikaria.

Prior to and in connection with the Spin-Out, the exercise price of each Adjusted Ikaria Option and Bellerophon Option was adjusted by allocating the relative post Spin-Out estimated fair values of Ikaria and the Company in a ratio of 85% and 15%, respectively, to the original Ikaria option exercise price. The expiration date of the options was not modified. The

Company's allocable portion of Ikaria's stock-based compensation expense related to options for the period from January 1, 2014 through February 11, 2014 was approximately $0.1 million.

A summary of option activity under the assumed Ikaria 2007 stock option plan and the assumed Ikaria 2010 long term incentive plan for the year ended December 31, 2015 is presented below:

	Ikaria Equity Incentive Plans for Periods Prior to February 12, 2014			
	Shares	Range of Exercise Price	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)
Options issued and vested at date of Spin-Out as of February 12, 2014	618,212	$ 0.26 - 17.92	$ 7.24	
Exercised	(8,182)	7.77 - 8.77	7.99	
Forfeited	(32,055)	7.77 - 14.91	9.39	
Options outstanding, vested and exercisable as of December 31, 2014	577,975	$ 0.26 - 17.92	$ 7.11	4.5
Exercised	(126,499)	1.13 - 7.77	1.47	
Forfeited	(337,767)	7.77 - 17.92	8.61	
Options outstanding, vested and exercisable as of December 31, 2015	113,709	$ 0.26 - 17.92	$ 8.93	5.2

The intrinsic value of options exercised during the year ended December 31, 2015 and 2014 was $0.4 million and de minimis, respectively. The intrinsic value of options outstanding, vested and exercisable as of December 31, 2015 was de minimis.

Restricted Stock Units

In February 2014, prior to the Spin-Out, each Ikaria restricted stock unit, or RSU, was adjusted such that it became an RSU with respect to the same number of shares of Ikaria non-voting common stock as were subject to the Ikaria RSU, or an Adjusted Ikaria RSU, and an RSU with respect to the same number of non-voting limited liability company units of the Company as were subject to the Ikaria RSU, or a Bellerophon RSU. In connection with the Merger and the Spin-Out, the vesting of each Adjusted Ikaria RSU and Bellerophon RSU was fully accelerated. The compensation expense incurred upon the acceleration of the RSUs was recognized by Ikaria. Fully vested Bellerophon RSUs of 372,947 became Bellerophon non-voting units as of the date of the Spin-Out.

Ikaria had granted RSUs to employees that generally vested over four years. RSUs granted prior to January 1, 2011 vested 25% annually. RSUs granted on and after January 1, 2011 vested 25% on the second and third anniversary of the date of grant and 50% on the fourth anniversary of the date of grant. Shares of Ikaria non-voting common stock were delivered to the employee upon vesting, subject to payment of applicable withholding taxes, which were paid in cash or an equivalent amount of shares withheld. Compensation expense for all RSUs was based on the grant date fair value of the RSU issued, which was based on the fair value of common stock of Ikaria. Compensation expense for RSUs was recognized by Ikaria on a straight-line basis over the requisite service period. The RSU expense allocated from Ikaria totaled $0.2 million for the period from January 1, 2014 through February 11, 2014.

Stock-Based Compensation Expense, Net of Estimated Forfeitures

The following table summarizes the stock-based compensation expense for the years ended December 31, 2015, 2014 and 2013. The following disclosures include stock-based compensation expense recognized under the 2015 Plan and the 2014 Plan and expenses for dates prior to the Spin-Out that were allocated to the Company related to Ikaria share-based awards.

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	Year Ended December 31,		
(in thousands)	2015	2014	2013
Research and development	$ 364	$ 271	$ 1,120
General and administrative	1,387	1,568	601
Total expense	$ 1,751	$ 1,839	$ 1,721

(8) Related-Party Transactions

During the years ended December 31, 2013 and 2014, Ikaria was a related party of the Company. Included below and elsewhere in the financial statements are transactions and balances that relate to agreements entered into while Ikaria was a related party of the Company. Amendments to those agreements entered into during the year ended December 31, 2015 were entered into while the Company was no longer a related party.

Separation and Distribution Agreement

In connection with the Spin-Out, in February 2014, the Company and Ikaria entered into a separation and distribution agreement which sets forth provisions relating to the separation of the Company's business from Ikaria's other businesses. The separation and distribution agreement described the assets and liabilities that remained with or were transferred to the Company and those that remained with or were transferred to Ikaria. The separation and distribution agreement provides for a full and complete release and discharge of all liabilities between Ikaria and the Company, except as expressly set forth in the agreement. The Company and Ikaria each agreed to indemnify, defend and hold harmless the other party and its subsidiaries, and each of their respective past and present directors, officers and employees, and each of their respective permitted successors and assigns, from any and all damages relating to, arising out of or resulting from, among other things, the Company's business and certain additional specified liabilities or Ikaria's business and certain additional specified liabilities, as applicable.

License Agreement

In February 2014, the Company entered into a cross-license, technology transfer and regulatory matters agreement with a subsidiary of Ikaria. Pursuant to the terms of the license agreement, Ikaria granted to the Company a fully paid-up, non-royalty-bearing, exclusive license under specified intellectual property rights controlled by Ikaria to engage in the development, manufacture and commercialization of nitric oxide, devices to deliver nitric oxide and related services for or in connection with out-patient, chronic treatment of patients who have PAH, PH-COPD or PH associated with idiopathic pulmonary fibrosis, or PH-IPF. Pursuant to the terms of the license agreement, the Company granted Ikaria a fully paid-up, non-royalty-bearing, exclusive license under specified intellectual property rights that the Company controls to engage in the development, manufacture and commercialization of products and services for or used in connection with the diagnosis, prevention or treatment, whether in- or out-patient, of certain conditions and diseases other than PAH, PH-COPD or PH-IPF and for the use of nitric oxide to treat or prevent conditions that are primarily managed in the hospital. The Company agreed that, during the term of the license agreement, it will not, without the prior written consent of Ikaria, grant a sublicense under any of the intellectual property licensed to the Company under the license agreement to any of its affiliates or any third party, in either case, that directly or indirectly competes with Ikaria's nitric oxide business.

On July 27, 2015, the Company entered into an amendment to the license agreement to expand the scope of the Company's license to allow the Company to develop its INOpulse program for the treatment of three additional indications: chronic thromboembolic PH, or CTEPH, PH associated with sarcoidosis and PH associated with pulmonary edema from high altitude sickness. Subject to the terms set forth therein, the amendment to the license agreement also provides that the Company will pay Ikaria a royalty equal to 5% of net sales of any commercialized products for the three additional indications.

In November 2015, the Company entered into an amendment to its exclusive cross-license, technology transfer and regulatory matters agreement with Ikaria that included a royalty equal to 3% of net sales of any commercial products for PAH.

Agreements Not to Compete

In September 2013, October 2013 and February 2014, the Company and each of its subsidiaries entered into an agreement not to compete with a subsidiary of Ikaria, each of which was amended in July 2015, or, collectively, the agreements not to compete. Pursuant to the agreements not to compete, as amended, the Company and each of its subsidiaries agreed not to engage, anywhere in the world, in any manner, directly or indirectly, until the earlier of five years after the effective date of such agreement not to compete amendments or the date on which Ikaria and all of its subsidiaries are no longer engaged in such business as specified in the agreements.

Transition Services Agreement

In February 2014, the Company and Ikaria entered into the TSA, pursuant to which Ikaria agreed to use commercially reasonable efforts to provide certain transition services to the Company, which services include management/executive, human resources, real estate, information technology, accounting, financial planning and analysis, legal, quality and regulatory

support. Ikaria also agreed to use reasonable efforts to provide the Company with the use of office space at Ikaria's headquarters in Hampton, New Jersey pursuant to the terms of the TSA. In July 2015, the Company entered into an amendment to the TSA advancing the termination date from February 9, 2016 to September 30, 2015. Concurrently, the Company also entered into a new lease agreement for its office space - see Note 9. In exchange for the services, beginning in February 2014, the Company was obligated to pay Ikaria monthly services fees in the amount of $772,000 plus out of pocket expenses and certain other expenses. At December 31, 2015, the Company had no accrued expenses due to Ikaria in connection with the TSA. At December 31, 2014, related accrued expenses due to Ikaria amounted to $0.5 million.

At the time of the Spin-Out, the Company deposited the sum of $18.5 million, representing the aggregate of the $772,000 monthly service fees payable by the Company under the TSA, in escrow to guarantee payment of the monthly services fees by the Company. The escrowed cash is classified as restricted cash as of December 31, 2014. Pursuant to the July 2015 amendment, during October 2015, the Company received from escrow $3.3 million, which is equal to the amount it deposited to pay amounts owed to Ikaria under the TSA for the remainder of the original term.

Effective as of January 1, 2015, the Company entered into a services agreement with Ikaria, or the 2015 Services Agreement, pursuant to which the Company had agreed to use commercially reasonable efforts to provide certain services to Ikaria, including services related to regulatory matters, drug and device safety, clinical operations, biometrics and scientific affairs. In connection with the execution of the 2015 Services Agreement, Ikaria paid the Company a one-time service fee in the amount of $916,666 and was obligated to pay the Company a service fee in the amount of $83,333 per month, subject to performance of the services. The Company has no receivable due from Ikaria in connection with this agreement as of December 31, 2015. In July 2015, the Company entered into an amendment to the 2015 Services Agreement advancing the termination date from February 8, 2016 to September 30, 2015. In addition, pursuant to the 2015 Services Agreement, Ikaria had agreed to use commercially reasonable efforts to provide services to the Company, including information technology and servicing and upgrades of devices.

The following table summarizes the amounts recorded under the TSA and the 2015 Services Agreement for the years ended December 31, 2015 and 2014:

	Year Ended December 31,	
(in millions)	**2015**	**2014**
Expense in connection with the TSA	7.0	8.2
Other operating income in connection with the 2015 Services Agreement	(1.7)	—
Expense in connection with the 2015 Services Agreement	0.2	—

Supply Agreements

In February 2014, the Company entered into drug supply and device supply agreements with a subsidiary of Ikaria. Under these agreements, Ikaria agreed to use commercially reasonable efforts to supply inhaled nitric oxide and nitric oxide delivery devices for use in the Company's clinical trials, and in the case of the drug supply agreement, the Company has agreed to purchase its clinical supply of inhaled nitric oxide from Ikaria. The Company also granted Ikaria a right of first negotiation in the event that the Company desires to enter into a commercial supply agreement with a third party for supply of nitric oxide for inhalation. The device supply agreement expired on February 9, 2015 and no amounts were due to Ikaria under that agreement as of December 31, 2015 or 2014.

In November 2015, the Company amended its drug supply agreement with Ikaria to secure future supply and pricing for cartridges and nitric oxide. Under the amended supply agreement, the Company paid Ikaria $6.6 million, $0.6 million of which was applied to outstanding amounts owed to Ikaria under the drug supply agreement. The remaining $6.0 million resulted in a prepayment to Ikaria in exchange for defined levels of cartridges and nitric oxide. The amendment to the agreement also fixes pricing for any additional cartridges or nitric oxide beyond the defined levels. Additionally, the amendment requires the Company to pay to Ikaria an additional $1.75 million upon successful completion of the initial PAH phase 3 clinical trial and a perpetual royalty calculated as 3% of PAH sales on a quarterly basis. As of December 31, 2015, no amount was due to Ikaria under the drug supply agreement.

(9) Commitments and Contingencies

Legal Proceedings

The Company periodically becomes subject to legal proceedings and claims arising in connection with its business.

BioLineRx Ltd., or BioLine, previously indicated to the Company that it believed that the Company had breached the license agreement in several ways, including, but not limited to, failure to use commercially reasonable efforts to develop bioabsorbable cardiac matrix, or BCM, failure to provide BioLine with material information concerning the development and commercialization plans for BCM and failure to notify BioLine in advance of material public disclosures regarding BCM. The Company and BioLine also previously disagreed about the timing of a certain milestone payment that the Company would owe BioLine based upon progress in the Company's BCM clinical development program. The Company believed it had complied with its obligations under the license agreement to use commercially reasonable efforts to develop BCM and was not in breach of its other obligations under the license agreement. No amounts were previously accrued for this matter since no loss was probable as of December 31, 2014. On January 8, 2015, the Company and BioLine agreed to amend the license agreement, which resolved the prior disputes and provided for a release of claims by BioLine. The amendment also changed certain milestones and related payments, but the total potential milestone payments to be paid to BioLine under the license agreement remained the same. No additional milestones have been met as of December 31, 2015.

As of the date of this report, the Company is not aware of any proceeding, claim or litigation, pending or threatened, that could, individually or in the aggregate, have a material adverse effect on the Company's business, operating results, financial condition and/or liquidity.

Operating Leases

The following is a summary of the Company's long-term contractual cash obligations as of December 31, 2015 (in thousands).

	Operating Lease(1)
2016	$ 413
2017	631
2018	641
2019	653
2020	663
Thereafter	1,532
Total	$ 4,533

(1) Operating lease obligations include the lease agreement the Company entered into on August 6, 2015 for office space in Warren, New Jersey and the Company's lease of an operating facility located in North Brunswick, New Jersey.

Rent expense, including direct and allocated expenses for year prior to 2015, is calculated on the straight-line basis and amounted to approximately $0.4 million for the year ended December 31, 2015 and $0.5 million for each of the years ended December 31, 2014 and 2013.

Royalty payments and success-based milestones associated with the Company's license and supply agreements with Ikaria have not been included in the above table of contractual obligations as the Company cannot reasonably estimate if or when they will occur.

In the course of its normal business operations, the Company also enters into agreements with contract service providers and others to assist in the performance of its research and development and manufacturing activities. The Company can elect to discontinue the work under these contracts and purchase orders at any time with notice, and such contracts and purchase orders do not contain minimum purchase obligations.

BioLineRx Ltd.

In August 2009, the Company entered into a license agreement with BioLineRx Ltd. and BioLine Innovations Jerusalem L.P., which are referred to collectively as BioLine, under which the Company obtained an exclusive worldwide

license to BCM.

The Company does not intend to proceed with further clinical development of BCM until and unless it can determine an alternative path forward. Consequently, any future milestone and royalty payments to BioLine would depend on finding a path forward for future clinical development. Under the terms of the license agreement, the Company is obligated to use commercially reasonable efforts to develop and commercialize at least one product containing BCM. Under the terms of the license agreement, if the Company achieves certain clinical and regulatory events specified in the license agreement, the Company will be obligated to pay milestone payments to BioLine that could total, in the aggregate, up to $115.5 million, and if the Company achieves certain commercialization targets specified in the license agreement, the Company will be obligated to pay additional milestone payments to BioLine that could total, in the aggregate, up to $150.0 million. In addition, the Company is obligated to pay BioLine a specified percentage of any upfront consideration it receives for sublicensing BCM, as well as royalties on net sales, if any, at a percentage ranging from 11% to 15%, depending on net sales level, of any approved product containing BCM, subject to offsets for specified payments to third parties made in connection with BCM. The Company has reimbursed BioLine for certain legal fees in the amount of $250,000 following completion of its IPO.

(10) Net Loss Per Share/Unit

Basic net loss per share/unit is calculated by dividing net loss by the weighted average number of shares or units outstanding during the period, as applicable. Diluted net loss per share/unit is calculated by dividing net loss by the weighted average number of shares/units outstanding, adjusted to reflect potentially dilutive securities (options) using the treasury stock method, except when the effect would be anti-dilutive. No net loss per unit information is presented for periods prior to the Spin-Out.

The Company is reporting a net loss for the years ended December 31, 2015 and 2014, therefore diluted net loss per share/unit is the same as the basic net loss per share/unit.

As of December 31, 2015, the Company had 818,899 options to purchase units and 77,793 restricted stock awards outstanding that have been excluded from the computation of diluted weighted average units outstanding, because such securities had an antidilutive impact due to the loss reported.

(11) Fair Value Measurements

Assets and liabilities recorded at fair value on the balance sheets are categorized based upon the level of judgment associated with the inputs used to measure the fair value. Level inputs are as follows:

- Level 1 - Values are based on unadjusted quoted prices for identical assets or liabilities in an active market which the company has the ability to access at the measurement date.
- Level 2 - Values are based on quoted market prices in markets where trading occurs infrequently or whose values are based on quoted prices of instruments with similar attributes in active markets.
- Level 3 - Values are based on prices or valuation techniques that require inputs that are both unobservable and significant to the overall fair value measurement. These inputs reflect management's own assumptions about the assumptions a market participant would use in pricing the asset.

The following table summarizes fair value measurements by level at December 31, 2015 for financial instruments measured at fair value on a recurring basis:

(Dollar amounts in thousands)	Level 1	Level 2	Level 3	Total
Marketable securities	$ —	$ 17,807	$ —	$ 17,807

There were no marketable securities at December 31, 2014.

(12) Marketable Securities

The Company considers all of its current investments to be available-for-sale. Marketable securities as of December 31, 2015 consist of the following (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Certificates of deposit	10,140	—	—	10,140
Corporate bonds	4,938	—	(11)	4,927
Agency bonds	2,748	—	(8)	2,740
Total	17,826	—	(19)	17,807

Maturities of marketable securities classified as available-for-sale were as follows at December 31, 2015 (in thousands):

	Fair Value
Due within one year	10,230
Due after one year through two years	7,577
	17,807

There were no marketable securities as of December 31, 2014.

(13) Quarterly Financial Data (unaudited)

(in thousands, except share/unit and per share/per unit data)	Three Months Ended December 31,		Three Months Ended September 30,		Three Months Ended June 30,		Three Months Ended March 31,	
	2015	2014	2015	2014	2015	2014	2015	2014
Operating expenses:								
Research and development	$ 8,329	$ 9,610	$ 7,090	$ 11,559	$ 8,426	$ 12,769	$ 9,520	$ 12,040
General and administrative	2,533	3,177	4,329	3,934	3,435	4,194	4,573	2,470
Total operating expenses	10,862	12,787	11,419	15,493	11,861	16,963	14,093	14,510
Other operating income	—	—	250	—	251	—	1,166	—
Loss from operations	(10,862)	(12,787)	(11,169)	(15,493)	(11,610)	(16,963)	(12,927)	(14,510)
Interest income	36	18	27	13	27	48	19	—
Pre-tax loss	(10,826)	(12,769)	(11,142)	(15,480)	(11,583)	(16,915)	(12,908)	(14,510)
Income tax benefit (expense)	—	—	—	—	—	—	—	—
Net loss and comprehensive loss	$ (10,826)	$ (12,769)	$ (11,142)	$ (15,480)	$ (11,583)	$ (16,915)	$ (12,908)	$ (14,510)
Weighted average units outstanding:								
Basic and diluted	13,026,816	7,898,922	12,911,905	7,897,143	12,910,975	7,898,301	10,152,487	7,899,251
Net loss per unit:								
Basic and diluted	$ (0.83)	$ (1.62)	$ (0.86)	$ (1.96)	$ (0.90)	$ (2.14)	$ (1.27)	$ (1.84)

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal 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 a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2015, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Annual Report on Internal Control Over Financial Reporting

Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended, as a process designed by, or under the supervision of, the company's principal executive and principal financial officers and effected by the company's board of directors, management and other personnel 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. The company's internal control over financial reporting includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements.

Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

The company's management assessed the effectiveness of the company's internal control over financial reporting as of December 31, 2015. In making this assessment, management used the criteria set forth in the Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

Based on our assessment, management believes that, as of December 31, 2015, the company's internal control over financial reporting is effective based on those criteria**.**

Changes in Internal Control Over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal quarter ended December 31, 2015 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

On March 12, 2016, we entered into an amended and restated employment agreement with Mr. Peacock which provides that, among other things, (i) Mr. Peacock will be required to commit fifty-percent (50%) of his full business time and efforts to the business and affairs of the Corporation, and he will be permitted to spend up to fifty-percent (50%) of his full business time performing services for Perceptive Bioscience Investments Limited, (ii) a reduction of Mr. Peacock's annual salary to $200,000, and (iii) such other terms as the Compensation Committee of the Board may deem necessary, desirable or appropriate.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Executive Officers, Key Employees and Directors

The following table sets forth the name, age and position of each of our executive officers, key employees and directors as of March 10, 2016.

Name	Age	Position
Jonathan M. Peacock	57	Chief Executive Officer, President and Chairman of the Board
Fabian Tenenbaum	42	Chief Financial Officer and Chief Business Officer
Peter Fernandes	61	Chief Regulatory and Safety Officer
Deborah A. Quinn, M.D.	62	Chief Medical Officer
Martin Dekker	43	Vice President of Device Engineering and Supply
Amy Edmonds	44	Vice President of Clinical Operations and Administration
Naseem Amin, M.D.(1)	54	Director
Scott P. Bruder, M.D., Ph.D.(2)	54	Director
Mary Ann Cloyd(1)	61	Director
Matthew Holt(2)(3)	39	Director
Jens Luehring(1)	42	Director
Andre V. Moura(3)	34	Director
Daniel Tassé	56	Director
Adam B. Weinstein	37	Director

(1) Member of the Audit Committee

(2) Member of the Compensation Committee

(3) Member of the Nominating and Corporate Governance Committee

Jonathan M. Peacock has served as our Chief Executive and President and as the Chairman of our board of directors since June 2014. Prior to joining us, Mr. Peacock served as the Chief Financial Officer of Amgen Inc., a biotechnology company, from September 2010 to January 2014. From November 2005 to September 2010, he served as Chief Financial and Administrative Officer of Novartis Pharmaceuticals AG, the Pharmaceuticals and Biotechnology division of Novartis AG. Mr. Peacock was a partner at McKinsey and Company, a global strategy consulting firm, from 1998 to 2005. Before that, he was a partner at Price Waterhouse LLP, a global accounting firm (now PricewaterhouseCoopers LLP), from 1993 to 1998. He currently serves on the board of directors of Kite Pharma, Inc., a biopharmaceutical company. Mr. Peacock received an M.A. degree in economics from the University of St. Andrews. We believe that Mr. Peacock is qualified to serve on our board of directors because of his global management experience, his experience as an officer of a public company in our industry, his financial expertise and his position as our Chief Executive Officer and President.

Fabian Tenenbaum has served as our Chief Financial Officer and Chief Business Officer since February 2016. Mr. Tenenbaum joined us from Anterios, Inc. a clinical-stage biopharmaceutical company focused on the development of dermatology products, where he served as Chief Financial Officer and Chief Business Officer from 2014 to 2016. Prior to that, Mr. Tenenbaum served as Chief Executive Officer with Syneron Beauty from 2011 to 2014, and Chief Financial Officer and Executive Vice President of Syneron Medical from 2007 to 2011. Prior to Syneron Medical, Mr. Tenenbaum was Vice President Americas for Radiancy, Inc., from 2002 to 2006, and Director, Commercial Operations and Corporate Development at Sunlight Medical, Inc. from 1999 to 2002. Mr. Tenenbaum holds a Bachelor in Medicine (B.Md.) from Ben Gurion University, Israel and an MBA from Columbia Business School.

Peter Fernandes has been our Chief Regulatory Officer since May 2015. In this role he manages safety for us and is the Executive Lead for the INOpulse drug-device combination development program. Prior to joining us, Mr. Fernandes was Vice President of Global Regulatory Affairs at Ikaria Inc., from October 2012 to May 2015, and in this capacity also led our

regulatory group since its inception in February of 2014. Previously, he led Regulatory Affairs and Quality Assurance for OptiNose, Inc. from October 2010 to September 2012, was Vice President US Drug Regulatory Affairs Respiratory and US DRA Respiratory Franchise Head for Novartis Pharmaceuticals from November 2007 to October 2010. He has also served as the Head of US Development Site and Vice President of Regulatory Affairs and Quality Assurance at Altana Pharma, a subsidiary of Nycomed Inc., and led the US Respiratory and GI Drug Regulatory Affairs group at Boehringer Ingelheim. Mr. Fernandes has an M. Pharm. from the Grant Medical College and a B. Pharm. from the K.M. K College of Pharmacy, both at the University of Bombay in India.

Deborah A. Quinn, M.D. served as our Vice President and Medical Lead for the INOpulse programs from January 2015 and has been our Chief Medical Officer since September 2015. Prior to joining us, Dr. Quinn held several positions at Novartis Pharmaceuticals AG from December 2006 to January 2015, most recently as medical director for both pulmonary arterial hypertension and heart failure programs. Previously, Dr. Quinn worked at the Massachusetts General Hospital from 1998 to 2011 where she was an Instructor in Medicine from 1998 to 2006 and a Clinical Assistant Professor in Medicine at Harvard Medical School from 2006 to 2011. Her postdoctoral training in Medicine and Pulmonary and Critical Care Fellowship were at Massachusetts General Hospital. She received an M.D. from the University of Massachusetts Medical School.

Martin Dekker has served as our Vice President of Device Engineering since January 2015. Prior to joining us, Mr. Dekker held several positions at Spacelabs Healthcare, a company that develops and manufactures medical devices, from November 1998 to January 2015, most recently as Director of Global Operations Engineering. During his time at Spacelabs Healthcare, Mr. Dekker led and co-designed new products, developed and launched transformative manufacturing technologies and championed cross-functional quality/engineering projects. He is a member of the Institute of Electrical and Electronic Engineers. Mr. Dekker received a B.S. in electronics from Noordelijke Hogeschool Leeuwarden, the Netherlands.

Amy Edmonds has served as our Vice President of Clinical Operations and Administration since September 2015 with responsibilities for Clinical Operations, Contracts & Outsourcing, Human Resources and Information Technology. Ms. Edmonds has over twenty years of global Clinical Operations and Training experience. Prior to joining us in 2014, Ms. Edmonds was responsible for Ikaria's Clinical Operations and Contracts & Outsourcing departments from October 2012 to February 2014 and held several positions of increasing responsibility at Celgene from November 2002 through October 2012. During her time at Celgene, Ms. Edmonds served as Global Clinical Operations Lead for the Americas for multiple therapeutic programs, the Head of North America Monitoring, and the Head of Clinical Operations Training. Ms. Edmonds has also worked in Clinical Operations and Training for Pfizer, Knoll Pharmaceuticals and ICON Clinical Research. Ms. Edmonds holds a Bachelor's degree from the University of Richmond.

Naseem Amin has served as a member of our board of directors since June 2015. Dr. Amin had served as the Chief Scientific Officer of Smith and Nephew Plc until 2014. Previously, Dr. Amin was Senior Vice President, Business Development at Biogen Idec from 2005 to 2009 and was with Genzyme Corporation from 1999 to 2005, most recently as Head, International Business Development and where he has also led the clinical development of five currently marketed therapeutic products. Dr. Amin began his career at Baxter Healthcare Corporation, where he served as Director, Medical Marketing and Portfolio Strategy, Renal Division. Dr. Amin is a Venture Partner at Advent Life Sciences, serves as an Advisory Board member for Imperial College, Department of Biomedical Engineering, and serves as Chairman of OPEN-London, a non-profit organization focused on encouraging and mentoring South Asians from Pakistan who are interested in starting entrepreneurial companies. Dr. Amin received his medical degree from the Royal Free School of Medicine, London, and an MBA from the Kellogg Graduate School of Management, Northwestern University. We believe that Dr. Amin is qualified to serve on our board of directors because of his broad industry experience in the Biotech and Medical Device industry.

Scott Bruder has served as a member of our board of directors since May 2015. Dr. Bruder is currently an adjunct Professor of Biomedical Engineering at the Case Western Reserve University School of Medicine, where he previously served as an adjunct faculty member in the Department of Orthopaedic Surgery for thirteen years. Dr. Bruder served as the Chief Medical and Scientific Officer of Stryker Corporation from 2013 until 2014, and was the Chief Science and Technology Officer for Becton, Dickinson and Company from 2007 until 2013. Previously, Dr. Bruder has also held a number of senior executive and scientific roles at Johnson & Johnson, Anika Therapeutics and Osiris Therapeutics. Dr. Bruder recently served on an FDA Advisory Committee for Cellular, Tissue and Gene Therapies, and he continues to serve on several Academic Advisory Boards for biomedical engineering at leading universities. Dr. Bruder is a magna cum laude graduate from Brown University with a Sc.B. in Biology, and a graduate of Case Western Reserve University School of Medicine, where he simultaneously earned an M.D. and a Ph.D. in stem cell biology. He obtained additional clinical training at the Albert Einstein Medical Center and the University of Pennsylvania. We believe that Dr. Bruder is qualified to serve on our board of directors because of his experience in medical devices, biotechnology, life sciences, and biomedical engineering.

Mary Ann Cloyd has served as a member of our board of directors since February 2016. From 1990 to 2015, Ms. Cloyd

was a partner at PricewaterhouseCoopers LLP ("PwC"), where she served multinational corporate clients in a variety of industries, including the biotechnology and pharmaceutical industries. She was the Leader of the PwC Center for Board Governance from 2012 to 2015. Ms. Cloyd has also served on both PwC's Global and U.S. Boards. On the U.S. Board, she chaired the Risk Management, Ethics & Compliance Committee and the Partner Admissions Committee, and on the Global Board, she served on the Risk and Operations Committee and the Clients Committee. Ms. Cloyd is on the Board of Trustees of the PwC Charitable Foundation, Inc., and she previously served as President of the Foundation. Ms. Cloyd is currently the Chair of the UCLA Iris Cantor Women's Center Advisory Board. Ms. Cloyd earned a bachelor of business administration from Baylor University, summa cum laude. We believe that Ms. Cloyd is qualified to serve on our board of directors because of her experience in finance, senior management and corporate governance.

Matthew Holt has served as a member of our board of directors since February 2014. Since 2001, Mr. Holt has been employed by New Mountain Capital, a private equity group, where he currently serves as a Managing Director. Prior to joining New Mountain Capital, Mr. Holt served in the mergers and acquisitions Group at Lehman Brothers, a financial services firm. Mr. Holt has served on the board of directors of Ikaria since March 2007. Mr. Holt received an A.B. in English and American literature and language from Harvard College. We believe that Mr. Holt is qualified to serve on our board of directors because of his financial expertise and his years of experience providing strategic advisory services across many industries.

Jens Luehring has served as a member of our board of directors since January 2015. Mr. Luehring has been the Head of Finance, Americas, of The Linde Group since April 2012. In this position, his responsibilities include accounting, tax, business planning, investments, treasury and insurance. Prior to his current role, Mr. Luehring was the Head of Mergers & Acquisitions of The Linde Group from April 2007 to March 2012. Mr. Luehring received a Master of Business Economics from Hanover University in 1998. Prior to joining The Linde Group in January 2006, Mr. Luehring worked in investment banking, covering corporate finance, private equity, equity capital markets and mergers and acquisitions. We believe that Mr. Luehring is qualified to serve on our board of directors because of his financial, business and strategic expertise.

Andre V. Moura has served as a member of our board of directors since February 2014. Mr. Moura joined New Mountain Capital in 2005, where he currently serves as a Director. Prior to joining New Mountain Capital, Mr. Moura was employed by McKinsey & Company, a global management consulting firm. Mr. Moura also serves on the board of directors of two privately held companies. Mr. Moura received an A.B. in computer science from Harvard College and an M.B.A. from Harvard Business School. We believe that Mr. Moura is qualified to serve on our board of directors because of his financial expertise and his years of experience providing strategic advisory services to diverse companies across multiple industries.

Daniel Tassé has served as a member of our board of directors since February 2014. Prior to the acquisition of Ikaria by Mallinckrodt in April 2015, Mr. Tassé was President and Chief Executive Officer and Chairman of the board of directors of Ikaria and served as our Interim Chief Executive Officer and President from February 2014 to June 2014. Previously, Mr. Tassé was the General Manager of the Pharmaceuticals and Technologies Business Unit of Baxter International, Inc., a global diversified healthcare company and Vice President and Regional Director for Australasia at GlaxoSmithKline. Mr. Tassé currently serves as a Director of Indivior PLC, a London Stock Exchange publicly traded company, and serves on its Audit and Compensation committees. Mr. Tassé is a member of the Healthcare Leadership Council. He also is a member of the Health Section Governing Board of the Biotechnology Industry Organization, where he participates on the bioethics, regulatory environment and reimbursement committees. Additionally, Mr. Tassé is a member of the Board of Directors of the Pharmaceutical Research and Manufacturers Association of America, where he participates on the FDA and biomedical research committee. Mr. Tassé received a B.S. in biochemistry from the University of Montreal. We believe Mr. Tassé is qualified to serve on our board of directors because of his former service as our Chief Executive Officer and President, his extensive track record of business building in the healthcare industry, his strong background within critical care, his global management experience and his detailed knowledge of the pharmaceutical industry, our company, employees, client base and competitors.

Adam B. Weinstein has served as a member of our board of directors since February 2014. He is a Managing Director of New Mountain Capital, LLC, and he joined that organization in 2005. At New Mountain, Mr. Weinstein serves as a Chief Financial Officer and is an Executive Vice President and is on the Board of Directors of New Mountain Finance Corporation, a publicly traded business development company. Prior to joining New Mountain, Mr. Weinstein held roles in the mergers and acquisitions and private equity investor services areas of Deloitte & Touche, LLP, in that firm's merger and acquisition and private equity investor services areas. Mr. Weinstein is a New York State Certified Public Accountant and received his B.S., summa cum laude, in accounting from Binghamton University. We believe that Mr. Weinstein is qualified to serve on our board of directors because of his financial and accounting expertise and valuable corporate governance experience.

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

Audit Committee and Audit Committee Financial Expert

Our board of directors has established an audit committee, which operates under a charter that has been approved by our board of directors. The members of our audit committee are Mr. Luehring, Dr. Amin and Ms. Cloyd. Dr. Amin chairs our audit committee. In addition, our board of directors has determined that Mr. Luehring is an "audit committee financial expert" as defined in applicable SEC rules.

The rules established by the NASDAQ Stock Market, or NASDAQ rules, require that, subject to specified exceptions, each member of a listed company's audit committee be independent and that audit committee members also satisfy independence criteria set forth in Rule 10A-3 under the Exchange Act. In order to be considered independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors or any other board committee, accept, directly or indirectly, any consulting, advisory or other compensatory fee from the listed company or any of its subsidiaries or otherwise be an affiliated person of the listed company or any of its subsidiaries.

Our board of directors has determined that Mr. Luehring, Dr. Amin and Ms. Cloyd, who are members of our audit committee, satisfy the independence standards for the audit committee established by the SEC and NASDAQ rules, including, the independence requirements of Rule 10A-3 under the Exchange Act.

Our audit committee assists our board of directors in its oversight of our accounting and financial reporting process and the audits of our financial statements. Our audit committee's responsibilities include:

- appointing, approving the compensation of, and assessing the independence of our registered public accounting firm;
- overseeing the work of our independent registered public accounting firm, including through the receipt and consideration of reports from such firm;
- reviewing and discussing with management and our independent registered public accounting firm our annual and quarterly financial statements and related disclosures;
- monitoring our internal control over financial reporting, disclosure controls and procedures and code of business conduct and ethics;
- overseeing our internal audit function;
- overseeing our risk assessment and risk management policies;
- establishing policies regarding hiring employees from our independent registered public accounting firm and procedures for the receipt and retention of accounting related complaints and concerns;
- meeting independently with our internal auditing staff, our independent registered public accounting firm and management;
- reviewing and approving or ratifying any related person transactions; and
- preparing the audit committee report required by SEC rules.

All audit and non-audit services, other than *de minimis* non-audit services, to be provided to us by our independent registered public accounting firm must be approved in advance by our audit committee. A copy of our audit committee's written charter is publicly available on our website, www.bellerophon.com.

Code of Ethics and Code of Conduct

We have adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. We have posted a current copy of the code on our website, www.bellerophon.com. If we make any substantive amendments to, or grant any waivers from, the code of business conduct and ethics for any officer or director, we will disclose the nature of such amendment or waiver on our website or in a current report on Form 8-K.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act, requires our directors and officers, and persons who own more than 10% of a registered class of our equity securities to file with the SEC reports of ownership and changes in ownership of our ordinary shares and our other equity securities. Officers, directors and greater-than-10% shareholders are required by SEC regulations to furnish us with copies of all Section 16(a) forms they file.

Based solely on a review of the copies of such reports furnished to us or written representations that no other reports were required, we believe that during and with respect to the 2015 fiscal year all filing requirements applicable to our officers, directors and greater-than-10% beneficial owners were complied with and all filings were timely filed.

Item 11. Executive Compensation

This section describes the material elements of compensation awarded to, earned by or paid to each of our named executive officers. We were formed on October 17, 2013 as a subsidiary of Ikaria and we became an independent, stand-alone operating company as a result of the Spin-Out on February 12, 2014. Because the costs and liabilities with respect to compensation of our employees for the fiscal year ended December 31, 2013 and prior periods were paid by Ikaria on the basis of criteria and methodology not relevant to us and work performed with respect to businesses in addition to ours, we are not presenting compensation information for historical periods prior to the fiscal year ended December 31, 2014.

As we gain experience as a public company, we expect that the specific direction, emphasis and components of our executive compensation program will continue to evolve. Our compensation committee will review and approve the compensation of our executive officers and oversee and administer our executive compensation programs and initiatives.

Summary Compensation Table

The following table sets forth information regarding compensation earned by Jonathan Peacock, our President and Chief Executive Officer, Deborah Quinn, Chief Medical Officer, Martin Dekker, Vice President of Device Engineering and Supply, Reinilde Heyrman, our former Chief Clinical Development Officer, and Martin Meglasson, our former Chief Scientific Officer, during our fiscal year ended December 31, 2015. The following table includes information for Dr. Quinn and Mr. Dekker starting from their hire dates of January 26, 2015 and January 19, 2015, respectively. We refer to Mr. Peacock, Dr. Quinn and Mr. Dekker as our named executive officers.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)(1)(2)	Option Awards ($)(1)	All Other Compensation ($)	Total ($)
Jonathan Peacock, *President and Chief Executive Officer*							
	2015	400,000	400,000 (2)	13,278	356,534	11,215 (3)	1,181,027
	2014	201,539	224,000 (4)	—	4,470,833	58,351 (5)	4,954,723
Deborah Quinn, *Chief Medical Office*							
	2015	271,154	195,000 (2),(6)	5,476	68,414	10,361 (3)	550,405
Martin Dekker, *Vice President of Device Engineering and Supply*							
	2015	190,000	88,000 (2)	4,015	68,414	61,654 (7)	412,083
Reinilde Heyrman, *former Chief Clinical Development Officer*							
	2015	333,462	—	—	17,097	197,796 (8)	548,356
	2014	366,808	288,720 (9)	—	79,246	—	734,774
Martin Meglasson, *former Chief Scientific Officer*							
	2015	279,230	106,612 (10)	—	17,097	465,842 (11)	868,782
	2014	307,154	266,160 (12)	—	79,246	—	652,560

(1) The amounts reported in the "Stock Awards" and “Option Awards” columns reflect the aggregate fair value of stock-based compensation awarded during the year computed in accordance with the provisions of FASB ASC Topic 718. See Note 7 to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K regarding assumptions underlying the valuation of equity awards.

(2) The amounts in the "Bonus" column represents amounts earned in 2015 but paid in 2016, through the grant of restricted stock awards, or RSAs, which amount reflects the cash bonus forgone. The excess of the aggregate fair value of the RSAs computed in accordance with FASB ASC Topic 718 over the cash bonus forgone is included in the "Stock Awards" column. See Note 7 to our consolidated financial statements appearing elsewhere in this Annual Report on 10-K regarding assumptions underlying the valuation of equity awards. Refer to the "Grants of Plan Based Awards" table for further details.

(3) Consists of amounts that we matched pursuant to our 401(k) plan.

(4) Represents amounts earned in 2014 but paid in 2015, of which $112,000 was paid in cash and $112,000 was paid through the grant of stock options, which amount reflects the aggregate fair value of the stock options computed in accordance with FASB ASC Topic 718. See Note 7 to our consolidated financial statements appearing elsewhere in this Annual Report on 10-K regarding assumptions underlying the valuation of equity awards.

(5) Consists of $52,197 of relocation costs incurred by us in connection with Mr. Peacock becoming our President and Chief Executive Officer, and $6,154 that we matched pursuant to our 401(k) plan.

(6) Includes a $75,000 signing bonus from when Dr. Quinn became our Vice President, Medical Lead. Dr. Quinn was subsequently promoted to Chief Medical Officer.

(7) Consists of $50,000 of relocation costs and $11,654 that we matched pursuant to our 401(k) plan.

(8) Consists of severance earned in 2015 of $173,400 which represents four out of twelve monthly payments paid between 2015 and 2016 prior to the cessation of such payments pending resolution of certain matters. Further, includes accrued but

unpaid vacation time of $2,115 related to Dr. Heyrman's termination and $22,281 that we matched pursuant to our 401(k) plan.

(9) Includes a one-time $150,000 retention bonus in addition to $138,720 earned in 2014 but paid in 2015, of which $69,360 was paid in cash and $69,360 was paid through the grant of stock options, which amount reflects the aggregate fair value of the stock options computed in accordance with FASB ASC Topic 718. See Note 7 to our consolidated financial statements appearing elsewhere in this Annual Report on 10-K regarding assumptions underlying the valuation of equity awards.

(10) Represents amounts earned in 2015 but paid in 2016, of which $53,306 was paid in cash and $53,306 was paid through the grant of restricted stock awards, or RSAs, which amount reflects the aggregate fair value of the RSAs computed in accordance with FASB ASC Topic 718. See Note 7 to our consolidated financial statements appearing elsewhere in this Annual Report on 10-K regarding assumptions underlying the valuation of equity awards.

(11) Consists of severance of $435,600 and accrued but unpaid vacation time of $17,076 related to Dr. Meglasson's termination and $13,166 that we matched pursuant to our 401(k) plan.

(12) Includes a one-time $150,000 retention bonus in addition to $116,160 earned in 2014 but paid in 2015, of which $58,080 was paid in cash and $58,080 was paid through the grant of stock options, which amount reflects the aggregate fair value of the stock options computed in accordance with FASB ASC Topic 718. See Note 7 to our consolidated financial statements appearing elsewhere in this Annual Report on 10-K regarding assumptions underlying the valuation of equity awards.

Narrative to Summary Compensation Table

Base Salary. In 2015, we paid salaries of $400,000 to Mr. Peacock, $271,154 to Dr. Quinn, $190,000 to Mr. Dekker, $333,462 to Dr. Heyrman and $279,230 to Dr. Meglasson. In 2014, we paid salaries of $201,539 to Mr. Peacock, $366,808 to Dr. Heyrman and $307,158 to Dr. Meglasson. Base salaries are used to recognize the experience, skills, knowledge and responsibilities required of all of our employees, including our executive officers. We did not engage in any form of benchmarking in the determination of base salaries of our executive officers. Our compensation committee will review the salaries of our executives annually at the beginning of each calendar year and recommend to our board of directors changes in salaries based primarily on changes in job responsibilities, experience, individual performance and comparative market data.

In 2014, we paid salaries of $201,539 to Mr. Peacock, $366,808 to Dr. Heyrman and $307,158 to Dr. Meglasson. On an annualized basis, the 2014 base salaries of our named executive officers were: $400,000 to Mr. Peacock, $433,500 to Dr. Heyrman and $363,000 to Dr. Meglasson.

Bonus Compensation. Our named executive officers are expected to be eligible to receive an annual bonus award in accordance with the management incentive program then in effect with respect to such executive officer and based on an annualized target of base salary, as specified in their respective employment agreements, if applicable. Our named executive officers are also expected to be eligible for performance-based annual bonus awards based on metrics to be determined by our board of directors, in consultation with the executive officer, and our board of directors will determine the extent to which the metrics have been satisfied and the amount of the annual bonus, if any. The performance-based bonuses are designed to motivate our employees to achieve annual goals based on our strategic, financial and operating performance objectives.

On February 3, 2014, we delivered a letter to Dr. Heyrman and to Dr. Meglasson offering them each a one-time $150,000 "retention bonus" payment if she or he remained an active employee of Bellerophon in good standing through December 19, 2014. We paid these retention bonus payments, less applicable taxes, to Dr. Heyrman and Dr. Meglasson in December 2014.

With respect to 2015, the compensation committee awarded total bonus compensation, paid in 2016 in restricted stock awards, with a value of $400,000 or 165,975 shares to Mr. Peacock, $195,000 or 49,792 shares to Dr. Quinn, $88,000 or 36,514 shares to Mr. Dekker and $53,306 or 22,118 shares to Dr. Meglasson.

With respect to 2014, the compensation committee awarded total bonus compensation, paid in 2015 partially in cash and partially in stock options, with a value of $224,000 to Mr. Peacock, $138,720 to Dr. Heyrman and $116,160 to Dr. Meglasson. The cash portion of each named executive officer's bonus was: $112,000 to Mr. Peacock, $69,360 to Dr. Heyrman and $58,080 to Dr. Meglasson. The remaining portion of each named executive officer's bonus amount was paid through the grant of stock options in the following amounts: 16,000 shares to Mr. Peacock, 9,909 shares to Dr. Heyrman and 8,297 shares to Dr. Meglasson.

Long-Term Equity Based Incentive Awards. We believe that equity grants provide our executives with a strong link to our long-term performance, create an ownership culture and help to align the interests of our executives and our stockholders. In addition, we believe that equity grants with a time-based vesting feature promote executive retention because this feature incentivizes our named executive officers to remain in our employment during the vesting period. Accordingly, our compensation committee and board of directors periodically review the equity incentive compensation of our named executive officers and from time to time may grant additional equity incentive awards to them in the form of stock options or restricted share awards.

Grants of Plan Based Awards

The following table shows information regarding grants of equity awards that we made during the fiscal year ended December 31, 2015 to each of our executive officers named in the Summary Compensation Table.

Name	Grant Date	All Other Stock Awards (number of shares)(1)	All Other Option Awards (number of securities	Exercise Price of Option Awards ($ per share)	Grant Date Fair Value of Stock and Option Awards ($)(2)
Jonathan Peacock, President and Chief Executive Officer					
	3/12/2015		50,216	10.22	356,534
	1/25/2016	165,975			413,278
Deborah Quinn, Chief Medical Officer					
	2/13/2015		7,983	12.00	68,414
	1/19/2016	49,792			125,476
Martin Dekker, Vice President of Device Engineering and Supply					
	2/13/2015		7,983	12.00	68,414
	1/19/2016	36,514			92,015
Reinilde Heyrman, former Chief Clinical Development Officer					
	2/13/2015		1,995	12.00	17,097
Martin Meglasson, former Chief Scientific Officer					
	2/13/2015		1,995	12.00	17,097

(1) The amounts included in the "All Other Stock Awards" column represents bonus amounts earned in 2015 but paid in 2016, through the grant of restricted stock awards, or RSAs.

(2) The amounts reported above reflect the aggregate fair value of stock-based compensation awarded during the year computed in accordance with the provisions of FASB ASC Topic 718. See Note 7 to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K regarding assumptions underlying the valuation of equity awards.

Outstanding Equity Awards at 2015 Fiscal Year-End

The following table sets forth information regarding outstanding stock options held by our named executive officers as of December 31, 2015:

	Option Awards			
Name	Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Unexercisable (#)	Option Exercise Price ($)	Option Expiration Date
Jonathan Peacock	180,164	270,247 (1)	$ 13.28	6/20/2024
	4,000	12,000 (2)	10.22	3/12/2025
	—	60,000 (3)	10.22	3/12/2025
Deborah Quinn	—	7,983 (4)	12.00	2/13/2025
Martin Dekker	—	7,983 (4)	12.00	2/13/2025
Reinilde Heyrman	—	—		
Martin Meglasson	—	7,983 (5)	13.28	5/12/2018
	—	1,995 (4)	12.00	5/13/2019

(1) This option vested as to 20% of the underlying shares on June 20, 2014 and vests as to an additional 20% of the underlying shares annually thereafter through June 20, 2018.
(2) This option vested as to 25% of the underlying shares on March 15, 2015 and vests as to an additional 25% of the underlying shares annually thereafter through March 15, 2018.
(3) This option vests as to 25% of the underlying shares on March 15, 2016 and vests as to an additional 25% of the underlying shares annually thereafter through March 15, 2019
(4) This option vests as to 25% of the underlying shares on February 13, 2016 and vests as to an additional 25% of the underlying shares annually thereafter through February 13, 2019
(5) This option vests as to (i) 25% of the underlying shares on February 12, 2016, (ii) 25% of the underlying shares on February 12, 2017 and (iii) 50% of the underlying shares on February 12, 2018.

Employment Agreements with Our Executive Officers

Agreement with Mr. Peacock

In June 2014, we entered into an employment agreement with Mr. Peacock in connection with the commencement of his employment with us. The agreement provides that Mr. Peacock is employed at will, and either we or Mr. Peacock may terminate the employment relationship for any reason, at any time. Mr. Peacock is required to give us at least 30 days' prior notice if he elects to terminate his employment other than for good reason (as defined in the employment agreement). Following the end of each calendar year, Mr. Peacock is eligible to receive an annual bonus for such calendar year in accordance with the terms of our management incentive program, calculated as a percentage of his annual base salary. As of the date of this Annual Report on Form 10-K, Mr. Peacock's target bonus percentage is 100%. In March 2015, we entered into an amendment with Mr. Peacock to his employment agreement to provide that, beginning with the 2014 annual bonus and for years thereafter, we, in our sole discretion, may pay such bonus compensation in cash, equity or a combination thereof on such terms as are determined by the compensation committee. On March 12, 2016, we entered into an amended and restated employment agreement with Mr. Peacock which provides that, among other things, (i) Mr. Peacock will be required to commit fifty-percent (50%) of his full business time and efforts to the business and affairs of the Corporation, and he will be permitted to spend up to fifty-percent (50%) of his full business time performing services for Perceptive Bioscience Investments Limited, (ii) a reduction of Mr. Peacock's annual salary to $200,000, and (iii) such other terms as the Compensation Committee of the Board may deem necessary, desirable or appropriate.

If we terminate Mr. Peacock's employment without cause (as defined in the employment agreement) or if Mr. Peacock terminates his employment with us for good reason (as defined in the employment agreement), Mr. Peacock is entitled to receive: (1) a lump sum payment in an amount equal to earned but unpaid base salary through the date of his termination of employment and any unpaid annual bonus that was earned by Mr. Peacock and declared due and owing by us, any accrued but unpaid vacation time, and any incurred but unreimbursed expenses, together with any other benefits to which Mr. Peacock is entitled under our benefit plans and arrangements; and (2) subject to his continued compliance with the restrictive covenants of the agreement and his execution and nonrevocation of a general release of claims against us: (a) a pro-rated portion of his annual bonus target for the year in which his employment terminates, payable in a single lump sum; (b) payments for a period of 18 months following the date of termination in an aggregate amount equal to one and one half times the sum of (i) Mr. Peacock's annual base salary and (ii) the greater of his applicable annual bonus target and the actual annual bonus most recently paid to Mr. Peacock, determined on a monthly basis; and (c) continued coverage, under our medical, dental and vision

benefit plans at active-employee rates for 18 months following the date of termination.

We have agreed to indemnify and hold Mr. Peacock harmless from and against any liabilities Mr. Peacock may incur under Section 409A of the Internal Revenue Code of 1986, as amended, on account of any payments made to Mr. Peacock pursuant to his employment agreement.

Mr. Peacock is subject to confidentiality, invention assignment, non-competition and non-solicitation obligations pursuant to the terms of his employment agreement.

Agreement with Mr. Tenenbaum

In February 2016, we entered into an employment agreement with Mr. Tenenbaum in connection with the commencement of his employment with us. The agreement provides that Mr. Tenenbaum is employed at will, and either we or Mr. Tenenbaum may terminate the employment relationship for any reason, at any time. Mr. Tenenbaum is required to give us at least 30 days' prior notice if he elects to terminate his employment other than for good reason (as defined in the employment agreement). Following the end of each calendar year, Mr. Tenenbaum is eligible to receive an annual bonus for such calendar year in accordance with the terms of our management incentive program, calculated as a percentage of his annual base salary. As of the date of this Annual Report on Form 10-K, Mr. Tenenbaum's target bonus percentage is 40%.

If we terminate Mr. Tenenbaum's employment without cause (as defined in the employment agreement) or if Mr. Tenenbaum terminates his employment with us for good reason (as defined in the employment agreement) within twelve months following a change in control (as defined in the employment agreement), Mr. Tenenbaum is entitled to receive subject to his continued compliance with the restrictive covenants of the agreement and his execution and nonrevocation of a general release of claims against us: (1) for a period of twelve months following his termination of employment monthly severance pay in an amount equal to his base salary rate; (2) an annual bonus at the target level in cash or equity or any combination thereof; and (3) continued coverage, under our medical, dental and vision benefit plans at active employee rates for 12 months following the date of termination.

Mr. Tenenbaum is subject to confidentiality, work product assignment, non-competition and non-solicitation obligations pursuant to the terms of his employment agreement.

Agreements with Other Named Executive Officers

We also have written employment agreements with Dr. Heyrman and Dr. Meglasson. On September 11, 2015, each of Dr. Heyrman and Dr. Meglasson agreed that their employment with us terminated effective September 25, 2015. Each of these officers is subject to confidentiality, invention assignment, non-competition and non-solicitation agreements. Refer to the "Narrative to Summary Compensation Table" for further discussion of severance recorded during the year ended December 31, 2015.

In January 2015, we entered into an offer letter with Dr. Quinn in connection with the commencement of her employment with us. The letter provides that Dr. Quinn is employed at will, and either we or Dr. Quinn may terminate the employment relationship for any reason, at any time. Following the end of each calendar year, Dr. Quinn is eligible to receive an annual bonus for such calendar year in accordance with the terms of our management incentive program, calculated as a percentage of her annual base salary. As of the date of this Annual Report on Form 10-K, Dr. Quinn's target bonus percentage is 40%.

In December 2014, we entered into an offer letter with Mr. Dekker in connection with the commencement of his employment with us. The letter provides that Mr. Dekker is employed at will, and either we or Mr. Dekker may terminate the employment relationship for any reason, at any time. Following the end of each calendar year, Mr. Dekker is eligible to receive an annual bonus for such calendar year in accordance with the terms of our management incentive program, calculated as a percentage of his annual base salary. As of the date of this Annual Report on Form 10-K, Mr. Dekker's target bonus percentage is 40%.

Stock Option and Other Compensation Plans

The four equity incentive plans described in this section are (i) the assumed 2007 Ikaria stock option plan, which we refer to as the 2007 Ikaria plan, (ii) the assumed Ikaria 2010 long term incentive plan, which we refer to as the 2010 Ikaria plan, (iii) our 2014 equity incentive plan and (iv) our 2015 equity incentive plan. Following the effectiveness of the registration statement for our IPO, we have been granting awards to eligible participants only under the 2015 equity incentive plan.

Assumed 2007 Ikaria Plan

The 2007 Ikaria plan was adopted by Ikaria in March 2007, and we assumed the terms of the 2007 Ikaria plan in connection with the Spin-Out. Stock options granted under the 2007 Ikaria plan have a contractual life of ten years. Pursuant to the terms of the 2007 Ikaria plan, in the event of a liquidation or dissolution of our company, each outstanding option under the 2007 Ikaria plan will terminate immediately prior to the consummation of the action, unless the administrator determines otherwise. In the event of a merger or other reorganization event, each outstanding option will be assumed or an equivalent option or right will be substituted by the successor entity, unless such successor entity does not agree to assume the award or to substitute an equivalent option or right in which case such option will terminate upon the consummation of the merger or reorganization event.

Assumed 2010 Ikaria Plan

The 2010 Ikaria plan was adopted by Ikaria in February 2010 and amended and restated in May 2010, and we assumed the terms of the 2010 Ikaria plan in connection with the Spin-Out. Pursuant to the terms of the 2010 Ikaria plan, upon our liquidation, dissolution, merger or consolidation, except as otherwise provided in an applicable option or award agreement, each option or award will be (i) treated as provided in the agreement related to the transaction, or (ii) if not so provided in such agreement, each holder of an option or award will be entitled to receive, in respect of each share subject to outstanding options or awards, the same number of stock, securities, cash, property or other consideration that he or she would have received had he or she exercised such options or awards prior to the transaction. The stock, securities, cash, property or other consideration shall remain subject to all of the conditions, restrictions and performance criteria which were applicable to the options and awards prior to any such transaction. If the consideration paid or distributed is not entirely shares of common stock of the acquiring or resulting corporation, the treatment of outstanding options and stock appreciation rights may include the cancellation of outstanding options and stock appreciation rights upon consummation of the transaction as long as the holders of affected options and stock appreciation rights, at the election of the compensation committee, either:

- have been given a period of at least 15 days prior to the date of the consummation of the transaction to exercise the options or stock appreciation rights (whether or not they were otherwise exercisable); or
- are paid (in cash or cash equivalents) in respect of each share covered by the option or stock appreciation right being cancelled an amount equal to the excess, if any, of the per share price paid or distributed to stockholders in the transaction (the value of any non-cash consideration to be determined by the compensation committee in its sole discretion) over the exercise price of the option or stock appreciation right.

2014 Equity Incentive Plan

In June 2014, our board of directors adopted, and our stockholders approved, the 2014 equity incentive plan. The 2014 equity incentive plan is administered by our board of directors or by a committee appointed by our board of directors. The 2014 equity incentive plan provided for the grant of options. Following the effectiveness of our registration statement filed in connection with our IPO, no options may be granted under the 2014 Plan.

Our employees, officers, directors, consultants and advisors were eligible to receive awards under the 2014 equity incentive plan.

Awards under the 2014 equity incentive plan are subject to adjustment in the event of a split, reverse split, dividend, recapitalization, combination or reclassification of our common stock, spin-off or other similar change in our capitalization or event or any dividend or distribution to holders of our common stock other than an ordinary cash dividend.

Upon a merger or other reorganization event (as defined in the 2014 equity incentive plan), our board of directors, may, in its sole discretion, take any one or more of the following actions pursuant to the 2014 equity incentive plan, as to some or all outstanding options:

- provide that all outstanding options will be assumed, or substantially equivalent awards shall be substituted, by the acquiring or successor corporation or an affiliate thereof;
- upon written notice to a participant, provide that the participant's unvested and/or unexercised options will terminate immediately prior to the consummation of such transaction unless exercised by the participant;

- provide that outstanding options will become exercisable, realizable or deliverable, or restrictions applicable to an option will lapse, in whole or in part, prior to or upon the reorganization event;

- in the event of a reorganization event pursuant to which holders of shares of non-voting common stock will receive a cash payment for each share of non-voting common stock surrendered in the reorganization event, make or provide for a cash payment to the participants with respect to each option held by the participant equal to (1) the number of shares of non-voting common stock subject to the vested portion of the option, after giving effect to any acceleration of vesting that occurs upon or immediately prior to such reorganization event, multiplied by (2) the excess, if any, of the cash payment for each share of non-voting common stock surrendered in the reorganization event over the exercise price of such option and any applicable tax withholdings, in exchange for the termination of such option; and

- provide that, in connection with a liquidation or dissolution, options convert into the right to receive liquidation proceeds.

At any time, our board of directors may, in its sole discretion, provide that any award under the 2014 equity incentive plan will become immediately exercisable in full or in part, free of some or all restrictions or conditions, or otherwise realizable in full or in part.

Our board of directors may amend, suspend or terminate the 2014 equity incentive plan at any time, except that stockholder approval will be required to comply with applicable law or stock market requirements.

2015 Equity Incentive Plan

In January 2015, our board of directors adopted, and in February 2015, our stockholders approved, the 2015 equity incentive plan, which became effective immediately prior to the effectiveness of the registration statement for our IPO. The 2015 equity incentive plan provides for the grant of incentive stock options, nonstatutory stock options, share appreciation rights, restricted share awards, restricted share unit awards and other share-based awards. Upon the effectiveness of the 2015 equity incentive plan, the number of shares of our common stock that were reserved for issuance under the 2015 equity incentive plan was equal to the sum of (1) 449,591 plus (2) the number of shares (up to 558,851 shares) equal to the sum of the number of shares of our common stock available for issuance under the 2014 equity incentive plan immediately prior to the effectiveness of the registration statement for our IPO and the number of shares of our common stock subject to outstanding awards under the 2014 equity incentive plan that expire, terminate or are otherwise surrendered, cancelled, forfeited or repurchased by us at their original issuance price pursuant to a contractual repurchase right plus (3) an annual increase, to be added on the first day of each fiscal year, beginning with the fiscal year ending December 31, 2016 and continuing until, and including, the fiscal year ending December 31, 2025, equal to the least of (i) 798,358 shares of our common stock, (ii) a number equal to the difference between 5% of the number of shares of our common stock outstanding on the first day of the fiscal year (treating all shares of our common stock issuable upon the exercise of outstanding options and upon the conversion of outstanding shares of preferred stock, warrants or other securities convertible into shares of our common stock as outstanding for this purpose) and the number of shares of our common stock available for grant under the 2015 equity incentive plan on the first day of the fiscal year and (iii) an amount determined by our board of directors. Solely for purposes of the 2015 equity incentive plan, from and after the Corporate Conversion until the closing of our IPO "shares of our common stock" referred to shares of our non-voting common stock. Upon the closing of our IPO, "shares of our common stock" shall refer to shares of our voting common stock and awards granted prior to the closing of our IPO automatically became awards covering shares of our voting common stock at such time.

Our employees, officers, directors, consultants and advisors are eligible to receive awards under the 2015 equity incentive plan. However, incentive stock options may only be granted to our employees. We granted options to purchase an aggregate of 99,367 shares to certain of our employees upon the commencement of trading of our common stock on the NASDAQ Global Market under the 2015 equity incentive plan.

Pursuant to the terms of the 2015 equity incentive plan, our board of directors (or a committee delegated by our board of directors) administers the plan and, subject to any limitations in the plan, selects the recipients of awards and determines:

- the number of shares of our common stock covered by options and the dates upon which the options become exercisable;

- the type of options to be granted;

- the duration of options, which may not be in excess of ten years;
- the exercise price of options, which must be at least equal to the fair market value of our common stock on the date of grant;
- the methods of payment of the exercise of options; and
- the number of shares of our common stock subject to and the terms of any share appreciation rights, restricted share awards, restricted share units or other share-based awards and the terms and conditions of such awards, including conditions for repurchase, issue price and repurchase price (though the measurement price of share appreciation rights must be at least equal to the fair market value of our common stock on the date of grant and the duration of such awards may not be in excess of ten years).

If our board of directors delegates authority to an officer to grant awards under the 2015 equity incentive plan, the officer will have the power to make awards to all of our officers, except executive officers. Our board of directors will fix the terms of the awards to be granted by such officer, including the exercise price of such awards (which may include a formula by which the exercise will be determined), and the maximum number of shares subject to awards that such officer may make.

Upon a merger or other reorganization event, our board of directors may, except to the extent specifically provided otherwise in an award or other agreement between us and the plan participant, take any one or more of the following actions pursuant to the 2015 equity incentive plan as to some or all outstanding awards other than restricted shares:

- provide that all outstanding awards shall be assumed, or substantially equivalent awards shall be substituted, by the acquiring or succeeding corporation (or an affiliate thereof);
- upon written notice to a participant, provide that all of the participant's unvested and/or unexercised awards will terminate immediately prior to the consummation of such reorganization event unless exercised by the participant (to the extent then exercisable) within a specified period;
- provide that outstanding awards shall become exercisable, realizable or deliverable, or restrictions applicable to an award shall lapse, in whole or in part, prior to or upon such reorganization event;
- in the event of a reorganization event pursuant to which holders of shares of our common stock will receive a cash payment for each share surrendered in the reorganization event, make or provide for a cash payment to the participants with respect to each award held by a participant equal to (1) the number of shares of our common stock subject to the vested portion of the award (after giving effect to any acceleration of vesting that occurs upon or immediately prior to such reorganization event) multiplied by (2) the excess, if any, of the cash payment for each share surrendered in the reorganization event over the exercise, measurement or purchase price of such award and any applicable tax withholdings, in exchange for the termination of such award;
- provide that, in connection with a liquidation or dissolution, awards shall convert into the right to receive liquidation proceeds (if applicable, net of the exercise, measurement or purchase price thereof and any applicable tax withholdings); and/or
- any combination of the foregoing.

Our board of directors does not need to take the same action with respect to all awards, all awards held by a participant or all awards of the same type.

In the case of certain restricted share units, no assumption or substitution is permitted, and the restricted share units will instead be settled in accordance with the terms of the applicable restricted share unit agreement.

Upon the occurrence of a reorganization event other than a liquidation or dissolution, the repurchase and other rights with respect to outstanding restricted share awards will continue for the benefit of the successor company and will, unless the board of directors may otherwise determine, apply to the cash, securities or other property into which shares of our common stock are converted or exchanged pursuant to the reorganization event, provided that our board of directors may provide for the termination or deemed satisfaction of such repurchase or other rights under the applicable award agreement or any other agreement between the participant and us. Upon the occurrence of a reorganization event involving a liquidation or dissolution, all restrictions and conditions on each outstanding restricted share award will automatically be deemed terminated or satisfied,

unless otherwise provided in the agreement evidencing the restricted share award or in any other agreement between the participant and us.

At any time, our board of directors may, in its sole discretion, provide that any award under the 2015 equity incentive plan will become immediately exercisable in full or in part, free of some or all restrictions or conditions, or otherwise realizable in full or in part.

No award may be granted under the 2015 equity incentive plan on or after February 12, 2025. Our board of directors may amend, suspend or terminate the 2015 equity incentive plan at any time, except that stockholder approval may be required to comply with applicable law or stock market requirements.

401(k) Retirement Plan

We maintain a 401(k) retirement plan that is intended to be a tax-qualified defined contribution plan under Section 401(k) of the Internal Revenue Code. In general, all of our employees are eligible to participate, beginning on the first day of the month following commencement of their employment. The 401(k) plan includes a salary deferral arrangement pursuant to which participants may elect to reduce their current compensation by up to the statutorily prescribed limit, equal to $18,000 in 2015, and have the amount of the reduction contributed to the 401(k) plan.

Limitations on Liability and Indemnification

Our certificate of incorporation limits the personal liability of directors for breach of fiduciary duty to the maximum extent permitted by the Delaware General Corporation Law and provides that no director will have personal liability to us or to our stockholders for monetary damages for breach of fiduciary duty or other duty as a director. However, these provisions do not eliminate or limit the liability of any of our directors:

- for any breach of the director's duty of loyalty to us or our stockholders;
- for acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- for voting for or assenting to unlawful payments of dividends, stock repurchases or other distributions; or
- for any transaction from which the director derived an improper personal benefit.

Any amendment to or repeal of these provisions will not eliminate or reduce the effect of these provisions in respect of any act, omission or claim that occurred or arose prior to such amendment or repeal. If the Delaware General Corporation Law is amended to provide for further limitations on the personal liability of directors of corporations, then the personal liability of our directors will be further limited to the greatest extent permitted by the Delaware General Corporation Law.

In addition, our certificate of incorporation provides that we must indemnify our directors and officers and we must advance expenses, including attorneys' fees, to our directors and officers in connection with legal proceedings, subject to very limited exceptions.

In addition, we have entered into indemnification agreements with each of our directors and officers. These indemnification agreements may require us, among other things, to indemnify each such director or officer for some expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by him or her in any action or proceeding arising out of his or her service as one of our directors or officers.

We maintain a general liability insurance policy that covers certain liabilities of our directors and officers arising out of claims based on acts or omissions in their capacities as directors or officers.

Certain of our non-employee directors may, through their relationships with their employers, be insured and/or indemnified against certain liabilities incurred in their capacity as members of our board of directors.

Rule 10b5-1 Sales Plans

Our directors and executive officers may adopt written plans, known as Rule 10b5-1 plans, in which they will contract with a broker to buy or sell shares of our common stock on a periodic basis. Under a Rule 10b5-1 plan, a broker executes trades pursuant to parameters established by the director or officer when entering into the plan, without further direction from the

director or officer. The director or officer may adopt, amend or terminate a plan when not in possession of material, non-public information. In addition, our directors and executive officers may also buy or sell additional shares outside of a Rule 10b5-1 plan when they are not in possession of material, nonpublic information.

Director Compensation

On May 12, 2015, the Board approved certain amendments to our policy for the compensation of our non-employee directors, effective immediately. Following the amendments, our director compensation policy consists of the following:

- each non-employee director will receive, on an annual basis, a cash retainer of $35,000;
- each non-employee director who has then served on the Board for at least six months will receive, on the date of the first Board meeting held after each year's annual meeting of stockholders, an option to purchase 10,000 shares of Common Stock, which shall vest in three equal annual installments;
- the chairman of the Board, if a non-employee director, will receive an additional cash retainer of $30,000;
- each non-employee director who serves on the Audit Committee will receive a cash retainer of $7,500 per year ($15,000 for the chair);
- each non-employee director who serves on the Compensation Committee will receive a cash retainer of $5,000 per year ($10,000 for the chair);
- each non-employee director who serves on the Nominating and Corporate Governance Committee will receive a cash retainer of $5,000 ($7,500 for the chair); and
- each non-employee director upon initial election to the Board will receive a one-time award of an option to purchase 25,000 shares of Common Stock, which option shall vest in three equal annual installments.

In addition, we will continue to reimburse our non-employee directors for reasonable travel and out-of-pocket expenses incurred in connection with attending Board and committee meetings.

Prior to our IPO in February 2015, we did not have a formal non-employee director compensation policy. We did not compensate any of our non-employee directors for such directors' service as a director in 2014. We have historically reimbursed our non-employee directors for reasonable travel and out-of-pocket expenses incurred in connection with attending board of director and committee meetings. Jonathan Peacock, one of our directors who also serves as our President and Chief Executive Officer, does not receive any additional compensation for his service as a director. The compensation that we pay to Mr. Peacock for his service as our President and Chief Executive Officer is discussed in the "Executive Compensation" section of this Annual Report on Form 10-K.

The New Mountain Entities have advised us that, in connection with the affiliation of Messrs. Holt, Moura and Weinstein with the New Mountain Entities, all equity based compensation, including grants of stock options in respect of shares of our common stock, received or receivable by Messrs. Holt, Moura and Weinstein in consideration for their services rendered to us will be held by such director for the benefit of New Mountain Capital, L.L.C., an affiliate of the New Mountain Entities. In addition, the New Mountain Entities have advised us that any cash compensation received by such directors in consideration for their services rendered to us will be paid to New Mountain Capital, L.L.C.

The following table shows the total compensation paid or accrued during the fiscal year ended December 31, 2015 to each of our non-employee directors. Directors who are employed by us are not compensated for their service on our Board of Directors.

Name	Fees Earned or Paid in Cash ($)	Option Awards ($)(1)	Total ($)
Naseem Amin	21,978	130,500	152,478
Scott P. Bruder	25,385	147,000	172,385
Matthew Holt	42,187	—	42,187
Scott Huennekens (2)	23,506	147,000	170,506
Jens Luehring	36,090	—	36,090
Andre V. Moura	37,792	—	37,792
Robert T. Nelsen (2)	30,634	—	30,634
Adam B. Weinstein	42,062	—	42,062
Daniel Tasse	29,506	—	29,506

(1) The amounts reported above reflect the aggregate fair value of stock-based compensation awarded during the year computed in accordance with the provisions of FASB ASC Topic 718. See Note 7 to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K regarding assumptions underlying the valuation of equity awards.

(2) Mr. Huennekens and Mr. Nelsen resigned from the board of directors effective December 1, 2015. Upon Mr. Huennekens resignation, his option award was forfeited.

Compensation Committee Interlocks and Insider Participation

None of our executive officers serves as a member of the board of directors or compensation committee, or other committee serving an equivalent function, of any other entity that has one or more of its executive officers serving as a member of our board of directors or our compensation committee. None of the members of our compensation committee is, or has ever been, an officer or employee of our company.

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

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth information with respect to the beneficial ownership of our common stock as of March 10, 2016 by:

- each person, or group of affiliated persons, who is known by us to beneficially own more than 5% of our common stock;
- each of our named executive officers;
- each of our directors; and
- all of our executive officers and directors as a group.

Beneficial ownership is determined in accordance with the rules and regulations of the SEC and includes voting or investment power with respect to our common stock. Shares of our common stock subject to options that are currently exercisable or exercisable within 60 days of March 10, 2016 are considered outstanding and beneficially owned by the person holding the options for the purpose of calculating the percentage ownership of that person but not for the purpose of calculating the percentage ownership of any other person. Except as otherwise noted, to our knowledge, the persons and entities in this table have sole voting and investing power with respect to all of the shares of our common stock beneficially owned by them, subject to community property laws, where applicable. The information is not necessarily indicative of beneficial ownership for any other purpose.

The percentage ownership calculations for beneficial ownership are based on 13,477,296 shares of common stock outstanding as of March 10, 2016.

Except as otherwise set forth below, the address of the beneficial owner is c/o Bellerophon Therapeutics, Inc., 184 Liberty Corner Road, Suite 302, Warren, NJ 07059.

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned
5% Stockholders		
New Mountain Entities(1)	4,859,885	36.1 %
Linde(2)	1,629,804	12.1 %
Fidelity Investments (FMR LLC)(3)	1,302,070	9.7 %
ARCH(4)	965,660	7.2 %
Venrock(5)	962,415	7.1 %
Executive Officers and Directors		
Jonathan M. Peacock(6)	420,866	3.1 %
Fabian Tenenbaum	—	*
Peter Fernandes(7)	60,297	*
Deborah Quinn(8)	51,787	*
Amy Edmonds(9)	40,209	*
Martin Dekker(10)	38,509	*
Naseem Amin	—	*
Scott Bruder	—	*
Matthew S. Holt(11)	4,859,885	36.1 %
Jens Luehring(12)	1,629,804	12.1 %
Andre V. Moura	—	*
Daniel Tassé	128,898	1.0 %
Adam B. Weinstein(13)	4,859,885	36.1 %
All executive officers and directors as a group (11 persons)(14)	7,230,255	53.6 %

* Less than one percent.

(1) Based on information provided in a Schedule 13G filed by New Mountain Investments II, LLC on February 16, 2016, consists of 346,974 shares held by Allegheny New Mountain Partners, L.P., 80,165 shares held by New Mountain Affiliated Investors II, L.P., 3,842,663 shares held by New Mountain Partners II (AIV-A), L.P. and 590,083 shares held by New Mountain Partners II (AIV-B), L.P. The general partner of each of the New Mountain Entities is New Mountain Investments II, L.L.C. and the manager of each of the New Mountain Entities is New Mountain Capital L.L.C. Steven Klinsky is the managing member of New Mountain Investments II, L.L.C. Adam Weinstein, a member of our board of directors, is a member of New Mountain Investments II, L.L.C. Matthew Holt, a member of our board of directors, is a member of New Mountain Investments II, L.L.C. New Mountain Investments II, L.L.C. has decision-making power over the disposition and voting of shares of portfolio investments of each of the New Mountain Entities. New Mountain Capital, L.L.C. also has voting power over the shares of portfolio investments of the New Mountain Entities in its role as the investment advisor. New Mountain Capital, L.L.C. is a wholly-owned subsidiary of New Mountain Capital Group, L.L.C. New Mountain Capital Group, L.L.C. is 100% owned by Steven Klinsky. Since New Mountain Investments II, L.L.C. has decision-making power over the New Mountain Entities, Mr. Klinsky may be deemed to beneficially own the shares that the New Mountain Entities hold of record or may be deemed to beneficially own. Mr. Klinsky, Mr. Weinstein, Mr. Holt, New Mountain Investments II, L.L.C. and New Mountain Capital, L.L.C. disclaim beneficial ownership over the shares held by the New Mountain Entities, except to the extent of their pecuniary interest therein. The address of the New Mountain Entities is c/o New Mountain Capital, L.L.C., 787 Seventh Avenue, 48th Floor, New York, New York 10019.

(2) Consists of 1,629,804 shares held by Linde North America, Inc., an indirect wholly-owned subsidiary of Linde AG. Jens Luehring, a member of our board of directors, is a director and chief financial officer of Linde North America, Inc. Mr. Luehring disclaims beneficial ownership of all shares held by Linde, except to the extent of his pecuniary interest therein, if any. The address of Linde North America, Inc. is 575 Mountain Avenue, Murray Hill, New Jersey 07974.

(3) Based on information provided in a Schedule 13G/A filed by FMR LLC on February 12, 2016. Edward C. Johnson 3d, a Director and Chairman of FMR LLC, and Abigail P. Johnson, a Director, Vice Chairman, and the Chief Executive Officer of FMR LLC, are the predominant owners, directly or through trusts, of Series B voting common shares of FMR LLC, representing 49% of the voting power of FMR LLC. The Johnson family group and all other Series B shareholders have entered into a shareholders' voting agreement under which all Series B voting common shares will be voted in accordance with the majority vote of Series B voting common shares. Accordingly, through their ownership of voting common shares and the execution of the shareholders' voting agreement, members of the Johnson family may be deemed, under the Investment Company Act of 1940, as amended, to form a controlling group with respect to FMR LLC. Neither FMR LLC nor Edward C. Johnson 3d nor Abigail P. Johnson has the sole power to vote or direct the voting of the shares owned directly by the various investment companies registered under the Investment Company Act, which we refer to as the Fidelity Funds, advised by Fidelity Management & Research Company, which we refer to as FMR Co, a wholly owned subsidiary of FMR LLC, which power resides with the Fidelity Funds' Boards of Trustees. FMR Co carries out the voting of the shares under written guidelines established by the Fidelity Funds' Boards of Trustees. FMR LLC reports that it holds sole dispositive power with respect to 1,292,882 shares. The address of FMR LLC is 245 Summer Street, Boston, Massachusetts 02210.

(4) Based on information provided in a Schedule 13D filed by Arch Venture Fund VI LP on February 25, 2016 consists of 965,660 shares held by ARCH Venture Fund VI, L.P., or ARCH VI. ARCH Venture Partners VI, L.P., or the GPLP, as the sole general partner of ARCH VI, may be deemed to beneficially own certain of the shares held of record by ARCH VI. The GPLP disclaims beneficial ownership of all shares held of record by ARCH VI in which the GPLP does not have an actual pecuniary interest. ARCH Venture Partners VI, LLC, or the GPLLC, as the sole general partner of the GPLP, may be deemed to beneficially own certain of the shares held of record by ARCH VI. The GPLLC disclaims beneficial ownership of all shares held of record by ARCH VI in which it does not have an actual pecuniary interest. Keith Crandell, Clinton Bybee and Robert Nelsen are the managing directors of the GPLLC and may be deemed to beneficially own certain of the shares held of record by ARCH VI. The managing directors disclaim beneficial ownership of all shares held of record by ARCH VI in which they do not have an actual pecuniary interest. ARCH VI reports that it holds shared voting power and shares dispositive power with respect to 965,660 shares. The address of ARCH VI is 8725 West Higgins Road, Suite 290, Chicago, Illinois 60631.

(5) Based on information provided in a Schedule 13D filed by Venrock Associates IV LP on February 25, 2016 consists of 783,407 shares held by Venrock Associates IV, L.P.; 159,761 shares that are held by Venrock Partners, L.P. and 19,247 shares that are held by Venrock Entrepreneurs Fund IV, L.P. Venrock Management IV, LLC, Venrock Partners Management, LLC and VEF Management IV, LLC are the sole general partners of Venrock Associates IV, L.P., Venrock Partners, L.P. and Venrock Entrepreneurs Fund IV, L.P., respectively. Venrock Management IV, LLC, Venrock Partners Management, LLC and VEF Management IV, LLC disclaim beneficial ownership of all shares held by Venrock Associates IV, L.P., Venrock Partners, L.P. and Venrock Entrepreneurs Fund IV, L.P., except to the extent of their pecuniary interest therein. The address of Venrock is 3340 Hillview Avenue, Palo Alto, California 94304.

(6) Includes 203,164 shares of common stock issuable upon the exercise of options exercisable within 60 days after March 10, 2016.

(7) Includes 4,790 shares of common stock issuable upon the exercise of options exercisable within 60 days after March 10, 2016.

(8) Includes 1,995 shares of common stock issuable upon the exercise of options exercisable within 60 days after March 10, 2016.

(9) Includes 3,695 shares of common stock issuable upon the exercise of options exercisable within 60 days after March 10, 2016.

(10) Includes 1,995 shares of common stock issuable upon the exercise of options exercisable within 60 days after March 10, 2016.

(11) Consists of 346,974 shares held by Allegheny New Mountain Partners, L.P., 80,165 shares held by New Mountain Affiliated Investors II, L.P., 3,842,663 shares held by New Mountain Partners II (AIV-A), L.P. and 590,083 shares held by New Mountain Partners II (AIV-B), L.P. The general partner of each of the New Mountain Entities is New Mountain Investments II, L.L.C. and the manager of each of the New Mountain Entities is New Mountain Capital L.L.C. Matthew Holt, a member of our board of directors, is a member of New Mountain Investments II, L.L.C. New Mountain Investments II, L.L.C. has decision-making power over the disposition and voting of shares of portfolio investments of

each of the New Mountain Entities. New Mountain Capital, L.L.C. also has voting power over the shares of portfolio investments of the New Mountain Entities in its role as the investment advisor. New Mountain Capital, L.L.C. is a wholly-owned subsidiary of New Mountain Capital Group, L.L.C. Mr. Holt disclaims beneficial ownership over the shares held by the New Mountain Entities, except to the extent of his pecuniary interest therein.

(12) Consists of 1,629,804 shares held by Linde North America, Inc., an indirect wholly-owned subsidiary of Linde AG. Jens Luehring, a member of our board of directors, is a director and the chief financial officer of Linde North America, Inc. Mr. Luehring disclaims beneficial ownership of all shares held by Linde, except to the extent of his pecuniary interest therein, if any.

(13) Consists of 346,974 shares held by Allegheny New Mountain Partners, L.P., 80,165 shares held by New Mountain Affiliated Investors II, L.P., 3,842,663 shares held by New Mountain Partners II (AIV-A), L.P. and 590,083 shares held by New Mountain Partners II (AIV-B), L.P. The general partner of each of the New Mountain Entities is New Mountain Investments II, L.L.C. and the manager of each of the New Mountain Entities is New Mountain Capital L.L.C. Adam Weinstein, a member of our board of directors, is a member of New Mountain Investments II, L.L.C. New Mountain Investments II, L.L.C. has decision-making power over the disposition and voting of shares of portfolio investments of each of the New Mountain Entities. New Mountain Capital, L.L.C. also has voting power over the shares of portfolio investments of the New Mountain Entities in its role as the investment advisor. New Mountain Capital, L.L.C. is a wholly-owned subsidiary of New Mountain Capital Group, L.L.C. Mr. Weinstein disclaims beneficial ownership over the shares held by the New Mountain Entities, except to the extent of his pecuniary interest therein.

(14) Includes 215,639 shares of common stock issuable upon the exercise of options exercisable within 60 days after March 10, 2016.

Securities Authorized for Issuance under Equity Compensation Plans

The following table contains information about our equity compensation plans as of December 31, 2015.

Equity Compensation Plan Information

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights		Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column(a))	
	(a)		(b)	(c)	
Equity compensation plans approved by security holders	818,889	(1)	$ 11.80	212,353	(2)
Equity compensation plans not approved by security holders	—		—	—	
Total	818,889		$ 11.80	212,353	

(1) Consists of stock options outstanding as of December 31, 2015 under the 2007 Ikaria plan, 2010 Ikaria plan, 2014 equity incentive plan and 2015 equity plan.

(2) Consists of shares of common stock authorized under the 2015 equity incentive plan and under the 2014 equity incentive plan that remained available for grant under future awards as of December 31, 2015. In January 2015, in connection with our IPO, our board of directors determined that we would not grant any further stock options under our 2014 equity incentive plan following the effectiveness of the registration statement for our IPO, which occurred in February 2015. In addition, in January 2015, our board of directors adopted, and in February 2015, our stockholders approved, our 2015 equity incentive plan, which became effective on February 13, 2015. Upon the effectiveness of the 2015 equity incentive plan, the number of shares of our common stock that were reserved for issuance under the 2015 equity incentive plan was equal to the sum of (1) 449,591 plus (2) the number of shares (up to 558,851 shares) equal to the sum of the number of shares of our common stock available for issuance under the 2014 equity incentive plan immediately prior to the effectiveness of the registration statement for our IPO and the number of shares of our common

stock subject to outstanding awards under the 2014 equity incentive plan that expire, terminate or are otherwise surrendered, cancelled, forfeited or repurchased by us at their original issuance price pursuant to a contractual repurchase right plus (3) an annual increase, to be added on the first day of each fiscal year, beginning with the fiscal year ending December 31, 2016 and continuing until, and including, the fiscal year ending December 31, 2025, equal to the least of (i) 798,358 shares of our common stock, (ii) a number equal to the difference between 5% of the number of shares of our common stock outstanding on the first day of the fiscal year (treating all shares of our common stock issuable upon the exercise of outstanding options and upon the conversion of outstanding shares of preferred stock, warrants or other securities convertible into shares of our common stock as outstanding for this purpose) and the number of shares of our common stock available for grant under the 2015 equity incentive plan on the first day of the fiscal year and (iii) an amount determined by our board of directors.

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

The following is a description of transactions since January 1, 2015 to which we have been a party, and in which any of our directors, executive officers and holders of more than 5% of our voting securities and affiliates of our directors, executive officers and holders of more than 5% of our voting securities, had or will have a direct or indirect material interest. We believe that all of the transactions described below were made on terms no less favorable to us than could have been obtained from unaffiliated third parties.

Corporate Conversion

On February 12, 2015, we completed transactions pursuant to which we converted from a Delaware limited liability company into a Delaware corporation and changed our name to Bellerophon Therapeutics, Inc. As required by the limited liability company agreement of Bellerophon Therapeutics LLC, the conversion was approved by the board of directors of Bellerophon Therapeutics LLC. In connection with the Corporate Conversion, holders of our outstanding voting units received one share of voting common stock for each voting unit held immediately prior to the Corporate Conversion, holders of our outstanding non-voting units received one share of non-voting common stock for each non-voting unit held immediately prior to the Corporate Conversion and options to purchase non-voting units became options to purchase one non-voting share of common stock for each unit underlying such options immediately prior to the Corporate Conversion, at the same aggregate exercise price in effect prior to the Corporate Conversion.

Following the Corporate Conversion and prior to our registration statement being declared effective, certain entities affiliated with certain of our principal stockholders were merged with and into us. We refer to these mergers as the Mergers. In connection with the conversion and the Mergers, these certain entities affiliated with certain of our principal stockholders received, in exchange for their equity interests in the entities being merged into us, the number of shares of our common stock that they would have held had they held our equity interests directly.

In connection with the Corporate Conversion, we entered into the following agreements:

Merger Agreement

We entered into a merger agreement with certain of our principal stockholders to effect the Mergers. Concurrently with the consummation of the conversion to a corporation, our limited liability company agreement, or the LLC agreement, was terminated (other than the provisions thereof relating to certain pre-closing tax matters and liabilities for breaches of the LLC agreement).

In the merger agreement, the companies that merged into us represented and warrantied that they did not have any liabilities, operations or businesses other than activities related to holding our common stock and other than liabilities for (i) deferred income taxes that reflect only timing differences between the treatment of items for accounting and income tax purposes and (ii) income taxes with respect to pre-closing periods which are not yet due and payable and for which we are fully indemnified. The Mergers were structured so that we did not acquire any assets (other than certain income tax receivables and an amount of cash that has been estimated in good faith to be sufficient to pay all pre-closing income taxes of the entities to be merged into us) or become responsible for any liabilities other than (i) deferred income taxes that reflect only timing differences between the treatment of items for accounting and income tax purposes and (ii) income taxes with respect to pre-closing periods which are not yet due and payable and for which we are fully indemnified. Each of our principal stockholders party to the merger agreement will indemnify us with respect to any liabilities (including tax liabilities related to pre-closing periods, other than with respect to deferred income tax liabilities that reflect only timing differences between the treatment of items for accounting and income tax purposes) of the entity related to such principal stockholder that we acquire in the merger. Any assets (other than our equity interests, certain income tax receivables and an amount of cash that has been estimated in

good faith to be sufficient to pay all liabilities, including pre-closing income taxes, of the entities to be merged into us) in the entities to be merged into us were distributed to the equity holders of those entities prior to the Mergers.

Registration Rights Agreement

We have entered into a registration rights agreement with certain holders of our common stock, including our 5% stockholders and their affiliates and entities affiliated with our directors. The registration rights agreement provides these holders the right to demand that we file a registration statement or request that their shares be covered by a registration statement that we are otherwise filing.

Stockholders Agreements

New Mountain Stockholders Agreement

In February 2015, in connection with our IPO, we entered into a stockholders agreement with the New Mountain Entities, which provides that the New Mountain Entities are entitled to designate one director for nomination to our board of directors, to designate one director to the board of directors (or equivalent governing body) of each of our subsidiaries and to appoint the lead director of our board of directors, in each case, for so long as the New Mountain Entities or certain of their respective assignees beneficially own (i) 50% or more of the sum of (a) the number of shares of our common stock that they owned immediately prior to the closing of our IPO and (b) the number of shares of common stock, if any, acquired following the closing of our IPO (subject to in each case adjustment in the event of any stock split, reverse stock split, stock dividend, recapitalization, combination of shares, reclassification or other similar change in our capitalization) and (ii) 15% or more of our common stock outstanding (as set forth on the cover of our then most recently filed annual report on Form 10-K or quarterly report on Form 10-Q). Subject to the same ownership thresholds, the director nominated by the New Mountain Entities is entitled to serve on each committee of our board of directors and of the board of directors (or equivalent governing body) of each of our subsidiaries and the consent of the New Mountain Entities is required to establish any new committee of our board of directors or the board of directors (or equivalent governing body) of any of our subsidiaries, in each case except to the extent prohibited by applicable law or applicable listing exchange rules.

The New Mountain Entities may assign their rights to designate one director for nomination to our board of directors, to designate a director to the board of directors (or equivalent governing body) of each of our subsidiaries and to appoint the lead director of our board of directors to a person who acquires, in a transaction other than a registered public offering or a sale pursuant to Rule 144 under the Securities Act, at least 50% of the aggregate number of shares of our common stock owned, directly or indirectly, by the New Mountain Entities as of immediately prior to such transaction.

In addition, the stockholders agreement provides that, we are required to obtain the prior written approval of the New Mountain Entities to take certain actions, including, among other things, actions to:

- consolidate or merge into or with any other person, sell, lease or transfer all or a significant portion of our assets or capital stock to another person or enter into any other similar business combination transaction, or effect a liquidation;
- authorize, issue, sell, offer for sale or solicit offers to buy any shares of our common stock or any convertible securities or any other equity or debt securities or rights to acquire any of our or our subsidiaries' equity or debt securities, subject to certain exceptions, including among other things, the issuance under our stock incentive plan of grants that have been approved by our board of directors (or a board committee) and at least one director appointed by the New Mountain Entities;
- incur indebtedness or refinance any indebtedness, in each case in an amount in excess of a specified threshold;
- hire or replace our chief executive officer; or
- agree or otherwise commit to do any of the foregoing (unless the commitment is conditioned on obtaining the approval of the New Mountain Entities).

These approval rights of the New Mountain Entities will terminate when the New Mountain Entities or certain of their respective assignees beneficially own either (i) less than 50% of the sum of (a) the aggregate number of shares of our common stock that they collectively owned immediately prior to the closing of our IPO and (b) the number of shares of our common stock, if any, acquired following the closing of our IPO (subject to in each case adjustment in the event of any stock split,

reverse stock split, stock dividend, recapitalization, combination of shares, reclassification or similar changes in our capitalization) or (ii) less than 15% of our common stock outstanding (as set forth on the cover of our then most recently filed annual report on Form 10-K or quarterly report on Form 10-Q). As of March 10, 2016, the New Mountain Entities held approximately 36.1% of our outstanding common stock.

Linde Stockholders Agreement

In February 2015, in connection with our IPO, we also entered into a stockholders agreement with Linde, which provides that Linde is entitled to designate one director for nomination to our board of directors and to designate one director to the board of directors (or equivalent governing body) of each of our subsidiaries, in each case, for so long as Linde or certain of its assignees beneficially own (i) 50% or more of the sum of (a) the number of shares of our common stock that they owned immediately prior to the closing of our IPO and (b) the number of shares of common stock, if any, acquired following the closing of our IPO (subject to in each case adjustment in the event of any stock split, reverse stock split, stock dividend, recapitalization, combination of shares, reclassification or other similar change in our capitalization) and (ii) 10% or more of our common stock outstanding (as set forth on the cover of our then most recently filed annual report on Form 10-K or quarterly report on Form 10-Q). Subject to the same ownership thresholds, the director designated by Linde is entitled to serve on each committee of our board of directors and of the board of directors (or equivalent governing body) of each of our subsidiaries and the consent of Linde is required to establish any new committee of our board of directors or the board of directors (or equivalent governing body) of any of our subsidiaries, in each case except to the extent prohibited by applicable law or applicable listing exchange rules.

Linde may assign its rights to designate one director for nomination to our board of directors and to designate a director for nomination to the board of directors (or equivalent governing body) of each of our subsidiaries to a person who acquires, in a transaction other than a registered public offering or a sale pursuant to Rule 144 under the Securities Act, at least 50% of the aggregate number of shares of our common stock owned, directly or indirectly, by Linde as of immediately prior to such transaction. As of March 16, 2015, Linde held approximately 12.6% of our outstanding common stock.

Management Rights Letters

We have entered into management rights letters with entities affiliated with certain of our principal stockholders, pursuant to which such entities are entitled to routinely consult with and advise management regarding our operations and have the right to inspect our books and records. We will also be required to deliver financial statements to such entities within 45 days after the end of each of the first three quarters of each fiscal year and 120 days after the end of each fiscal year and any other periodic reports as soon as they become available. Our management rights letter with the New Mountain Entities also provides that at any time during which the New Mountain Entities do not have the direct contractual right to designate a representative to serve on our board of directors, the New Mountain Entities will have the right to designate one observer to our board of directors. Such observer shall be entitled to attend all meetings of our board of directors and to receive copies of all materials provided to the directors, subject to customary exceptions specified in the management rights letter. Each management rights letter will terminate on the date the entity party thereto (or principal stockholder with which such entity is affiliated) no longer holds any of our securities.

Indemnification Agreements

Our certificate of incorporation provides that we will indemnify our directors and officers to the fullest extent permitted by Delaware law. In addition, we have entered into indemnification agreements with each of our directors and officers. See “Executive Compensation-Limitations on Liability and Indemnification” for additional information regarding these agreements.

Relationship with Ikaria

Prior to the Spin-Out on February 12, 2014, we were a wholly-owned subsidiary of Ikaria. See “Business-Relationship with Ikaria after the Spin-Out.” Following the Spin-Out, Ikaria ceased to hold any of our equity interests and we became a stand-alone company. On April 16, 2015, Mallinckrodt announced that it had completed its acquisition of Ikaria.

Separation and Distribution Agreement

In connection with the Spin-Out, we and Ikaria entered into a separation and distribution agreement which sets forth the key provisions relating to the separation of our business from Ikaria’s other businesses. The separation and distribution agreement described the assets and liabilities that remained with or were transferred to us and those that remained with or were

transferred to Ikaria and the terms of Ikaria's distribution of all of our then outstanding units to its stockholders. The separation and distribution agreement provides for a full and complete release and discharge of all liabilities between Ikaria and us, except as set forth in the agreement. We and Ikaria each agreed to indemnify, defend and hold harmless the other party and its subsidiaries, and each of their respective past and present directors, officers and employees, and each of their respective permitted successors and assigns, from any and all damages relating to, arising out of or resulting from, among other things, our business and certain additional specified liabilities or Ikaria's business and certain additional specified liabilities, as applicable. The separation and distribution agreement also provides that we and Ikaria will each use reasonable best efforts, including by cooperating with the other party, to, among other things, effect the transfer of any assets being transferred in connection with the Spin-Out that had not been transferred as of the date of the Spin-Out.

In connection with the Spin-Out, we and Ikaria have entered into other agreements that will govern various interim and ongoing relationships between us and Ikaria. These agreements, the material terms of which are summarized below, include:

- transition services agreements;
- an exclusive cross-license, technology transfer, and regulatory matters agreement;
- an employee matters agreement;
- agreements not to compete; and
- drug and device supply agreements.

The principal agreements described below are filed as exhibits to this Annual Report on Form 10-K, and the summaries of each of these agreements below set forth the terms of the agreements that we believe are material. These summaries are qualified in their entireties by reference to the full text of the applicable agreements, which are incorporated by reference into this Annual Report on Form 10-K.

Services Agreements

Transition Services Agreement. In February 2014, we entered into the TSA. Pursuant to the terms and conditions of the TSA, Ikaria agreed to use commercially reasonable efforts to provide certain services to us, including human resources support, real estate support, information technology support, accounting and tax support, treasury support, financial planning and analysis support, purchasing support, management/executive services, legal services, quality services, regulatory services, drug and device safety services, business development support, biometrics support and manufacturing support. Ikaria was obligated, subject to the terms of the TSA (including the early termination provisions thereof and our obligation to use commercially reasonable efforts to provide the services for ourselves as soon as practicable), to provide such services until February 2016. Ikaria also agreed, on the terms and subject to the conditions of the TSA, to use commercially reasonable efforts to allow our employees to remain in Ikaria's Hampton, New Jersey facility for the continued operation of our business during the term of the TSA. In July 2015, we entered into an amendment to the TSA advancing the termination date from February 9, 2016 to September 30, 2015. Amounts incurred in 2015 totaled $7.0 million.

We were obligated to pay Ikaria a service fee in the amount of $772,000 per month and to reimburse Ikaria for any out-of-pocket expenses incurred in connection with its provisions of services under the TSA, any taxes imposed on Ikaria in connection with the performance or delivery of services under the TSA and any costs and expenses incurred by Ikaria in connection with the performance of any services that require resources outside of the existing resources of Ikaria or that otherwise interfere with the ordinary operations of Ikaria's business. This monthly service fee was payable by us regardless of the frequency or quantity of services actually utilized by us under the TSA. We were also obligated to pay any fees, costs, expenses or other amounts incurred by Ikaria to obtain the right to allow our employees to remain in the Hampton, New Jersey facility during the term of the TSA. At the time of the Spin-Out, we deposited the sum of $18.5 million into escrow, representing the aggregate of the $772,000 monthly service fees payable by us under the TSA, to guarantee payment of the monthly service fees by us. Pursuant to the July 2015 amendment, during October 2015, we received from escrow $3.3 million, which is equal to the amount it deposited to pay amounts owed to Ikaria under the TSA for the period from October 1, 2015 to February 9, 2016.

2015 Services Agreement. We entered into a services agreement with Ikaria, effective as of January 1, 2015, which we refer to as the 2015 Services Agreement. Pursuant to the terms of the 2015 Services Agreement, we had agreed to use commercially reasonable efforts to provide certain services to Ikaria, including services related to regulatory matters, drug and device safety, clinical operations, biometrics and scientific affairs. We were obligated, subject to the terms of the 2015 Services

Agreement, to provide such services until February 2016. In July 2015, we entered into an amendment to the 2015 Services Agreement advancing the termination date from February 8, 2016 to September 30, 2015. In connection with the execution of the 2015 Services Agreement, Ikaria paid us a one-time service fee in the amount of $916,666 and was obligated to pay us a service fee in the amount of $83,333 per month, subject to our obligation to perform the services.

In addition, pursuant to the terms and conditions of the 2015 Services Agreement, Ikaria had agreed to use commercially reasonable efforts to provide certain services to us, including services related to information technology, and servicing and upgrades of INOpulse devices. Ikaria was obligated, subject to the terms of the 2015 Services Agreement, to provide such services until February 2016. We were obligated to pay Ikaria certain fees under the 2015 Services Agreement that total, in the aggregate, approximately $215,000, subject to termination of the 2015 Services Agreement. In July 2015, we entered into an amendment to the 2015 Services Agreement advancing the termination date from February 8, 2016 to September 30, 2015. Amounts incurred in 2015 total $0.2 million.

Exclusive Cross-License, Technology Transfer and Regulatory Matters Agreement

In February 2014, we entered into an exclusive cross-license, technology transfer and regulatory matters agreement with Ikaria. Pursuant to the terms of the license agreement, Ikaria granted to us a fully paid-up, non-royalty bearing, exclusive license under specified intellectual property rights controlled by Ikaria to engage in the development, manufacture and commercialization of nitric oxide, devices to deliver nitric oxide and related services for or in connection with out-patient, chronic treatment of patients with PAH, PH-COPD or PH-IPF, which we refer to collectively as the Bellerophon indications. In November 2015, we entered into an amendment to our exclusive cross-license, technology transfer and regulatory matters agreement with Ikaria that included a royalty equal to 3% of net sales of any commercial products for PAH.

On July 27, 2015, we entered into an amendment to the license agreement to expand the scope of our license to allow the Company to develop our INOpulse program for the treatment of three additional indications: chronic thromboembolic pulmonary hypertension, or CTEPH, pulmonary hypertension associated with sarcoidosis and pulmonary hypertension associated with pulmonary edema from high altitude sickness. Subject to the terms set forth therein, the amendment to the license agreement also provides that we will pay Ikaria a royalty equal to 5% of net sales of any commercialized products for the three additional indications.

We have granted to Ikaria a fully paid-up, non-royalty-bearing, exclusive license under specified intellectual property rights that we control to engage in the development, manufacture and commercialization of products and services for or used in connection with the diagnosis, prevention or treatment, whether in- or out-patient, of certain conditions and diseases other than the Bellerophon indications and for the use of nitric oxide to treat or prevent conditions that are primarily managed in the hospital, which we refer to collectively as the Ikaria nitric oxide business.

We have agreed that, during the term of the license agreement, we will not, without the prior written consent of Ikaria, grant a sublicense under any of the intellectual property licensed to us under the license agreement to any of our affiliates or any third party, in either case, that directly or indirectly competes with the Ikaria nitric oxide business. We have also agreed that we will include certain restrictions in our agreements with customers of our products to ensure that such products will only be used for the Bellerophon indications.

The license agreement will expire on a product-by-product basis for products for a specific Bellerophon indication at such time as we are no longer developing or commercializing any product for such indication. The license agreement may be terminated by either party in the event an act or order of a court or governmental authority prohibits either party from substantially performing under the license agreement. Either party may also terminate the license agreement in the event of an uncured material breach by the other party or in the event the other party is insolvent or in bankruptcy proceedings. Ikaria may also terminate the license agreement if we or any of our affiliates breach the agreements not to compete described below, or if we or any successor to our rights under the license agreement markets a generic nitric oxide product that is competitive with INOmax. Under certain circumstances, if the license agreement is terminated, the licenses granted to Ikaria by us will survive such termination.

Employee Matters Agreement

In February 2014, we entered into an employee matters agreement with Ikaria, pursuant to which the employment of certain Ikaria employees was transferred to us or our subsidiaries on the terms and conditions set forth therein. The employee matters agreement also sets forth the treatment of outstanding Ikaria stock options and RSUs in connection with the Spin-Out. We have agreed to assume and pay, perform, fulfill and discharge, in accordance with the terms of the employee matters

agreement, all liabilities to or relating to such transferred employees. Effective as of the date of the Spin-Out, such transferred employees terminated participation in Ikaria's employee benefit plans, and we or our subsidiaries adopted employee benefit plans substantially similar to the following Ikaria plans: a 401(k) plan, a medical and dental plan, long-term disability, short-term disability, life and accidental death and dismemberment and flexible spending accounts, pursuant to the terms of the employee matters agreement.

Agreements Not to Compete

In September 2013, October 2013 and February 2014, we and each of our subsidiaries entered into an agreement not to compete with a subsidiary of Ikaria, each of which was amended in July 2015, or, collectively, the agreements not to compete. Pursuant to the agreements not to compete, as amended, we and each of our subsidiaries agreed not to engage, anywhere in the world, in any manner, directly or indirectly, until the earlier of five years after the effective date of such agreement not to compete amendments or the date on which Ikaria and all of its subsidiaries are no longer engaged in such business, in:

- the development, manufacture, commercialization, promotion, sale, import, export, servicing, repair, training, storage, distribution, transportation, licensing or other handling or disposition of any product or service (including, without limitation, any product or service that utilizes, contains or includes nitric oxide for inhalation, a device intended to deliver nitric oxide or a service that delivers or supports the delivery of nitric oxide), bundled or unbundled, for or used in connection with (a) the diagnosis, prevention or treatment, in both adult and/or pediatric populations, and whether in- or out-patient, of: (i) hypoxic respiratory failure associated with pulmonary hypertension, (ii) pulmonary hypertensive episodes and right heart failure associated with cardiovascular surgery, (iii) bronchopulmonary dysplasia, (iv) the management of ventilation-perfusion mismatch in acute lung injury, (v) the management of ventilation-perfusion mismatch in acute respiratory distress syndrome, (vi) the management of pulmonary hypertension episodes and right heart failure in congestive heart failure, (vii) pulmonary edema from high altitude sickness, (viii) the management of pulmonary hypertension episodes and right heart failure in pulmonary or cardiac surgery, (ix) the management of pulmonary hypertension episodes and right heart failure in organ transplant, (x) sickle cell vaso-occlusive crisis, (xi) hypoxia associated with pneumonia or (xii) ischemia-reperfusion injury or (b) the use of nitric oxide to treat or prevent conditions that are primarily managed in the hospital; or

- any and all development, manufacture, commercialization, promotion, sale, import, export, storage, distribution, transportation, licensing, or other handling or disposition of any terlipressin or any other product within the pressin family, (a) intended to treat (i) hepatorenal syndrome in any form, (ii) bleeding esophageal varices or (iii) septic shock or (b) for or in connection with the management of low blood pressure.

The agreements not to compete expressly exclude the Bellerophon indications.

Supply Agreements

Device Clinical Supply Agreement. In February 2014, we entered into the device supply agreement, pursuant to which Ikaria will use commercially reasonable efforts to manufacture and supply our requirements for certain nitric oxide delivery devices specified in the device supply agreement for use in our clinical programs for PAH and PH-COPD. Pursuant to the device supply agreement, we will pay to Ikaria an amount equal to Ikaria's internal and external manufacturing cost plus 20%. The device supply agreement expired on February 9, 2015.

Drug Clinical Supply Agreement. In February 2014, we entered into the drug supply agreement, pursuant to which Ikaria has agreed to use commercially reasonable efforts to manufacture and supply, and we have agreed to acquire from Ikaria, our requirements for nitric oxide for inhalation and corresponding placebo for use in our clinical programs for PAH, PH-COPD and PH-IPF. Under the terms of the drug supply agreement, we have also granted Ikaria a right of first negotiation in the event that we desire to obtain supply of nitric oxide for inhalation and corresponding placebo (or any variant thereof or any version with different specifications) for commercial use. The drug supply agreement will expire on a product-by-product basis on the date we discontinue clinical development of such product. In addition, either party may terminate the drug supply agreement in the event of an uncured material breach by the other party.

In November 2015, we amended our drug supply agreement with Ikaria to secure future supply and pricing for cartridges and nitric oxide. Under the amended supply agreement, we paid Ikaria $6.6 million, $0.6 million of which was applied to outstanding amounts owed to Ikaria under the drug supply agreement. The remaining $6.0 million resulted in a prepayment to Ikaria in exchange for defined levels of cartridges and nitric oxide. The amendment to the agreement also fixes pricing for any additional cartridges or nitric oxide beyond the defined levels. Additionally, the amendment requires us to pay to Ikaria an

additional $1.75 million upon successful completion of the initial PAH phase 3 clinical trial and a perpetual royalty calculated as 3% of PAH sales on a quarterly basis.

Participation in Initial Public Offering

In our IPO, certain of our directors, executive officers and 5% stockholders and their affiliates purchased an aggregate of 1,914,464 shares of our common stock. Each of those purchases was made through the underwriters or through the directed share program at the IPO price of $12.00 per share. The following table sets forth the aggregate number of shares of our common stock that these directors, executive officers and 5% stockholders and their affiliates purchased in our IPO:

Purchaser(1)	Shares of common stock	Total purchase price
New Mountain Entities	1,070,166	12,841,992
Linde	358,916	4,306,992
ARCH	212,666	2,551,992
Venrock	211,916	2,542,992
Jonathan M. Peacock	20,800	249,600
Manesh Naidu	1,500	18,000
Reinilde Heyrman	1,500	18,000
Martin Meglasson	12,000	144,000
Daniel Tassé	25,000	300,000

(1) See “Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters” for more information about the shares held by the below identified entities, directors and executive officers.

Policies and Procedures for Related Person Transactions

Our board of directors has adopted written policies and procedures for the review of any transaction, arrangement or relationship in which we were or are to be a participant, the amount involved exceeds $120,000 and one of our executive officers, directors, director nominees or 5% stockholders, or their immediate family members, each of whom we refer to as a “related person,” has a direct or indirect material interest.

If a related person proposes to enter into such a transaction, arrangement or relationship, which we refer to as a “related person transaction,” the related person must report the proposed related person transaction to our General Counsel or Chief Financial Officer, or in each case an individual performing similar functions. The policy calls for the proposed related person transaction to be reviewed and, if deemed appropriate, approved by our audit committee. Whenever practicable, the reporting, review and approval will occur prior to entry into the transaction. If advance review and approval is not practicable, the audit committee will review, and, in its discretion, may ratify the related person transaction. The policy also permits the chairman of the audit committee to review and, if deemed appropriate, approve proposed related person transactions that arise between committee meetings, subject to ratification by the committee at its next meeting. Any related person transactions that are ongoing in nature will be reviewed annually.

A related person transaction reviewed under the policy will be considered approved or ratified if it is authorized by the audit committee after full disclosure of the related person’s interest in the transaction. As appropriate for the circumstances, the committee will review and consider:

- the related person’s interest in the related person transaction;
- the approximate dollar value of the amount involved in the related person transaction;
- the approximate dollar value of the amount of the related person’s interest in the transaction without regard to the amount of any profit or loss;
- whether the transaction was undertaken in the ordinary course of our business;
- whether the terms of the transaction are no less favorable to us than terms that could have been reached with an unrelated third party;

- the purpose of, and the potential benefits to us of, the transaction; and

- any other information regarding the related person transaction or the related person in the context of the proposed transaction that would be material to investors in light of the circumstances of the particular transaction.

The audit committee may approve or ratify the transaction only if the committee determines that, under all of the circumstances, the transaction is in our best interests. The committee may impose any conditions on the related person transaction that it deems appropriate.

In addition to the transactions that are excluded by the instructions to the SEC's related person transaction disclosure rule, our board of directors has determined that the following transactions do not create a material direct or indirect interest on behalf of related persons and, therefore, are not related person transactions for purposes of this policy:

- interests arising solely from the related person's position as an executive officer of another entity (whether or not the person is also a director of such entity) that is a participant in the transaction, where (a) the related person and all other related persons own in the aggregate less than a 10% equity interest in such entity, (b) the related person and his or her immediate family members are not involved in the negotiation of the terms of the transaction and do not receive any special benefits as a result of the transaction and (c) the amount involved in the transaction is less than the greater of $200,000 or 5% of the annual gross revenues of the company receiving payment under the transaction; and

- a transaction that is specifically contemplated by provisions of our charter or bylaws.

The policy provides that transactions involving compensation of executive officers shall be reviewed and approved by the compensation committee in the manner specified in its charter.

We did not have a written policy regarding the review and approval of related person transactions prior to our IPO. Nevertheless, with respect to such transactions, it was our policy for our board of directors to consider the nature of and business reason for such transactions, how the terms of such transactions compared to those which might be obtained from unaffiliated third parties and whether such transactions were otherwise fair to and in the best interests of, or not contrary to, our best interests. In addition, all related person transactions required prior approval, or later ratification, by our board of directors.

Director Independence

NASDAQ rules require that a majority of our board of directors be independent within one year of listing, which in our case was February 13, 2015. In addition, the NASDAQ rules require that, subject to specified exceptions, each member of a listed company's audit, compensation and nominating and corporate governance committees be independent and that audit committee members also satisfy independence criteria set forth in Rule 10A-3 under the Exchange Act. Under NASDAQ rules, a director will only qualify as an "independent director" if, in the opinion of our board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In order to be considered independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors or any other board committee, accept, directly or indirectly, any consulting, advisory or other compensatory fee from the listed company or any of its subsidiaries or otherwise be an affiliated person of the listed company or any of its subsidiaries. Our board of directors has determined that Messrs. Bruder, Holt, Luehring, Moura, and Weinstein, Dr. Amin and Ms. Cloyd and are "independent directors," as defined under Rule 5605(a)(2) of the NASDAQ rules. In making such determination, our board of directors considered the relationships that each such non-employee director has with our company and all other facts and circumstances that our board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director.

The phase-in periods with respect to director independence under the applicable NASDAQ rules allow us to have only one independent member on each of the audit committee, compensation committee and nominating and corporate governance committee upon the listing date of our common stock, a majority of independent members on each of these committees within 90 days of the listing date and fully independent committees within one year of the listing date.

Our board of directors has determined that Mr. Leuhring, Dr. Amin and Ms. Cloyd, who are members of our audit committee, Messrs. Bruder and Holt, who are members of our compensation committee, and Messrs. Holt and Moura, who are members of our nominating and corporate governance committee, satisfy the independence standards for their respective

committees established by the SEC and NASDAQ rules, as applicable, including, in the case of the audit committee member, the independence requirements of Rule 10A-3 under the Exchange Act and, in the case of the compensation committee members, the independence requirements under Rule 10C-1 under the Exchange Act. In making such determinations, our board of directors considered the relationships that each such non-employee director has with our company and all other facts and circumstances that our board of directors deemed relevant in determining independence, including the beneficial ownership of our capital stock by each non-employee director.

Item 14. Principal Accountant Fees and Services

Auditors' Fees

The following table summarizes the fees of KPMG LLP, our independent registered public accounting firm, for professional services rendered for the audit of our fiscal 2015 and 2014 consolidated financial statements and the fees billed to us for other services for each of the last two fiscal years.

Fee Category	2015	2014
Audit Fees(1)	$ 362,500	$ 843,806
Audit-Related Fees	—	—
Tax Fees(2)	111,500	—
All Other Fees	—	—
Total Fees	$ 474,000	$ 843,806

(1) Audit fees consist of fees for the audit of our financial statements and the review of our interim financial statements and, in 2014, services associated with our registration statement on Form S-1.
(2) Tax fees include fees for tax services, including tax compliance.

Pre-Approval Policies and Procedures

The audit committee of our board of directors has adopted policies and procedures for the pre-approval of audit and non-audit services for the purpose of maintaining the independence of our independent auditor. We may not engage our independent auditor to render any audit or non-audit service unless either the service is approved in advance by the audit committee, or the engagement to render the service is entered into pursuant to the audit committee's pre-approval policies and procedures. Notwithstanding the foregoing, pre-approval is not required with respect to the provision of services, other than audit, review or attest services, by the independent auditor if the aggregate amount of all such services is no more than 5% of the total amount paid by us to the independent auditor during the fiscal year in which the services are provided, such services were not recognized by us at the time of the engagement to be non-audit services and such services are promptly brought to the attention of the audit committee and approved prior to completion of the audit by the audit committee.

may not engage our independent auditor to render any audit or non-audit service unless either the service is approved in advance by the audit committee, or the engagement to render the service is entered into pursuant to the audit committee's pre-approval policies and procedures. Notwithstanding the foregoing, pre-approval is not required with respect to the provision of services, other than audit, review or attest services, by the independent auditor if the aggregate amount of all such services is no more than 5% of the total amount paid by us to the independent auditor during the fiscal year in which the services are provided, such services were not recognized by us at the time of the engagement to be non-audit services and such services are promptly brought to the attention of the audit committee and approved prior to completion of the audit by the audit committee.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(1) Financial Statements

Our consolidated financial statements are set forth in Part II, Item 8 of this Annual Report on Form 10-K and are incorporated herein by reference.

(2) Financial Statement Schedules

No financial statement schedules have been filed as part of this Annual Report on Form 10-K because they are not applicable or are not required or because the information is otherwise included herein.

(3) Exhibits

The exhibits filed as part of this Annual Report on Form 10-K are set forth on the Exhibit Index immediately following our financial statements. The Exhibit Index is incorporated herein by reference.

SIGNATURES

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

Date: March 15, 2016

BELLEROPHON THERAPEUTICS, INC.

By: /s/ Jonathan M. Peacock
Jonathan M. Peacock
Chairman, President and Chief Executive Officer
(Principal Executive Officer)

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/ Jonathan M. Peacock Jonathan M. Peacock	Chairman, President and Chief Executive Officer (Principal Executive Officer)	March 15, 2016
/s/ Fabian Tenenbaum Fabian Tenenbaum	Chief Financial Officer and Chief Business Officer (Principal Financial Officer)	March 15, 2016
/s/ Naseem Amin Naseem Amin	Director	March 15, 2016
/s/ Scott Bruder Scott Bruder	Director	March 15, 2016
/s/ Mary Ann Cloyd Mary Ann Cloyd	Director	March 15, 2016
/s/ Matthew Holt Matthew Holt	Director	March 15, 2016
/s/ Jens Luehring Jens Luehring	Director	March 15, 2016
/s/ Andre V. Moura Andre V. Moura	Director	March 15, 2016
/s/ Daniel Tassé Daniel Tassé	Director	March 15, 2016
/s/ Adam Weinstein Adam Weinstein	Director	March 15, 2016

EXHIBIT INDEX

Exhibit Number	Description of Exhibit
2.1*	Plan of Conversion
2.2*	Agreement and Plan of Merger
3.1	Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-36845) filed with the SEC on February 25, 2015)
3.2	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. 001-36845) filed with the SEC on February 25, 2015)
4.1	Specimen Stock Certificate evidencing the shares of common stock (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1/A (File No. 333-201474) filed with the SEC on February 3, 2015)
4.2	Stockholders Agreement, dated February 12, 2015, between the Registrant and Linde North America, Inc.
4.3	Stockholders Agreement, dated February 12, 2015, among the Registrant and New Mountain Partners II (AIV-A), L.P., New Mountain Partners II (AIV-B), L.P., New Mountain Affiliated Investors II, L.P. and Allegheny New Mountain Partners, L.P.
10.1+	Assumed 2007 Ikaria Stock Option Plan (incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-201474) filed with the SEC on January 13, 2015)
10.2+	Assumed 2010 Ikaria Long Term Incentive Plan (incorporated by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form S-1 (File No. 333-201474) filed with the SEC on January 13, 2015)
10.3+	2014 Equity Incentive Plan (incorporated by reference to Exhibit 10.3 to the Registrant's Registration Statement on Form S-1 (File No. 333-201474) filed with the SEC on January 13, 2015)
10.4+	Form of Option Agreement under 2014 Equity Incentive Plan (incorporated by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form S-1 (File No. 333-201474) filed with the SEC on January 13, 2015)
10.5+	2015 Equity Incentive Plan (incorporated by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form S-1 (File No. 333-201474) filed with the SEC on February 3, 2015)
10.6+	Form of Incentive Stock Option Agreement under 2015 Equity Incentive Plan (incorporated by reference to Exhibit 10.6 to the Registrant's Registration Statement on Form S-1 (File No. 333-201474) filed with the SEC on February 3, 2015)
10.7+	Form of Nonstatutory Stock Option Agreement under 2015 Equity Incentive Plan (incorporated by reference to Exhibit 10.7 to the Registrant's Registration Statement on Form S-1 (File No. 333-201474) filed with the SEC on February 3, 2015)
10.8†	Amended and Restated License and Commercialization Agreement, dated as of August 26, 2009, among Ikaria Development Subsidiary One LLC, BioLineRx Ltd. and BioLine Innovations Jerusalem L.P., as amended (incorporated by reference to Exhibit 10.8 to the Registrant's Annual Report on Form 10-K (File No. 001-36845) filed with the SEC on March 31, 2015)
10.9	Form of Agreement Not to Compete, entered into by Ikaria Acquisition LLC and each of the Registrant, Bellerophon BCM LLC, Bellerophon Pulse Technologies LLC and Bellerophon Services, Inc. (incorporated by reference to Exhibit 10.9 to the Registrant's Registration Statement on Form S-1 (File No. 333-201474) filed with the SEC on January 13, 2015)
10.10†	Separation and Distribution Agreement, dated as of February 9, 2014, among the Registrant, Ikaria, Inc. and Ikaria Acquisition LLC (incorporated by reference to Exhibit 10.10 to the Registrant's Registration Statement on Form S-1 (File No. 333-201474) filed with the SEC on January 13, 2015)
10.11†	Services Agreement, effective as of January 1, 2015, between the Registrant and Ikaria, Inc. (incorporated by reference to Exhibit 10.11 to the Registrant's Registration Statement on Form S-1 (File No. 333-201474) filed with the SEC on February 3, 2015)
10.12†	Drug Clinical Supply Agreement, dated as of February 9, 2014, between Bellerophon Pulse Technologies LLC and INO Therapeutics LLC (incorporated by reference to Exhibit 10.12 to the Registrant's Registration Statement on Form S-1 (File No. 333-201474) filed with the SEC on January 13, 2015)
10.13†	Employee Matters Agreement, dated as of February 9, 2014, between the Registrant and Ikaria, Inc. (incorporated by reference to Exhibit 10.13 to the Registrant's Registration Statement on Form S-1 (File No. 333-201474) filed with the SEC on January 13, 2015)
10.14†	Exclusive Cross-License, Technology Transfer and Regulatory Matters Agreement, dated February 9, 2014, between Bellerophon Pulse Technologies LLC and INO Therapeutics LLC, as amended on March 27, 2014 (incorporated by reference to Exhibit 10.14 to the Registrant's Registration Statement on Form S-1 (File No. 333-201474) filed with the SEC on January 13, 2015)

10.15†	Transition Services Agreement, dated as of February 9, 2014, between the Registrant and Ikaria, Inc. (incorporated by reference to Exhibit 10.15 to the Registrant's Registration Statement on Form S-1 (File No. 333-201474) filed with the SEC on January 13, 2015)
10.16	Registration Rights Agreement, dated February 12, 2015, among the Registrant, New Mountain Partners II (AIV-A), L.P., New Mountain Partners II (AIV-B), L.P., Allegheny New Mountain Partners, L.P., New Mountain Affiliated Investors II, L.P., ARCH Venture Fund VI, L.P., Venrock Partners, L.P., Venrock Associates IV, L.P., Venrock Entrepreneurs Fund IV, L.P., Linde North America, Inc., 5AM Ventures LLC and Aravis Venture I L.P. (incorporated by reference to Exhibit 10.16 to the Registrant's Annual Report on Form 10-K (File No. 001-36845) filed with the SEC on March 31, 2015)
10.17	Form of Indemnification Agreement between the Registrant and each of its executive officers and directors (incorporated by reference to Exhibit 10.17 to the Registrant's Registration Statement on Form S-1 (File No. 333-201474) filed with the SEC on January 13, 2015)
10.18+	Assumed Employment Agreement, dated January 4, 2012, between Manesh Naidu and Ikaria, Inc. (incorporated by reference to Exhibit 10.18 to the Registrant's Registration Statement on Form S-1 (File No. 333-201474) filed with the SEC on January 13, 2015)
10.19+	Assumed Employment Agreement, dated August 10, 2010, between Martin Meglasson and Ikaria, Inc. (incorporated by reference to Exhibit 10.19 to the Registrant's Registration Statement on Form S-1 (File No. 333-201474) filed with the SEC on January 13, 2015)
10.20+	Assumed Employment Agreement, dated March 26, 2012, between Reinilde Heyrman and Ikaria, Inc. (incorporated by reference to Exhibit 10.20 to the Registrant's Registration Statement on Form S-1 (File No. 333-201474) filed with the SEC on January 13, 2015)
10.21+	Form of Retention Bonus Letter for Executive Officers (incorporated by reference to Exhibit 10.21 to the Registrant's Registration Statement on Form S-1 (File No. 333-201474) filed with the SEC on January 13, 2015)
10.22+	Employment Agreement, dated June 20, 2014, between Jonathan M. Peacock, the Registrant and Bellerophon Services, Inc. (incorporated by reference to Exhibit 10.22 to the Registrant's Registration Statement on Form S-1 (File No. 333-201474) filed with the SEC on January 13, 2015)
10.23	Form of Management Rights Letter between the Registrant and certain of its stockholders (incorporated by reference to Exhibit 10.23 to the Registrant's Registration Statement on Form S-1 (File No. 333-201474) filed with the SEC on January 13, 2015)
10.24+	Amendment to Assumed Employment Agreement, dated as March 13, 2015, between Jonathan M. Peacock and the Registrant (incorporated by reference to Exhibit 10.9 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-36845) filed with the SEC on May 15, 2015)
10.25+	Amendment to Assumed Employment Agreement, dated as March 13, 2015, between Manesh Naidu and the Registrant (incorporated by reference to Exhibit 10.10 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-36845) filed with the SEC on May 15, 2015)
10.26+	Amendment to Assumed Employment Agreement, dated as March 13, 2015, between Martin Meglasson and the Registrant (incorporated by reference to Exhibit 10.11 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-36845) filed with the SEC on May 15, 2015)
10.27+	Amendment to Assumed Employment Agreement, dated as March 13, 2015, between Reinilde Heyrman and the Registrant (incorporated by reference to Exhibit 10.12 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-36845) filed with the SEC on May 15, 2015)
10.28+	Offer Letter, dated May 14, 2015, between Amit Agrawal and the Registrant (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-36845) filed with the SEC on August 14, 2015)
10.29+	Offer Letter, dated April 20, 2015, between Peter Fernandes and the Registrant (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-36845) filed with the SEC on August 14, 2015)
10.30+	Offer Letter, dated December 8, 2014, between Martin Dekker and the Registrant (incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-36845) filed with the SEC on August 14, 2015)
10.31	Lease Agreement between 184 Property Owner, LLC and the Registrant dated August 6, 2015 (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-36845) filed with the SEC on November 12, 2015)
10.32	Second Amendment to the Exclusive Cross-License, Technology Transfer, and Regulatory Matters Agreement between Bellerophon Pulse Technologies LLC and INO Therapeutics LLC, dated July 27, 2015 (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-36845) filed with the SEC on November 12, 2015)
10.33	Form of Amendment to Agreement Not to Compete, entered into by Ikaria Acquisition LLC and each of the Registrant, Bellerophon BCM LLC, Bellerophon Pulse Technologies LLC and Bellerophon Services, Inc. dated July 27, 2015 (incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-36845) filed with the SEC on November 12, 2015)

10.34	First Amendment to Transition Services Agreement between Ikaria, Inc. and the Registrant dated July 9, 2015 (incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-36845) filed with the SEC on November 12, 2015)
10.35	First Amendment to Services Agreement between Ikaria, Inc. and the Registrant dated July 9, 2015 (incorporated by reference to Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-36845) filed with the SEC on November 12, 2015)
10.36	Severance and Release Agreement between Manesh Naidu and the Registrant dated July 31, 2015 (incorporated by reference to Exhibit 10.6 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-36845) filed with the SEC on November 12, 2015)
10.37	Professional Services Agreement between Martin Meglasson and the Registrant dated September 23, 2015 (incorporated by reference to Exhibit 10.7 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-36845) filed with the SEC on November 12, 2015)
10.38+	Offer Letter between Deborah Quinn and the Registrant dated December 8, 2014 (incorporated by reference to Exhibit 10.8 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-36845) filed with the SEC on November 12, 2015)
10.39+	Offer Letter between Amy Edmonds and the Registrant dated February 14, 2014 (incorporated by reference to Exhibit 10.9 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-36845) filed with the SEC on November 12, 2015)
10.40+	Form of Retention Letter by and between the Registrant and each of David Abrams, Martin Dekker, Peter Fernandes, Deborah Quinn and Amy Edmonds (incorporated by reference to Exhibit 10.10 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-36845) filed with the SEC on November 12, 2015)
10.41+	Form of Restricted Stock Agreement under 2015 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-36845) filed with the SEC on December 4, 2015)
10.42	Second Amendment to Drug Clinical Supply Agreement and Third Amendment to Exclusive Cross-License, Technology Transfer, and Regulatory Matters Agreement, dated November 16, 2015, between Bellerophon Pulse Technologies LLC and INO Therapeutics LLC (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-36845) filed with the SEC on January 12, 2016)
10.43+	Offer Letter between Fabian Tenenbaum and the Registrant dated February 12, 2016
10.44+	Amended and Restated Employment Agreement between Jonathan M. Peacock and the Registrant dated March 12, 2016
21.1	Subsidiaries of the Registrant (incorporated by reference to Exhibit 21.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-201474) filed with the SEC on January 13, 2015)
23.1	Consent of KPMG LLP independent registered public accounting firm
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended
32	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

* Schedules and exhibits have been omitted pursuant to Item 601(b)(2) of Regulation S-K. The Registrant hereby undertakes to furnish copies of any of the omitted schedules and exhibits upon request by the Securities and Exchange Commission.

† Confidential treatment has been granted as to certain portions, which portions have been omitted and separately filed with the Securities and Exchange Commission.

\+ Management contract or compensatory plan or arrangement filed in response to Item 15(a)(3) of the Instructions to the Annual Report on Form 10-K.

Exhibit 10.43

February 8, 2016

Mr. Fabian Tenenbaum

Dear Fabian:

On behalf of Bellerophon Therapeutics (the "Company"), I am pleased to offer you employment as Chief Financial Officer and Chief Business Officer of the Company. The purpose of this letter is to summarize the terms of your employment with the Company, should you accept our offer.

1. POSITION

- You will be employed to serve on a full-time basis as the Company's Chief Financial Officer and Chief Business Officer reporting directly to me. You will primarily be responsible for management of the Finance and Business Development functions, oversight of the Operating Plan, and will be a member of the Bellerophon Leadership Team. Your employment with the Company will begin on a date between February 15th and March 1st, 2016 as mutually agreed upon by you and the Company (the "Start Date").

2. COMPENSATION

- Your base salary will be at the annualized rate of $360,000.00, less all applicable taxes and withholdings, to be paid in bi-weekly installments in accordance with the regular payroll practices of the Company. Your base salary will be subject to annual review by the Board of Directors of the Company (the "Board") or the Compensation Committee thereof (the "Committee").

- Following the end of each calendar year and subject to the approval of the Board or the Committee, you will be eligible to receive a retention and performance bonus. The target amount of such annual bonus will be 40% of your annualized base salary, which shall be paid in cash or equity or any combination thereof, in each instance as determined by Compensation Committee, in its sole discretion and on such terms (including, without limitation, vesting terms, which shall be no greater than one year from the date of the grant, for any bonus paid, in whole or in part, in equity) as it may in its sole discretion establish. Your actual annual bonus may be more or less than the above-stated target amount, and will be determined by the Committee based on the Company's performance and your performance during the applicable calendar year, as determined by the Board in its sole discretion. You must be employed by the Company on the date any annual bonus is distributed in order to be eligible for and to earn a bonus award, as it also serves as an incentive to remain employed by the Company. Any bonus would be pro-rated for the 2016 calendar year.

- The Company will, subject to approval of the Committee, grant you an option to purchase 130,000 shares of Bellerophon common stock (such shares, including any securities into which such shares are changed or for which such shares are exchanged, the "Common Stock") at a per share exercise price equal to the fair value of the Common Stock on the date of grant (as determined by the Board of Directors of the Company) (the 'Option"). The Option, subject to the approval of the Committee, will (a) vest in four equal installments, with the first installment vesting one year following the Start Date, and the remaining three installments vesting annually of the following three anniversaries of the State Date and (b) include 100% accelerated vesting in the event of a Change in Control (as defined below) and (c) formally provide an alternative vesting schedule solely in the event that the Company terminates your employment without Cause (as defined below) following the vesting of the first installment, such that the Option will be deemed to have vested in equal monthly installments following the Start Date. The Option shall be evidenced by the form of Stock Option Agreement provided to you and your acknowledged receipt thereof.

3. BENEFITS

- You may participate in all employee benefit plans made generally available by the Company from time to time to its employees, provided that you are eligible under (and subject to all provisions of) the plan documents that govern those plans. The Company currently offers medical, dental, disability, life insurance and 401(k) benefit plans. Benefits are subject to change at any time in the Company's sole discretion.

- You will be eligible to receive, on the same basis as other similarly situated employees of the Company, any other employee benefits, including ten (10) paid holidays and twenty (20) paid time off (PTO) days each calendar year. The number of PTO days for which you are eligible will accrue ratably each month that you are employed during a calendar year. Upon your separation from the Company, you will receive payment for any accrued, unused PTO days in accordance with Company policy and applicable law.

- The Company will provide reimbursement of travel and entertainment (T&E) expenses incurred in connection with Bellerophon business activities in accordance with the Company's Travel & Entertainment Policy.

3. REIMBURSEMENT FOR LEGAL SERVICES

- Within 90 days of employment, the Company will reimburse you for the cost of legal services you incurred to prepare your offer letter up to a maximum of $3,000. In order to receive reimbursement, you may be required to provide copies of your legal invoices to the Company.

4. OTHER TERMS AND CONDITIONS OF EMPLOYMENT

- In the event the Company terminates your employment without Cause (as defined below) at any time, or if you terminate your employment for Good Reason (as defined below) within twelve (12) months following a Change in Control (as defined below), the Company will provide you with the following severance benefits (the "Severance Benefits": (a) for a period of twelve (12) months following your termination of employment, the Company will continue

to pay to you monthly, as severance pay, an amount equal to your base salary rate as of your termination date, (b) the Company will provide you with your Annual Bonus at the target level in cash or equity or any combination thereof, where cash or equity or the combination is determined by the Committee in its sole discretion, and (c) the Company shall, provided that you are eligible for and elect to continue receiving group medical, dental and/or vision coverage under COBRA, and for a period ending on the earlier of (x) twelve (12) months following your termination date and (y) the date you become eligible to receive such insurance coverage from a new employer, reimburse you for the portion of the premiums for such coverage that it pays on behalf of active and similarly situated employees. You agree to inform the Company in writing within five (5) business days of becoming eligible to receive group insurance coverage from a new employer. All Severance Benefits are subject to applicable taxes and withholdings. Your receipt of any and all Severance Benefits is contingent upon your executing and allowing to become effective (within 60 days following your termination or such shorter period as the Company may specify) a severance and release of claims agreement in the form provided by the Company (the 'Severance Agreement'). The Severance Benefits will commence on the first regular payday whose cutoff date occurs after the Severance Agreement becomes effective, provided that if the sixtieth day following your separation from employment ends in a calendar year subsequent to the year in which your employment is terminated, payment will not begin before the first business day of that subsequent year if the Severance Pay is subject to Section 409A of the Internal Revenue Code of 1986, as amended (the 'Code').

- For purposes of this letter:

  "Cause" means: (i) commission of, indictment, or conviction for, any crime involving moral turpitude or any felony; (ii) participation in any fraud against the Company; (iii) your substantial failure to perform (other than by reason of physical or mental illness or disability for a period of less than three consecutive months or in aggregate less than twenty-six weeks), or gross negligence in the performance of , your duties and responsibilities to the Company; (iv) other conduct by you that is reasonably anticipated to harm the business, interests or reputation of the Company; or (v) your breach of a material term of this offer letter, the Confidentiality Agreement (as defined below), or any other written agreement between you and the Company.

  "Good Reason" means: without your prior consent, (i) a material diminution of your duties, authority or responsibilities, (ii) a material diminution in your annualized base salary, other than in an amount proportionate to reductions made in the annualized base salaries of other comparable senior executives, (iii) the relocation of the principal place at which you provide services to the Company by more than 25 miles from the Company, other than in a direction that reduces your daily commute, or (iv) a material breach of this letter. To terminate your employment for Good Reason, you must (x) provide notice to the Company of the purported event giving rise to Good Reason within 30 days after it occurs, (y) provide the Company with at least 30 days to cure, and (iv) if not cured, resign for Good Reason within 60 days after the end of the cure period.

- A "Change in Control" shall have occurred if, after the Start Date, (A) any "Person" (as the term "person" is used for purposes of Section 13(d) or 14(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), including a "group" as defined or described in Section 13(d) of the Exchange Act) (other than any Person that includes New Mountain

Partners II (AIV-A), L.P., New Mountain Partners II (AIV-B), L.P., New Mountain Affiliated Investors II, L.P. or Allegheny New Mountain Partners, L.P. or any of their affiliates (any such Person, an "Excluded Person")), is the "Beneficial Owner" (within the meaning of Rule 13d-3 promulgated under the Exchange Act), directly or indirectly of more than 50% of the voting capital stock of the Company, or (B) the Company, sells in a single transaction or series of related transactions all or substantially all of its assets (including equity interests in any subsidiaries of affiliates) to any Person other than an Excluded Person; and provided, that, for avoidance of doubt, an initial public offering of securities of the Company (or any successor of the Company) shall not constitute Change in Control for purposes of this letter.

- You will be required to execute, as a condition of your employment with the Company, the Company's standard Employee Confidentiality, Non-Solicitation, Non- Competition, and Work Product Assignment Agreement (the "Confidentiality Agreement") to be provided by the Company.

- Your employment with the Company is conditioned on your eligibility to work in the United States. You agree to provide to the Company, within three (3) days of your Start Date, documentation proving your eligibility to work in the United States, as required by the Immigration Reform and Control Act of 1986. To that end, a copy of an 1-9 Form is enclosed for your information. Please bring the appropriate documents listed on that form with you when you report to work.

- While you are employed by the Company you will be expected to devote your full working time, energy, skill and experience to the performance of your duties, which may be redefined or modified by the Company from time to time. For the first 3 months, it is expected that you will provide limited support for Anterios-Allergan integration activities.

- The Company's employment offer is contingent upon your successful completion of a background check, drug screen and completed reference check. It is also contingent upon approval of the Board.

- By signing this letter you agree that this offer is personal and confidential and should not be discussed with any other employees in the Company.

- Your employment with the Company is at will. This means that you or the Company may terminate the employment relationship at any time, for any reason, with or without Cause or notice. This letter is not a contract, nor a promise of employment for any specific duration. Similarly, nothing in this letter shall be construed as an agreement, either express or implied, to pay you any compensation or grant you any benefit beyond the end of your employment with the Company, except as explicitly set forth above.

- For purposes of this letter, a termination of employment will mean a 'separation from service' as defined in Section 409A, and each amount to be paid or provided as a Severance Benefit will be construed as a separate identified payment for purposes of Section 409A. If and to the extent any portion of any payment, compensation or other benefit provided to you in connection with your employment termination is determined to constitute `nonqualified deferred compensation' within the meaning of Section 409A and you are a specified employee as defined in Section 409A(a)(2)(B)(i), as determined by the Company in accordance with its procedures, by which determination you hereby agree that you are bound, such portion of the

payment, compensation or other benefit shall not be paid before the earlier of (i) the expiration of the six month period measured from the date of your 'separation from service' (as determined under Section 409A) or (ii) the tenth day following the date of your death following such separation from service (the 'New Payment Date'). The aggregate of any payments that otherwise would have been paid to you during the period between the date of separation from service and the New Payment Date shall be paid to you in a lump sum in the first payroll period beginning after such New Payment Date, and any remaining payments will be paid on their original schedule. All compensatory payments are subject to applicable tax and other required withholding.

- This letter constitutes the final and complete agreement with respect to your employment and supersedes any and all prior or contemporaneous discussions, representations or commitments, whether written or oral, relating to the terms of your employment, including without limitation those set forth in the January 25, 2016, January 28, 2016, and February 3, 2016 offer letters, which are null and void.

- You represent that you are not bound by any employment contract, restrictive covenant or other restriction preventing you from entering into employment with or carrying out your responsibilities for the Company, or which is in any way inconsistent with the terms of this letter.

If you agree with the terms and conditions of this offer, please sign and date this letter in the space provided below and return it to me by the close of business on Friday, February 12, 2016.

We are very much looking forward to having you join our team.

/s/ Jonathan Peacock

Jonathan Peacock
Chairman & CEO
Bellerophon Therapeutics

The foregoing correctly sets forth the terms of my at-will employment with Bellerophon Therapeutics. I am not relying on any representations other than those set forth above.

/s/ Fabian Tenenbaum 02/12/16
Fabian Tenenbaum Date

Exhibit 10.44

AMENDED AND RESTATED EMPLOYMENT AGREEMENT

THIS AMENDED AND RESTATED EMPLOYMENT AGREEMENT is made by and between Bellerophon Therapeutics, Inc. (the "Company") and Jonathan M. Peacock (the "Executive"), dated as of March 12, 2016 (this "Agreement").

WHEREAS, the Executive is currently employed by the Company as its Chairman and Chief Executive Officer, pursuant to a June 20, 2014 Employment Agreement by and between the Executive, Bellerophon Therapeutics, LLC and Bellerophon Services, Inc., as amended March 13, 2015 (the "Prior Employment Agreement"), with an effective date of June 20, 2014 (the "Prior Effective Date");

WHEREAS, the Company desires to continue to employ the Executive pursuant to the terms and conditions set forth in this Agreement; and

WHEREAS. The Executive has agreed to accept such continued employment on the terms and conditions set forth in this Agreement;

NOW, THEREFORE, in consideration of the promises and mutual covenants herein contained, the parties hereto agree as follows:

1. Employment Period. The Company shall continue to employ the Executive, and the Executive shall continue to serve the Company, on the terms and conditions set forth in this Agreement, for the period commencing on March 12, 2016 (the "Effective Date"), and continuing until terminated in accordance with the terms of Section 4 hereof (the "Employment Period").

2. Position and Duties.

(a) During the Employment Period, the Executive shall serve as Chairman and Chief Executive Officer of the Company, or, in the sole discretion of the Company, as Chairman only, with such duties and responsibilities as are customarily assigned to such position(s) or specified in the Company's by-laws (as applicable), and such other duties and responsibilities not inconsistent therewith as may be assigned to the Executive from time to time by the Board of Directors of the Company (the "Company Board"). In such capacity, the Executive shall report to the Company Board. During the Employment Period, the Executive shall serve as a member of the Company Board.

(b) During the Employment Period, and excluding any periods of vacation and sick leave to which the Executive is entitled, the Executive shall devote fifty percent (50%) of his full business time and efforts to the business and affairs of the Company and use his best efforts to carry out such responsibilities faithfully and efficiently. During the Employment Period, the Executive shall not be engaged in any other business activity without the prior written consent of the Company except for: (i) up to 50% of his full business time spent in performing services for Perceptive Bioscience Investments Limited ("Perceptive"), and (ii) time spent in managing his personal, financial, charitable and legal affairs, in each case only if, and to the extent that, such activities do not materially interfere with the performance of the Executive's duties and responsibilities hereunder or otherwise result in a breach of this Agreement. Notwithstanding the foregoing, the Company agrees that the Executive may continue to serve on the Board of Directors of Kite Pharma and as Trustee of the Natural History Museum of Los Angeles.

(c) The Executive's services hereunder shall be performed at the Company's Warren, New Jersey headquarters, subject to such business travel as may be required from time to time.

3. Compensation.

(a) Base Salary. During the Employment Period, the Executive shall receive a base salary (such base salary, as it may be increased from time to time hereunder, the "Annual Base Salary") at the annual rate of $200,000. The Annual Base Salary shall be payable in accordance with the Company's payroll practices as in effect from time to time, subject to applicable taxes and withholding. During the Employment Period, the Annual Base Salary shall be reviewed for possible merit increases at least annually but shall not be reduced during the Employment Period.

(b) Annual Bonus. For each calendar year ending during the Employment Period, the Executive shall be eligible to earn an annual cash bonus payable in accordance with the terms of the Company's management incentive program, to be established and implemented in consultation with the Executive, at a target of 100% of Annual Base Salary, or such higher level established by the Company from time to time (the "Annual Bonus"). With respect to any bonus hereunder, the Company, in its sole discretion, may pay such bonus in cash or equity or a combination thereof, in each instance on such terms as are determined by the Compensation Committee of the Board of Directors (the "Compensation Committee").

(c) Stock Option Grant. The Executive was, following the Prior Effective Date, granted an option to purchase a number of non-voting units of the Company representing 5% of the fully diluted equity of the Company as of the date of grant (the "Option"). The Option (i) has an exercise price per unit equal to the fair market value of a unit on the date of grant (subject to adjustment for any stock splits, dividends paid in stock, reverse stock splits, or similar events affecting the units), (ii) has an exercise period of 10 years, (iii) vests in five (5) equal annual 20% installments with the first installment vesting on the Prior Effective Date, and the remaining installments vesting on each anniversary of the Prior Effective Date, and (iv) includes 100% accelerated vesting in the event of a Change in Control (as defined below). For purposes of this Agreement, a "Change in Control" shall have occurred if, after the Effective Date, (A) any "Person" (as the term "person" is used for purposes of Section 13(d) or 14(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), including a "group" as defined or described in Section 13(d) of the Exchange Act) (other than any Person that includes New Mountain Partners II (AIV-A), L.P., a Delaware limited partnership, New Mountain Affiliated Investors II, L.P., a Delaware limited partnership, or Allegheny New Mountain Partners, L.P., a Delaware limited partnership (collectively the "NMP Entities") or any of their affiliates (any such Person, an "Excluded Person")), is the "Beneficial Owner" (within the meaning of Rule 13d-3 promulgated under the Exchange Act), directly or indirectly, of more than 50% of the voting equity interests of the Company, or (B) the Company sells in a single transaction or series of related transactions all or substantially all of its assets (including equity interests in any subsidiaries of affiliates) to any Person other than an Excluded Person; and provided, that, for avoidance of doubt, an initial public offering of securities of the Company (or any successor of Company) shall not constitute a Change in Control for purposes of this Agreement.

(d) Benefits. During the Employment Period, the Executive and/or the Executive's family, as the case may be, shall be provided with such employee benefits, and under the same terms, as are provided by the Company from time to time to its senior executives, provided that the Executive remains eligible for such benefits under the terms of the Company's benefits plans. If during calendar year 2016 the Executive is no longer eligible to participate in the Company's group medical, dental and vision insurance plans (the "reduction date"), then his eligibility date under the law known as COBRA shall be the reduction date, and if the Executive is eligible for and elects to continue receiving such group insurance coverage pursuant to

COBRA, the Company will, until the earlier of (i) the last day of the Executive's employment with the Company or (ii) December 31, 2016, pay that portion of the Executive's monthly COBRA premium payments that the Company pays for active and similarly situated employees receiving the same type of coverage. In the event the Company's payment under this Section 3(d) would violate the nondiscrimination rules of the Patient Protection and Affordable Care Act ("PPACA"), the parties agree to reform this provision to comply with the PPACA while maintaining the intended economic benefit to the Executive. The Company reserves the right to modify or terminate its benefits plans generally for employees.

(e) Vacation. During each year of the Employment Period, the Executive shall be entitled to paid vacation consistent with the Company's practices, policies and programs for its senior executives; provided that the Executive shall be entitled to no less than two (2) weeks of paid vacation during each year of the Employment Period.

(f) Business and Entertainment Expenses. During the Employment Period, the Executive shall be entitled to receive prompt reimbursement for all reasonable expenses incurred by the Executive in carrying out the Executive's duties under this Agreement; provided that the Executive complies with the policies, practices and procedures of the Company for submission of expense reports, receipts, or similar documentation of such expenses.

4. Termination of Employment.

(a) Death or Disability. The Executive's employment hereunder shall terminate automatically upon the Executive's death during the Term. The Company shall, to the full extent permitted by law, be entitled to terminate the Executive's employment because of the Executive's "Disability" (as herein defined) during the Term. "Disability" means the permanent disability of the Executive in accordance with the long-term disability plan of the Company applicable to the Executive.

(b) By the Company. The Company may terminate the Executive's employment hereunder for Cause or without Cause. For purposes of this Agreement, the term "Cause" shall be defined as: (A) disloyalty or dishonesty which results or is intended to result in personal enrichment to the Executive at the material expense of the Company or any of its subsidiaries (including, without limitation, fraud, embezzlement or dishonesty or breach of business ethics); (B) fraudulent conduct in connection with the business or affairs of the Company or any of its subsidiaries; (C) conviction of a felony or any crime involving moral turpitude (or entering into a plea of nolo contendere with respect to such crime); (D) gross misconduct that materially and adversely affects the Company; (E) any breach or intended breach of any Company policies or procedures as in effect from time to time, in each case constituting a material violation of such policies or procedures, and in each case causing material harm to the Company; or (F) failure by the Executive to provide thirty (30) days advance written notice of resignation without Good Reason (defined below); provided that in the case of Subsection (E) of this Section 4(b), the Company shall give written notice to the Executive within ninety (90) days of the Company's knowledge of any event triggering this Subsection (E) ("Notice of Termination for Cause"), which notice shall set out in detail the ways in which the Executive has materially breached or expressed an intent to breach materially a Company policy or procedure in such a way as to cause the Company material harm, and the Executive shall have failed to cure such breach within thirty (30) days of the date the Executive receives the Notice of Termination for Cause; and provided further that with respect to the Executive's violation of Subsection (E) of this Section 4(b), the Executive shall have only one (1) opportunity to cure such failure and thereafter may be terminated immediately in connection with subsequent violations of Subsection (E) of this Section 4(b).

(c) By the Executive. The Executive may terminate the Executive's employment hereunder for Good Reason or other than for Good Reason upon thirty (30) days' notice. For purposes of this Agreement, "Good Reason" means that the Company has engaged in any of the following without the Executive's consent:

A. any material and adverse change in the Executive's position, title or status, any change in the Executive's job duties, authority or responsibilities to those of lesser status, any obligation that the Executive report other than to the Company Board or the lead director or Chairman of the Company Board, or the Executive's removal from the Company Board; provided, however, that the Company's appointment of a new Chief Executive Officer, and/or the Company's change of the Executive's position and title to Chairman of the Board only, with such duties commensurate with such Chairman role, shall not constitute Good Reason hereunder;

B. any material and adverse breach of this Agreement by the Company; provided, however, that the Company's appointment of a new Chief Executive Officer, and/or the Company's change of the Executive's position and title to Chairman of the Board only, with such duties commensurate with such Chairman role, , shall not constitute Good Reason hereunder; provided, that any failure of a successor to assume and agree to perform under this Agreement required by Section 7(c) shall be deemed to be a material and adverse breach of this Agreement by the Company;

C. relocation of the Company's headquarters more than fifty (50) miles from its present location or transfer of the Executive to any location more than fifty (50) miles from the location of the current headquarters; or

D. any material and adverse change in the Executive's compensation or benefits.

A termination of employment by the Executive for Good Reason shall be effectuated by giving the Company written notice ("Notice of Termination for Good Reason") of the termination, setting forth the conduct of the Company that constitutes Good Reason, within ninety (90) days of the first date on which the Executive has knowledge of such conduct. The Executive shall further provide the Company at least thirty (30) days following the date on which such notice is provided to cure such conduct. Failing such cure, a termination of employment by the Executive for Good Reason shall be effective on the day following the expiration of such cure period.

(d) No Waiver. The failure to set forth any fact or circumstance in a Notice of Termination for Cause or a Notice of Termination for Good Reason shall not constitute a waiver of the right to assert, and shall not preclude the party giving notice from asserting, such fact or circumstance in an attempt to enforce any right under or provision of this Agreement.

(e) Date of Termination. The "Date of Termination" means the date of the Executive's death, the date on which the Executive is designated as having a Disability, or the date on which the termination of the Executive's employment by the Company or by the Executive is effective.

5. Obligations of the Company upon Termination.

(a) Termination Other Than for Cause; Resignation for Good Reason. If either (A) the Company terminates the Executive's employment, for any reason other than for Cause, death or Disability, or (B) the Executive terminates his employment for Good Reason, then the Company shall pay the amounts and provide the benefits, subject to and in accordance with Section 5(d) hereof, in each case as set forth in Sections 5(a)A-D below.

A. The Executive's earned and accrued but unpaid cash compensation, in the form of a lump-sum payment, to be paid not later than the regularly scheduled pay period next following the Date of Termination, which shall equal the sum of (i) any portion of the Executive's Annual Base Salary earned through the Date of Termination that has not yet been paid, (ii) any unpaid Annual Bonus that was earned by the Executive and declared due and owing by the Company, (iii) any accrued but unpaid vacation time, in each case subject to applicable taxes and withholding, and (iv) any incurred and unreimbursed expenses through the Date of Termination pursuant to Sections 3(f)-(h) (the amounts set forth in sub clauses (i)-(iv) constitute the "Accrued Obligations"). The Company shall also provide the Executive with any other benefits (other than severance benefits) to which the Executive is entitled under the Company's benefit plans and arrangements as and when due under such plans and arrangements (the "Accrued Benefits").

B. A pro rata portion of the Executive's Annual Bonus payable in cash or equity or any combination thereof, and on such terms, as determined by the Compensation Committee in its sole discretion, which shall equal the sum of the Executive's Annual Bonus at target for the year in which Termination occurs, multiplied by the number equal to the sum of any partial and full months worked by the Executive in the year of termination, divided by the number twelve (12) (the "Pro Rata Bonus").

C. Payments, payable in accordance with the Company's standard monthly payroll practices and subject to withholding and taxes of an amount equal to the sum of one and one half (1.5) times the sum of (i) the Executive's Annual Base Salary and (ii) the greater of the Annual Bonus at the target level and the actual Annual Bonus most recently paid to the Executive, determined on a monthly basis, for a period of eighteen (18) months from the Date of Termination (the "Salary Continuation Severance Payments").

D. For eighteen (18) months from the Date of Termination (or for such shorter period for which the Executive may be eligible, if he has already commenced COBRA continuation coverage prior to the Date of Termination), and subject to the Executive electing COBRA continuation coverage, the Company shall provide the Executive with medical, dental and vision benefits at active-employee rates (the "Health Benefit"). In the event the Company's payment under this Section 5(a)(D) would violate the nondiscrimination rules of the PPACA, the parties agree to reform this provision to comply with the PPACA while maintaining the intended economic benefit to the Executive.

(b) Death or Disability. If the Executive's employment is terminated by reason of the Executive's death or Disability during the Term, the Company shall pay the Accrued Obligations to the Executive or the Executive's estate or legal representative, as applicable, in a lump-sum payment (subject to applicable taxes and withholding) not later than the next regularly scheduled pay period following the Date of Termination, and, following the Date of Termination, the Company shall provide the Executive with the Accrued Benefits as and when due.

(c) Cause; Resignation other than for Good Reason. If the Executive's employment is terminated by the Company for Cause, or if the Executive terminates his employment other than for Good Reason, the Company shall pay the Executive, in a lump-sum payment (subject to applicable taxes and withholding) not later than the next regularly scheduled pay period following the Date of Termination, the Accrued Obligations, and, following the Date of Termination, the Company shall provide the Executive with the Accrued Benefits as and when due.

(d) Timing of Severance Payments and Benefits.

The Company's obligations to make the payments, or otherwise perform, as set forth

in Sections 5(a)(B)-(D), shall be conditioned upon: (i) the Executive's continued compliance with his obligations under Section 6 and (ii) the Executive's execution, delivery and non-revocation of a valid and enforceable general release of claims against the Company and its affiliates in the form attached hereto as Exhibit A (the "Release") within sixty (60) days after the Executive's Date of Termination.

The payments and benefits described in Sections 5(a)(B)-(D) shall be made, provided, or commenced, as applicable, promptly after the Date of Termination, provided that the Executive has executed and delivered the Release, and the Release has become irrevocable by such date.

If no stock of the Company is publicly traded on an established securities market or otherwise on the Date of Termination, the payments and benefits described in Sections 5(a)(B)-(D) shall be made, provided, or commenced, as applicable, on the sixtieth (60^{th}) day after the Date of Termination. If stock of the Company is publicly traded on an established securities market or otherwise on the Date of Termination, the payments and benefits described in Sections 5(a)(B)-(D) shall be made, provided, or commenced, as applicable, upon the day following the day that is six (6) months after the Date of Termination unless such payments can be made, provided, or commence on the 60^{th} day after the Date of Termination without violating Section 409A (as defined below).

The payments described in Sections 5(a)(B)-(D) shall constitute the exclusive payments in the nature of severance which shall be due to the Executive upon a termination of employment as described in Section 5(a), and shall be in lieu of any other such payments under any severance plan, program, policy or other severance arrangement of the Company or any affiliate. The Executive shall have no obligation to mitigate any amounts payable or arrangements made under any provision of this Agreement, whether by seeking employment or otherwise.

If the Executive dies during the period between the Date of Termination and the date on which the payments and benefits described in Section 5(b) are due to be paid, all such payments and benefits shall be paid to the personal representative of the Executive's estate.

(e) Separate Payments. The Pro Rata Bonus, each of the Salary Continuation Severance Payments and each monthly provision of the Health Benefit are each intended to be separate payments for purposes of Section 409A of the Internal Revenue Code of 1986, as amended, and regulations and other guidance of the Department of the Treasury and the Internal Revenue Service thereunder (together, "Section 409A").

(f) Section 409A; Indemnification by the Company. Any taxable reimbursement of business or other expenses as specified under this Agreement shall be subject to the following conditions: (A) the expenses eligible for reimbursement in one taxable year shall not affect the expenses eligible for reimbursement in any other taxable year; (B) the reimbursement of an eligible expense shall be made no later than the end of the year after the year in which such expense was incurred; and (C) the right to reimbursement shall not be subject to liquidation or exchange for another benefit. If and to the extent necessary to comply with Section 409A, references to the Date of Termination shall mean the date of the Executive's "separation from service," as defined in Section 409A, from the Company. The Company shall defend, indemnify, and hold the Executive harmless from and against any liabilities the Executive may incur by virtue of the applicability of Section 409A to any payments made pursuant to this Agreement.

(g) Taxes and Withholding. All payments and benefits to be made or otherwise provided to the Executive hereunder shall be subject to applicable taxes and withholding.

6. Confidential Information; Noncompetition; Work Product. The Executive acknowledges that his employment by the Company will, throughout the Employment Period continue to bring him into close

contact with the confidential affairs of the Company and its affiliates, including information about their client and customer lists and information concerning proprietary manufacturing formulations and processes, costs, profits, real estate, markets, sales, products, key personnel, pricing policies, operational methods, patents, research and development, technical processes, and other business affairs and methods, plans for future product development, business development opportunities and strategies and other information not readily available to the public. The Executive further acknowledges that the services to be performed under this Agreement are of a special, unique, unusual, extraordinary and intellectual character. The Executive further acknowledges that the business of the Company and its subsidiaries is international in scope, that their products are marketed throughout the world, that the Company and its subsidiaries competes in nearly all of their business activities with other entities that are or could be located in nearly any part of the world and that the nature of the Executive's services, position and expertise are such that he is capable of competing with the Company and its subsidiaries from nearly any location in the world. In recognition of the foregoing, the Executive covenants and agrees:

(a) The Executive, at all times during the Employment Period and thereafter, shall hold in a fiduciary capacity for the benefit of the Company all secret, trade, proprietary or confidential information, knowledge or data relating to the Company or any of its affiliated companies and shareholders, and their respective businesses, that the Executive obtains during the Executive's employment by the Company or any of its affiliated companies and that is not public knowledge (other than as a result of the Executive's violation of this Section 6(a)) ("Confidential Information"). The Executive shall not communicate, divulge or disseminate Confidential Information at any time during or after the Executive's employment with the Company, except with the prior written consent of the Company or as otherwise required by law or legal process. The Executive shall deliver promptly to the Company on termination of the Executive's employment by the Company, or at any other time the Company may so request, at the Company's expense, all memoranda, notes, records, reports and other documents (and all copies thereof) relating to the Company's business, which the Executive obtained while employed by, or otherwise serving or acting on behalf of, the Company and which the Executive may then possess or have under the Executive's control.

(b) During the "Noncompetition Period," the Executive shall not, without the prior written consent of the Company Board, engage in or become associated with a "Competitive Activity." For purposes of this Section 6: (i) the "Noncompetition Period" means the period commencing on the Effective Date and ending on the eighteen-month anniversary of the date upon which the Executive's employment with the Company is terminated for any reason; (ii) a "Competitive Activity" means any business or other endeavor that engages in clinical or pre-clinical research or development, manufacturing, marketing, sales, or commercialization of products or services that directly or indirectly compete with, or are a therapeutic alternative to, either (x) the products of, or services engaged in by, the Company or any of its subsidiaries at the Date of Termination in any geographic location in the United States, or (y) the products proposed to be developed or commercialized, or services proposed to be engaged in, by the Company or any of its subsidiaries at the Date of Termination in any geographic location in the United States, provided that, "products" as used in clauses (x) and (y) shall apply only to products under Phase 1 development or later. Notwithstanding the foregoing, the Executive shall not be engaged in a Competitive Activity if he is providing services to a division or subsidiary of a multi-division entity or holding company, so long as no division or subsidiary to which the Executive provides services is in competition with the Company or its subsidiaries or affiliates, and the Executive does not otherwise engage in a Competitive Activity on behalf of the multi-division entity or any competing division or subsidiary; and (iii) the Executive shall be considered to have become "associated with a Competitive Activity" if the Executive becomes directly or indirectly involved as an owner, investor (other than a passive stockholder of less than five percent (5%) of a corporation the securities of which are traded on a national securities exchange), employee, officer, director, consultant, independent contractor, agent, partner, advisor, or in any other capacity calling for the rendition of the Executive's personal services,

with any individual, partnership, corporation or other organization that is engaged or is formed to engage directly or indirectly in a Competitive Activity.

(c) During the Noncompetition Period, the Executive shall not, on his own behalf or on behalf of any other person, firm or entity (x) directly or indirectly solicit, induce or attempt to solicit or induce any employee of the Company or any of its subsidiaries to terminate his employment with the Company or any of its subsidiaries, or to provide any assistance whatsoever to any person, firm or entity engaged in a Competitive Activity, or (y) directly or indirectly induce any business, entity or person with which the Company or any of their subsidiaries or affiliates has a business relationship to terminate or alter such business relationship.

(d) In addition to such other rights and remedies as the Company may have at equity or in law with respect to any breach of this Agreement, if the Executive commits a material breach of any of the provisions of Section 6, the Company shall have the right to have such provisions specifically enforced by any court having equity jurisdiction (without any obligation to post a bond or other security); it being acknowledged and agreed that any such breach or threatened breach will cause irreparable injury to the Company and that money damages alone will not provide an adequate remedy to the Company.

(e) The Executive acknowledges that during the Employment Period, the Executive may conceive of, discover, invent or create inventions, improvements, new contributions, literary property, computer programs and software material, ideas and discoveries, whether patentable or copyrightable or not (all of the foregoing being collectively referred to herein as "Work Product"), and that various business opportunities shall be presented to the Executive by reason of the Executive's employment by the Company. The Executive acknowledges that all of the foregoing shall be owned by and belong exclusively to the Company and that the Executive shall have no personal interest therein; provided that they are either related in any manner to the business (commercial, clinical or experimental) of the Company or any of its subsidiaries, or are, in the case of Work Product, conceived or made on the Company's time or with the use of the Company's facilities or materials, or, in the case of business opportunities, are presented to the Executive for the possible interest or participation of the Company or any of its subsidiaries. The Executive shall (i) promptly disclose any such Work Product and business opportunities to the Company; (ii) assign to the Company, upon request and without additional compensation, the entire rights to such Work Product and business opportunities; (iii) sign all papers necessary to carry out the foregoing; and (iv) give testimony in support of the Executive's inventorship or creation in any appropriate case. The Executive agrees that the Executive will not assert any rights to any Work Product or business opportunity as having been made or acquired by the Executive prior to the date of this Agreement except for Work Product disclosed on Exhibit B to this Agreement (for the avoidance of doubt, Exhibit B excludes any of the Executive's investments as of the date hereof in companies or entities that as of the date hereof own or have rights to certain Work Product which Work Product does not belong to the Company and is not being assigned hereunder).

(f) The Executive acknowledges and agrees that the provisions of this Section 6 are necessary to protect the business operations and affairs of the the Company and its respective subsidiaries. The Executive understands that the restrictions set forth in this Agreement may limit his ability to earn a livelihood in a business similar that of the Company, but he nevertheless believes that he has received and will receive sufficient consideration and other benefits as an employee of the Company to justify clearly such restrictions which, in any event (given his education, skills and ability), the Executive does not believe would prevent him from earning a livelihood.

7. Successors.

(a) This Agreement is personal to the Executive and, without the prior written consent of the Company, shall not be assignable by the Executive otherwise than by will or the laws of descent and distribution. This Agreement shall inure to the benefit of and be enforceable by the Executive's legal representatives.

(b) This Agreement shall inure to the benefit of and be binding upon Company and its successors and assigns, and may be assigned by the Company in connection with any sale, transfer or other disposition of all or substantially all of its business and assets.

(c) The Company, as applicable, shall require any successor (whether direct or indirect, by purchase, merger, consolidation or otherwise) to all or substantially all of the business and/or assets of the Company expressly to assume and agree to perform under this Agreement in the same manner and to the same extent that the Company would have been required to perform it if no such succession had taken place, except under circumstances in which such assumption occurs by operation of law. As used in this Agreement, "Company" shall mean the Company as defined above and any such successor of the Company, as applicable, that assumes and agrees to perform this Agreement, by operation of law or otherwise.

8. Indemnification. The Executive shall be entitled to defense by and full indemnification from the Company for any claims brought against him based on any alleged act or omission related in any way to the Executive's employment by the Company to the maximum extent permitted under applicable law and the Company's bylaws. In addition, during the term of the Executive's employment, the Executive shall be covered under any directors' and officers' insurance policy maintained by the the Company.

9. Post-Termination Assistance. After the termination of the Executive's employment for any reason, for so long as the Executive is receiving any payments pursuant to this Agreement, the Executive shall cooperate, at the reasonable request of the Company or any of their respective subsidiaries, (i) in the transition of any matter for which the Executive had authority or responsibility during the Employment Period, or (ii) with respect to any other matter involving the Company or any of their respective subsidiaries for which the Executive may be of assistance. Any such cooperation required from the Executive shall take into account any responsibilities to which the Executive is subject to a subsequent employer or otherwise.

10. Miscellaneous.

(a) This Agreement shall be governed by, and construed in accordance with, the laws of the State of New Jersey, applicable to agreements made and to be performed entirely within such state. The captions of this Agreement are not part of the provisions hereof and shall have no force or effect. This Agreement may not be amended or modified except by a written agreement executed by the parties hereto or their respective successors and legal representatives.

(b) All notices and other communications under this Agreement shall be in writing and shall be given by hand delivery to the other party or by registered or certified mail, return receipt requested, postage prepaid, addressed as follows:

If to the Executive, to the Executive's address as maintained by the Company.

If to the Company:

Bellerophon Therapeutics, Inc.
184 Liberty Corner Road

Suite 302
Warren, New Jersey 07059

with a copy to:

New Mountain Capital, LLC
787 Seventh Avenue, 49th Floor
New York, New York 10019
Attention: Matthew Holt

or to such other address as either party furnishes to the other in writing in accordance with this Section 10. Notices and communications shall be effective when actually received by the addressee.

(c) The invalidity or unenforceability of any provision of this Agreement shall not affect the validity or enforceability of any other provision of this Agreement. If any provision of this Agreement shall be held invalid or unenforceable in part, the remaining portion of such provision, together with all other provisions of this Agreement, shall remain valid and enforceable and continue in full force and effect to the fullest extent consistent with law, and the invalid or unenforceable provision shall be deemed to have been redrafted as if in the original, so as to be valid and enforceable to the maximum extent permissible under applicable law.

(d) Notwithstanding any other provision of this Agreement, the Company may withhold from amounts payable under this Agreement all federal, state, local and foreign taxes that are required to be withheld by applicable laws or regulations.

(e) The failure of the Executive or the Company to insist upon strict compliance with any provision of, or to assert any right under, this Agreement shall not be deemed to be a waiver of such provision or right or of any other provision of or right under this Agreement.

(f) The Executive and the Company acknowledge that this Agreement represents the complete agreement between the parties and supersedes any other agreement between them concerning the subject matter hereof, including the Prior Employment Agreement. This Agreement may not be modified except by express written agreement between the parties.

(g) This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, and which together shall constitute one instrument.

(h) Whenever this Agreement provides for any payment to the Executive's estate, such payment may be made instead to such beneficiary or beneficiaries as the Executive may designate by written notice to the Company. The Executive shall have the right to revoke any such designation and to redesignate a beneficiary or beneficiaries by written notice to the Company (and to any applicable insurance company) to such effect.

(i) The Executive represents and warrants to the Company that this Agreement is legal, valid and binding upon the Executive and the execution of this Agreement and the performance of the Executive's obligations hereunder does not and will not constitute a breach of, or conflict with the terms or provisions of, any agreement or understanding to which the Executive is a party (including, without limitation, any employment agreement he has entered into or may enter into with Perceptive or any other employment agreement). The Company represent and warrant to the Executive that this Agreement is legal, valid and

binding upon the Company, as applicable and the execution of this Agreement and the performance of the Company's obligations hereunder does not and will not constitute a breach of, or conflict with the terms or provisions of, any agreement or understanding to which the Company, as applicable, is a party.

(j) Neither the Executive, his legal representative nor any beneficiary designated by the Executive shall have any right, without the prior written consent of the Company, to assign, transfer, pledge, hypothecate, anticipate or commute to any person or entity any payment due in the future pursuant to any provision of this Agreement, and any attempt to do so shall be void and shall not be recognized by the Company.

(k) Each party (i) hereby irrevocably submits itself to and acknowledges and recognizes the jurisdiction of the courts of the State of New Jersey in the County of Somerset (which court, together with all applicable appellate courts, for purposes of this Agreement, are the only "courts of competent jurisdiction"), for the purpose of any suit, action or other proceeding arising out of, under, or in connection with, relating to, or based upon this Agreement, (ii) agrees that any service of process in connection with any such suit, action or other proceeding may be made upon it by means of the United States mail or such other service as may be authorized by any such court, (iii) agrees that the courts of competent jurisdiction shall be the sole and exclusive courts and forums for the purpose of any such suit, action or proceeding and (iv) waives and agrees not to assert, by way of motion, as a defense, or otherwise, in any such suit, action or proceeding, any claim that it is not subject to the jurisdiction of courts of competent jurisdiction, that such suit, action or proceeding is brought in an inconvenient forum, that the venue of the suit, action or proceeding is improper or that this Agreement or the subject matter hereof may not be enforced in or by such court. Each party agrees that its submission to jurisdiction and its consent to service of process by mail is made for the express benefit of the other party.

(l) Each of the parties has been represented by counsel (or has had the opportunity to be so represented) in the negotiation and preparation of this Agreement. The parties agree that this Agreement is to be construed as jointly drafted. Accordingly, this Agreement will be construed according to the fair meaning of its language, and the rule of construction that ambiguities are to be resolved against the drafting party will not be employed in the interpretation of this Agreement.

(m) The Executive acknowledges and agrees that the Company may satisfy its obligations to make payments to the Executive under this Agreement by causing one or more of its subsidiaries to make such payments to the Executive. The Executive agrees that any such payment made by any such subsidiary shall fully satisfy and discharge the Company's obligation to make such payment to the Executive hereunder (but only to the extent of such payment).

(n) Notwithstanding the termination of this Agreement, the provisions of Sections 5 (as applicable), 6, 7, 8, 9 and 10 of the Agreement shall continue in full force and effect and remain fully binding upon the parties.

[*signature page follows*]

IN WITNESS WHEREOF, the Executive has hereunto set the Executive's hand and, pursuant to the authorization of its Board and the Company have caused this Agreement to be executed in its name on its behalf, all as of the day and year first above written.

/s/ Jonathan M. Peacock
Jonathan M. Peacock

Bellerophon Therapeutics, Inc.

By: /s/ Matthew Holt
By: Matthew Holt
Title: Chairman, Compensation Committee

Exhibits:
A: Form of Waiver and Release of Claims
B: Disclosed Work Product and Business Opportunities

Exhibit A
Form of Waiver and Release of Claims

WAIVER AND RELEASE OF CLAIMS

1. General Release. In consideration of the payments and benefits to be made under the Amended and Restated Employment Agreement, dated as of [DATE], 2016, to which Bellerophon Therapeutics, Inc. (the "Company") and Jonathan M. Peacock (the "Executive") are parties (the "Agreement"), the Executive, with the intention of binding the Executive and the Executive's heirs, executors, administrators and assigns, does hereby release, remise, acquit and forever discharge the Company and each of its subsidiaries and affiliates (the "Company Affiliated Group"), their present and former officers, directors, executives, agents, shareholders, attorneys, employees and employee benefits plans (and the fiduciaries thereof), and the successors, predecessors and assigns of each of the foregoing (collectively, the "Company Released Parties"), of and from any and all claims, actions, causes of action, complaints, charges, demands, rights, damages, debts, sums of money, accounts, financial obligations, suits, expenses, attorneys' fees and liabilities of whatever kind or nature in law, equity or otherwise, whether accrued, absolute, contingent, unliquidated or otherwise and whether now known, unknown, suspected or unsuspected which the Executive, individually or as a member of a class, now has, owns or holds, or has at any time heretofore had, owned or held, against any Company Released Party (an "Action") arising out of or in connection with the Executive's service as an employee, officer and/or director to any member of the Company Affiliated Group (or the predecessors thereof), including (i) the termination of such service in any such capacity, (ii) for severance or vacation benefits, unpaid wages, salary or incentive payments, (iii) for breach of contract, wrongful discharge, impairment of economic opportunity, defamation, intentional infliction of emotional harm or other tort and (iv) for any violation of applicable state and local labor and employment laws (including, without limitation, all laws concerning harassment, discrimination, retaliation and other unlawful or unfair labor and employment practices), any and all Actions based on the Employee Retirement Income Security Act of 1974 ("ERISA"), and any and all Actions arising under the civil rights laws of any federal, state or local jurisdiction, including, without limitation, Title VII of the Civil Rights Act of 1964 ("Title VII"), the Americans with Disabilities Act ("ADA"), Sections 503 and 504 of the Rehabilitation Act, the Family and Medical Leave Act and the Age Discrimination in Employment Act (" ADEA"), excepting only:

(a) rights of the Executive under this Waiver and Release of Claims and Section 5 of the Agreement;

(b) rights of the Executive relating to equity awards held by the Executive as of his date of termination;

(c) the right of the Executive to receive COBRA continuation coverage in accordance with applicable law and the Agreement;

(d) rights to indemnification the Executive may have (i) under applicable corporate law, (ii) under the by-laws or certificate of incorporation of any Company Released Party or (iii) as an insured under any director's and officer's liability insurance policy now or previously in force;

(e) claims (i) for benefits under any health, disability, retirement, deferred compensation, life insurance or other, similar employee benefit plan or arrangement of the Company Affiliated Group and (ii) for earned but unused vacation pay through the date of termination in accordance with applicable Company policy;

(f) claims for the reimbursement of unreimbursed business and other expenses incurred prior to the date of termination pursuant to applicable Company policy and the Agreement;

(g) claims that cannot be released or waived by law.

2. No Admissions, Complaints or Other Claims. The Executive acknowledges and agrees that this Waiver and Release of Claims is not to be construed in any way as an admission of any liability whatsoever by any Company Released Party, any such liability being expressly denied. The Executive also acknowledges and agrees that he has not, with respect to any transaction or state of facts existing prior to the date hereof, filed any Actions against any Company Released Party with any governmental agency, court or tribunal.

3. Application to all Forms of Relief. Except as to those claims excluded from this Waiver and Release of Claims, this Waiver and Release of Claims applies to any relief no matter how called, including, without limitation, wages, back pay, front pay, compensatory damages, liquidated damages, punitive damages for pain or suffering, costs and attorney's fees and expenses.

4. Specific Waiver. The Executive specifically acknowledges that his acceptance of the terms of this Waiver and Release of Claims is, among other things, a specific waiver of any and all Actions under Title VII, ADEA, ADA and any state or local law or regulation in respect of discrimination of any kind; provided, however, that nothing herein shall be deemed, nor does anything herein purport, to be a waiver of any right or Action which by law the Executive is not permitted to waive.

5. Voluntariness. The Executive acknowledges and agrees that he is relying solely upon his own judgment; that the Executive is over eighteen years of age and is legally competent to sign this Waiver and Release of Claims; that the Executive is signing this Waiver and Release of Claims of his own free will; that the Executive has read and understood the Waiver and Release of Claims before signing it; and that the Executive is signing this Waiver and Release of Claims in exchange for consideration that he believes is satisfactory and adequate. The Executive also acknowledges and agrees that he has been informed of the right to consult with legal counsel and has been encouraged to do so.

6. Complete Agreement/Severability. This Waiver and Release of Claims constitutes the complete and final agreement between the parties and supersedes and replaces all prior or contemporaneous agreements, negotiations, or discussions relating to the subject matter of this Waiver and

Release of Claims. All provisions and portions of this Waiver and Release of Claims are severable. If any provision or portion of this Waiver and Release of Claims or the application of any provision or portion of the Waiver and Release of Claims shall be determined to be invalid or unenforceable to any extent or for any reason, all other provisions and portions of this Waiver and Release of Claims shall remain in full force and shall continue to be enforceable to the fullest and greatest extent permitted by law.

7. Acceptance and Revocability. The Executive acknowledges that he has been given a period of 21 days within which to consider this Waiver and Release of Claims, unless applicable law requires a longer period, in which case the Executive shall be advised of such longer period and such longer period shall apply. The Executive may accept this Waiver and Release of Claims at any time within this period of time by signing the Waiver and Release of Claims and returning it to the Company. This Waiver and Release of Claims shall not become effective or enforceable until seven calendar days after the Executive signs it. The Executive may revoke his acceptance of this Waiver and Release of Claims at any time within that seven calendar day period by sending written notice to the Company. Such notice must be received by the Company within the seven calendar day period in order to be effective and, if so received, would void this Waiver and Release of Claims for all purposes.

8. Governing Law. Except for issues or matters as to which federal law is applicable, this Waiver and Release of Claims shall be governed by and construed and enforced in accordance with the laws of the State of New Jersey without giving effect to the conflicts of law principles thereof.

Jonathan M. Peacock

EXHIBIT B

Disclosed Work Product and Business Opportunities

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

The Board of Directors
Bellerophon Therapeutics, Inc.:

We consent to the incorporation by reference in the registration statement (No. 333-202069) on Form S-8 of Bellerophon Therapeutics, Inc. of our report dated March 21, 2016, with respect to the consolidated balance sheets of Bellerophon Therapeutics LLC as of December 31, 2015 and 2014, and the related consolidated statements of operations, comprehensive loss, changes in stockholders'/members' equity and invested equity (deficit), and cash flows for each of the years in the three-year period ended December 31, 2015, which report appears in the December 31, 2015 annual report on Form 10-K of Bellerophon Therapeutics, Inc.

/s/ KPMG LLP
Short Hills, New Jersey
March 21, 2016

Exhibit 31.1

CERTIFICATION

I, Jonathan M. Peacock, certify that:

1. I have reviewed this Annual Report on Form 10-K of Bellerophon Therapeutics, 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 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 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: March 21, 2016

By: /s/ Jonathan M. Peacock

Jonathan M. Peacock
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Fabian Tenenbaum, certify that:

1. I have reviewed this Annual Report on Form 10-K of Bellerophon Therapeutics, 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 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 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: March 21, 2016

By: /s/ Fabian Tenenbaum

Fabian Tenenbaum
Chief Financial Officer and Chief Business Officer
(Principal Financial Officer)

Exhibit 32

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

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), each of the undersigned officers of Bellerophon Therapeutics, Inc. (the "Company"), a Delaware corporation (the "Company"), does hereby certify, to such officer's knowledge, that:

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

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

Date: March 21, 2016

By: /s/ Jonathan M. Peacock

Jonathan M. Peacock
Chief Executive Officer
(Principal Executive Officer)

Date: March 21, 2016

By: /s/ Fabian Tenenbaum

Fabian Tenenbaum
Chief Financial Officer and Chief Business Officer
(Principal Financial Officer)