

Bellerophon Therapeutics, Inc.
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Registration Statement No. 333-214230

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PROSPECTUS

17,142,858 Class A Units consisting of Common Stock and Warrants and

3,000 Class B Units consisting of Series A Convertible Preferred Stock and Warrants⁽¹⁾

(3,529,412 shares of Common Stock underlying the Series A Convertible Preferred Stock)

(17,142,858 shares of Common Stock underlying the Warrants included in the Class A and Class B Units)

We are offering 17,142,858 Class A Units (consisting of one share of our common stock and a warrant to purchase one share of our common stock at an exercise price per full share of common stock equal to \$0.80 (each, a “Warrant”)). Each Warrant will be immediately exercisable and will expire five years from the date on which such Warrants become exercisable. The shares of common stock and Warrants that form part of a Class A Unit are immediately separable and will be issued separately in this offering.

We are also offering to those purchasers, if any, whose purchase of Class A Units in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% of our outstanding common stock immediately following the consummation of this offering, the opportunity, in lieu of purchasing Class A Units, to purchase 3,000 Class B Units. Each Class B Unit will consist of one share of our Series A convertible preferred stock, with a stated value of \$1,000 per share and convertible into shares of our common stock at the public offering price of the Class A Units, together with the equivalent number of Warrants as would have been issued to such purchaser if they had purchased Class A Units based on the public offering price. The shares of Series A convertible preferred stock do not generally have any voting rights but are convertible into shares of common stock. The placement agent has informed us that it has not received any indications of interest for Class B Units, thus we do not expect to confirm any sales of such Class B Units. The shares of Series A convertible preferred stock and Warrants are immediately separable and will be issued separately in this offering. We are also offering the shares of common stock that are issuable from time to time upon conversion of the Series A convertible preferred stock and upon the exercise of the Warrants being offered by this prospectus.

For a more detailed description of the Series A convertible preferred stock, see the section entitled “Description of Securities We Are Offering — Series A Convertible Preferred Stock.” For a more detailed description of the Warrants, see the section entitled “Description of Securities We Are Offering — Warrants to Purchase Common Stock.” For a more detailed description of our common stock, see the section entitled “Description of Capital Stock — Common Stock.”

Investors purchasing \$100,000 or more of the securities offered hereby will execute a securities purchase agreement with us, providing such investors with certain representations, warranties and covenants from us, which representations, warranties and covenants will not be available to investors of lesser amounts of our securities. Therefore, investors purchasing \$100,000 or less of the securities shall rely solely on this prospectus in connection with the purchase of securities in this offering.

We refer to the Series A convertible preferred stock issued hereunder, the Warrants and the shares of common stock issued hereunder and issuable upon conversion of the Series A convertible preferred stock and upon exercise of the Warrants, collectively, as the securities.

Our common stock is listed on the NASDAQ Global Market under the symbol “BLPH.” On November 22, 2016, the last reported sale price of our common stock on the NASDAQ Global Market was \$0.75 per share. We do not intend to list the Series A convertible preferred stock or the Warrants to be sold in this offering on the NASDAQ Global Market or any other national securities exchange or any other nationally recognized trading system.

We are an “emerging growth company” as that term is used in the Jumpstart Our Business Startups Act of 2012 and, as such, we have elected to comply with certain reduced public company reporting requirements for this prospectus and future filings.

	Per Class A Unit	Per Class B Unit	Total
Public offering price ⁽¹⁾	\$0.7000	\$1,000	\$12,000,000.60
Placement agent fees ⁽²⁾	\$0.0396	\$0	\$679,680.04
Proceeds, before expenses, to us	\$0.6604	\$0	\$11,320,320.56

(1) The public offering price is \$0.70 per unit.

(2) In addition, we have agreed to reimburse the placement agent for certain expenses. See “Plan of Distribution” on page 75 of this prospectus for additional information.

We have retained H.C. Wainwright & Co., LLC as our exclusive placement agent to use their reasonable best efforts to solicit offers to purchase the securities in this offering. The placement agent has no obligation to buy any of the securities from us or to arrange for the purchase or sale of any specific number or dollar amount of the securities. We expect that delivery of the securities being offered pursuant to this prospectus will be made on or about November 29, 2016.

Entities affiliated with New Mountain Capital, LLC and Linde North America, existing stockholders, have agreed to purchase an aggregate of 7,634,286 Class A Units. The placement agent will receive a fee of 4.0% from any units purchased by these parties.

Investing in our securities involves a high degree of risk. See the section entitled “Risk Factors” appearing on page 8 of this prospectus and elsewhere in this prospectus for a discussion of information that should be considered in connection with an investment in our securities.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

H.C. Wainwright & Co.

The date of this prospectus is November 22, 2016

(1) The placement agent has informed us that it has not received any indications of interest for Class B Units, thus we do not expect to confirm any sales of such Class B Units.

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We have not, and the placement agent has not, authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectuses prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the shares offered hereby, and only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus or in any applicable free writing prospectus is current only as of its date, regardless of its time of delivery or any sale of our securities. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside the United States: We have not, and the placement agent has not, done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the securities and the distribution of this prospectus outside the United States.

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PROSPECTUS SUMMARY

This summary highlights information contained in other parts of this prospectus or incorporated by reference into this prospectus from our filings with the Securities and Exchange Commission, or SEC, listed in the section of the prospectus entitled “Incorporation of Certain Information by Reference.” Because it is only a summary, it does not contain all of the information that you should consider before investing in our securities and it is qualified in its entirety by, and should be read in conjunction with, the more detailed information appearing elsewhere or incorporated by reference into this prospectus. You should read the entire prospectus, the registration statement of which this prospectus is a part, and the information incorporated by reference herein in their entirety, including the “Risk Factors” and our financial statements and the related notes incorporated by reference into this prospectus, before investing in our securities. Unless the context requires otherwise, references in this prospectus to “Bellerophon,” “we,” “us” and “our” refer to Bellerophon Therapeutics, Inc., together with its wholly-owned subsidiaries.

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. Our focus 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 platform is based on our proprietary pulsatile nitric oxide delivery device.

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 indicates a sustainability of benefit to PAH patients who received INOpulse therapy at the 75 mcg/kg of ideal body weight/hour dose for an average of greater than 12 hours per day and were on long-term oxygen therapy, or LTOT. 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. The first of the two Phase 3 trials has been initiated with the first patient enrolled in June 2016. We plan to have our Data Monitoring Committee conduct an unblinded interim analysis on the first trial after approximately half of the subjects have completed a total of 18 weeks to assess for efficacy, futility and potential sample size reassessment.

We completed a randomized, placebo-controlled, double-blind, dose-confirmation Phase 2 clinical trial of INOpulse for PH-COPD in July 2014. We received results from this trial, and we have initiated 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. In July 2016, the results were published in the International Journal of COPD in an article titled "Pulmonary vascular effects of pulsed inhaled nitric oxide in COPD patients with pulmonary hypertension". Building upon this and other work we have done over recent quarters, we have initiated Phase 2 testing for the use of the INOpulse device for PH-COPD patients to evaluate the potential benefit of chronic use on exercise capacity, with the first patient enrolled in October 2016.

We have begun 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. Our first patient was enrolled in our Phase 2 study in the second quarter of 2016. In addition, other opportunities for the application of our INOpulse platform include the following indications: chronic thromboembolic PH, or CTEPH, PH associated with sarcoidosis and PH associated with pulmonary edema from high altitude sickness.

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

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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.

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.

Risks Associated with Our Business

Our business and our ability to implement our business strategy are subject to numerous risks, as more fully described in the section entitled “Risk Factors” in our Annual on Form 10-K for the year ended December 31, 2015, incorporated herein by reference. You should read these risks before you invest in our securities. We may be unable, for many reasons, including those that are beyond our control, to implement our business strategy. In particular, risks associated with our business include:

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

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

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. Moreover, if we are unable to obtain additional funds on a timely basis, there will be substantial doubt about our ability to continue as a going concern and increased risk of insolvency and loss of investment by our stockholders.

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 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.

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.

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 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.

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.

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

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 prospectus. We have included our website address in this prospectus 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.

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Implications of Being an Emerging Growth Company and a Smaller Reporting Company

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 stockholder 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 the registration statement of which this prospectus is a part. 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.

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The Offering

Class A Units offered by us We are offering 17,142,858 Class A Units. Each Class A Unit will consist of one share of our common stock and a warrant to purchase one share of our common stock at an exercise price per full share of common stock equal to \$0.80 (each, a “Warrant”). The Class A Units will not be certificated and the share of common stock and Warrants part of such unit are immediately separable and will be issued separately in this offering.

This prospectus also relates to the offering of shares of our common stock issuable upon the exercise of the warrants that are part of the Class A Units.

Class B Units offered by us We are also offering to those purchasers, if any, whose purchase of Class A Units in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% of our outstanding common stock immediately following the consummation of this offering, the opportunity, in lieu of purchasing Class A Units, to purchase Class B Units. Each Class B Unit will consist of one share of our Series A convertible preferred stock, with a stated value of \$1,000 and convertible into shares of our common stock at the public offering price of the Class A Units, together with the equivalent number of Warrants as would have been issued to such purchaser if they had purchased Class A Units based on the public offering price.

Ownership of the Class B Units alone will not increase the purchaser’s beneficial ownership percentage (up to 9.99%) of common stock unless and until a portion or all of such Series A convertible preferred stock has been converted. In addition, holders of Series A convertible preferred stock will be prohibited from converting Series A convertible preferred stock if, as a result of such conversion, the holder, together with its affiliates and certain related parties, and any persons acting as a group together with such holder or any such affiliate, would beneficially own more than 4.99% of the total number of shares of our outstanding common stock.

However, any holder may decrease or increase such ownership percentage to any other percentage, provided that any increase in such percentage shall not be effective until 61 days after such notice to us. Exceeding 4.99% ownership in shares of our outstanding common stock will trigger certain SEC filing requirements by such holder, including the submission of a Schedule 13G or Schedule 13D, as applicable, while such ownership percentage remains above 4.99%.

Shares of Series A convertible preferred stock do not generally have any voting rights but are convertible into shares of common stock. The Class B Units will not be certificated and the shares of Series A convertible preferred stock and Warrants that are part of such unit are immediately separable and will be issued separately in this offering.

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This prospectus also relates to the offering of shares of our common stock issuable upon conversion of the Series A convertible preferred stock and the Warrants part of the Class B Units. The placement agent has informed us that it has not received any indications of interest for Class B Units, thus we do not expect to confirm any sales of such Class B Units.

Each Warrant included in the units will have an exercise price per full share of common stock equal to Warrants \$0.80, will be immediately exercisable and will expire five years from the date on which such Warrants become exercisable.

There is no established public trading market for the warrants, and we do not expect a market to develop. In addition, we do not intend to apply for a listing of the Warrants on any national securities exchange.

Common stock outstanding before this offering	14,559,766 shares
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Common stock to be outstanding immediately after this offering	31,702,624 shares
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Use of proceeds	We intend to use the net proceeds from this offering for general corporate purposes, including manufacturing expenses, clinical trial expenses, research and development expenses and general and administrative expenses. See “Use of Proceeds.”
Risk factors	You should read the “Risk Factors” section of this prospectus for a discussion of certain of the factors to consider carefully before deciding to purchase any securities in this offering.
National Securities Exchange Listing	Our common stock is listed on the NASDAQ Global Market under the symbol “BLPH.” We do not intend to list the warrants on any securities exchange or nationally recognized trading system.
No market for the units or Series A convertible preferred stock or warrants	The units will not be certificated, and the securities that are part of such units are immediately separable and will be issued separately in this offering. There is no established public trading market for the Series A convertible preferred stock or the Warrants to be issued in this offering, and we do not intend to apply to list such securities on any securities exchange or automated quotation system.

The number of shares of our common stock to be outstanding immediately after this offering is based on 14,559,766 shares of common stock outstanding as of November 21, 2016 and excludes as of that date:

- 1,444,416 shares of common stock issuable upon the exercise of outstanding stock options at a weighted average exercise price of \$6.76 per share;
- 19,385 shares of common stock reserved for future issuance under our 2015 equity incentive plan (the “2015 Equity Incentive Plan”); and
- 17,142,858 shares of our common stock issuable upon the exercise of warrants offered hereby.

Entities affiliated with New Mountain Capital, LLC and Linde North America, existing stockholders, have agreed to purchase an aggregate of 7,634,286 Class A Units.

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The following table summarizes certain of our financial data. We derived the consolidated summary statement of operations data for the years ended December 31, 2015 and 2014 from our audited consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2015, incorporated by reference into this prospectus. The consolidated summary statement of operations data for the nine months ended September 30, 2016 and 2015 and the consolidated summary balance sheet data as of September 30, 2016 were derived from our unaudited consolidated financial statements included in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2016, incorporated by reference into this prospectus. The unaudited consolidated financial statements have been prepared on a basis consistent with our audited consolidated financial statements included in this prospectus and include, in our opinion, all normal and recurring adjustments that are considered necessary for the fair presentation of the financial information in those statements. Our historical results are not necessarily indicative of the results that may be expected in the future and results of interim periods are not necessarily indicative of the results for the entire year. The consolidated summary financial data should be read together with our consolidated financial statements and related notes and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in our Annual Report on Form 10-K for the year ended December 31, 2015, incorporated by reference in this prospectus.

	Year Ended December 31		Nine Months Ended September 30	
	2015	2014	2016	2015
Consolidated Statements of Operations Data			(unaudited)	
Operating expenses:				
Research and development	\$33,365	\$45,978	\$11,539	\$25,036
General and administrative	14,870	13,775	4,926	12,337
Total operating expenses	48,235	59,753	16,465	37,373
Other operating income	1,667	—	—	1,667
Loss from operations	(46,568)	(59,753)	(16,465)	(35,706)
Interest income	109	79	74	73
Pre-tax loss	(46,459)	(59,674)	(16,391)	(35,633)
Income tax benefit (expense)	—	—	—	—
Net loss	\$(46,459)	\$(59,674)	\$(16,391)	\$(35,633)
Weighted average shares/units outstanding:				
Basic and diluted	12,267,693	7,898,289	13,335,358	12,012,002
Net loss per share/unit:				
Basic and diluted	\$(3.79)	\$(7.56)	\$(1.23)	\$(2.97)

The unaudited as -adjusted balance sheet data set forth below give effect to our issuance and sale of shares of our common stock in this offering at the public offering price, after deducting the estimated placement agent fees and expenses and estimated offering expenses payable by us.

	As of September 30, 2016	
	Actual	As adjusted
	(unaudited)	
	(in thousands except share and per share data)	
Consolidated Balance Sheet Data		
Cash and cash equivalents	\$ 3,930	\$ 14,798
Working capital	12,737	23,605
Total assets	22,784	33,652
Total liabilities	4,788	4,788
Accumulated deficit	(117,069)	(117,069)
Total stockholders' equity	17,996	28,864

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RISK FACTORS

Investing in our securities involves a high degree of risk. You should consider carefully the risks described below, together with all of the other information included or incorporated by reference in this prospectus, including the risks and uncertainties discussed under “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2015, before deciding whether to purchase securities in this offering. All of these risk factors are incorporated herein in their entirety. The risks described below and incorporated by reference are material risks currently known, expected or reasonably foreseeable by us. If any of these risks actually materialize, our business, prospects, financial condition, and results of operations could be seriously harmed. This could cause the trading price of our common stock and the value of the warrants to decline, resulting in a loss of all or part of your investment.

Risks Related to this Offering

There is no public market for the Series A convertible preferred stock or Warrants being offered in this offering.

There is no established public trading market for the Series A convertible preferred stock or the Warrants being offered in this offering, and we do not expect a market to develop. In addition, we do not intend to apply to list the Series A convertible preferred stock or Warrants on any securities exchange or nationally recognized trading system, including the NASDAQ Global Market. Without an active market, the liquidity of the Series A convertible preferred stock and the Warrants will be limited.

We will have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds from this offering, including for any of the purposes described in the section entitled “Use of Proceeds,” and you will not have the opportunity as part of your investment decision to assess whether the net proceeds are being used appropriately. Because of the number and variability of factors that will determine our use of the net proceeds from this offering, their ultimate use may vary substantially from their currently intended use. Our management may not apply the net proceeds from this offering in ways that ultimately increase the value of your investment. The failure by our management to apply these funds effectively could harm our business. Pending their use, we may invest the net proceeds from this offering in short-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our stockholders. If we do not invest or apply the net proceeds from this offering in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause our stock price to decline.

There may be future sales of our securities or other dilution of our equity, which may adversely affect the market price of our common stock.

We are generally not restricted from issuing additional common stock, including any securities that are convertible into or exchangeable for, or that represent the right to receive, common stock. The market price of our common stock could decline as a result of sales of common stock or securities that are convertible into or exchangeable for, or that represent the right to receive, common stock after this offering or the perception that such sales could occur.

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Neither the holders of Warrants purchased in this offering nor the purchasers of the Series A convertible preferred stock will have rights as common stockholders until such holders exercise their warrants and/or preferred stock and acquire our common stock.

Until holders of Warrants and/or purchasers of the Series A convertible preferred stock acquire shares of our common stock upon exercise of the Warrants and/or Series A convertible preferred stock, holders of Warrants and Series A convertible preferred stock will have no rights with respect to the shares of our common stock underlying such Warrants and/or Series A convertible preferred stock. Upon exercise of the Warrants and/or Series A convertible preferred stock, the holders will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs after the exercise date.

Even if this offering is successful, we will need to raise additional capital in the future to continue operations, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development efforts or other operations.

We have had recurring losses from operations, negative operating cash flow and an accumulated deficit. We do not generate any cash from operations and must raise additional funds in order to continue operating our business. We expect to continue to fund our operations primarily through equity and debt financings in the future. If additional capital is not available to us when needed or on acceptable terms, we may not be able to continue to operate our business pursuant to our business plan or we may have to discontinue our operations entirely. As of September 30, 2016, we had cash and cash equivalents of \$3.9 million. We estimate that we will receive net proceeds of approximately \$10.9 million from the sale of the securities offered by us in this offering, and after deducting the estimated placement agent fees and expenses and estimated offering expenses payable by us, and excluding the proceeds, if any, from the exercise of the warrants issued in this offering. We currently anticipate that our existing resources, together with the expected net proceeds from this offering, will be sufficient to fund our planned operations until at least the end of 2017. In the event of a decrease in the net proceeds to us from this offering as a result of a decrease in the assumed public offering price or the number of shares offered by us, based on the assumptions discussed in “Use of Proceeds”, we would expect that our existing resources, together with such reduced expected net proceeds from this offering, would be sufficient to fund our planned operations until at least September 30, 2017.

Developing drugs and conducting clinical trials is expensive. Our future funding requirements will depend on many factors, including:

- the costs and timing of our research and development activities;

- the progress and cost of our clinical trials and other research and development activities;

the cost and timing of securing manufacturing capabilities for our clinical product candidates and commercial products, if any;

- the terms and timing of any collaborative, licensing, acquisition or other arrangements that we may establish;

- the costs and timing of seeking regulatory approvals;

the costs of filing, prosecuting, defending and enforcing any patent applications, claims, patents and other intellectual property rights; and

- the costs of lawsuits involving us or our product candidates.

We may seek funds through arrangements with collaborators or others that may require us to relinquish rights to the products candidates that we might otherwise seek to develop or commercialize independently. We cannot be certain that we will be able to enter into any such arrangements on reasonable terms, if at all.

We may seek to raise capital through a variety of sources, including:

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- the public equity market;
- private equity financings;
- collaborative arrangements;
- licensing arrangements; and/or
- public or private debt.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. Our ability to raise additional funds will depend, in part, on the success of our preclinical studies and clinical trials and other product development activities, regulatory events, our ability to identify and enter into in-licensing or other strategic arrangements, and other events or conditions that may affect our value or prospects, as well as factors related to financial, economic and market conditions, many of which are beyond our control. We cannot be certain that sufficient funds will be available to us when required or on acceptable terms, if at all. Raising additional capital through the sale of securities could cause significant dilution to our stockholders. If we are unable to secure additional funds on a timely basis or on acceptable terms, we may be required to defer, reduce or eliminate significant planned expenditures, restructure, curtail or eliminate some or all of our development programs or other operations, dispose of technology or assets, pursue an acquisition of our company by a third party at a price that may result in a loss on investment for our stockholders, enter into arrangements that may require us to relinquish rights to certain of our product candidates, technologies or potential markets, file for bankruptcy or cease operations altogether. Any of these events could have a material adverse effect on our business, financial condition and results of operations. Moreover, if we are unable to obtain additional funds on a timely basis, there will be substantial doubt about our ability to continue as a going concern and increased risk of insolvency and loss of investment by our stockholders.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and the documents incorporated by reference herein contain forward-looking statements. The forward-looking statements are contained principally in the sections entitled “Prospectus Summary,” “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Business” in this prospectus or the documents incorporated herein by reference. These statements relate to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

the timing of the ongoing and expected clinical trials of our product candidates, including statements regarding the timing of completion or analysis of the trials and the respective periods during which the results of the trials will become available;

· our ability to obtain adequate financing to meet our future operational and capital needs;

· 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 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.

In some cases, you can identify these statements by terms such as “anticipate,” “believe,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “will,” “would” or the negative of those terms, and similar expressions, which convey uncertainty of future events or outcomes. These forward-looking statements reflect our management’s beliefs and views with respect to future events and are based on estimates and assumptions as of the date of this prospectus and are subject to risks and uncertainties. We discuss many of these risks in greater detail in the documents incorporated by reference herein, usually under the heading “Risk Factors.” Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. Given these uncertainties, you should not place undue reliance on these forward-looking statements.

You should carefully read this prospectus, the documents that we incorporate by reference into this

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prospectus and the documents we reference in this prospectus and have filed as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of the forward-looking statements in this prospectus by these cautionary statements.

Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in any forward-looking statements, whether as a result of new information, future events or otherwise.

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USE OF PROCEEDS

We will receive net proceeds of approximately \$10.9 million from the sale of the securities offered by us in this offering after deducting placement agent fees and expenses and estimated offering expenses payable by us and excluding the proceeds, if any, from the exercise of the warrants issued pursuant to this offering and assuming we sell the maximum number of securities we are offering pursuant to the prospectus supplement.

We currently intend to use the net proceeds from this offering for general corporate purposes, including manufacturing expenses, clinical trial expenses, research and development expenses and general and administrative expense.

Our expected use of net proceeds from this offering represents our current intentions based upon our present plans and business condition. As of the date of this prospectus, we cannot currently allocate specific percentages of the net proceeds that we may use for the purposes specified above, and we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering, or the amounts that we will actually spend on the uses set forth above. The amounts and timing of our actual use of the net proceeds will vary depending on numerous factors, including our ability to obtain additional financing, the progress, cost and results of our preclinical and clinical development programs, and whether we are able to enter into future licensing or collaboration arrangements. We may find it necessary or advisable to use the net proceeds for other purposes, and our management will have broad discretion in the application of the net proceeds, and investors will be relying on our judgment regarding