Bellerophon Therapeutics, Inc.
Form 10-Q
November 08, 2016

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-Q

(Mark One)

ý QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2016
or
o 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 (Address of principal executive offices)	07059 (Zip Code)

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

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 ý No o

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 ý No o

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 o	Accelerated filer o
Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company ý

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

The number of shares outstanding of the registrant's common stock as of November 7, 2016: 14,506,997

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REFERENCES TO BELLEROPHON

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

· references to the “Company,” “Bellerophon,” “we,” “us” and “our” following the date of the Corporate Conversion ref 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 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 Quarterly Report on Form 10-Q contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Quarterly Report on Form 10-Q, 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," "p "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 Quarterly Report on Form 10-Q 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;

· 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.

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 Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K for the year ended December 31, 2015, 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 Quarterly Report on Form 10-Q and the documents that we have filed as exhibits to this Quarterly Report on Form 10-Q 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 Quarterly Report on Form 10-Q 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. FINANCIAL INFORMATION

Item 1. Financial Statements.

BELLEROPHON THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)
(in thousands except share and per share data)

	As of September 30, 2016	As of December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 3,930	$ 6,260
Marketable securities	7,230	17,807
Prepaid expenses and other current assets	6,365	5,385
Total current assets	17,525	29,452
Restricted cash, non-current	457	457
Other non-current assets	3,304	6,701
Property and equipment, net	1,498	1,799
Total assets	$ 22,784	$ 38,409
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,235	$ 1,613
Accrued research and development	1,085	2,825
Accrued expenses	1,302	3,487
Due to Ikaria, Inc.	166	148
Total current liabilities	4,788	8,073
Total liabilities	4,788	8,073
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.01 par value per share; 125,000,000 shares authorized, 14,506,997 and 13,130,800 shares issued and outstanding at September 30, 2016 and December 31, 2015, respectively	145	131
Preferred stock, $0.01 par value per share; 5,000,000 shares authorized, zero shares issued and outstanding at September 30, 2016 and December 31, 2015, respectively	—	—
Additional paid-in capital	134,921	130,902
Accumulated other comprehensive loss	(1)	(19)
Accumulated deficit	(117,069)	(100,678)
Total stockholders' equity	17,996	30,336
Total liabilities and stockholders' equity	$ 22,784	$ 38,409

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

BELLEROPHON THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)
(in thousands except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Operating expenses:				
Research and development	$2,472	$7,090	$11,539	$25,036
General and administrative	1,745	4,329	4,926	12,337
Total operating expenses	4,217	11,419	16,465	37,373
Other operating income	—	250	—	1,667
Loss from operations	(4,217)	(11,169)	(16,465)	(35,706)
Interest income	22	27	74	73
Loss before taxes	(4,195)	(11,142)	(16,391)	(35,633)
Income tax benefit	—	—	—	—
Net loss	$(4,195)	$(11,142)	$(16,391)	$(35,633)
Weighted average shares outstanding:				
Basic and diluted	13,854,188	2,911,905	13,335,358	12,012,002
Net loss per share:				
Basic and diluted	$(0.30)	$(0.86)	$(1.23)	$(2.97)

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

BELLEROPHON THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS (UNAUDITED)
(in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Net loss	$(4,195)	$(11,142)	$(16,391)	$(35,633)
Other comprehensive (loss) income				
Unrealized gain (loss) on available-for-sale marketable securities	(3)	1	18	1
Total other comprehensive (loss) income	(3)	1	18	1
Comprehensive loss	$(4,198)	$(11,141)	$(16,373)	$(35,632)

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

BELLEROPHON THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY (UNAUDITED)
(in thousands except share data)

	Common Stock		Additional	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Paid in Capital	Income (Loss)	Deficit	Equity
December 31, 2015	13,130,800	$ 131	$ 130,902	$ (19)	$ (100,678)	$ 30,336
Net loss	—	—	—	—	(16,391)	(16,391)
Other comprehensive income	—	—	—	18	—	18
Sale of common stock in ATM Offering, net of commissions and offering expenses of $149	973,024	10	2,003	—	—	2,013
Stock-based compensation, net	403,173	4	2,016	—	—	2,020
September 30, 2016	14,506,997	$ 145	$ 134,921	$ (1)	$ (117,069)	$ 17,996

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

BELLEROPHON THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)
(in thousands)

	Nine Months Ended September 30,	
	2016	2015
Cash flows from operating activities:		
Net loss	$(16,391)	$(35,633)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	301	273
Stock-based compensation	2,148	1,244
Accretion and amortization of discounts and premiums on marketable securities, net	29	5
Changes in operating assets and liabilities:		
Receivables due from Ikaria, Inc.	—	(250)
Prepaid expenses and other current assets	(980)	158
Restricted cash held for Ikaria, Inc.	—	6,949
Restricted cash held as security deposit	—	(457)
Other non-current assets	3,397	—
Accounts payable, accrued research and development, and accrued expenses	(3,316)	(1,826)
Amounts due to Ikaria, Inc.	18	570
Net cash used in operating activities	(14,794)	(28,967)
Cash flows from investing activities:		
Capital expenditures	(22)	(424)
Purchase of marketable securities	—	(18,865)
Proceeds from sale of marketable securities	10,566	1,470
Net cash provided by (used in) investing activities	10,544	(17,819)
Cash flows from financing activities:		
Proceeds from sale of membership units	—	1
Proceeds received from exercise of stock options	—	51
Proceeds from sale of common stock in ATM Offering, net of commissions and offering expenses	2,048	—
Tax withholding payments for stock compensation	(128)	—
Proceeds from issuance of common stock from initial public offering, net of issuance costs	—	53,827
Net cash provided by financing activities	1,920	53,879
Net change in cash and cash equivalents	(2,330)	7,093
Cash and cash equivalents at beginning of period	6,260	16,815
Cash and cash equivalents at end of period	$3,930	$23,908
Supplemental disclosure of cash flow information:		
Non-cash financing activities:		
Unpaid expenses related to ATM Offering	$35	$—
Non-cash investing activities:		
Change in unrealized holding losses on marketable securities, net	$18	$1

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

BELLEROPHON THERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

(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 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 was formerly the research and development operating segment of Ikaria, Inc. (a subsidiary of Mallinckrodt plc), or Ikaria. In 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. 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.

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.

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.

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.

On May 5, 2016, the Company filed a shelf registration statement with the Securities and Exchange Commission, or the SEC, on Form S-3, which as amended became effective on May 23, 2016. The shelf registration will allow the Company to issue, from time to time at prices and on terms to be determined prior to the time of any such offering, up to $30.0 million of any combination of the Company’s common stock, preferred stock, debt securities, warrants, rights, purchase contracts or units, either individually or in units.

On May 27, 2016, the Company entered into an At Market Issuance Sales Agreement, or Sales Agreement, with FBR Capital Markets & Co. and MLV & Co. LLC, or the Distribution Agents, pursuant to which the Company may issue and sell shares of the Company's common stock having an aggregate offering price of up to $5.7 million through the Distribution Agents. Any sales of shares of the Company's common stock pursuant to the Sales Agreement, or ATM Offering, will be made under the Company’s effective shelf registration statement on Form S-3 and the related prospectus supplement. As of September 30, 2016, the Company has sold 973,024 shares for gross and net proceeds of $2.2 million and $2.0 million, respectively.

(2) Summary of Significant Accounting Policies

(a) Basis of Presentation

The accompanying unaudited condensed consolidated financial statements were prepared following the requirements of the Securities and Exchange Commission for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by accounting principles generally accepted in the United States of America, or U.S. GAAP, can be condensed or omitted. The Company operates in one reportable segment and solely within the United States. Accordingly, no segment or geographic information has been presented.

The Company is responsible for the unaudited condensed consolidated financial statements. The condensed consolidated financial statements include all normal and recurring adjustments that are considered necessary for the fair presentation of the Company's financial position, results of operations, comprehensive loss and its cash flows for the periods presented. These condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements for the year ended December 31, 2015, included in the Company's Annual Report on Form 10-K for the year ended December 31, 2015. The results of operations for the three and nine months ended September 30, 2016 for the Company are not necessarily indicative of the results expected for the full year.

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 expenses, accrued research and development expenses, stock-based compensation, and income taxes. Actual results could differ from those estimates.

(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) 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 6 - Stock-Based Compensation for a description of these assumptions.

(d) 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.

The Company’s estimated tax rate for 2016 is expected to be zero because the Company expects to generate additional losses and currently has a full valuation allowance. The deferred tax assets balance before valuation allowance as of September 30, 2016 was approximately $47.7 million. The increase in deferred tax assets in the three and nine months ended

September 30, 2016 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 orphan drug costs, and orphan drug federal income tax credits. The valuation allowance is required until the Company has sufficient positive evidence of taxable income necessary to support realization of its deferred tax assets. The Company did not have material uncertain tax positions as of September 30, 2016.

(e) 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.

(f) 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.

(g) New Accounting Pronouncements

In May 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 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.

In January 2016, the FASB issued ASU 2016-01, "Financial Instruments - Overall - Recognition and Measurement of Financial Assets and Financial Liabilities," which addresses certain aspects of recognition, measurement, presentation, and disclosure of financial instruments. This standard will be effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. The Company is assessing ASU 2016-01'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 assessing ASU 2016-02’s impact and will adopt it when effective.

In March 2016, the FASB issued ASU 2016-09, "Compensation - Stock Compensation - Improvements to Employee Share-Based Payment Accounting" which provides for simplification of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the

statement of cash flows. This standard will be effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. The Company is assessing ASU 2016-09's impact and will adopt it when effective.

In August 2016, the FASB issued ASU 2016-15, "Statement of Cash Flows: Clarification of Certain Cash Receipts and Cash Payments", which eliminates the diversity in practice related to the classification of certain cash receipts and payments in the statement of cash flows, by adding or clarifying guidance on eight specific cash flow issues. ASU 2016-15 is effective for annual and interim reporting periods beginning after December 15, 2017 and early adoption is permitted. ASU 2016-15 provides for retrospective application for all periods presented. The Company is assessing ASU 2016-15's impact and will adopt it when effective.

(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 $3.9 million and marketable securities of $7.2 million as of September 30, 2016. 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 September 30, 2016 will be used primarily to fund the first of two INOpulse for PAH Phase 3 trials, in which the Company enrolled the first patient in June 2016. As of September 30, 2016, the Company had $8.6 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 corresponding prepayments balance as of December 31, 2015 was $11.3 million.

On May 27, 2016, the Company entered into a Sales Agreement, with Distribution Agents, pursuant to which the Company may issue and sell shares of the Company's common stock having an aggregate offering price of up to $5.7 million through the Distribution Agents. Any sales of shares of the Company's common stock pursuant to the Sales Agreement, or the ATM Offering, will be made under the Company's effective shelf registration statement on Form S-3 and the related prospectus supplement dated May 27, 2016 and filed with the SEC on May 27, 2016. As of September 30, 2016, the Company had sold 973,024 shares for gross and net proceeds of $2.2 million and $2.0 million, respectively.

During December 2015, the Company entered into a letter agreement with Global Corporate Finance, or GCF. In accordance with the terms of the letter agreement, the Company has agreed to place with GCF up to $20.0 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 the Company's outstanding shares. The first two drawdowns under this letter agreement may not exceed $2.0 million. Thereafter, the drawdown amounts will depend on the average daily trading volume of the Company's shares. At September 30, 2016, the amount that could be drawn down under this agreement was approximately $4.0 million.

The Company continues to pursue potential sources of funding, including equity financing.

The Company believes, as of September 30, 2016, its existing funds, combined with the additional funding available under the ATM Offering, along with alternatives available to the Company, as discussed above, will be sufficient to satisfy its operating cash needs for at least the next 12 months. However, if the Company is unable to raise capital on acceptable terms, it plans to reduce research and development expenses until additional funding becomes available by postponing certain programs and to reduce certain general and administrative expenses, as well as move certain external costs in house.

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, it 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 the Company's 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.

If the Company is unable to raise capital when needed, it could be forced to delay, reduce or eliminate its product development programs or commercialization efforts. Moreover, if the Company is unable to obtain additional funds on a timely basis, there will be substantial doubt about its ability to continue as a going concern.

(4) Marketable Securities

The Company considers all of its investments to be available-for-sale. Marketable securities as of September 30, 2016 consist of the following (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Certificates of deposit	5,274	—	—	5,274
Corporate bonds	1,957	—	(1)	1,956
Total	7,231	—	(1)	7,230

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 September 30, 2016 and December 31, 2015 (in thousands):

	September 30, 2016	December 31, 2015
Due within one year	6,533	10,230
Due after one year through two years	697	7,577
	7,230	17,807

(5) Income Taxes

The effective tax rate for each of the three and nine month periods ended September 30, 2016 and 2015, respectively was 0.0%. For the three and nine months ended September 30, 2016 and 2015, the effective rate was lower than the federal statutory rates primarily due to losses incurred and a full valuation allowance on deferred tax assets.

As of September 30, 2016, there were no material uncertain tax positions. There are no tax positions for which a material change in any unrecognized tax benefit liability is reasonably possible in the next 12 months.

(6) 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. 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 the Company's current estimates, such amounts will be recorded as an adjustment in the period in which estimates are revised.

Bellerophon 2015 and 2014 Equity Incentive Plans

During 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 September 30, 2016, there was approximately $2.7 million of total unrecognized compensation expense related to unvested stock awards. This expense is expected to be recognized over a weighted-average period of 1.9 years.

No tax benefit was recognized during the nine months ended September 30, 2016 and 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.

Stock Options

Compensation expense is measured based on the fair value of the stock 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. Stock options are forfeited if the employee ceases to be employed by the Company prior to vesting.

During 2014, the Company adopted the 2014 Equity Incentive Plan, or the 2014 Plan, which provided for the grant of stock options. Following the effectiveness of the Company's registration statement filed in connection with its IPO, no stock 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 stock options issued during the nine months ended September 30, 2016 and 2015 was $1.52 and $6.55, respectively. The following are the weighted average assumptions used in estimating the fair value of stock options issued during the nine months ended September 30, 2016 and 2015:

	Nine Months Ended September 30, 2016		Nine Months Ended September 30, 2015	
Valuation assumptions:				
Risk-free rate	1.34	%	1.60	%
Expected volatility	81.8	%	79.2	%
Expected term (years)	6.1		6.1	
Dividend yield	—		—	

A summary of stock option activity under the 2015 Plan and 2014 Plan for the nine months ended September 30, 2016 is presented below:

	Options	Range of Exercise Price	Weighted Average Price	Weighted Average Remaining Contractual Life (in years)
Options outstanding as of December 31, 2015	705,180	$4.12 - 13.28	$ 12.08	8.7
Granted	230,000	1.40 - 2.30	2.17	
Exercised	—			
Forfeited	(45,072)	10.22 - 13.28	11.68	
Options outstanding as of September 30, 2016	890,108	$1.40 - 13.28	$ 9.54	8.3
Options vested and exercisable as of September 30, 2016	334,025	$4.12 - 13.28	$ 12.58	7.8

Restricted Stock

A summary of restricted stock activity under the 2015 Plan for the nine months ended September 30, 2016 is presented below:

	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, 2015	77,793	$ 3.99	$ 0.3	0.7
Granted	519,871	2.40	1.2	
Released	(251,842)	2.86	(0.7)	
Forfeited	(24,001)	3.69	(0.1)	
Restricted stock outstanding as of September 30, 2016	321,821	$ 2.33	$ 0.7	0.3

Ikaria Equity Incentive Plans prior to February 12, 2014

Stock Options

Following the internal reorganization of Ikaria, in February 2014, Ikaria distributed all of the Company's 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. The Company refers to Ikaria’s distribution of the Company's then outstanding units to its stockholders as the Spin-Out. In February 2014, prior to the Spin-Out, each Ikaria stock option, other than stock 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.

A summary of option activity under the assumed Ikaria 2007 stock option plan and the assumed Ikaria 2010 long term incentive plan for the nine months ended September 30, 2016, is presented below:

	Ikaria Equity Incentive Plans			
	Options	Range of Exercise Price	Weighted Average Price	Weighted Average Remaining Contractual Life (in years)
Options outstanding as of December 31, 2015	113,709	$0.26 - 17.92	$ 8.93	5.2
Exercised	—			
Forfeited	(25,542)	0.26 - 17.92	8.13	
Options outstanding as of September 30, 2016	88,167	$7.77 - 17.92	$ 9.16	4.6
Options vested and exercisable as of September 30, 2016	88,167	$7.77 - 17.92	$ 9.16	4.6

The intrinsic value of options outstanding, vested and exercisable as of September 30, 2016 was zero.

Stock-Based Compensation Expense, Net of Estimated Forfeitures

The following table summarizes the stock-based compensation expense by the unaudited condensed consolidated statement of operations line items for the three and nine months ended September 30, 2016 and 2015, respectively:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2016	2015	2016	2015
Research and development	$203	$32	$656	$274
General and administrative	576	405	1,492	970
Total stock-based compensation expense	$779	$437	$2,148	$1,244

(7) Related-Party Transactions

During the years ended December 31, 2014 and 2013, 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 set 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 provided 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 platform 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 a transition services agreement, or 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. 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. Following the final payment in October 2015, the Company no longer had accrued expenses due to Ikaria in connection with the TSA.

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. Pursuant to the July 2015 amendment, during October 2015, the Company received from escrow $3.3 million, which was 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.

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. 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 three and nine months ended September 30, 2015:

(in millions)	Three Months Ended September 30, 2015	Nine Months Ended September 30, 2015
Expense in connection with the TSA	$ 2.4	$ 7.0
Other operating income in connection with the 2015 Services Agreement	(0.2)	(1.7)
Expense in connection with the 2015 Services Agreement	—	0.1

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 desired 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 March 31, 2015, or any subsequent periods.
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. Subsequent to the amendment, no amounts were due to Ikaria under the drug supply agreement.

(8) Commitments and Contingencies

Legal Proceedings

The Company periodically becomes subject to legal proceedings and claims arising in connection with its business. The ultimate legal and financial liability of the Company in respect to all proceedings, claims and lawsuits, pending or threatened, cannot be estimated with any certainty.

As 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.

(9) Net Loss Per Share

Basic net loss per share is calculated by dividing net loss by the weighted average number of shares outstanding during the period, as applicable. Diluted net loss per share is calculated by dividing net loss by the weighted average number of shares outstanding, adjusted to reflect potentially dilutive securities (options) using the treasury stock method, except when the effect would be anti-dilutive.

The Company reported a net loss for the three and nine months ended September 30, 2016 and 2015, therefore diluted net loss per share is the same as the basic net loss per share.

As of September 30, 2016, the Company had 978,275 options to purchase shares and 321,821 restricted shares outstanding that have been excluded from the computation of diluted weighted average shares outstanding, because such securities had an anti-dilutive impact due to the loss reported.

(10) 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 September 30, 2016 for assets and liabilities measured at fair value on a recurring basis:

(Dollar amounts in thousands)	Level 1	Level 2	Level 3	Total
Marketable securities	—	$7,230	—	$7,230

The following table summarizes fair value measurements by level at December 31, 2015 for assets and liabilities 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

(11) 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 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 includes a general release of claims against the Company.

The following table summarizes restructuring activities for the nine months ended September 30, 2016:

	Amounts (in thousands)
Accrual balance at December 31, 2015	$ 969
Reversals (a)	(352)
Cash payments	(393)
Accrual balance at September 30, 2016 (b)	$ 224

(a) Credited to general and administrative expense
(b) Included in Accrued expenses.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of our financial condition and results of operations together with our condensed consolidated financial statements and the related notes appearing elsewhere in this Quarterly Report on Form 10-Q. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. You should read the "Risk Factors" section in Part II—Item 1A. of this Quarterly Report on Form 10-Q and in Part I—Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2015 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. 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 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.

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.

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 preclinical studies;
•expenses relating to vendors in connection with research and development activities;
•the cost of acquiring and manufacturing clinical trial materials;
•facilities and allocated expenses;
•lab supplies, reagents, active pharmaceutical ingredients and other direct and indirect costs in support of our preclinical and clinical activities;
•device development and drug manufacturing engineering;
•upfront and development milestone payments and 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 continuing the Phase 3 PAH program for INOpulse, advancing INOpulse for PH-IPF, advancing INOpulse for PH-COPD, and seeking to identify additional early-stage product candidates.

We track external research and development expenses and direct personnel expenses on a program-by-program basis. We use our employee and infrastructure resources, including regulatory, quality, clinical supply distribution, clinical development and clinical operations, across our clinical development programs and have included these expenses in research and development infrastructure. Engineering activities related to INOpulse and the manufacture of cartridges related to INOpulse are included in INOpulse engineering.

It is difficult to determine with certainty the duration and completion costs of our current or any future preclinical 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 preclinical 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, 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.

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 from October 2014. After reaching agreement with the FDA and the EMA on our Phase 3 protocol, we are moving forward with Phase 3 development and enrolled our first patient in June 2016.

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. We received health authority approval in Belgium and enrolled the first patient in October 2016.

INOpulse for PH-IPF

We initiated our Phase 2 studies in PH-IPF consisting of an exploratory acute hemodynamic study, for which the first patient was enrolled in the second quarter of 2016, to be followed by exercise capacity.

BCM

Our Bioabsorbable Cardiac Matrix, or BCM, is a medical device intended to prevent congestive heart failure following an ST segment elevation myocardial infarction, which is a type of severe heart attack. 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. Following the results of our PRESERVATION I clinical trial, 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. Our second generation INOpulse device, as well as a custom triple-lumen cannula, have several significantly improved characteristics. 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 have begun using and will continue to use in future clinical trials of INOpulse for PAH and INOpulse for PH-COPD and PH-IPF.

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. Other general and administrative expenses include corporate facilities, 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.

Results of Operations

Comparison of Three Months Ended September 30, 2016 and 2015

The following table summarizes our results of operations for the three months ended September 30, 2016 and 2015:

(Dollar amounts in thousands)	Three Months Ended September 30, 2016	2015	$ Change	% Change
Research and development expenses:				
BCM	$16	$720	$(704)	(98)%
PAH	856	3,008	(2,152)	(72)%
PH-COPD and PH-IPF	11	(14)	25	(179)%
Clinical programs	883	3,714	(2,831)	(76)%
Research and development infrastructure	1,106	2,072	(966)	(47)%
INOpulse engineering	483	1,304	(821)	(63)%
Total research and development expenses	2,472	7,090	(4,618)	(65)%
General and administrative expenses	1,745	4,329	(2,584)	(60)%
Total operating expenses	4,217	11,419	(7,202)	(63)%
Other operating income	—	250	(250)	(100)%
Loss from operations	(4,217)	(11,169)	6,952	(62)%
Interest income	22	27	(5)	(19)%
Net loss	$(4,195)	$(11,142)	$6,947	(62)%

Total Operating Expenses. Total operating expenses for the three months ended September 30, 2016 were $4.2 million compared to $11.4 million for the three months ended September 30, 2015, a decrease of $7.2 million, or 63%. This decrease was primarily due to reductions in expenses incurred on our clinical programs, reduced research and development infrastructure costs and reduced general and administration expenses.

Research and Development Expenses. Total research and development expenses for the three months ended September 30, 2016 were $2.5 million compared to $7.1 million for the three months ended September 30, 2015, a decrease of $4.6 million, or 65%. Total research and development expenses consisted of the following:

•BCM research and development expenses for the three months ended September 30, 2016, were $16,000 compared to $0.7 million for the three months ended September 30, 2015, a decrease of $0.7 million, or 98%. The decrease was due to us ceasing further clinical development of BCM following the PRESERVATION I results.

•PAH research and development expenses were $0.9 million for the three months ended September 30, 2016, compared to $3.0 million for the three months ended September 30, 2015, a decrease of $2.2 million, or 72%. The decrease was primarily driven by the closure in 2016 of the PAH Phase 2 trial.

•Research and development infrastructure expenses for the three months ended September 30, 2016 were $1.1 million compared to $2.1 million for the three months ended September 30, 2015, a decrease of $1.0 million, or 47%. The decrease was primarily due to reduced expenses payable to Ikaria as a result of the termination of the TSA on September 30, 2015, and reduced personnel costs as a result of the restructuring that occurred in 2015.

•INOpulse engineering expenses for the three months ended September 30, 2016 were $0.5 million compared to $1.3 million for the three months ended September 30, 2015, a decrease of $0.8 million, or 63%. The decrease was primarily the result of reduced expenses payable to Ikaria as a result of the termination of the TSA on September 30, 2015, as well as a reduction in development costs for the INOpulse device and triple-lumen cannula and reduced personnel costs as a result of the restructuring that occurred in 2015.

General and Administrative Expenses. General and administrative expenses for the three months ended September 30, 2016 were $1.7 million compared to $4.3 million for the three months ended September 30, 2015, a decrease of $2.6 million, or 60%. The decrease was primarily due to reduced personnel and consulting costs as a result of the restructuring that occurred in 2015 and reduced expenses payable to Ikaria as a result of the termination of the TSA on September 30, 2015.

Other Operating Income. We had no other operating income for the three months ended September 30, 2016 and other operating income for the three months ended September 30, 2015 was $0.3 million related to the 2015 Services Agreement with Ikaria.

Comparison of Nine Months Ended September 30, 2016 and 2015

The following table summarizes our results of operations for the nine months ended September 30, 2016 and 2015:

	Nine Months Ended September 30,			
(Dollar amounts in thousands)	2016	2015	$ Change	% Change
Research and development expenses:				
BCM	$371	$7,388	$(7,017)	(95)%
PAH	6,267	6,447	(180)	(3)%
PH-COPD and PH-IPF	65	(79)	144	(182)%
Clinical programs	6,703	13,756	(7,053)	(51)%
Research and development infrastructure	3,346	7,217	(3,871)	(54)%
INOpulse engineering	1,490	4,063	(2,573)	(63)%
Total research and development expenses	11,539	25,036	(13,497)	(54)%
General and administrative expenses	4,926	12,337	(7,411)	(60)%
Total operating expenses	16,465	37,373	(20,908)	(56)%
Other operating income	—	1,667	(1,667)	(100)%
Loss from operations	(16,465)	(35,706)	19,241	(54)%
Interest income	74	73	1	1 %
Net loss	$(16,391)	$(35,633)	$19,242	(54)%

Total Operating Expenses. Total operating expenses for the nine months ended September 30, 2016 were $16.5 million compared to $37.4 million for the nine months ended September 30, 2015, a decrease of $20.9 million, or 56%. This decrease was primarily due to reductions in research and development expenses pertaining to our development of BCM, reduced research and development infrastructure expenses, reduced INOpulse engineering expenses and reduced general and administration expenses.

Research and Development Expenses. Total research and development expenses for the nine months ended September 30, 2016 were $11.5 million compared to $25.0 million for the nine months ended September 30, 2015, a decrease of $13.5 million, or 54%. Total research and development expenses consisted of the following:

•BCM research and development expenses for the nine months ended September 30, 2016 were $0.4 million compared to $7.4 million for the nine months ended September 30, 2015, a decrease of $7.0 million, or 95%. The decrease was due to us ceasing further clinical development of BCM following the PRESERVATION I results.

•PAH research and development expenses were $6.3 million for the nine months ended September 30, 2016, compared to $6.4 million for the nine months ended September 30, 2015, a decrease of $0.2 million, or 3%.

•Research and development infrastructure expenses for the nine months ended September 30, 2016 were $3.3 million compared to $7.2 million for the nine months ended September 30, 2015, a decrease of $3.9 million, or 54%. The decrease was primarily due to reduced expenses payable to Ikaria as a result of the termination of the TSA and reduced personnel costs as a result of the restructuring that occurred in 2015.

•INOpulse engineering expenses for the nine months ended September 30, 2016, were $1.5 million compared to $4.1 million for the nine months ended September 30, 2015, a decrease of $2.6 million, or 63%. The decrease was primarily the result of reduced expenses payable to Ikaria as a result of the termination of the TSA, reduced development costs for the INOpulse device and triple-lumen cannula and reduced personnel costs as a result of the restructuring that occurred in 2015.

General and Administrative Expenses. General and administrative expenses for the nine months ended September 30, 2016 were $4.9 million compared to $12.3 million for the nine months ended September 30, 2015, a decrease of $7.4 million, or 60%. The decrease was primarily due to reduced personnel and consulting costs as a result of the restructuring that occurred in 2015 and a reduction in expenses payable to Ikaria as a result of the termination of the TSA on September 30, 2015.

Other Operating Income. We had no other operating income for the nine months ended September 30, 2016 and other operating income for the nine months ended September 30, 2015 was $1.7 million related to the 2015 Services Agreement with Ikaria.

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 expect to continue to incur significant expenses and operating losses for the foreseeable future as we continue to develop, conduct clinical trials 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 have a sales, marketing, manufacture or distribution infrastructure for a pharmaceutical product. 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.

We had cash and cash equivalents of $3.9 million and marketable securities of $7.2 million as of September 30, 2016. Our existing cash and cash equivalents and marketable securities as of September 30, 2016, will be used primarily to fund the first of two INOpulse for PAH Phase 3 trials, in which we enrolled the first patient in June 2016. As of September 30, 2016, we had $8.6 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. The corresponding prepayments balance as of December 31, 2015 was $11.3 million.

On May 27, 2016, we entered into an At Market Issuance Sales Agreement, or Sales Agreement, with FBR Capital Markets & Co. and MLV & Co. LLC, or the Distribution Agents, pursuant to which we may issue and sell shares of our common stock having an aggregate offering price of up to $5.7 million through the Distribution Agents. Any sales of shares of our common stock pursuant to the Sales Agreement, or the ATM Offering, will be made under our effective shelf registration statement on Form S-3 and the related prospectus supplement. As of September 30, 2016, we have sold 973,024 shares for gross and net proceeds of $2.2 million and $2.0 million, respectively.

During December 2015, we entered into a letter agreement with Global Corporate Finance, or GCF. In accordance with the terms of the letter agreement, we have agreed to place with GCF up to $20.0 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 drawdowns under this letter agreement may not exceed $2.0 million. Thereafter, the drawdown amounts will depend on the average daily trading volume of our shares. At September 30, 2016, the amount that could be drawn down under this agreement was approximately $4.0 million.

We continue to pursue potential sources of funding, including equity financing.

We believe, as of September 30, 2016, our existing funds, combined with the additional funds available under the ATM Offering, along with alternatives available to us as discussed above, will be sufficient to satisfy our operating cash needs for at least the next 12 months. However, if we are unable to raise capital on acceptable terms, we plan to reduce research and development expenses until additional funding becomes available by postponing certain programs and to reduce certain general and administrative expenses, as well as move certain external costs in-house.

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:

- progress and cost of our clinical trials and other research and development activities;
- our ability to manufacture sufficient supply of our product candidates and the costs thereof;
- the cost and timing of seeking regulatory approvals;
- 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 cost of filing, prosecuting, defending and enforcing patent applications, claims, patents and other intellectual property rights; 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.

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.

Cash Flows

The following table summarizes our cash flows for the nine months ended September 30, 2016 and 2015:

	Nine Months Ended September 30,	
(Amounts in thousands)	2016	2015
Operating activities	$(14,794)	$(28,967)
Investing activities	10,544	(17,819)
Financing activities	1,920	53,879
Net change in cash and cash equivalents	$(2,330)	$7,093

Net Cash Used in Operating Activities

Cash used in operating activities for the nine months ended September 30, 2016 was $14.8 million compared to $29.0 million for the nine months ended September 30, 2015, a decrease of $14.2 million, or 49%. The decrease in cash used in operating activities was primarily due to reduced operating expenses.

Net Cash Provided by/(Used in) Investing Activities

Cash provided by investing activities for the nine months ended September 30, 2016 was $10.5 million, primarily due to proceeds from the sale of marketable securities. Cash used in investing activities for the nine months ended September 30, 2015 was $17.8 million, primarily for the purchase of marketable securities.

Net Cash Provided by Financing Activities

Cash provided by financing activities for the nine months ended September 30, 2016 was $1.9 million, which included the net proceeds from our ATM Offering, compared to $53.9 million for the nine months ended September 30, 2015, which included the net proceeds from our IPO.

Contractual Obligations and Commitments

There were no material changes, outside the ordinary course of business, in our outstanding contractual obligations from those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2015.

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 SEC 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 accounting principles generally accepted in the United States. 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, and stock-based compensation. 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.

During the nine months ended September 30, 2016, there were no material changes to our critical accounting policies. Our critical accounting policies are described under Management's Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report on Form 10-K for the fiscal year ended December 31, 2015.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risk related to changes in interest rates. As of September 30, 2016, we had cash and cash equivalents of $3.9 million, consisting primarily of demand deposits with U.S. banking institutions and marketable securities of $7.2 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 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 4. 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 September 30, 2016. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or 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 September 30, 2016, 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.

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 September 30, 2016 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.
We are currently not a party to any material legal proceedings.

Item 1A. Risk Factors.

There have been no material changes to our risk factors contained in our Annual Report on Form 10-K for the year ended December 31, 2015. For a further discussion of our Risk Factors, refer to the "Risk Factors" discussion contained in our Annual Report on Form 10-K for the year ended December 31, 2015.
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

Use of Proceeds

We effected the initial public offering of our common stock through 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 initial public offering, or 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.

As of September 30, 2016, we have used approximately $40.7 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 September 30, 2016, 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.

On May 27, 2016, we entered into the Sales Agreement, with the Distribution Agents, pursuant to which we may issue and sell shares of our common stock having an aggregate offering price of up to $5.7 million through the Distribution Agents. Any sales of shares of our common stock pursuant to the Sales Agreement will be made under our effective shelf registration statement on Form S-3 (File No. 333-211166), declared effective on May 23, 2016, and the related prospectus supplement dated May 27, 2016 and filed with the SEC on May 27, 2016. As of September 30, 2016, we issued 973,024 shares of common stock resulting in gross and net proceeds to us of $2.2 million and $2.0 million, respectively. As of September 30, 2016, we have not used any of the net proceeds from these sales. There has been no material change in our planned use of the net proceeds from the offering as described in our prospectus supplement filed with the SEC pursuant to Rule 424(b) under the Securities Act of 1933.

Item 3. Defaults Upon Senior Securities.
None.

Item 4. Mine Safety Disclosures.
Not applicable.

Item 5. Other Information.
None.

Item 6. Exhibits.

The exhibits listed in the Exhibit Index to this Quarterly Report on Form 10-Q are incorporated herein by reference.

SIGNATURES

Pursuant to the requirements 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.

BELLEROPHON THERAPEUTICS, INC.

Date: November 8, 2016

By: /s/ Jonathan M. Peacock

Jonathan M. Peacock
Chairman, President and Chief Executive Officer
(Principal Executive Officer)

Date: November 8, 2016

By: /s/ Fabian Tenenbaum

Fabian Tenenbaum
Chief Financial Officer and Chief Business Officer (Principal Financial and Accounting Officer)

Exhibit Index

Exhibit Number	Description
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
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

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