Bellerophon Therapeutics, Inc.
Form 10-Q
November 12, 2015
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2015

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)

53 Frontage Road, Suite 301

Hampton, New Jersey 08827

(Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report)

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 x 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 x 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	x	(Do not check if a smaller reporting company)	Smaller reporting company	o

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

The number of shares outstanding of the registrant s common stock as of November 9, 2015: 13,099,864

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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 r 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 ref 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, Inc. into shares of common stock of Bellerophon Therapeutics, Inc.

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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, believ 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;

- 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 operate, and the implementation of our business strategy, as a stand-alone company;

- our ability to comply with government laws and regulations;

- our commercialization, marketing and manufacturing capabilities and strategy;

- our estimates regarding the potential market opportunity for our product candidates;

- the timing of or our ability to enter into partnerships to market and commercialize our product candidates;

- the rate and degree of market acceptance of any product candidate for which we receive marketing approval;

- our intellectual property position;

- our expectations related to the use of proceeds from our initial public offering in February 2015;

- our estimates regarding expenses, future revenues, capital requirements and needs for additional funding and our ability to obtain additional funding;

- the success of competing treatments;

- our competitive position; and

- our expectations regarding the time during which we will be an emerging growth company under the Jumpstart Our Business Startups Act of 2012.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K for the year ended December 31, 2014, 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.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements.

BELLEROPHON THERAPEUTICS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)

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

	September 30, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$ 23,908	$ 16,815
Restricted cash	3,863	9,264
Marketable securities	17,391	
Receivables - Due from Ikaria, Inc.	250	
Prepaid expenses and other current assets	1,444	1,602
Total current assets	46,856	27,681
Restricted cash, non-current	457	1,548
Deferred transaction costs		2,466
Property and equipment, net	1,847	1,696
Total assets	$ 49,160	$ 33,391
Liabilities and Stockholders / Members Equity		
Current liabilities:		
Accounts payable	$ 934	$ 376
Accrued research and development	3,041	6,666
Accrued expenses	3,438	2,751
Due to Ikaria, Inc.	1,231	661
Total current liabilities	8,644	10,454
Total liabilities	8,644	10,454
Commitments and contingencies (Note 9)		
Stockholders / members equity:		
Common stock, $0.01 par value per share; 94,273,819 shares authorized, 12,979,878 shares issued and outstanding at September 30, 2015	130	
Additional paid-in capital	130,237	
Accumulated other comprehensive income	1	
Membership units, no par value per unit; 94,273,819 voting units authorized, 7,524,196 voting units issued and outstanding at December 31, 2014; 19,416,481 non-voting units authorized, 381,129 non-voting units issued and outstanding at December 31, 2014		77,156
Accumulated deficit	(89,852)	(54,219)

Total stockholders / members equity		40,516		22,937
Total liabilities and stockholders / members equity	$	49,160	$	33,391

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

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BELLEROPHON THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Operating expenses:				
Research and development	$ 7,090	$ 11,559	$ 25,036	$ 36,368
General and administrative	4,329	3,934	12,337	10,598
Total operating expenses	11,419	15,493	37,373	46,966
Other operating income	250		1,667	
Loss from operations	(11,169)	(15,493)	(35,706)	(46,966)
Interest income	27	13	73	61
Pre-tax loss	(11,142)	(15,480)	(35,633)	(46,905)
Income tax benefit (expense)				
Net loss	$ (11,142)	$ (15,480)	$ (35,633)	$ (46,905)
Weighted average shares/units outstanding:				
Basic and diluted	12,911,905	7,897,143	12,012,002	7,898,041
Net loss per share/unit:				
Basic and diluted	$ (0.86)	$ (1.96)	$ (2.97)	$ (5.94)

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

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BELLEROPHON THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS (UNAUDITED)

(in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Net loss	$ (11,142)	$ (15,480)	$ (35,633)	$ (46,905)
Other comprehensive income				
Unrealized gains on available-for-sale marketable securities	1		1	
Total other comprehensive income	1		1	
Comprehensive loss	$ (11,141)	$ (15,480)	$ (35,632)	$ (46,905)

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

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BELLEROPHON THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS / MEMBERS EQUITY (UNAUDITED)

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

	Membership Units		Common Stock			Accumulated Other		
	Units	Amount	Shares	Amount	Additional Paid in Capital	Comprehensive Income	Accumulated Deficit	Total Stockholders / Members Equity
Balance at December 31, 2014	7,905,325	$ 77,156		$	$	$	$ (54,219)	$ 22,937
Net loss							(35,633)	(35,633)
Other comprehensive income						1		1
Sale of membership units	67	1						1
Conversion of membership units into common stock in connection with conversion of LLC into a C-Corp.	(7,905,392)	(77,157)	7,905,392	79	77,078			
Sale of common stock in initial public offering ($12.00 per share), net of underwriting discounts and commissions and offering expenses of $8,085			5,000,000	50	51,865			51,915
Exercise of options			6,513		51			51
Stock-based compensation			67,973	1	1,243			1,244
Balance at September 30, 2015		$	12,979,878	$ 130	$ 130,237	$ 1	$ (89,852)	$ 40,516

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

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BELLEROPHON THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)

(in thousands)

	Nine months ended September 30,	
	2015	2014
Cash flows from operating activities:		
Net loss	$ (35,633)	$ (46,905)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	273	294
Stock based compensation	1,244	1,299
Accretion and amortization of discounts and premiums on marketable securities, net	5	
Changes in operating assets and liabilities:		
Increase in receivables due from Ikaria, Inc.	(250)	
Decrease (increase) in prepaid expenses and other current assets	158	(19)
Decrease (increase) in restricted cash held for Ikaria, Inc.	6,949	(13,127)
Increase in restricted cash held as security deposit	(457)	
Decrease in accounts payable, accrued research and development, and accrued expenses	(1,826)	(344)
Increase in amounts due to Ikaria, Inc.	570	631
Net cash used in operating activities	(28,967)	(58,171)
Cash flows from investing activities:		
Capital expenditures	(424)	
Purchase of marketable securities	(18,865)	
Proceeds from sale of marketable securities	1,470	
Net cash used in investing activities	(17,819)	
Cash flows from financing activities:		
Contribution from Ikaria, Inc. in connection with Spin-Out		80,000
Cash contributions from Ikaria, Inc., net		9,252
Transaction costs paid		(447)
Proceeds from sale of membership units	1	
Proceeds received from exercise of options	51	
Repurchase of units		(29)
Cash proceeds from issuance of common stock from initial public offering, net of issuance costs	53,827	
Net cash provided by financing activities	53,879	88,776
Net change in cash and cash equivalents	7,093	30,605
Cash and cash equivalents at beginning of period	16,815	
Cash and cash equivalents at end of period	$ 23,908	$ 30,605
Supplemental disclosure of cash flow information:		
Non-cash financing activities:		
Investment by Ikaria, Inc., net	$	$ 7,491
Non-cash investing activities:		
Change in unrealized holding gains on marketable securities, net	$ 1	$

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

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BELLEROPHON THERAPEUTICS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

(1) Organization, Nature of the Business and Management s Plans Regarding Financing of Future Operations

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 and cardiac diseases. The focus of the Company s clinical program is the continued development of its nitric oxide therapy for patients with pulmonary hypertension, or PH, using its proprietary delivery system, INOpulse, with pulmonary arterial hypertension, or PAH, representing the lead indication.

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

- The risk that the Company will not achieve success in its research and development efforts, including clinical trials conducted by it or its potential collaborative partners.

- The expectation that the Company will experience operating losses for the next several years.

- Decisions by regulatory authorities regarding whether and when to approve the Company s regulatory applications as well as their decisions regarding labeling and other matters which could affect the commercial potential of the Company s products or product candidates.

- The risk that the Company will fail to obtain adequate financing to meet its future capital and financing needs.

- The risk that key personnel will leave the Company and/or that the Company will be unable to recruit and retain senior level officers to manage its business.

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

INOpulse for pulmonary hypertension associated with chronic obstructive pulmonary disease, or PH-COPD, to the Company and/or its subsidiaries.

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

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

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

In connection with the Spin-Out, $80.0 million of cash was distributed to the Company. At the time of the Spin-Out, $18.5 million of the $80.0 million cash held by the Company was deposited in escrow to guarantee payment of the monthly services fees payable by the Company to Ikaria in exchange for the services to be provided by Ikaria pursuant to the Company s transition services agreement with Ikaria, or the TSA, during the 24 months following the Spin-Out. At September 30, 2015, the escrowed cash balance was approximately $3.9 million and is classified as restricted cash, all of which is reflected as current, on the condensed consolidated balance sheet at September 30, 2015. See Note 7 *Related-Party Transactions*. On July 9, 2015, the Company entered into an amendment to the TSA advancing the termination date from February 9, 2016 to September 30, 2015. Pursuant to this amendment, during October 2015, the Company received from escrow $3.3 million, which is equal to the amount it deposited to pay amounts owed to Ikaria under the TSA for the period from October 1, 2015 to February 9, 2016.

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

(2) Summary of Significant Accounting Policies

(a) Basis of Presentation

The 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

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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 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, 2014 included in the Company s Annual Report on Form 10-K for the year ended December 31, 2014. The results of operations for the three and nine months ended September 30, 2015 for the Company are not necessarily indicative of the results expected for the full year.

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

In February 2015, the Company converted from a limited liability company to a C-corporation.

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

For periods prior to the Spin-Out, the financial statements were carved out of the consolidated financial statements of Ikaria. Management believes that the statements of operations for the nine months ended September 30, 2014 (which include a period of forty-two days prior to the Spin-Out) include reasonable allocations of costs and expenses incurred by Ikaria which benefited the Company. However, such amounts may not be indicative of the actual level of costs and expenses that would have been incurred by the Company if it had operated as an independent stand-alone company or of the costs and expenses expected to be incurred in the future. As such, the financial information for the nine months ended September 30, 2014 may not necessarily reflect the results of operations and cash flows of the Company had it been an independent stand-alone company for the period, or the results of operations and cash flows expected in the future.

(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.

(c) Restricted Cash

Restricted cash classified under current assets represents amounts held on deposit with a bank in relation to the TSA. The funds related to the TSA are held in an account to settle the required payment to Ikaria for services to be provided in connection with the TSA. See Note 7 *Related-Party Transactions*. Restricted cash, non-current, represents amounts held on deposit with a bank as a security deposit for the lease of office space. The required payments to be paid in excess of one year from the balance sheet date are classified as long-term restricted cash.

(d) 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.

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

(e) Deferred Transaction Costs

Deferred transaction costs represent IPO-related costs primarily associated with third-party professional legal, accounting and printing fees associated with the initial public offering of the Company s shares. These IPO-related costs were deferred and charged against the gross proceeds of the offering when the public offering of equity securities was complete as a reduction of additional paid-in capital. As of September 30, 2015, the Company charged all deferred transaction costs against the gross proceeds of the offering.

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(f) Income Taxes

Prior to its conversion to a Delaware corporation in February 2015, the Company was a Delaware limited liability company that passed through income and losses to its members for U.S. federal and state income tax purposes. As a result of its conversion to a Delaware corporation, the Company recognized deferred income taxes through income tax expense related to temporary differences that existed as of the date of its tax status change. The Company uses the asset and liability approach to account for income taxes as required by ASC 740, *Income Taxes*, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Valuation allowances are provided when necessary to reduce deferred tax assets to the amount expected to be realized, on a more likely than not basis. The Company recognizes the benefit of an uncertain tax position that it has taken or expects to take on income tax returns it files if such tax position is more likely than not to be sustained on examination by the taxing authorities, based on the technical merits of the position. These tax benefits are measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate resolution.

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

The Company s estimated tax rate for 2015 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, 2015 was approximately $33.4 million. The increase in deferred tax assets after the corporate conversion is principally due to the year-to-date loss, adjusted for nondeductible items including stock compensation expense related to the Company s equity incentive plan, the nondeductible portion of the orphan drug costs, and the orphan drug credits. The valuation allowance is required until the Company has sufficient positive evidence of taxable income necessary to support realization of its deferred tax assets. A valuation allowance release is generally recognized in income tax expense (as a benefit). The Company did not have material uncertain tax positions as of September 30, 2015.

(g) 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.

(h) 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.

(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 $23.9 million, restricted cash classified under current assets of $3.9 million and marketable securities of $17.4 million as of September 30, 2015. The Company received net proceeds of $51.9 million in February 2015 as a result of the IPO, after deducting underwriting discounts and commissions of $4.2 million and offering costs of $3.9 million. The Company s cash and marketable securities will be used primarily to fund the first of two INOpulse for PAH Phase 3 trials, in which the Company expects to enroll the first patient by the end of 2015. The Company expects these funds will be sufficient

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to complete this Phase 3 trial due in part to the fact that the Company has implemented certain restructuring and cost reduction programs. See Note 12 *Restructuring Charges* for a description of the restructuring plan. The Company believes, as of September 30, 2015, it has sufficient funds to satisfy its operating cash needs for at least the next 12 months.

The Company s ultimate success depends on the outcome of its research and development activities. Management recognizes the Company will need to raise additional capital through the potential issuance of additional equity or borrowings or entering into strategic alliances with partner companies to fund all necessary research and development activities to successfully commercialize its product candidates. However, if such financing is not available at adequate levels or strategic alliances with partner companies do not occur, the Company will need to reevaluate its plans.

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.

(4) Property, Plant and Equipment

At the date of the Spin-Out, Ikaria transferred specifically identified assets to the Company at the carrying amount of the assets as of February 12, 2014. Prior to the date of the Spin-Out, property, plant and equipment and accumulated depreciation were either specifically identified or allocated to the Company by Ikaria. Property, plant and equipment as of September 30, 2015 and December 31, 2014 consisted of the following (in thousands):

	September 30, 2015	December 31, 2014
Machinery, equipment and furniture	$ 2,943	$ 2,943
Less accumulated depreciation	(1,520)	(1,247)
Construction in progress	424	
	$ 1,847	$ 1,696

Construction in progress as of September 30, 2015 consists of leasehold improvements and furniture and fixtures for which the Company took possession in October 2015 related to the Company s new office space in Warren, New Jersey.

(5) Income Taxes

The effective tax rate for each of the three and nine months ended September 30, 2015 and 2014 was 0.0%. For the three and nine months ended September 30, 2015, the effective rate was lower than the federal statutory rates primarily due to the losses incurred and the full valuation

allowance on deferred tax assets. For the three and nine months ended September 30, 2014, the effective rate was lower than the federal statutory rates because the Company was a limited liability company and a pass through entity for tax purposes.

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As of September 30, 2015, 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. For restricted stock, the fair value is the closing market price per share on the grant date. The estimation of the number of stock awards that will ultimately vest requires judgment, and to the extent actual results or updated estimates differ from 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 the nine months ended September 30, 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, 2015, the Company is authorized to issue equity compensation under the 2015 Plan in an amount up to an aggregate of 500,162 shares to eligible employees, directors and consultants.

As of September 30, 2015, there was approximately $4.2 million of total unrecognized compensation expense related to unvested stock awards. This expense is expected to be recognized over a weighted-average period of 2.7 years.

No tax benefit was recognized during the nine months ended September 30, 2015 related to stock-based compensation expense since the Company incurred operating losses and has established a full valuation allowance to offset all the potential tax benefits associated with its deferred tax assets.

Options

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

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

The weighted average grant-date fair value of options issued during the nine months ended September 30, 2015 and 2014 was $6.55 and $9.98, respectively. The following are the weighted average assumptions used in estimating the fair value of options issued during the nine months ended September 30, 2015 and 2014.

	Nine Months Ended September 30, 2015	Nine Months Ended September 30, 2014
Valuation assumptions:		
Risk-free rate	1.60%	1.71%
Expected volatility	79.18%	90.29%
Expected term (years)	6.1	6.2
Dividend yield	%	%

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

	Bellerophon 2015 and 2014 Equity Incentive Plans			
	Options	Range of Exercise Price	Weighted Average Price	Weighted Average Remaining Contractual Life (in years)
Options outstanding as of December 31, 2014	508,280	$ 13.28	$ 13.28	9.5
Granted	443,607	4.12 - 12.00	9.53	
Exercised				
Forfeited	(153,356)	8.23 - 13.28	10.07	
Options outstanding as of September 30, 2015	798,531	$ 4.12 - 13.28	$ 11.81	9.1
Options vested and exercisable as of September 30, 2015	240,740	$ 8.23 - 13.28	$ 12.34	8.9

Restricted Stock

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

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

	Bellerophon 2015 Equity Incentive Plan			
	Shares	Weighted Average Fair Value	Aggregate Grant Date Fair Value (in millions)	Weighted Average Remaining Contractual Life (in years)
Restricted stock outstanding as of December 31, 2014		$	$	
Granted	67,973	4.12	0.3	
Exercised				
Forfeited				
Restricted stock outstanding as of September 30, 2015	67,973	$ 4.12	$ 0.3	1.0

Ikaria Equity Incentive Plans prior to February 12, 2014

Options

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

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

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

A summary of option activity under the assumed Ikaria 2007 stock option plan and the assumed Ikaria 2010 long term incentive plan for the nine months ended September 30, 2015 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, 2014	577,975	$ 0.26 - 17.92	$ 7.11	4.5
Granted				
Exercised	(6,513)	7.77	7.77	
Forfeited	(287,918)	7.77 - 15.66	8.67	
Options outstanding as of September 30, 2015	283,544	$ 0.26 - 17.92	$ 5.50	3.8
Options vested and exercisable as of September 30, 2015	283,544	$ 0.26 - 17.92	$ 5.50	3.8

The intrinsic value of options exercised during the nine months ended September 30, 2015 was deminimis. The intrinsic value of options outstanding, vested and exercisable as of September 30, 2015 was $0.5 million.

Restricted Stock Units

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

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

Stock-Based Compensation Expense, Net of Estimated Forfeitures

The following table summarizes the stock-based compensation expense by the unaudited condensed consolidated statement of operations line items for the three and nine months ended September 30, 2015 and 2014. For comparison purposes, the following disclosures include share-based compensation expenses recognized under the 2015 Plan and the 2014 Plan and expenses for dates prior to the Spin-Out that were allocated to the Company related to Ikaria share-based awards.

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	**2015**	**2014**	**2015**	**2014**
Research and development	$ 32	$	$ 274	$ 272
General and administrative	405	263	970	1,027
Total expense	$ 437	$ 263	$ 1,244	$ 1,299

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(7) Related-Party Transactions

Separation and Distribution Agreement

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

License Agreement

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

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

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, in:

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

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

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Transition Services Agreement

In February 2014, the Company and Ikaria entered into the TSA, pursuant to which Ikaria agreed to use commercially reasonable efforts to provide certain transition services to the Company, which services include management/executive, human resources, real estate, information technology, accounting, financial planning and analysis, legal, quality and regulatory support. Ikaria also has 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. In exchange for the services, beginning in February 2014, the Company was obligated to pay Ikaria monthly services fees in the amount of $772,000 plus out of pocket expenses and certain other expenses. At September 30, 2015, the Company had accrued expenses due to Ikaria of $0.5 million 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. The escrowed cash is classified as restricted cash as of September 30, 2015. Pursuant to the July 2015 amendment, during October 2015, the Company received from escrow $3.3 million, which is equal to the amount it deposited to pay amounts owed to Ikaria under the TSA for the 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 will be obligated to pay the Company a service fee in the amount of $83,333 per month, subject to performance of the services. The Company has a $0.2 million receivable due from Ikaria in connection with this agreement as of September 30, 2015. In July 2015, the Company entered into an amendment to the 2015 Services Agreement advancing the termination date from February 8, 2016 to September 30, 2015. In addition, pursuant to the 2015 Services Agreement, Ikaria had agreed to use commercially reasonable efforts to provide services to the Company, including information technology and servicing and upgrades of devices, for which the Company incurred $0.2 million.

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 and 2014:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in millions)	**2015**	**2014**	**2015**	**2014**
Expense in connection with the TSA	$ 2.4	$ 2.3	$ 7.0	$ 6.9
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 has agreed to use commercially reasonable efforts to supply inhaled nitric oxide and nitric oxide delivery devices for use in the Company s clinical trials, in each case at Ikaria s manufacturing cost plus a 20% mark-up, and in the case of the drug supply agreement, the Company has agreed to purchase its clinical supply of inhaled nitric oxide from Ikaria. The Company also granted Ikaria a right of first negotiation in the event that the Company desires to enter into a commercial supply agreement with a third party for supply of nitric oxide for inhalation. As of September 30, 2015, the amount due to Ikaria under the drug supply agreement was approximately $0.6 million. The device supply agreement expired on February 9, 2015 and no amounts were due to Ikaria under that agreement as of December 31, 2014 or September 30, 2015.

(8) Segments and Geographic Information

The Company operates in one reportable segment and solely within the United States. Accordingly, no segment or geographic information has been presented.

(9) 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.

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BioLineRx Ltd., or BioLine, previously indicated to the Company that it believed that the Company had breached the license agreement in several ways, including, but not limited to, failure to use commercially reasonable efforts to develop bioabsorbable cardiac matrix, or BCM, failure to provide BioLine with material information concerning the development and commercialization plans for BCM and failure to notify BioLine in advance of material public disclosures regarding BCM. The Company and BioLine also previously disagreed about the timing of a certain milestone payment that the Company would owe BioLine based upon progress in the Company s BCM clinical development program. The Company believed it had complied with its obligations under the license agreement to use commercially reasonable efforts to develop BCM and was not in breach of its other obligations under the license agreement. No amounts were previously accrued for this matter since no loss was probable as of December 31, 2014. On January 8, 2015, the Company and BioLine agreed to amend the license agreement, which resolved the prior disputes and provided for a release of claims by BioLine. The amendment also changed certain milestones and related payments, but the total potential milestone payments to be paid to BioLine under the license agreement remained the same. No additional milestones have been met as of September 30, 2015.

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.

(10) Net Loss Per Share/Unit

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

The Company reported a net loss for the three and nine months ended September 30, 2015 and 2014, therefore diluted net loss per share/unit is the same as the basic net loss per share/unit.

As of September 30, 2015, the Company had 1,082,075 options to purchase shares and 67,973 restricted shares outstanding that have been excluded from the computation of diluted weighted average shares/units outstanding, because such securities had an antidilutive impact due to the loss reported.

(11) Fair Value Measurements

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

- Level 1 Values are based on unadjusted quoted prices for identical assets or liabilities in an active market which the company has the ability to access at the measurement date.

- Level 2 Values are based on quoted market prices in markets where trading occurs infrequently or whose values are based on quoted prices of instruments with similar attributes in active markets.

- Level 3 Values are based on prices or valuation techniques that require inputs that are both unobservable and significant to the overall fair value measurement. These inputs reflect management s own assumptions about the assumptions a market participant would use in pricing the asset.

The following table summarizes fair value measurements by level at September 30, 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		$ 17,391		$ 17,391

There were no marketable securities at December 31, 2014.

(12) 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 is expected to include a workforce reduction of approximately 20 people and is expected to be completed by the end of 2015.

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

The following table summarizes restructuring activities for the nine months ended September 30, 2015, all of which occurred in the third quarter of 2015:

	Amounts (in thousands)
Accrual balance at December 31, 2014	$
Charged to research and development expense	227
Charged to general and administrative expense	1,083
Cash payments	(23)
Accrual balance at September 30, 2015	$ 1,287

(13) Subsequent Events

On July 9, 2015, the Company entered into an amendment to the TSA advancing the termination date from February 9, 2016 to September 30, 2015. Pursuant to this amendment, during October 2015, the Company received from escrow $3.3 million, which is equal to the amount it deposited to pay amounts owed to Ikaria under the TSA for the period from October 1, 2015 to February 9, 2016.

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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, 2014 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 and cardiac diseases. The focus of our clinical program is the continued development of our nitric oxide therapy for patients with pulmonary hypertension, or PH, using our proprietary delivery system, INOpulse, with pulmonary arterial hypertension, or PAH, representing the lead indication.

Our INOpulse program is based on our proprietary pulsatile nitric oxide delivery device. We are currently developing two product candidates under our INOpulse program: one for the treatment of PAH and the other for the treatment of pulmonary hypertension associated with chronic obstructive pulmonary disease, or PH-COPD.

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

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

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

We presented detailed results from the PRESERVATION I trial for our Bioabsorbable Cardiac Matrix, or BCM, program at the European Society of Cardiology meeting in London on September 1, 2015. Following the results, further exploratory work is under consideration but we do not intend to proceed with further clinical development of BCM at this point.

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

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

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Restructuring

Following the results of our PRESERVATION I clinical trial for BCM, on September 11, 2015, our Board of Directors approved a staff reduction plan in order to reduce operating expenses and conserve cash resources, which we refer to as the Restructuring. The Restructuring is expected to include a workforce reduction of approximately 20 people and is expected to be completed by the end of 2015. We have offered severance benefits to the affected employees, including cash severance payments. Each affected employee s eligibility for the severance benefits is contingent upon such employee s execution (and non-revocation) of a separation agreement, which includes a general release of claims against us. We currently expect to incur pre-tax charges of approximately $1.4 million associated with the Restructuring, primarily consisting of the cash severance payments specified above. These charges were incurred largely in the third quarter of 2015 and are anticipated to be paid out in cash over the 12 months following approval of the Restructuring.

Separation and Spin-Out from Ikaria

Prior to February 2014, we were a wholly-owned subsidiary of Ikaria, Inc. (a subsidiary of Mallinckrodt plc), or Ikaria. As part of an internal reorganization of Ikaria in October 2013, Ikaria transferred to us exclusive worldwide rights, with no royalty obligations, to develop and commercialize pulsed nitric oxide in PAH, PH-COPD and PH-IPF. Following the internal reorganization, in February 2014, Ikaria distributed all of our then outstanding units to its stockholders through the payment of a special dividend on a pro rata basis based on each stockholder s ownership of Ikaria capital stock, which we refer to as the Spin-Out, and as a result we became a stand-alone company.

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

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

Under our services agreement with Ikaria, or the 2015 Services Agreement, which became effective on January 1, 2015, Ikaria provided to us certain information technology and device servicing services. In exchange for the services provided by Ikaria pursuant to the 2015 Services Agreement, we paid to Ikaria fees that totaled, in the aggregate, approximately $0.2 million. In July 2015, we entered into an amendment to the 2015 Services Agreement advancing the termination date from February 8, 2016 to September 30, 2015.

We have developed and begun implementing plans to replace services previously provided to us by Ikaria under the TSA and the 2015 Services Agreement. These services include, among others, accounting and financial management support, human resources support, drug and device safety services, biometrics support, information technology services and manufacturing and device servicing support. We expect the costs

related to replacing the services previously provided by Ikaria under the TSA, in the aggregate, will be less than the $772,000 per month that we previously paid under the TSA, and we expect the costs related to replacing the services previously provided by Ikaria under the 2015 Services Agreement will be approximately the same as the amounts we paid under the 2015 Services Agreement. However, although we believe our estimates are reasonable based on the information we have to date, certain estimates are preliminary and subject to change.

Accounting for the Separation and Spin-Out

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

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Due to this presentation, the financial information for the nine months ended September 30, 2014 included in this Quarterly Report on Form 10-Q does not reflect what our financial position, results of operations and cash flows will be in the future or what our financial position, results of operations and cash flows would have been in the past had we been a public, stand-alone company throughout the periods presented.

Financial Position and Outlook

Since inception, we have never been profitable and have incurred significant operating losses. Our net losses were $11.1 million and $35.6 million for the three and nine months periods ended September 30, 2015, respectively, compared to $15.5 million and $46.9 million for the three and nine months periods ended September 30, 2014, respectively. As of September 30, 2015, our sources of funding were the net proceeds from our initial public offering as well as investments in us by our former parent company, Ikaria.

On February 19, 2015, we completed the sale of 5,000,000 shares of common stock 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.

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

We have entered into license agreements with Ikaria and BioLine pursuant to which we obtained rights to our product candidates. In the future, we may enter into additional licensing agreements for new product candidates or strategic or co-promotion agreements with partners for the development and/or commercialization of product candidates in the United States or other countries.

We are currently incurring and expect to continue to incur additional costs associated with operating as a public company. Unless and until we generate sufficient revenue to be profitable, we will seek to fund our operations primarily through public or private equity or debt financings or other means, which may include strategic partnerships with third parties in the United States or other countries with respect to certain or all of our programs. Other additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed could have a material adverse effect on our business, results of operations, financial condition, cash flows and future prospects.

Financial Operations Overview

Revenue

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

Research and Development Expenses

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

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

Research and development expenses primarily consist of:

- employee-related expenses, including salary, benefits and stock-based compensation expense;

- expenses incurred under agreements with contract research organizations, investigative sites that conduct our clinical trials and consultants that conduct a portion of our pre-clinical studies;

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- expenses relating to vendors in connection with research and development activities;

- the cost of acquiring and manufacturing clinical trial materials;

- facilities, depreciation of fixed assets and allocated expenses;

- lab supplies, reagents, active pharmaceutical ingredients and other direct and indirect costs in support of our pre-clinical and clinical activities;

- device development and drug manufacturing engineering;

- license fees related to in-licensed products and technology; and

- costs associated with non-clinical activities and regulatory approvals.

We expense research and development costs as incurred.

Conducting a significant amount of research and development is central to our business model. Product candidates in late stages of clinical development generally have higher development costs than those in earlier stages of clinical development primarily due to the increased size and duration of late-stage clinical trials. We plan to increase our research and development expenses for ongoing clinical programs for the foreseeable future as we seek to continue multiple clinical trials for our product candidates, including to potentially advance INOpulse for PH-IPF, and seek to identify additional early-stage product candidates.

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

INOpulse for PAH

We completed a randomized, placebo-controlled, double-blind Phase 2 clinical trial of INOpulse for PAH in October 2014. The goal of the trial was to determine the safety, tolerability and efficacy of two different doses of INOpulse for PAH. In September 2015, we performed an interim 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 interim analysis reinforced the results from Part 1 of our Phase 2 clinical trial of INOpulse for PAH. After reaching agreement with the FDA and the EMA on our Phase 3 protocol, we are moving forward with Phase 3 development.

INOpulse for PH-COPD

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

BCM

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

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

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INOpulse for PH-COPD utilized the first generation INOpulse DS device. We are near completion of a second generation INOpulse Mark2 device, which we refer to as the Mark2, as well as a custom triple-lumen cannula, each of which we believe will significantly improve several characteristics of our INOpulse delivery system but will require verification and validation. 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 Mark2 devices that we expect to use in future clinical trials of INOpulse for PAH and INOpulse for PH-COPD.

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

General and Administrative Expenses

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

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

- we expect to incur reduced general and administrative expenses following the completion of the Restructuring;

- we expect to incur reduced general and administrative expenses previously paid to Ikaria following the expiration of the TSA and the 2015 Services Agreement, in each case on September 30, 2015;

- we expect to incur additional general and administrative expenses to replace services previously provided to us by Ikaria under the TSA such as accounting and financial management support, human resources support, drug and

device safety services, biometrics support, information technology services and manufacturing and device servicing support; and

- we expect to incur additional general and administrative expenses to support ourselves as a stand-alone company, such as director compensation and director and officer insurance premiums associated with being a public company.

Results of Operations

Comparison of Three Months Ended September 30, 2015 and 2014

The following table summarizes our results of operations for the three months ended September 30, 2015 and 2014.

	Three Months Ended September 30,	
(Dollar amounts in thousands)	**2015**	**2014**
Research and development expenses:		
BCM	$ 720	$ 3,740
PAH	3,008	3,060
PH-COPD	(14)	(418)
Clinical programs	3,714	6,382
Research and development infrastructure	2,072	2,492
INOpulse engineering	1,304	2,685
Total research and development expenses	7,090	11,559
General and administrative expenses	4,329	3,934
Total operating expenses	11,419	15,493
Other operating income	(250)	
Loss from operations	(11,169)	(15,493)
Interest income	(27)	(13)
Net loss	$ (11,142)	$ (15,480)

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Total Operating Expenses. Total operating expenses for the three months ended September 30, 2015 were $11.4 million compared to $15.5 million for the three months ended September 30, 2014, a decrease of $4.1 million, or 26%. This decrease was primarily due to reductions in research and development expenses pertaining to our development of BCM.

Research and Development Expenses. Total research and development expenses for the three months ended September 30, 2015 were $7.1 million compared to $11.6 million for the three months ended September 30, 2014, a decrease of $4.5 million, or 39%. Total research and development expenses consisted of the following:

- BCM research and development expenses for the three months ended September 30, 2015 were $0.7 million compared to $3.7 million for the three months ended September 30, 2014, a decrease of $3.0 million, or 81%. The decrease was primarily due to us ceasing further clinical development of BCM following the PRESERVATION I results.

- PAH research and development expenses were $3.0 million for the three months ended September 30, 2015 compared to $3.1 million for three months ended September 30, 2014, a decrease of $0.1 million, or 2%.

- PH-COPD research and development expenses for the three months ended September 30, 2015 were zero compared to $(0.4) million for the three months ended September 30, 2014.

- Research and development infrastructure expenses for the three months ended September 30, 2015 were $2.1 million compared to $2.5 million for the three months ended September 30, 2014, a decrease of $0.4 million, or 17%. The decrease was primarily due to the reversal of the 2015 bonus accrual that was recognized through June 30, 2015. In September 2015, the Company decided to pay 2015 bonuses by granting employees restricted stock awards which will vest over a one year-period from the date of grant. Accordingly, the related cost will be recognized over such period.

- INOpulse engineering expenses for the three months ended September 30, 2015 were $1.3 million compared to $2.7 million for the three months ended September 30, 2014, a decrease of $1.4 million, or 51%. The decrease was primarily the result of a slowdown in spending as we near completion of the Mark2, which we expect to use during the Phase 3 clinical trial of INOpulse for PAH in the fourth quarter of 2015.

General and Administrative Expenses. General and administrative expenses for the three months ended September 30, 2015

were $4.3 million compared to $3.9 million for the three months ended September 30, 2014, an increase of $0.4 million, or 10%. The increase was primarily due to restructuring charges offset, in part, by the reversal of 2015 bonus accrual that was recognized through June 30, 2015. In September 2015, the Company decided to pay 2015 bonuses by granting employees restricted stock awards which will vest over a one year-period from the date of grant. Accordingly, the related cost will be recognized over such period.

Other Operating Income. Other operating income for the three months ended September 30, 2015 was $0.3 million, and we had no operating income for the three months ended September 30, 2014**.** The increase resulted from payments received from Ikaria in connection with the 2015 Services Agreement.

Comparison of Nine Months Ended September 30, 2015 and 2014

The following table summarizes our results of operations for the nine months ended September 30, 2015 and 2014.

	Nine Months Ended September 30,	
(Dollar amounts in thousands)	**2015**	**2014**
Research and development expenses:		
BCM	$ 7,388	$ 10,007
PAH	6,447	8,315
PH-COPD	(79)	3,066
Clinical programs	13,756	21,388
Research and development infrastructure	7,217	9,395
INOpulse engineering	4,063	5,585
Total research and development expenses	25,036	36,368
General and administrative expenses	12,337	10,598
Total operating expenses	37,373	46,966
Other operating income	(1,667)	
Loss from operations	(35,706)	(46,966)
Interest income	(73)	(61)
Net loss	$ (35,633)	$ (46,905)

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Total Operating Expenses. Total operating expenses for the nine months ended September 30, 2015 were $37.4 million compared to $47.0 million for the nine months ended September 30, 2014, a decrease of $9.6 million, or 20%. This decrease was primarily due to reductions in research and development expenses pertaining to our development of INOpulse for PH-COPD and BCM and to research and development infrastructure expenses.

Research and Development Expenses. Total research and development expenses for the nine months ended September 30, 2015 were $25.0 million compared to $36.4 million for the nine months ended September 30, 2014, a decrease of $11.4 million, or 31%. Total research and development expenses consisted of the following:

- BCM research and development expenses for the nine months ended September 30, 2015 were $7.4 million compared to $10.0 million for the nine months ended September 30, 2014, a decrease of $2.6 million, or 26%. The decrease was primarily due to us ceasing further clinical development of BCM following the PRESERVATION I results.

- PAH research and development expenses for the nine months ended September 30, 2015 were $6.4 million compared to $8.3 million for the nine months ended September 30, 2014, a decrease of $1.9 million, or 22%. The decrease was primarily due to the completion of the Phase 2 clinical trial in late-2014 and a reversal of an accrual in the nine months ended September 30, 2015 partially offset by increased costs in anticipation of the start of the Phase 3 clinical trials, which we expect to commence in the fourth quarter of 2015.

- PH-COPD research and development expenses for the nine months ended September 30, 2015 were $(0.1) million compared to $3.1 million for the nine months ended September 30, 2014, a decrease of $3.2 million, or 103%. The decrease primarily resulted from the completion of the Phase 2a clinical trial in mid-2014.

- Research and development infrastructure expenses for the nine months ended September 30, 2015 were $7.2 million compared to $9.4 million for the nine months ended September 30, 2014, a decrease of $2.2 million, or 23%. The decrease was due to as reductions in infrastructure spending to support our INOpulse and BCM clinical programs and the reversal of the 2015 bonus accrual that was recognized through June 30, 2015. In September 2015, the Company decided to pay 2015 bonuses by granting employees restricted stock awards which will vest over a one year period from the date of grant. Accordingly, the related cost will be recognized over such period.

- INOpulse engineering expenses for the nine months ended September 30, 2015 were $4.1 million compared to $5.6 million for the nine months ended September 30, 2014, a decrease of $1.5 million, or 27%. The decrease was primarily the result of a slowdown in spending as we near completion of the Mark2, which we expect to use during the Phase 3 clinical trial of INOpulse for PAH in the fourth quarter of 2015.

General and Administrative Expenses. General and administrative expenses for the nine months ended September 30, 2015 were $12.3 million compared to $10.6 million for the nine months ended September 30, 2014, an increase of $1.7 million, or 16%. The increase was primarily due to restructuring charges and additional costs of operating as a stand-alone public company, including expenses related to transition services from Ikaria and other professional services offset, in part, by the reversal of the 2015 bonus accrual that was recognized through June 30, 2015. In September 2015, the Company decided to pay 2015 bonuses by granting employees restricted stock awards which will vest over a one year-period from the date of grant. Accordingly, the related cost will be recognized over such period.

Other Operating Income. Other operating income for the nine months ended September 30, 2015 was $1.7 million, and we had no operating income for the nine months ended September 30, 2014**.** The increase resulted from payments received from Ikaria in connection with entering into the 2015 Services Agreement.

Liquidity and Capital Resources

Since our inception, we have incurred net losses and negative cash flows from our operations. We incurred net losses of $35.6 million and $46.9 million for the nine months ended September 30, 2015 and 2014, respectively. Our operating activities used $29.0 million and $58.2 million of cash during the nine months ended September 30, 2015 and 2014, respectively. In addition, we had

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cash and cash equivalents of $23.9 million, restricted cash classified under current assets of $3.9 million and marketable securities of $17.4 million as of September 30, 2015.

Cash Flows

The following table summarizes our cash flows for the nine months ended September 30, 2015 and 2014:

	Nine months ended September 30,	
(Dollar amounts in thousands)	**2015**	**2014**
Operating activities	$ (28,967)	$ (58,171)
Investing activities	(17,819)	
Financing activities	53,879	88,776
Increase in cash and cash equivalents	$ 7,093	$ 30,605

Net Cash Used in Operating Activities

Cash used in operating activities for the nine months ended September 30, 2015 was $29.0 million compared to $58.2 million for the nine months ended September 30, 2014, a decrease of $29.2 million, or 50%. The decrease in cash used in operating activities was primarily due to reduced research and development expenses and the recognition in the nine months ended September 30, 2014 of the $18.5 million escrow payment due to Ikaria.

Net Cash Used in Investing Activities

Cash used in investing activities for the nine months ended September 30, 2015 was $17.8 million, including $0.4 million for capital expenditures related to our new office space in Warren, New Jersey and $18.9 million for the purchase of marketable securities, offset by $1.5 million of proceeds from the sale of marketable securities. There were no cash flows from investing activities for the nine months ended September 30, 2014.

Net Cash Provided by Financing Activities

Cash provided by financing activities for the nine months ended September 30, 2015 was $53.9 million compared to $88.8 million for the nine months ended September 30, 2014, a decrease of $34.9 million, or 39%. The decrease resulted from the difference between the $53.8 million net proceeds from our initial public offering in the nine months ended September 30, 2015, after deducting underwriting discounts and commissions of $4.2 million and offering costs of $2.0 million paid in the nine months ended September 30 2015, compared to the $89.3 million net investment by Ikaria, primarily due to a cash contribution of $80.0 million from Ikaria in the nine months ended September 30, 2014 in

connection with the Spin-Out.

Plan of Operations and Future Funding Requirements

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.

Our existing cash and cash equivalents and restricted cash as of September 30, 2015, which includes the proceeds of our initial public offering completed in February 2015, will be used primarily to fund the first of two INOpulse for PAH Phase 3 trials, in which we expect to enroll the first patient by the end of 2015. We expect these funds will be sufficient to complete this Phase 3 trial due in part to the Restructuring. We believe, as of September 30, 2015, we have sufficient funds to satisfy our operating cash needs for at least the next 12 months. We have based these estimates on assumptions that may prove to be wrong, and we may exhaust our capital resources sooner than we expect. In addition, the process of testing product candidates in clinical trials is costly, and the timing of progress in clinical trials is uncertain. Because our product candidates are in clinical development and the outcome of these efforts is uncertain, we cannot estimate the actual amounts that will be necessary to successfully complete the development and commercialization of our product candidates or whether, or when, we may achieve profitability. Our future capital requirements will depend on many factors, including:

- the timing, progress and results of our ongoing and planned clinical trials of INOpulse for PAH, PH-COPD and PH-IPF;

- our ability to manufacture sufficient supply of our product candidates and the costs thereof;

- discussions with regulatory agencies regarding the design and conduct of our clinical trials and the costs, timing and outcome of regulatory review of our product candidates;

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- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution for any of our product candidates for which we receive marketing approval;

- the number and development requirements of any other product candidates we pursue;

- our ability to enter into collaborative agreements and achieve milestones under those agreements;

- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;

- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;

- our expenses as a stand-alone company; and

- the extent to which we acquire or in-license other products and technologies.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity and debt offerings, existing working capital and funding from potential future collaboration arrangements. To the extent that we raise additional capital through the future sale of equity or debt, the ownership interest of our existing stockholders will be diluted, and the terms of such securities may include liquidation or other preferences 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.

Contractual Obligations and Commitments

The following is a summary of our long-term contractual cash obligations as of September 30, 2015 (in thousands). Other than as set forth below, 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, 2014:

As a result of the termination of the TSA and the 2015 Services Agreement with Ikaria on September 30, 2015, our long-term contractual obligations no longer include amounts owed to Ikaria.

	Payment due by period				
	Total	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years
Operating lease obligations (1)	$ 4,640	$ 364	$ 1,267	$ 1,311	$ 1,698
Flextronics agreement (2)	1,097	1,097			
Total	$ 5,737	$ 1,461	$ 1,267	$ 1,311	$ 1,698

(1) Operating lease obligations include the lease agreement we entered into on August 6, 2015 for office space in Warren, New Jersey.

(2) On March 25, 2015, we entered into an agreement with Flextronics to manufacture and service the Mark2 devices that we expect to use in future clinical trials of INOpulse for PAH and INOpulse for PH-COPD. Under the agreement, we have committed to purchase 500 devices within the 12 months following the execution of the agreement.

Milestone and royalty payments associated with our license agreement with BioLine have not been included in the above table of contractual obligations as we cannot reasonably estimate if or when they will occur. We do not intend to proceed with further clinical development of BCM until and unless we can determine an alternative path forward. Consequently, any future milestones payments to BioLine would depend on finding a path forward for future clinical development. Under the terms of the license agreement, if we achieve certain clinical and regulatory events specified in the license agreement, we will be obligated to pay milestone payments to BioLine, which could total, in the aggregate, up to $115.5 million, and if we achieve certain commercialization targets specified in the license agreement, we will be obligated to pay additional milestone payments to BioLine, which could total, in

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the aggregate, up to $150.0 million. In addition, we will be obligated to pay BioLine a specified percentage of any upfront consideration we receive for sublicensing BCM, as well as royalties on net sales, if any, at a percentage ranging from 11% to 15%, depending on net sales level, of any approved product containing BCM, subject to offsets for specified payments to third parties made in connection with BCM. We have reimbursed BioLine for certain legal fees in the amount of $250,000 following completion of our initial public offering.

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

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under applicable Securities and Exchange Commission, or 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, impairment of long-lived assets, stock-based compensation and income taxes. We base our estimates on historical experience, known trends and events and various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Other than as discussed below, during the nine months ended September 30, 2015, 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, 2014, which was filed with the SEC on March 31, 2015.

Income Taxes

We are subject to U.S. federal income taxes as well as state taxes. Prior to our conversion to a Delaware corporation in February 2015, we were a Delaware limited liability company that passed through income and losses to our members for U.S. federal and state income tax purposes. As a result, we were not subject to any U.S. federal or state income taxes as our taxable income was reported by our individual members.

Effective as of the completion of this conversion, we account for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in our consolidated financial statements or tax returns. In addition, deferred tax assets are recorded for the future benefit of utilizing net operating losses and research and development credit carry forwards. Valuation allowances are provided when necessary to reduce deferred tax assets to the amount expected to be realized.

Accordingly, we assess our needs for a valuation allowance quarterly based on the more-likely-than-not realization threshold criterion set forth in Accounting Standard Codification 740. In the assessment, appropriate consideration is given to all positive and negative evidence related to the realization of the deferred tax assets. This assessment considers, among other matters, the nature, frequency and severity of current and cumulative losses, forecasts of future profitability, the duration of statutory carryforward periods, our experience with operating losses and tax credit carryforwards expiring, and tax planning alternatives. Significant judgment is required to determine whether a valuation allowance is necessary and the amount of such valuation allowance, if appropriate.

Significant judgment is required in the application of the authoritative accounting guidance prescribing a threshold and measurement attribute for the financial recognition and measurement of a tax position taken or expected to be taken in a tax return. We recognize liabilities for uncertain tax positions based on a two-step process. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained on audit, including resolution of related appeals or litigation processes, if any. The second step requires us to estimate and

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measure the tax liability as the largest amount that is more likely than not to be realized upon ultimate settlement. Accounting guidance further requires that a change in judgment related to the expected ultimate resolution of uncertain tax positions to be recognized in earnings in the quarter in which such change occurs. We recognize interest and penalties, if any, related to unrecognized tax benefits in income tax expense.

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, 2015, we had cash and cash equivalents and restricted cash of approximately $28.2 million, consisting primarily of demand deposits with U.S. banking institutions (other than restricted cash, which is held in escrow) and marketable securities of approximately $17.4 million. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in cash and cash equivalents, federally insured certificates of deposit and corporate or agency bonds rated A or better. Due to the nature of our deposits and the low risk profile of our investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our deposits.

Item 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, 2015. 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, 2015, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

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, 2015 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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PART II. OTHER INFORMATION

Item 1A. Risk Factors.

Other than as discussed below, 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, 2014. The risk factors described below update and supersede the corresponding risk factors contained in our Annual Report on Form 10-K for the year ended December 31, 2014. 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, 2014.

Risks Related to Our Business and Industry

We may be unable to make, on a timely or cost-effective basis, the changes necessary to operate as a stand-alone company.

We have historically operated as part of Ikaria s broader corporate organization, and Ikaria has assisted us by providing certain corporate functions. However, following the Spin-Out, Ikaria was contractually obligated to provide to us only those services specified in the TSA, the 2015 Services Agreement and the other agreements we entered into with Ikaria to govern our relationship following the Spin-Out. See Certain Relationships and Related Person Transactions Relationship with Ikaria in Part III Item 13 in our Annual Report on Form 10-K for the year ended December 31, 2014 for a summary of these agreements. The TSA, as amended, and the 2015 Services Agreement, as amended, provided for certain services to be provided until September 2015. We may be unable to replace in a timely manner or on comparable terms the services or other benefits that Ikaria previously provided to us that are not specified in the TSA, the 2015 Services Agreement or the other agreements. Also, upon the termination of the services provided under the TSA and the 2015 Services Agreement, such services are now being provided internally or by unaffiliated third parties, and, in some instances, we have incurred and expect to continue to incur higher costs to obtain such services than we incurred under the terms of such agreements. Ultimately, we may be unable to replace in a timely manner or on comparable terms all of the services specified in such agreements.

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

In September 2015, we announced a staff reduction plan pursuant to which we intend to reduce our workforce by approximately 20 people. We are taking these actions in order to reduce operating expenses and conserve cash resources. The Restructuring is expected to be completed by the end of 2015.

As a result of the Restructuring, we expect to record restructuring charges and make future payments of approximately $1.4 million, a substantial portion of which was recorded in the third quarter of 2015. These estimated restructuring charges are based on a number of assumptions. Actual results may differ materially and additional charges not currently expected may be incurred in connection with, or as a result of, these reductions. In addition, we may not realize, in full or in part, the anticipated benefits, savings and improvements in our cost structure from our restructuring efforts due to unforeseen difficulties, delays or unexpected costs. If we are unable to achieve the anticipated benefits, savings or

improvements in our cost structure in the expected time frame or other unforeseen events occur, our business and results of operations may be adversely affected.

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

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

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

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

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

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

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

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

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

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

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

A significant portion of the research that we are conducting involves the development of innovative approaches to the pulsed delivery of nitric oxide. Our drug-device discovery efforts may not be successful in creating drugs or devices that have commercial value or therapeutic utility. Our research programs may initially show promise in creating potential product candidates, yet fail to yield viable product candidates for clinical development for a number of reasons, including that potential product candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be product candidates that will receive marketing approval and achieve market acceptance. Previously, we were dependent on Ikaria for our business development functions pursuant to the TSA. Since the expiration of the TSA, we have brought such functions in-house. Because we have not previously handled such functions internally, we may encounter unforeseen expenses and difficulties and may not be successful in such a transition.

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

Pursuant to the terms of our license agreement with Ikaria, we only have the right to develop and commercialize pulsed nitric oxide in PAH, PH-COPD, PH-IPF, CTEPH, pulmonary hypertension associated with sarcoidosis and pulmonary hypertension associated with pulmonary edema from high altitude sickness; Ikaria retains the right to develop and commercialize inhaled nitric oxide products, including pulsed products, in all other indications. Additionally, we are limited in the scope of potential product candidates that we can identify or discover due to non-competition agreements that we entered into with Ikaria, which agreements were amended in July 2015. Pursuant to these agreements, we and each of our subsidiaries agreed not to engage, anywhere in the world, in any manner, directly or indirectly, until the earlier of five years after the effective date of such non-competition agreement amendments or the date on which Ikaria and all of its subsidiaries are no longer engaged in such business, in:

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

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

In the event that we or one of our subsidiaries materially breach the provisions of the non-competition agreements and do not cure such breach within 30 days after receiving written notice thereof from Ikaria, Ikaria will have the right to terminate the license agreement.

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

Risks Related to Our Dependence on Third Parties

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

We have licensed the intellectual property underlying INOpulse from Ikaria.

The license agreement prohibits us from sublicensing to any competitor of Ikaria any intellectual property licensed to us by Ikaria. In addition, we are required to ensure that all of our products, if any, are used solely for the chronic treatment of PAH, PH-COPD, PH-IPF, CTEPH, pulmonary hypertension associated with sarcoidosis and pulmonary hypertension associated with pulmonary edema from high altitude sickness and to enter into written agreements with any customers that contain restrictions on the use of our products and termination rights in the event such restrictions are violated.

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

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licensed patents that are core to our business in the event Ikaria declines to take action with respect to such infringement, however, if Ikaria determines that our pursuit of any such action could materially impair its business operations or intellectual property rights, Ikaria may prohibit us from taking any such action.

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

On April 16, 2015, Mallinckrodt plc announced that it had completed its acquisition of Ikaria. While the license agreement imposes binding obligations on Ikaria to perform in accordance with the license agreement s terms, it is possible that as the new owner s influence on Ikaria s operations increases, Ikaria may perform differently under the license agreement than it has to date. Moreover, to the extent that we desire to expand the scope of the license agreement, it is possible that Ikaria will not be willing to do so on reasonable terms, or at all. In any of these circumstances, our business, product development and financial statements could be materially adversely affected.

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

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

On April 16, 2015, Mallinckrodt plc announced that it had completed its acquisition of Ikaria. While the drug clinical supply agreement imposes binding obligations on Ikaria to perform in accordance with the agreement s terms, it is possible that as the new owner s influence on Ikaria s operations increases, Ikaria may not continue to provide the same level of performance under the drug clinical supply agreement as Ikaria has provided to date. Moreover, to the extent that we desire to expand the scope of the drug clinical supply agreement (to cover commercial quantities of nitric oxide or otherwise), it is also possible that Ikaria will not be willing to do so on reasonable terms, or at all. In any of these circumstances, our business, product development and financial statements could be materially adversely affected.

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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 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, 2015, we have used approximately $6.0 million of the net proceeds of our initial public offering to fund our Phase 3 clinical development of INOpulse for PAH and for working capital and other general corporate purposes. As of September 30, 2015, we have invested the balance of the net proceeds from the offering in a variety of capital preservation investments, including demand deposits with U.S. banking institutions, federally insured certificates of deposit and corporate or agency bonds rated A or better. There has been no material change in our planned use of the balance of the net proceeds from the offering as described in our final prospectus filed with the SEC pursuant to Rule 424(b) under the Securities Act of 1933, as amended.

Item 6. Exhibits.

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

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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 12, 2015	By:	/s/ Jonathan M. Peacock Jonathan M. Peacock Chairman, President and Chief Executive Officer (Principal Executive Officer)
Date: November 12, 2015	By:	/s/ David Abrams David Abrams Treasurer (Principal Financial and Accounting Officer)

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Exhibit Index

Exhibit Number	Description
10.1	Lease Agreement between 184 Property Owner, LLC and the Registrant dated August 6, 2015
10.2	Second Amendment to the Exclusive Cross-License, Technology Transfer, and Regulatory Matters Agreement between Bellerophon Pulse Technologies LLC and INO Therapeutics LLC, dated July 27, 2015
10.3	Form of Amendment to Agreement Not to Compete, entered into by Ikaria Acquisition LLC and each of the Registrant, Bellerophon BCM LLC, Bellerophon Pulse Technologies LLC and Bellerophon Services, Inc. dated July 27, 2015
10.4	First Amendment to Transition Services Agreement between Ikaria, Inc. and the Registrant dated July 9, 2015
10.5	First Amendment to Services Agreement between Ikaria, Inc. and the Registrant dated July 9, 2015
10.6	Severance and Release Agreement between Manesh Naidu and the Registrant dated July 31, 2015
10.7	Professional Services Agreement between Martin Meglasson and the Registrant dated September 23, 2015
10.8	Offer Letter between Deborah Quinn and the Registrant dated December 8, 2014
10.9	Offer Letter between Amy Edmonds and the Registrant dated February 14, 2014
10.10	Form of Retention Letter by and between the Registrant and each of David Abrams, Martin Dekker, Peter Fernandes, Deborah Quinn and Amy Edmonds
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
32.1	Certification of Principal Executive Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of 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