Bellerophon Therapeutics, Inc.
Form 10-Q
May 15, 2015
Table of Contents

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 March 31, 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.)
53 Frontage Road, Suite 301	
Hampton, New Jersey	**08827**
(Address of principal executive offices)	(Zip Code)

(908) 574-4770

(Registrant s telephone number, including area code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes 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.

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 May 11, 2015: 12,905,392

Table of Contents

TABLE OF CONTENTS

Table of Contents

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 refer to Bellerophon Therapeutics, Inc. and its consolidated subsidiaries;

- references to the Company, Bellerophon, we, us and our prior to the date of the Corporate Conversion refer to Bellerophon Therapeutics LLC and its consolidated subsidiaries; and

- references to the Corporate Conversion or corporate conversion refer to all of the transactions related to the conversion of Bellerophon Therapeutics LLC into Bellerophon Therapeutics, Inc., including the conversion of all of the outstanding units of Bellerophon Therapeutics, Inc. into shares of common stock of Bellerophon Therapeutics, Inc.

Table of Contents

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 INOpulse and BCM 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 INOpulse and BCM 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

Table of Contents

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.

Table of Contents

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements.

BELLEROPHON THERAPEUTICS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)

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

	March 31, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$ 62,935	$ 16,815
Restricted cash	8,497	9,264
Receivables - Due from Ikaria, Inc.	167	
Prepaid expenses and other current assets	1,974	1,602
Total current assets	73,573	27,681
Restricted cash, non-current		1,548
Deferred transaction costs		2,466
Property and equipment, net	1,604	1,696
Total assets	$ 75,177	$ 33,391
Liabilities and Stockholders / Members Equity		
Current liabilities:		
Accounts payable	$ 659	$ 376
Accrued research and development	7,235	6,666
Accrued expenses	3,825	2,751
Due to Ikaria, Inc.	1,069	661
Total current liabilities	12,788	10,454
Total liabilities	12,788	10,454
Commitments and contingencies (Note 9)		
Stockholders / members equity:		
Common stock, $0.01 par value per share; 94,273,819 shares authorized, 12,905,392 shares issued and outstanding at March 31, 2015	129	
Additional paid-in capital	129,387	
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	(67,127)	(54,219)
Total stockholders / members equity	62,389	22,937

Total liabilities and stockholders / members equity	$	75,177	$	33,391

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

Table of Contents

BELLEROPHON THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS (UNAUDITED)

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

	Three Months Ended March 31,	
	2015	**2014**
Operating expenses:		
Research and development	$ 9,520	$ 12,040
General and administrative	4,573	2,470
Total operating expenses	14,093	14,510
Other operating income	1,166	
Loss from operations	(12,927)	(14,510)
Interest income	19	
Pre-tax loss	(12,908)	(14,510)
Income tax benefit (expense)		
Net loss and comprehensive loss	$ (12,908)	$ (14,510)
Weighted average shares/units outstanding:		
Basic and diluted	10,152,487	7,899,251
Net loss per share/unit:		
Basic and diluted	$ (1.27)	$ (1.84)

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

Table of Contents

BELLEROPHON THERAPEUTICS, INC.

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

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

	Membership Units		Common Stock		Additional	Accumulated	Total Stockholders /
	Units	Amount	Shares	Amount	Paid in Capital	Deficit	Members Equity
Balance at December 31, 2014	7,905,325	$ 77,156		$	$	$ (54,219)	$ 22,937
Net loss						(12,908)	(12,908)
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
Stock-based compensation					444		444
Balance at March 31, 2015		$	12,905,392	$ 129	$ 129,387	$ (67,127)	$ 62,389

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

Table of Contents

BELLEROPHON THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)

(Amounts in thousands)

	Three months ended March 31, 2015	2014
Cash flows from operating activities:		
Net loss	$ (12,908)	$ (14,510)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	92	102
Stock based compensation	444	271
Changes in operating assets and liabilities:		
Increase in due from Ikaria	(167)	
(Increase) decrease in prepaid expenses and other current assets	(372)	48
Decrease (increase) in restricted cash held for Ikaria, Inc.	2,315	(17,756)
Increase in accounts payable, accrued research and development, and accrued expenses	1,397	12
Increase in amounts due to Ikaria, Inc.	408	1,245
Net cash used in operating activities	(8,791)	(30,588)
Cash flows from investing activities:		
Net cash used in investing activities		
Cash flows from financing activities:		
Contribution from Ikaria, Inc. in connection with Spin-Out		80,000
Cash contributions from Ikaria, Inc., net		9,252
Proceeds from sale of membership units	1	
Cash proceeds from issuance of common stock from initial public offering, net of issuance costs	54,910	
Net cash provided by financing activities	54,911	89,252
Net change in cash and cash equivalents	46,120	58,664
Cash and cash equivalents at beginning of period	16,815	
Cash and cash equivalents at end of period	$ 62,935	$ 58,664
Supplemental disclosure of cash flow information:		
Non-cash financing activities:		
Investment by Ikaria, Inc., net	$	$ 7,491
Unpaid IPO transaction costs	$ 1,083	$

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

Table of Contents

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 Company has two programs in advanced clinical development. The first program, INOpulse, is based on the Company s proprietary pulsatile nitric oxide delivery device. The Company is currently developing two product candidates under its INOpulse program: one for the treatment of pulmonary arterial hypertension, or PAH, for which the Company intends to commence Phase 3 clinical trials in the second half of 2015, and the other for the treatment of pulmonary hypertension associated with chronic obstructive pulmonary disease, or PH-COPD, which is in Phase 2 development. The Company s second program is bioabsorbable cardiac matrix, or BCM, which is currently in a placebo-controlled clinical trial designed to support CE mark registration in the European Union. The Company completed enrollment of this trial in December 2014, with 303 patients having completed the treatment procedure, and the Company expects to report top line results in mid-2015. Assuming positive results from this trial, the Company intends to conduct a pivotal pre-market approval trial of BCM beginning in the first half of 2016, which will be designed to support registration in the United States. The Company is developing BCM for the prevention of cardiac remodeling, which often leads to congestive heart failure following an ST-segment elevated myocardial infarction, or STEMI.

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., 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 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.

Table of Contents

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 March 31, 2015, the escrowed cash balance was approximately $8.5 million and is classified as restricted cash, all of which is reflected as current, on the condensed consolidated balance sheet at March 31, 2015. See Note 7 *Related-Party Transactions*.

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 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 at March 31, 2015 and its results of operations and its cash flows for three months ended March 31, 2015 and 2014. 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. The results of operations for the three months ended March 31, 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 corporation 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 statement of operations for the three months ended March 31, 2014 (which includes a period of forty-two days prior to the Spin-Out) includes a reasonable allocation 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 three months ended March 31, 2014 may not necessarily reflect the results of

Table of Contents

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) Restricted Cash

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

(c) Stock-Based Compensation

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

(d) Deferred Transaction Costs

Deferred transaction costs are 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 are deferred and charged against the gross proceeds of the offering when the public offering of equity securities is complete as a reduction of additional paid-in capital. As of March 31, 2015 the Company charged all deferred transaction costs against the gross proceeds of the offering.

(e) 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 Accounting Standard Codification (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 partnership 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 $8.0 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 does not recognize a deferred tax asset for such costs.

Table of Contents

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 March 31, 2015 is approximately $21.6 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 incentive stock option 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 does not have material uncertain tax positions as of March 31, 2015.

(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 s ultimate success depends on the outcome of its research and development activities. Management expects to incur additional losses in the future to conduct product research and development and recognizes the need to raise additional capital through the potential issuance of additional equity or borrowings or entering into strategic alliances with partner companies. 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 has cash and cash equivalents of $62.9 million and restricted cash of $8.5 million at March 31, 2015. The Company received net proceeds of $51.9 million in February 2015 as a result of the IPO, after deducting underwriting discounts and commissions of $4.2 million and offering costs of $3.9 million. As a result, the Company s cash on hand is expected to be sufficient to satisfy the Company s operating cash needs at least into mid-2016. 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 additional capital is not available at adequate levels or such strategic alliances do not occur, the Company will need to evaluate 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 March 31, 2015 and December 31, 2014 consist of the following (in thousands):

Table of Contents

	March 31, 2015	December 31, 2014
Machinery, equipment and furniture	$ 2,943	$ 2,943
Less accumulated depreciation	$ (1,339)	$ (1,247)
	$ 1,604	$ 1,696

(5) Income Taxes

The effective tax rate for each of the three months ended March 31, 2015 and 2014 was 0.0%. For the three months ended March 31, 2015, the effective rate is lower than the federal statutory rates primarily as a result of the full valuation allowance on deferred tax assets. For the three months ended March 31, 2014, the effective rate is lower than the federal statutory rates because the Company was a limited liability company and a pass through entity for tax purposes.

As of March 31, 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 twelve months.

(6) Stock-Based Compensation

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

Bellerophon 2015 and 2014 Equity Incentive Plans

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

During the three months ended March 31, 2015, the Company awarded two separate grants of options awards to its executives and employees to purchase the equivalent number of shares: 87,424 options at exercise price of $10.22 per share (the closing stock price on the grant date) with a vesting period of three years, of which 25% of the awards immediately vest and 25% vest on each anniversary of the grant date; and 152,582 options at exercise price of $12.00 per share (the IPO price), of which 25% vest on each anniversary of the grant date.

Table of Contents

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 initial public offering, 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 following are the weighted average assumptions used in estimating the fair value of options issued during the three months ended March 31, 2015.

	Three Months Ended March 31, 2015
Valuation assumptions:	
Risk-free rate	1.71%
Expected volatility	80.81%
Expected term	6.1
Dividend yield	0.00%

A summary of option activity under the 2015 and 2014 Plans for the three months ended March 31, 2015 is presented below:

	Bellerophon 2015 and 2014 Equity Incentive Plans			
	Shares	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	240,006	10.22 - 12.00	$ 10.91	9.9
Exercised				
Forfeited				
Options outstanding as of March 31, 2015	748,286	10.22 - 13.28	12.52	9.4
Options vested and exercisable as of March 31, 2015	111,938	$ 10.22 - 13.28	$ 12.68	$ 9.4

As of March 31, 2015, there was approximately $ 4.9 million of total unrecognized compensation expense related to non-vested stock options. This expense is expected to be recognized over a weighted-average period of 3.4 years.

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

Ikaria Equity Incentive Plans prior to February 12, 2014

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

Table of Contents

options. The vesting of each Adjusted Ikaria Option and Bellerophon Option was fully accelerated on the date of the Spin-Out and all related compensation expense was recognized as an expense by Ikaria.

Prior to and in connection with the Spin-Out, the exercise price of each Adjusted Ikaria Option and Bellerophon Option was adjusted by allocating the relative post Spin-Out estimated fair values of Ikaria and the Company in a ratio of 85% and 15%, respectively, to the original Ikaria option exercise price. The expiration date of the options was not modified. The Company s allocable portion of Ikaria s stock-based compensation expense related to options for the period from January 1, 2014 through February 11, 2014 was approximately $0.1 million.

There were 577,975 Bellerophon options outstanding as of March 31, 2015 at exercise prices ranging from $0.26 to $17.92 per share. All options outstanding were fully vested at the time of the Spin-Out.

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

	Ikaria Equity Incentive Plans			
	Shares	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				
Forfeited				
Options outstanding, vested and exercisable as of March 31, 2015	577,975	$ 0.26 - 17.92	$ 7.11	4.2

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 condensed consolidated statement of operations and comprehensive loss line item for the three months ended March 31, 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.

Table of Contents

(in thousands)	Three Months Ended March 31, 2015	2014
Research and development	$ 165	$ 271
General and administrative	279	
Total expense	444	271
Tax benefit		
Expense, net of tax benefit	$ 444	$ 271

(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 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.

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, or, collectively, the agreements not to compete. Pursuant to the agreements not to compete, 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 or the date on which Ikaria and all of its subsidiaries are no longer engaged in such business, in:

Table of Contents

(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) pulmonary edema from high altitude sickness, (viii) the management of pulmonary hypertension episodes and right heart failure in pulmonary or cardiac surgery, (ix) the management of pulmonary hypertension episodes and right heart failure in organ transplant, (x) sickle cell vaso-occlusive crisis, (xi) hypoxia associated with pneumonia, or (xii) ischemia-reperfusion injury, or (b) the use of nitric oxide to treat or prevent conditions that are primarily managed in the hospital; or

(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.

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 for a twenty-four month term, 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 exchange for the services, beginning in February 2014, the Company is obligated to pay Ikaria monthly services fees in the amount of $772,000 plus out of pocket expenses and certain other expenses. 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 March 31, 2015. The Company recorded expenses of $2.3 million and $1.2 million for the three months periods ended March 31, 2015 and 2014, respectively, in connection with the TSA. At March 31, 2015, the Company had accrued expenses due to Ikaria of $0.5 million in connection with the TSA.

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 has 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 for 13 months, subject to performance of the services. During the three months ended March 31, 2015, the Company recorded $1.2 million of service fees related to the 2015 Services Agreement reflected in Other operating income on the accompanying statement of operations and comprehensive loss. In addition, pursuant to the 2015 Services Agreement, Ikaria has 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 will pay approximately $215,000, subject to termination of the 2015 Services Agreement. During the three months ended March 31, 2015, the Company recorded $0.1 million of operating expenses related to the 2015 Services Agreement reflected in General and administrative expenses on the accompanying condensed consolidated statement of operations and comprehensive loss. The Company has a $0.2 million receivable due from Ikaria in connection with this agreement. The 2015 Services Agreement will terminate in February 2016.

16

Table of Contents

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 March 31, 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 March 31, 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.

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 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 March 31, 2015.

As of this report, there is no 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 weighted average shares outstanding for basic and diluted net loss per share for the three months ended March 31, 2015 was 10,152,487. The weighted average units outstanding for basic and diluted net loss per unit for the three months ended March 31, 2014 was 7,899,251.

Table of Contents

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

As of March 31, 2015, the Company had 1,326,261 options to purchase 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.

Table of Contents

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 Item1A 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. We have two programs in advanced clinical development.

The first program, INOpulse, 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 pulmonary arterial hypertension, or 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. The goal of the trial is to determine the safety, tolerability and efficacy of two different doses of INOpulse for PAH. We believe the results of this trial provide sufficient indication of clinical benefit and safety to continue development of INOpulse for PAH in pivotal Phase 3 clinical trials. We had an End of Phase 2 meeting with the U.S. Food and Drug Administration, or FDA, on January 8, 2015. Based on feedback from the FDA at this meeting, we are moving forward with Phase 3 development and plan to conduct two adequate and well-controlled confirmatory Phase 3 clinical trials, either sequentially or in parallel. In March 2015, we requested feedback on the proposed trial design from the Scientific Advice Working Party, or SAWP, of the European Medicines Agency, or EMA, and had a pre-submission meeting with the EMA representatives on April 4, 2015. We subsequently submitted the SAWP package and the EMA has accepted and confirmed completeness of the package which has been distributed to the SAWP members for review. We expect to have a meeting with the SAWP in early July to get their feedback on the proposed clinical plan. We have also submitted a request for a Special Protocol Assessment to the FDA on April 30, 2015 and anticipate receiving feedback in mid-June 2015, at the end of the 45-day review period. We intend to finalize the clinical trial design following additional discussions with the FDA as well as with other regulatory authorities, including with the EMA.

Our second program is bioabsorbable cardiac matrix, or BCM, which is currently in a placebo-controlled clinical trial designed to support CE mark registration in the European Union. We completed enrollment of this trial in December 2014, with 303 patients having completed the treatment procedure, and we expect to report top line results in mid-2015. Assuming positive results from this trial, we intend to conduct a pivotal pre-market approval trial of BCM beginning in the first half of 2016, which will be designed to support registration in the United States. We are developing BCM for the prevention of cardiac remodeling, which often leads to congestive heart failure following an ST-segment elevated myocardial infarction, or STEMI.

We have devoted substantially all of our resources to our drug 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, we have incurred significant costs to scale up manufacturing for BCM from pre-clinical studies to 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.

Table of Contents

Separation and Spin-Out from Ikaria

Prior to February 2014, we were a wholly-owned subsidiary of Ikaria, Inc., 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 pulmonary hypertension associated with idiopathic pulmonary fibrosis, or 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, we entered into a transition services agreement with Ikaria, which we refer to as the TSA. Pursuant to the terms and conditions of the TSA, Ikaria has agreed to use commercially reasonable efforts to provide certain services to us until February 2016, subject to the terms of the TSA. In exchange for the services provided by Ikaria pursuant to the TSA, we pay to Ikaria a service fee in the amount of $772,000 per month and reimburse 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 and expires in February 2016, Ikaria provides to us certain information technology and device servicing services. In exchange for the services provided by Ikaria pursuant to the 2015 Services Agreement, we will pay to Ikaria fees that total, in the aggregate, approximately $215,000, subject to the termination of the 2015 Services Agreement.

On April 16, 2015, Mallinckrodt plc completed its previously announced acquisition of Ikaria, and as a result Ikaria became a subsidiary of Mallinckrodt plc.

We are in the process of developing and implementing plans to replace services currently 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 currently provided by Ikaria under the TSA will be approximately the same as the $772,000 per month that we are currently paying under the TSA, and we expect the costs related to replacing the services currently provided by Ikaria under the 2015 Services Agreement will be approximately the same as the amounts we are paying under the 2015 Services Agreement. However, although we believe our estimates are reasonable based on the information we have to date, certain significant components of our 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 statement of operations and comprehensive loss for the period of time prior to the Spin-Out includes a reasonable allocation of costs and expenses

Table of Contents

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.

Due to this presentation, the financial information for the three months ended March 31, 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 $12.9 million and $14.5 million for the three months periods ended March 31, 2015 and 2014, respectively. As of March 31, 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 INOpulse and/or BCM product candidates, each of which is currently in clinical development, 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 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.

Table of Contents

Research and Development Expenses

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

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

Research and development expenses primarily consist of:

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

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

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

We expense research and development costs as incurred.

Conducting a significant amount of research and development is central to our business model. Product candidates in late stages of clinical development generally have higher development costs than those in earlier stages of clinical development primarily due to the increased size and duration of late-stage clinical trials. We plan to increase our research and development expenses for the foreseeable future as we seek to continue multiple clinical trials for our INOpulse and BCM programs, 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 affairs, quality, biometrics support and program management, across our two 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.

Table of Contents

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 is to determine the safety, tolerability and efficacy of two different doses of INOpulse for PAH. We believe the results of this trial provide sufficient indication of clinical benefit and safety to continue development of INOpulse for PAH in pivotal Phase 3 clinical trials. We had an End of Phase 2 meeting with the FDA on January 8, 2015. Based on feedback from the FDA at this meeting, we are moving forward with Phase 3 development and plan to conduct two adequate and well-controlled confirmatory Phase 3 clinical trials, either sequentially or in parallel. In March 2015, we requested feedback on the proposed trial design from the Scientific Advice Working Party, or SAWP, of the EMA and had a pre-submission meeting with the EMA representatives on April 4, 2015. We subsequently submitted the SAWP package and the EMA has accepted and confirmed completeness of the package which has been distributed to the SAWP members for review. We expect to have a meeting with the SAWP in July 2015 to receive their feedback on the proposed clinical plan. We have also submitted a request for a Special Protocol Assessment to the FDA on April 30, 2015 and we expect to receive feedback at the end of the 45 day review period in June 2015. We intend to finalize the clinical trial design following additional discussions with the FDA as well as with other regulatory authorities, including with the EMA.

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 currently evaluating our trial design for a Phase 2b clinical trial and plan to finalize our protocol following discussions with regulatory authorities in the United States and the European Union.

BCM

We initiated a clinical trial of BCM, which we refer to as our PRESERVATION I trial, in December 2011 and enrolled the first patient in April 2012. This trial is a CE mark registration trial in the European Union and, if the results are positive, we intend to conduct a pivotal trial designed to support registration in the United States. We completed enrollment of this trial in December 2014, with 303 patients having completed the treatment procedure at almost 90 clinical sites in Europe, Australia, North America and Israel. We expect to report top line results in mid-2015.

Research and Development Infrastructure

We invest in regulatory, quality, pharmacovigilance and program management activities, which are expensed as incurred. These activities primarily support our INOpulse and BCM clinical development programs.

INOpulse Engineering

We have invested a significant amount of funds in INOpulse, which is configured to be highly portable and compatible with available modes of long-term oxygen therapy via nasal cannula delivery. Our Phase 2 clinical trials of INOpulse for PAH and INOpulse for PH-COPD utilized the first generation INOpulse DS device. We 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 prototype manufacturing and bench top testing, as well as verification and validation. We have also invested in design and engineering technology, through Ikaria, for the manufacture of our drug cartridges. We currently rely on Ikaria for manufacturing of our INOpulse drug cartridges. In addition, Ikaria is conducting substantial engineering and stability testing work with respect to the INOpulse devices on our behalf pursuant to the TSA. 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 for our INOpulse and BCM programs and any future

Table of Contents

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 additional general and administrative expenses to support ourselves as a stand-alone company, such as investing in new telecommunications services;

- we expect to incur, prior to the termination of the TSA and the 2015 Services Agreement, expenses in preparation for replacing services that are currently provided by Ikaria pursuant to the TSA and the 2015 Services Agreement, which will likely include dedicated accounting and human resources functions and certain information technology services;

- we expect to incur reduced general and administrative expenses payable to Ikaria upon the expiration of the TSA and the 2015 Services Agreement, in each case in February 2016;

- we expect to incur increased general and administrative expenses to support our research and development activities, which we expect will expand as we continue to pursue the development of our product candidates;

- we expect our general and administrative expenses will increase as a result of increased payroll, expanded infrastructure, higher consulting, legal, accounting and investor relations costs, director compensation and director and officer insurance premiums associated with being a public company; and

- we may begin to incur expenses related to sales and marketing of our product candidates in anticipation of commercial launch before we receive regulatory approval of a product candidate.

Table of Contents

Results of Operations

Comparison of Three Months Ended March 31, 2015 and 2014

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

(Dollar amounts in thousands)	Three Months Ended March 31, 2015	2014
Research and development expenses:		
BCM	$ 2,834	$ 2,637
PAH	2,930	2,266
PH-COPD	30	2,105
Clinical programs	5,794	7,008
Research and development infrastructure	2,507	3,921
INOpulse engineering	1,219	1,111
Total research and development expenses	9,520	12,040
General and administrative expenses	4,573	2,470
Total operating expenses	14,093	14,510
Other operating income	(1,166)	
Loss from operations	(12,927)	
Interest income	(19)	
Net loss and comprehensive loss	$ (12,908)	$ (14,510)

Table of Contents

Total Operating Expenses. Total operating expenses for the three months ended March 31, 2015 were $14.1 million compared to $14.5 million for the period ended March 31, 2014, a decrease of $0.4 million, or 3%. This decrease was primarily due to reductions in research and development expenses pertaining to our development of INOpulse for PH-COPD and to research and development infrastructure expenses, partially offset by increases in general and administrative expenses, research and development expenses pertaining to development activities related to INOpulse engineering, BCM, and INOpulse for PAH.

Research and Development Expenses. Total research and development expenses for the three months period ended March 31, 2015 were $9.5 million compared to $12.0 million for the three months ended March 31, 2014, a decrease of $2.5 million, or 21%. Total research and development expenses consisted of the following:

- BCM research and development expenses for the three months ended March 31, 2015 were $2.8 million compared to $2.6 million for the three months ended March 31, 2014, an increase of $0.2 million, or 7%. This increase was primarily related to continued evaluation of patients enrolled in the placebo-controlled clinical trial.

- PAH research and development expenses for the three months ended March 31, 2015 were $2.9 million compared to $2.3 million for the three months ended March 31, 2014, an increase of $0.7 million, or 29%. The increase was primarily due to increased costs in anticipation of the start of the Phase 3 clinical trials, which we expect to commence in the second half of 2015.

- PH-COPD research and development expenses for the three months ended March 31, 2015 were $30,000 compared to $2.1 million for the three months ended March 31, 2014, a decrease of $2.1 million, or 99%. The decrease primarily resulted from the completion of the Phase 2 clinical trial in mid-2014.

- Research and development infrastructure expenses for the three months ended March 31, 2015 were $2.5 million compared to $3.9 million for the three months ended March 31, 2014, a decrease of $1.4 million, or 36%. The decrease was primarily the result of reductions in infrastructure spending such as medical writing and regulatory affairs to support our INOpulse and BCM clinical programs.

- INOpulse engineering expenses for the three months ended March 31, 2015 were $1.2 million compared to $1.1 million for the three months ended March 31, 2014, an increase of $0.1 million, or 10%. The increase was primarily the result of continued investments in development of the Mark2 in anticipation of the Phase 3 clinical trial of INOpulse for PAH in the second half of 2015.

General and Administrative Expenses. General and administrative expenses for the three months ended March 31, 2015 were $4.6 million compared to $2.5 million for the three months ended March 31, 2014, an increase of $2.1 million, or 85%. The increase was primarily due to additional costs of operating as a standalone public company, including expenses related to transition services from Ikaria, and from certain one time items, including costs associated with the resolution of a dispute with BioLineRx Ltd. related to the company s license to BCM.

Other Operating Income. Other operating income for the three months ended March 31, 2015 was $1.2 million compared to zero for the three months ended March 31, 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 $12.9 million and $14.5 million for the three months ended March 31, 2015 and 2014, respectively. Our operating activities used $8.8 million and $30.6 million of cash during the three months ended March 31, 2015 and 2014, respectively. In addition, we had $60.8 million of working capital and $71.4 million of cash and cash equivalents and restricted cash as of March 31, 2015.

Table of Contents

Cash Flows

The following table summarizes our cash flows for the three months ended March 31, 2015 and 2014:

(Dollar amounts in thousands)	Three Months Ended March 31, 2015	2014	% Change
Operating activities	$ (8,791)	$ (30,588)	(71)%
Investing activities			
Financing activities	54,911	89,252	(38)%
Increase in cash and cash equivalents	$ 46,120	$ 58,664	

Net Cash Used in Operating Activities

Cash used in operating activities for the three months ended March 31, 2015 was $8.8 million compared to $30.6 million for the three months ended March 31, 2014, a decrease of $21.8 million, or 71%. The decrease in cash used in operating activities was primarily due to reduced research and development expenses, change in restricted cash due Ikaria and a change in timing of vendor payments.

Net Cash Used in Investing Activities

There were no cash flows from investing activities for the three months ended March 31, 2015 and 2014.

Net Cash Provided by Financing Activities

Cash provided by financing activities for the three months ended March 31, 2015 was $54.9 million compared to $89.3 million for the three months ended March 31, 2014, a decrease of $34.3 million, or 38%. The decrease resulted from the difference between the $54.9 million net proceeds from the initial public offering in the three months ended March 31, 2015, after deducting underwriting discounts and commissions of $4.2 million and offering costs of $0.9 million paid in the three months ended March 31 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 three months ended March 31, 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.

We believe our existing cash and cash equivalents and restricted cash as of March 31, 2015, which includes the proceeds of our initial public offering completed in February 2015, will be sufficient to enable us to fund our operating expenses and capital expenditure requirements at least into mid-2016. 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, INOpulse for PH-COPD and BCM;

Table of Contents

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

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

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

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

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

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

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

- our expenses as a stand-alone company; and

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

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity and debt offerings, existing working capital and funding from potential future collaboration arrangements. To the extent that we raise additional capital through the future sale of equity or debt, the ownership interest of our existing stockholders will be diluted, and the terms of such securities may include liquidation or other preferences 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 March 31, 2015 (in thousands), including the addition of the Flextronics agreement, which is the only material change, 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:

	Total	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years
Operating lease obligations	$ 115	$ 115	$	$	$
Transition Service Agreement (1)	8,497	8,497			
2015 Services Agreement (2)	126	126			
Flextonics Agreement (3)	1,695	1,695			
Total	$ 10,433	$ 10,433	$	$	$

(1) Under the TSA, Ikaria provides certain administrative and other services to us for a period of 24 months following February 9, 2014, unless terminated earlier. Ikaria also provides us with the use of office space and research laboratory facilities at Ikaria s headquarters located in Hampton, New Jersey. In exchange for the services provided by Ikaria pursuant to the TSA, we pay to Ikaria a service fee in the amount of $772,000 per month and reimburse 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. The monthly service fee is payable by us regardless of the frequency or quantity of services actually utilized by us, and our obligation to pay such

Table of Contents

monthly service fee for 24 months will survive any early termination of the TSA. At the time of the Spin Out, we deposited the sum of $18.5 million, representing the aggregate of the $772,000 monthly service fees payable by us under the TSA, in escrow to guarantee payment of the monthly service fees.

(2) Under the 2015 Services Agreement, which became effective on January 1, 2015 and expires in February 2016, Ikaria provides to us certain information technology and device servicing services. In exchange for the services provided by Ikaria pursuant to the 2015 Services Agreement, we will pay to Ikaria fees that total, in the aggregate, approximately $215,000, subject to the termination of the 2015 Services Agreement.

(3) 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 next 12 months.

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. Under the terms of the license agreement, if we achieve certain clinical and regulatory events specified in the license agreement, we will be obligated to pay milestone payments to BioLine, which could total, in the aggregate, up to $115.5 million, and if we achieve certain commercialization targets specified in the license agreement, we will be obligated to pay additional milestone payments to BioLine, which could total, in the aggregate, up to $150.0 million. In addition, we will be obligated to pay BioLine a specified percentage of any upfront consideration we receive for sublicensing BCM, as well as royalties on net sales, if any, at a percentage ranging from 11% to 15%, depending on net sales level, of any approved product containing BCM, subject to offsets for specified payments to third parties made in connection with BCM. Further, we have agreed to reimburse BioLine for certain legal fees in the amount of $250,000 following completion of our initial public offering, which was accrued as of March 31, 2015.

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

Off-Balance Sheet Arrangements

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

Critical Accounting Policies and Significant Judgments and Estimates

Our management s discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with 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 three months ended March 31, 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 Securities and Exchange Commission on March 31, 2015.

Table of Contents

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 (ASC) 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 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 March 31, 2015, we had cash and cash equivalents and restricted cash of approximately $71.4 million, consisting primarily of demand deposits with U.S. banking institutions (other than restricted cash, which is held in escrow). 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. Due to the short-term duration 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 March 31, 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 Securities and Exchange Commission s, or the SEC, 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

Table of Contents

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 March 31, 2015, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

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 March 31, 2015 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

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.

We may be unable to make, on a timely or cost-effective basis, the changes necessary to operate as a stand-alone company, and we may experience increased or unexpected costs after the Spin-Out or as a result of the Spin-Out.

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 is 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 and the 2015 Services Agreement provide for certain services to be provided until February 2016. 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 or other agreements, such services will be provided internally or by unaffiliated third parties, and we expect that in some instances, we will 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 the services specified in such agreements. In addition, during the transitional services period, we will rely, in part, on the same executive team at Ikaria that also will continue to manage the business of Ikaria during such time, and there may be conflicting demands on their time, which could result in an inadequate level of attention to the demands of our business. If Ikaria and its employees do not continue to perform effectively the transition services and the other services that are called for under the TSA, the 2015 Services Agreement and other agreements, we may not be able to operate our business effectively and our business and financial condition could be adversely affected.

On April 16, 2015, Mallinckrodt announced that it had completed its acquisition of Ikaria. While the TSA imposes binding obligations on Ikaria to perform in accordance with the TSA 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 TSA as Ikaria has provided to date. Moreover, to the extent that we desire to extend, renew or expand the scope of the TSA, 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.

Prior to the Spin-Out, we utilized the executive management team and administrative resources of Ikaria. Many daily functions were performed by Ikaria, including those related to the preparation of our financial statements and the engagement of auditors to audit our financial statements, which have become our responsibility following the Spin-Out. We may need to acquire assets and resources in addition to those provided to us by Ikaria, and we may face difficulty in integrating newly acquired assets into our business. Additionally, as a stand-alone company, we no longer have access to Ikaria s financial resources. Instead, our ability to fund our capital needs will depend on our ongoing ability to generate cash from operations, enter into partnering arrangements, obtain debt financing and access capital markets, which are subject to general economic, financial, competitive, regulatory and other factors that are beyond our control. Our business, financial condition and results of operations could be harmed, possibly materially, if we have difficulty operating as a stand-alone company, fail to acquire necessary capital or

assets that

Table of Contents

prove to be important to our operations, or are unable to enter into partnering or other business development arrangements.

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. Despite our best efforts, Ikaria may conclude that we have breached a material term of the license agreement and, as a result, seek to terminate the agreement. In the event the license agreement is terminated, we will lose our ability to market INOpulse, and, upon Ikaria s written request, we will be required to transfer any regulatory approvals that we have obtained for INOpulse to 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 and PH-IPF and to enter into written agreements with any customers that contain restrictions on the use of our products and termination rights in the event such restrictions are violated.

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

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

On April 16, 2015, Mallinckrodt 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

33

Table of Contents

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 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.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

Recent Sales of Unregistered Securities

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

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

Each of the foregoing issuances was made by us in a transaction not involving a public offering pursuant to an exemption from the registration requirements of the Securities Act of 1933, as amended, or the Securities Act in reliance upon Section 4(a)(2) of the Securities Act or Rule 701 promulgated under Section 3(b) of the Securities Act.

Table of Contents

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

Use of Proceeds

We effected the 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 March 31, 2015, we have not used any of the net proceeds from our initial public offering. As of March 31, 2015, we have invested the balance of the net proceeds from the offering in a variety of capital preservation investments, including demand deposits with U.S. banking institutions. 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.

Item 6. Exhibits.

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

Table of Contents

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: May 15, 2015	By:	/s/ Jonathan M. Peacock Jonathan M. Peacock Chairman, President and Chief Executive Officer (Principal Executive Officer)
Date: May 15, 2015	By:	/s/ David Abrams David Abrams Treasurer (Principal Financial and Accounting Officer)

Table of Contents

Exhibit Index

Exhibit Number	Description
2.1*	Plan of Conversion (incorporated by reference to Exhibit 2.1 to the Registrant s Annual Report on Form 10-K (File No. 001-36845) filed with the SEC on March 31, 2015)
2.2*	Agreement and Plan of Merger (incorporated by reference to Exhibit 2.2 to the Registrant s Annual Report on Form 10-K (File No. 001-36845) filed with the SEC on March 31, 2015)
3.1	Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant s Current Report on Form 8-K (File No. 001-36845) filed with the SEC on February 25, 2015)
3.2	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant s Current Report on Form 8-K (File No. 001-36845) filed with the SEC on February 25, 2015)
4.1	Specimen Stock Certificate evidencing the shares of common stock (incorporated by reference to Exhibit 4.1 to the Registrant s Registration Statement on Form S-1/A (File No. 333-201474) filed with the SEC on February 3, 2015)
4.2	Stockholders Agreement, dated February 12, 2015, between the Registrant and Linde North America, Inc. (incorporated by reference to Exhibit 4.2 to the Registrant s Annual Report on Form 10-K (File No. 001-36845) filed with the SEC on March 31, 2015)
4.3	Stockholders Agreement, dated February 12, 2015, among the Registrant and New Mountain Partners II (AIV-A), L.P., New Mountain Partners II (AIV-B), L.P., New Mountain Affiliated Investors II, L.P. and Allegheny New Mountain Partners, L.P. (incorporated by reference to Exhibit 4.3 to the Registrant s Annual Report on Form 10-K (File No. 001-36845) filed with the SEC on March 31, 2015)
10.1	2015 Equity Incentive Plan (incorporated by reference to Exhibit 10.5 to the Registrant s Registration Statement on Form S-1 (File No. 333-201474) filed with the SEC on February 3, 2015)
10.2	Form of Incentive Stock Option Agreement under 2015 Equity Incentive Plan (incorporated by reference to Exhibit 10.6 to the Registrant s Registration Statement on Form S-1 (File No. 333-201474) filed with the SEC on February 3, 2015)
10.3	Form of Nonstatutory Stock Option Agreement under 2015 Equity Incentive Plan (incorporated by reference to Exhibit 10.7 to the Registrant s Registration Statement on Form S-1 (File No. 333-201474) filed with the SEC on February 3, 2015)
10.4	Amended and Restated License and Commercialization Agreement, dated as of August 26, 2009, among Ikaria Development Subsidiary One LLC, BioLineRx Ltd. and BioLine Innovations Jerusalem L.P., as amended (incorporated by reference to Exhibit 10.8 to the Registrant s Annual Report on Form 10-K (File No. 001-36845) filed with the SEC on March 31, 2015)
10.5	Services Agreement, effective as of January 1, 2015, between the Registrant and Ikaria, Inc. (incorporated by reference to Exhibit 10.11 to the Registrant s Registration Statement on Form S-1 (File No. 333-201474) filed with the SEC on February 3, 2015)
10.6	Registration Rights Agreement, dated February 12, 2015, among the Registrant, New Mountain Partners II (AIV-A), L.P., New Mountain Partners II (AIV-B), L.P., Allegheny New Mountain Partners, L.P., New Mountain Affiliated Investors II, L.P., ARCH Venture Fund VI, L.P., Venrock Partners, L.P., Venrock Associates IV, L.P., Venrock Entrepreneurs Fund IV, L.P., Linde North America, Inc., 5AM Ventures LLC and Aravis Venture I L.P. (incorporated by reference to Exhibit 10.16 to the Registrant s Annual Report on Form 10-K (File No. 001-36845) filed with the SEC on March 31, 2015)
10.7	Form of Indemnification Agreement between the Registrant and each of its executive officers and directors (incorporated by reference to Exhibit 10.17 to the Registrant s Registration Statement on Form S-1 (File No. 333-201474) filed with the SEC on January 13, 2015)
10.8	Form of Management Rights Letter between the Registrant and certain of its stockholders (incorporated by reference to Exhibit 10.23 to the Registrant s Registration Statement on Form S-1 (File No. 333-201474) filed with the SEC on January 13, 2015)
10.9	Amendment to Assumed Employment Agreement, dated as March 13, 2015, between Jonathan M. Peacock and the Registrant

Table of Contents

Exhibit Number	Description
10.10	Amendment to Assumed Employment Agreement, dated as March 13, 2015, between Manesh Naidu and the Registrant
10.11	Amendment to Assumed Employment Agreement, dated as March 13, 2015, between Martin Meglasson and the Registrant
10.12	Amendment to Assumed Employment Agreement, dated as March 13, 2015, between Reinilde Heyrman and the Registrant
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

* Schedules and exhibits have been omitted pursuant to Item 601(b)(2) of Regulation S-K. The Registrant hereby undertakes to furnish copies of any of the omitted schedules and exhibits upon request by the Securities and Exchange Commission.

Confidential treatment has been granted as to certain portions, which portions have been omitted and separately filed with the Securities and Exchange Commission.