

Edgar Filing: Bellerophon Therapeutics, Inc. - Form 10-Q

Bellerophon Therapeutics, Inc.  
Form 10-Q  
August 07, 2017

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

(Mark One)

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

For the quarterly period ended June 30, 2017

or

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_  
Commission File Number 001-36845  
Bellerophon Therapeutics, Inc.  
(Exact name of registrant as specified in its charter)  
Delaware 47-3116175  
(State or other jurisdiction of (I.R.S. Employer  
incorporation or organization) Identification No.)  
184 Liberty Corner Road, Suite 302 07059  
Warren, New Jersey (Zip Code)  
(Address of principal executive offices)  
(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  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

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

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

If an emerging growth company, indicate by a check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section

13(a) of the Exchange Act.

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

The number of shares outstanding of the registrant's common stock as of August 3, 2017: 35,510,234

1

---

TABLE OF CONTENTS

	Page No.
PART I. FINANCIAL INFORMATION	<u>5</u>
Item 1. Financial Statements	<u>5</u>
Condensed Consolidated Balance Sheets as of June 30, 2017 and December 31, 2016 (Unaudited)	<u>5</u>
Condensed Consolidated Statements of Operations for the three and six months ended June 30, 2017 and 2016 (Unaudited)	<u>6</u>
Condensed Consolidated Statements of Comprehensive Loss for the three and six months ended June 30, 2017 and 2016 (Unaudited)	<u>7</u>
Condensed Consolidated Statement of Changes in Stockholders' Equity for the six months ended June 30, 2017 (Unaudited)	<u>8</u>
Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2017 and 2016 (Unaudited)	<u>9</u>
Notes to Condensed Consolidated Financial Statements (Unaudited)	<u>10</u>
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	<u>21</u>
Item 3. Quantitative and Qualitative Disclosures About Market Risk	<u>29</u>
Item 4. Controls and Procedures	<u>29</u>
PART II. OTHER INFORMATION	<u>30</u>
Item 1. Legal Proceedings	<u>30</u>
Item 1A. Risk Factors	<u>30</u>
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	<u>30</u>
Item 3. Defaults Upon Senior Securities	<u>30</u>
Item 4. Mine Safety Disclosures	<u>30</u>
Item 5. Other Information	<u>30</u>
Item 6. Exhibits	<u>30</u>
Signatures	<u>31</u>



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

## FORWARD-LOOKING STATEMENTS

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

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

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

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

our ability to continue as a going concern within one year beyond the filing of this Quarterly Report on Form 10-Q.

the timing of and our ability to obtain marketing approval of our product candidates, and the ability of our product candidates to meet existing or future regulatory standards;

our ability to comply with government laws and regulations;

our commercialization, marketing and manufacturing capabilities and strategy;

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

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

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

our intellectual property position;

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

the success of competing treatments;

our competitive position; and

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

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K for the year ended December 31, 2016, particularly in the “Risk Factors” section, that could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

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

This Quarterly Report on Form 10-Q includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information.



## PART I. FINANCIAL INFORMATION

## Item 1. Financial Statements.

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

	As of June 30, 2017	As of December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	\$ 10,968	\$ 14,453
Restricted cash	150	150
Marketable securities	3,901	5,571
Prepaid expenses and other current assets	5,362	6,331
Total current assets	20,381	26,505
Restricted cash, non-current	307	307
Other non-current assets	462	1,491
Property and equipment, net	1,207	1,399
Total assets	\$22,357	\$ 29,702
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$2,834	\$ 2,807
Accrued research and development	1,821	2,573
Accrued expenses	838	1,115
Total current liabilities	5,493	6,495
Common stock warrant liability	17,651	5,215
Total liabilities	23,144	11,710
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.01 par value per share; 125,000,000 shares authorized, 35,224,520 and 31,702,624 shares issued and outstanding at June 30, 2017 and December 31, 2016, respectively	352	317
Preferred stock, \$0.01 par value per share; 5,000,000 share authorized, zero shares issued and outstanding at June 30, 2017 and December 31, 2016	—	—
Additional paid-in capital	146,426	142,167
Accumulated other comprehensive income	—	—
Accumulated deficit	(147,565)	(124,492)
Total stockholders' equity	(787 )	17,992
Total liabilities and stockholders' equity	\$22,357	\$ 29,702

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



## BELLEROPHON THERAPEUTICS, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)

(in thousands except share and per share data)

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2017	2016	2017	2016
Operating expenses:				
Research and development	\$4,689	\$ 3,954	\$8,026	\$ 9,067
General and administrative	1,634	1,205	3,080	3,181
Total operating expenses	6,323	5,159	11,106	12,248
Loss from operations	(6,323 )	(5,159 )	(11,106 )	(12,248 )
Change in fair value of common stock warrant liability	2,367	—	(12,020 )	—
Interest and other income	26	22	53	52
Pre-tax loss	(3,930 )	(5,137 )	(23,073 )	(12,196 )
Income tax benefit (expense)	—	—	—	—
Net loss	\$(3,930)	\$(5,137 )	\$(23,073)	\$(12,196 )
Weighted average shares outstanding:				
Basic and diluted	33,558,669	33,093,176	32,750,949	33,073,202
Net loss per share:				
Basic and diluted	\$(0.12 )	\$(0.39 )	\$(0.70 )	\$(0.93 )

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

BELLEROPHON THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS (UNAUDITED)  
(in thousands)

	Three Months		Six Months Ended	
	Ended June 30,		June 30,	
	2017	2016	2017	2016
Net loss	\$(3,930)	\$(5,137)	\$(23,073)	\$(12,196)
Other comprehensive income				
Unrealized gains on available-for-sale marketable securities	—	—	—	21
Total other comprehensive income	—	—	—	21
Comprehensive loss	\$(3,930)	\$(5,137)	\$(23,073)	\$(12,175)

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

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

	Common Stock		Additional	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Paid in Capital	Income	Deficit	Equity
December 31, 2016	31,702,624	\$ 317	\$ 142,167	\$	—\$(124,492 )	\$ 17,992
Net loss	—	—	—	—	(23,073 )	(23,073 )
Other comprehensive income	—	—	—	—	—	—
Sale of common stock in Direct Offering, net of offering expenses of \$187	2,000,000	20	1,675	—	—	1,695
Warrant exercises	648,586	6	1,215	—	—	1,221
Stock-based compensation	873,310	9	1,369	—	—	1,378
June 30, 2017	35,224,520	\$ 352	\$ 146,426	\$	—\$(147,565 )	\$ (787 )

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

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

	Six Months Ended June 30,	
	2017	2016
Cash flows from operating activities:		
Net loss	\$(23,073)	\$(12,196)
Adjustments to reconcile net loss to net cash used in operating activities:		
Change in fair value of common stock warrant liability	12,020	—
Stock based compensation	1,378	1,369
Depreciation	192	202
Issuance costs attributable to common stock warrant liability	111	—
Accretion and amortization of discounts and premiums on marketable securities, net	—	23
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	969	(20 )
Other non-current assets	1,029	1,106
Accounts payable, accrued research and development, and accrued expenses	(796 )	(1,954 )
Net cash used in operating activities	(8,170 )	(11,470 )
Cash flows from investing activities:		
Capital expenditures	—	(22 )
Purchase of marketable securities	(1,980 )	—
Proceeds from sale of marketable securities	3,650	5,885
Net cash provided by investing activities	1,670	5,863
Cash flows from financing activities:		
Proceeds from sale of Units in Direct Offering, net of commissions and offering expenses	2,730	—
Proceeds received from exercise of warrants	520	—
Proceeds from sale of common stock in ATM Offering, net of commissions and offering expenses	—	651
Payment of offering expenses related to the secondary offering	(235 )	—
Net cash provided by financing activities	3,015	651
Net change in cash and cash equivalents	(3,485 )	(4,956 )
Cash and cash equivalents at beginning of period	14,453	6,260
Cash and cash equivalents at end of period	\$10,968	\$1,304
Non-cash financing activities:		
Conversion of warrant liability to common stock upon exercise of warrants	\$702	\$—
Unpaid expenses related to Direct Offering	\$28	\$—
Unpaid expenses related to ATM Offering	\$—	\$116
Non-cash investing activities:		
Change in unrealized holding gains on marketable securities, net	\$—	\$21

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

BELLEROPHON THERAPEUTICS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

(1) Organization and Nature of the Business

Bellerophon Therapeutics, Inc., or the Company, is a clinical-stage therapeutics company focused on developing innovative products at the intersection of drugs and devices that address significant unmet medical needs in the treatment of cardiopulmonary diseases. The focus of the Company's clinical program is the continued development of its nitric oxide therapy for patients with pulmonary hypertension, or PH, using its proprietary delivery system, INOpulse, with pulmonary arterial hypertension, or PAH, representing the lead indication. The Company has three wholly-owned subsidiaries: Bellerophon BCM LLC, a Delaware limited liability company; Bellerophon Pulse Technologies LLC, a Delaware limited liability company; and Bellerophon Services, Inc., a Delaware corporation.

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

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

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

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

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

• The risk that the Company will be unable to obtain additional funds on a timely basis and hence there will be substantial doubt about its ability to continue as a going concern.

• 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.

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

The Company is responsible for the unaudited condensed consolidated financial statements. The condensed consolidated financial statements include all normal and recurring adjustments that are considered necessary for the fair presentation of the Company's financial position, results of operations, comprehensive loss and its cash flows for the periods presented. These condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements for the year ended December 31, 2016, included in the Company's Annual Report on Form 10-K for the year ended December 31, 2016. The results of operations for the three and six months ended June 30, 2017 for the Company are not necessarily indicative of the results expected for

the full year.

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

(b) Cash and Cash Equivalents

10

---

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

(c) Stock-Based Compensation

The Company accounts for its stock-based compensation in accordance with Accounting Standards Codification, or ASC, 718 Compensation- Stock Compensation, which establishes accounting for share-based awards, including stock options and restricted stock, exchanged for services and requires companies to expense the estimated fair value of these awards over the requisite service period. The Company recognizes stock-based compensation expense in operations based on the fair value of the award on the date of the grant. The resulting compensation expense is recognized on a straight-line basis over the requisite service period or sooner if the awards immediately vest. The Company determines the fair value of stock options issued using a Black-Scholes-Merton option pricing model. Certain assumptions used in the model include expected volatility, dividend yield, risk-free interest rate, and expected term. For restricted stock, the fair value is the closing market price per share on the grant date. See Note 8 - Stock-Based Compensation for a description of these assumptions.

(d) Common Stock Warrant Liability

The Company accounts for common stock warrants issued as freestanding instruments in accordance with applicable accounting guidance provided in ASC Topic 480, Distinguishing Liabilities From Equity, as either liabilities or as equity instruments depending on the specific terms of the warrant agreement. The Company classifies warrant liabilities on the consolidated balance sheet as long-term liabilities, which are revalued at each balance sheet date subsequent to the initial issuance. Changes in the fair value of the warrants are reflected in the consolidated statement of operations as "Change in fair value of common stock warrant liability." The Company uses the Black-Scholes-Merton pricing model to value the related warrant liabilities. Certain assumptions used in the model include expected volatility, dividend yield, risk-free interest rate, and expected term. See Note 6 - Fair Value Measurements for a description of these assumptions.

(e) Income Taxes

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

The Company's estimated tax rate for 2017 excluding any benefits from any sales of net operating losses or research and development, or R&D, tax credits 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 June 30, 2017 was approximately \$56.5 million. The valuation allowance is required until the Company has sufficient positive evidence of taxable income necessary to support realization of its deferred tax assets. The Company did not have material uncertain tax positions as of June 30, 2017.

(f) Marketable Securities

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

(g) Research and Development Expense

11

---



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

(h) Reclassification

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

(i) Recently Issued Accounting Pronouncements

Adopted

In August 2014, the FASB issued ASU, 2014-15, "Presentation of Financial Statements - Going Concern: Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern." This guidance clarifies that an entity's management should evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued. The amendments in this update are effective for annual reporting periods ending after December 15, 2016, and annual and interim periods thereafter, and early application is permitted. The Company adopted ASU 2014-15 during the year ended December 31, 2016. Note 3 - Liquidity incorporates the disclosure requirements from the adoption of ASU 2014-15.

In March 2016, the FASB issued ASU 2016-09, "Compensation - Stock Compensation - Improvements to Employee Share-Based Payment Accounting" which provides for simplification of several aspects related to the accounting for share-based payment transactions. The provisions of ASU 2016-09 that are currently applicable to the Company are as follows: (a) forfeitures and (b) classification of employee taxes paid on the statement of cash flows when an employer withholds shares for tax-withholding purposes. This standard is effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. The Company adopted ASU 2016-09 during the quarter ended March 31, 2017. The adoption of this standard did not have a material impact on the Company's consolidated financial statements. The Company will continue to use its current method of estimated forfeitures each period rather than accounting for forfeitures as they occur. ASU 2016-09 requires the presentation of cash paid by an employer when directly withholding shares for tax-withholding purposes as a financing activity in the cash flow statement. The Company's historical accounting treatment is consistent with such guidance.

Not Yet Adopted

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

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

In February 2016, the FASB issued ASU 2016-02, "Leases," which is intended to improve financial reporting about leasing transactions. This standard requires a lessee to record on the balance sheet the assets and liabilities for the rights and obligations created by lease terms of more than 12 months. This standard will be effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. The Company is assessing ASU 2016-02's impact and will adopt it when effective.

In August 2016, the FASB issued ASU 2016-15, "Statement of Cash Flows: Clarification of Certain Cash Receipts and Cash Payments", which eliminates the diversity in practice related to the classification of certain cash receipts and payments in

the statement of cash flows, by adding or clarifying guidance on eight specific cash flow issues. ASU 2016-15 is effective for annual and interim reporting periods beginning after December 15, 2017 and early adoption is permitted. ASU 2016-15 provides for retrospective application for all periods presented. The Company is assessing ASU 2016-15's impact and will adopt it when effective.

In November 2016, the FASB issued ASU 2016-18 "Statement of Cash Flows: Restricted Cash", which eliminates the diversity in practice related to the inclusion of restricted cash in the statement of cash flows by requiring that a statement of cash flows include the change during the period in restricted cash when reconciling beginning-of-period and end-of-period total amounts shown on the statement of cash flows. ASU 2016-18 is effective for annual and interim reporting periods beginning after December 15, 2017 and early adoption is permitted. ASU 2016-18 provides for retrospective application for all periods presented. The Company is assessing ASU 2016-18's impact and will adopt it when effective.

In May 2017, the FASB issued ASU 2017-09, "Stock Compensation - Scope of Modification Accounting", guidance that clarifies that all changes to share-based payment awards are not necessarily accounted for as a modification. Under the new guidance, modification accounting is required only if the fair value, the vesting conditions, or the classification of the award changes as a result of the change in terms or conditions. The amendments in this guidance should be applied prospectively in annual periods beginning after December 15, 2017, including interim periods within those periods, with early adoption permitted. This guidance will apply to any future modifications. The Company is assessing ASU 2017-09's impact and if applicable, will adopt it when effective.

### (3) Liquidity

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

The Company had cash and cash equivalents of \$11.0 million and marketable securities of \$3.9 million as of June 30, 2017.

The Company's existing cash and cash equivalents and marketable securities as of June 30, 2017 will be used primarily to fund the first of two INOpulse for PAH Phase 3 trials and to a lesser extent for the Phase 2 trials for pulmonary hypertension associated with chronic obstructive pulmonary disease, or PH-COPD, and interstitial lung disease, or ILD. In addition, as of June 30, 2017, the Company had \$4.7 million prepayments of research and development expenses related to its amended drug supply agreement with Ikaria and the clinical research organization it has partnered with for the first of the two Phase 3 clinical trials for INOpulse for PAH. The corresponding prepayments balance as of December 31, 2016 was \$7.2 million. These prepayment amounts are presented on the respective consolidated balance sheets as follows (in thousands):

	June 30, December 31,	
	2017	2016
Prepaid expenses and other current assets	4,322	5,842
Other non-current assets	389	1,406
	4,711	7,248

On May 5, 2016, the Company filed a shelf registration statement with the SEC on Form S-3, which as amended became effective on May 23, 2016. The shelf registration will allow the Company to issue, from time to time at prices and on terms to be determined prior to the time of any such offering, up to \$30.0 million of any combination of the Company's common stock, preferred stock, debt securities, warrants, rights, purchase contracts or units, either individually or in units. As of June 30, 2017, the Company had sold 1,025,793 shares for gross and net proceeds of \$2.2 million and \$2.1 million, respectively, under the Company's effective shelf registration statement on Form S-3

and the related prospectus supplement dated May 27, 2016 and filed with the SEC on May 27, 2016.

On October 25, 2016, the Company filed a registration statement on Form S-1 with the SEC which as amended became effective on November 22, 2016. On November 29, 2016, the Company completed the sale of 17,142,858 Class A Units consisting of an aggregate of 17,142,858 shares of its common stock and warrants exercisable for up to 17,142,858 shares of its common stock at a price of \$0.70 per Unit, or the Secondary Offering, resulting in net proceeds of \$10.9 million, after deducting placement fees of \$0.8 million and offering costs of \$0.3 million. Each warrant has an exercise price per full share of common stock equal to \$0.80, is immediately exercisable and expires five years from the date on which such warrant becomes exercisable. The warrants require cash settlement by the Company under certain situations. During the six months ended

June 30, 2017, the Company received proceeds of \$0.5 million for the exercise of 648,586 warrants. Refer to Note 5 - Common Stock Warrant Liability for further details on the warrants.

On May 9, 2017, the Company entered into a Securities Purchase Agreement, or the Purchase Agreement, with a single institutional investor, or the investor, for the sale of 2,000,000 shares of its common stock at a purchase price of \$1.50 per share and warrants to purchase up to an aggregate of 1,000,000 shares of its common stock, or the Direct Offering. The warrants will be initially exercisable commencing six months from the issuance date at an exercise price equal to \$1.50 per full share of common stock, subject to adjustments as provided under the terms of the warrants. The warrants are exercisable for five years from the initial exercise date. In addition, the Company issued the placement agent of the Direct Offering, warrants to purchase up to 60,000 shares. The placement agent warrants have substantially the same terms as the warrants issued to the investor, except that the placement agent warrants have an exercise price equal to \$1.875 and will be exercisable for five years from the date of the closing of this offering. The closing of the sales of these securities under the Purchase Agreement occurred on May 15, 2017. The aggregate gross and net proceeds for the Direct Offering were \$3.0 million and \$2.7 million, respectively.

The Company evaluated whether there are any conditions and events, considered in the aggregate, that raise substantial doubt about its ability to continue as a going concern within one year beyond the filing of this Quarterly Report on Form 10-Q.

Based on such evaluation, management believes that the Company's existing cash and cash equivalents and marketable securities as of June 30, 2017 and proceeds that will become available to the Company upon sale of the Company's state net operating losses, or NOLs, and R&D tax credits under the State of New Jersey's Technology Business Tax Certificate Transfer Program will not be sufficient to satisfy the Company's operating cash needs for at least one year after the filing of this Quarterly Report on Form 10-Q. These factors raise substantial doubt about the Company's ability to continue as a going concern. The Company continues to pursue potential sources of funding, including equity financing.

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

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

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

(4) Marketable Securities

The Company considers all of its investments to be available-for-sale. Marketable securities as of June 30, 2017 consist of the following (in thousands):

14

---

Edgar Filing: Bellerophon Therapeutics, Inc. - Form 10-Q

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Certificates of deposit	2,902	—	—	2,902
Agency bonds	999	—	—	999
Total	3,901	—	—	3,901

Marketable securities as of December 31, 2016, consist of the following (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Certificates of deposit	3,619	—	—	3,619
Corporate bonds	1,952	—	—	1,952
Total	5,571	—	—	5,571

Maturities of marketable securities classified as available-for-sale were as follows at June 30, 2017 and December 31, 2016 (in thousands):

	June 30, 2017	December 31, 2016
Due within one year	3,901	5,571
Due after one year	—	—
	3,901	5,571

#### (5) Common Stock Warrant Liability

On November 29, 2016, the Company issued warrants to purchase 17,142,858 shares that were immediately exercisable and will expire five years from issuance at an exercise price of \$0.80 per share. As the warrants, under certain situations, could require cash settlement, the warrants were classified as liabilities and recorded at estimated fair value using a Black-Scholes-Merton pricing model.

On May 15, 2017, the Company issued to an investor a warrant to purchase 1,000,000 shares that will be initially exercisable commencing six months from their issuance and will expire five years from the initial exercise date at an exercise price of \$1.50 per share. In addition, the Company issued the placement agent warrants to purchase 60,000 shares that were immediately exercisable and will expire five years from issuance at an exercise price of \$1.875 per share. As the warrants, under certain situations, could require cash settlement, the warrants were classified as liabilities and recorded at estimated fair value using a Black-Scholes-Merton pricing model.

The following table summarizes warrant activity for the six months ended June 30, 2017 (fair value amount in thousands):

	Warrants	Estimated Fair Value
Beginning balance	17,142,858	\$5,215
Exercises	(648,586)	(702)
Additions	1,060,000	1,118
	—	12,020

Edgar Filing: Bellerophon Therapeutics, Inc. - Form 10-Q

Change in fair value of common stock warrant liability recognized in consolidated statement of operations

Ending balance 17,554,272 \$17,651

See Note 6 for determination of the fair value of common stock warrant liability.

(6) Fair Value Measurements

15

---



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

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

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

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

The following table summarizes fair value measurements by level at June 30, 2017 for assets and liabilities measured at fair value on a recurring basis (in thousands):

	Level 1	Level 2	Level 3	Total
Marketable securities	\$	—\$3,901	\$	—\$3,901
Common stock warrant liability	—	—	17,651	17,651

The following table summarizes fair value measurements by level at December 31, 2016 for assets and liabilities measured at fair value on a recurring basis (in thousands):

	Level 1	Level 2	Level 3	Total
Marketable securities	\$	—\$5,571	\$	—\$5,571
Common stock warrant liabilities	—	—	5,215	5,215

The Company uses a Black-Scholes-Merton option pricing model to value its common stock warrants. The significant unobservable inputs used in calculating the fair value of common stock warrants represent management's best estimates and involve inherent uncertainties and the application of management's judgment. For volatility, the Company uses comparable public companies as a basis for its expected volatility to calculate the fair value of common stock warrants 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 common stock warrant. Any significant increases or decreases in the unobservable inputs, with the exception of the risk-free interest rate, may result in significantly higher or lower fair value measurements.

The following are the weighted average assumptions used in estimating the fair value of warrants issued as of June 30, 2017 and December 31, 2016:

	June 30, 2017	December 31, 2016
Valuation assumptions:		
Risk-free interest rate	1.79 %	1.91 %
Expected volatility	90.81 %	83.73 %
Expected term (in years)	4.5	4.9
Dividend yield	— %	— %

(7) Restructuring Charges

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

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

The following table summarizes restructuring activities for the six months ended June 30, 2017 (in thousands):

	June 30, 2017
Opening balance (a)	\$ 110
Cash payments	(110 )
Ending balance	\$—

(a) Included in Accrued expenses.

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

### Bellerophon 2015 and 2014 Equity Incentive Plans

During 2015, the Company adopted the 2015 Equity Incentive Plan, or the 2015 Plan, which provides for the grant of options, restricted stock and other forms of equity compensation. On May 4, 2017, the Company's stockholders approved an amendment to the 2015 Plan to increase the aggregate number of shares available for the grant of awards to 5,000,000 and to increase the maximum number of shares available under the annual increase to 3,000,000 shares.

As of June 30, 2017, there was approximately \$2.9 million of total unrecognized compensation expense related to unvested stock awards. This expense is expected to be recognized over a weighted-average period of 1.6 years.

No tax benefit was recognized during the three and six months ended June 30, 2017 and 2016 related to stock-based compensation expense since the Company incurred operating losses and has established a full valuation allowance to offset all the potential tax benefits associated with its deferred tax assets.

### Options

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

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

The weighted average grant-date fair values of options issued during the six months ended June 30, 2017 and 2016 were \$1.03 and \$1.53, respectively. The following are the weighted average assumptions used in estimating the fair

values of options issued during the six months ended June 30, 2017 and 2016.

	Six Months Ended June 30, 2017	Six Months Ended June 30, 2016
--	--	--

Valuation assumptions:

Risk-free rate	1.94 %	1.34 %
Expected volatility	88.57 %	81.73 %
Expected term (years)	6.2	6.1
Dividend yield	—	—

A summary of option activity under the 2015 and 2014 Plans for the six months ended June 30, 2017 is presented below:

	Bellerophon 2015 and 2014 Equity Incentive Plans			
	Options	Range of Exercise Price	Weighted Average Price	Weighted Average Remaining Contractual Life (in years)
Options outstanding as of December 31, 2016	3,189,881	\$0.49-13.28	\$ 3.08	9.4
Granted	800	1.38 -1.38	1.38	
Forfeited	(7,375 )	0.49 -1.94	0.96	
Options outstanding as of June 30, 2017	3,183,306	\$0.49-13.28	\$ 3.09	8.9
Options vested and exercisable as of June 30, 2017	539,716	\$1.94-13.28	\$ 11.19	7.3

The intrinsic value of options outstanding, vested and exercisable as of June 30, 2017 was zero.

#### Restricted Stock

All restricted stock awards granted under the 2015 Plan as of June 30, 2017 were in relation to 2015 and 2016 incentives for employees or director compensation and vest in full one year or less from the grant date.

A summary of restricted stock activity under the 2015 Plan for the six months ended June 30, 2017 is presented below:

	Bellerophon 2015 Equity Incentive Plan			
	Shares	Weighted Average Fair Value	Aggregate Grant Date Fair Value (in millions)	Weighted Average Remaining Contractual Life (in years)
Restricted stock outstanding as of December 31, 2016	155,846	\$ 2.05	\$ 0.3	0.0
Granted	873,310	1.45	1.3	
Vested	(374,981)	(1.70 )	(0.6 )	
Restricted stock outstanding as of June 30, 2017	654,175	\$ 1.45	\$ 0.9	0.5

#### Ikaria Equity Incentive Plans prior to February 12, 2014

##### Options

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

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

modified.

A summary of option activity under the assumed Ikaria 2007 stock option plan and the assumed Ikaria 2010 long term incentive plan for the six months ended June 30, 2017, is presented below:

19

---

	Ikaria Equity Incentive Plans			Weighted Average Remaining Contractual Life (in years)
	Options	Range of Exercise Price	Weighted Average Price	
Options outstanding as of December 31, 2016	87,369	\$7.77-17.92	\$ 9.14	4.3
Forfeited	(10,530)	7.77 -14.91	8.88	
Options outstanding as of June 30, 2017	76,839	\$7.77-17.92	\$ 9.17	4.3
Options vested and exercisable as of June 30, 2017	76,839	\$7.77-17.92	\$ 9.17	4.3

The intrinsic value of options outstanding, vested and exercisable as of June 30, 2017 was zero.

#### Stock-Based Compensation Expense, Net of Estimated Forfeitures

The following table summarizes the stock-based compensation expense by the unaudited condensed consolidated statement of operations line items for the six months ended June 30, 2017 and 2016 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Research and development	\$182	\$237	\$473	\$453
General and administrative	467	531	905	916
Total expense	\$649	\$768	\$1,378	\$1,369

#### (9) Income Taxes

The effective tax rate for each of the three and six months ended June 30, 2017 and 2016 was 0.0%. For the three and six months ended June 30, 2017 and 2016, the effective rate was lower than the federal statutory rates primarily due to the losses incurred and the full valuation allowance on deferred tax assets.

As of June 30, 2017, there were no material uncertain tax positions. There are no tax positions for which a material change in any unrecognized tax benefit liability is reasonably possible in the next 12 months.

#### (10) Net Loss Per Share

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

The Company reported a net loss for the three and six months ended June 30, 2017 and 2016, therefore diluted net loss per share is the same as the basic net loss per share.

As of June 30, 2017, the Company had 3,260,145 options to purchase shares, 654,175 restricted shares and warrants to purchase 17,554,272 shares outstanding that have been excluded from the computation of diluted weighted average shares outstanding, because such securities had an anti-dilutive impact due to the loss reported.



(11) 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.

20

---

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

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

You should read the following discussion and analysis of our financial condition and results of operations together with our condensed consolidated financial statements and the related notes appearing elsewhere in this Quarterly Report on Form 10-Q. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. You should read the "Risk Factors" section in Part II—Item 1A. of this Quarterly Report on Form 10-Q and in Part I—Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2016 for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

### Overview

### Business

We are a clinical-stage therapeutics company focused on developing innovative products at the intersection of drugs and devices that address significant unmet medical needs in the treatment of cardiopulmonary diseases. Our focus is the continued development of our nitric oxide therapy for patients with pulmonary hypertension, or PH, using our proprietary delivery system, INOpulse, with pulmonary arterial hypertension, or PAH, representing the lead indication. Our INOpulse platform is based on our proprietary pulsatile nitric oxide delivery device. In February 2016, we announced positive data from the final analysis of our Phase 2 long-term extension clinical trial of INOpulse for PAH, which was Part 2 of our Phase 2 clinical trial of INOpulse for PAH. The data indicates a sustainability of benefit to PAH patients who received INOpulse therapy at the 75 mcg/kg of ideal body weight/hour dose for an average of greater than 12 hours per day and were on long-term oxygen therapy, or LTOT. After reaching agreement with the U.S. Food and Drug Administration, or FDA, and the European Medicines Agency, or EMA, on our Phase 3 protocol, we are moving forward with Phase 3 development. In September 2015, the FDA issued a Special Protocol Assessment, or SPA, for our Phase 3 PAH program for INOpulse, which will include two confirmatory clinical trials. The first of the two Phase 3 trials, or INOvation-1, has been initiated. During January 2017, we received confirmation from the FDA of its acceptance of all of our proposed modifications to our Phase 3 program. Under the newly modified Phase 3 program, the ongoing INOvation-1 study, and a second confirmatory randomized withdrawal study with approximately 40 patients who will be crossing over from the INOvation-1 study, can serve as the two adequate and well-controlled studies to support a NDA filing for INOpulse in PAH subjects on LTOT. Both studies include an interim analysis approximately half-way through each study to assess for efficacy and futility. The interim analysis for the INOvation-1 study also includes a potential sample size reassessment. We completed a randomized, placebo-controlled, double-blind, dose-confirmation Phase 2 clinical trial of INOpulse for PH-COPD in July 2014. We received results from this trial, and have initiated further Phase 2 testing to demonstrate the potential benefit on exercise capacity. In September 2015, an oral presentation of late-breaking data from a clinical trial sponsored by us was presented at the European Respiratory Society International Congress 2015 in Amsterdam. The data showed that INOpulse improved vasodilation in patients with PH-COPD. In July 2016, the results were published in the International Journal of COPD in an article titled "Pulmonary vascular effects of pulsed inhaled nitric oxide in COPD patients with pulmonary hypertension." During May 2017, we shared preliminary results of an ongoing Phase 2 PH-COPD study (n=10) designed to evaluate the acute effects of pulsed iNO on vasodilation as well as the chronic effect on hemodynamics and exercise tolerance. The interim data results from the first four patients showed a significant association between ventilation and vasodilation on acute treatment with iNO, suggesting that

regions with better ventilation experience greater vasodilation. In addition, a meaningful reduction in sPAP (average 17.4%) was seen on all patients with chronic treatment of iNO.

We have begun our clinical program in interstitial lung disease, based on feedback from the medical community and the large unmet medical need. During May 2017, we announced completion of our Phase 2 study using INOpulse therapy to treat PH associated with idiopathic pulmonary fibrosis, or PH-IPF. The clinical data showed that INOpulse was associated with clinically meaningful improvements in hemodynamics and exercise capacity in difficult-to-treat PH-IPF patients. The PH-IPF study was a proof of concept study (n=4) designed to evaluate the ability of pulsed inhaled nitric oxide (iNO) to provide selective vasodilation as well as to assess the potential for improvement in hemodynamics and exercise capacity in PH-IPF patients. The study met its primary endpoint showing an average of 15.3% increase in blood vessel volume ( $p < 0.001$ ) during acute inhalation of iNO as well as showing a significant association between ventilation and vasodilation, demonstrating the ability of INOpulse to provide selective vasodilation to the better ventilated areas of the lung. The study showed consistent

benefit in hemodynamics with a clinically meaningful average reduction of 14% in systolic pulmonary arterial pressure (sPAP) with acute exposure to iNO. The study also assessed the chronic effects of iNO on exercise capacity showing an average 75 meter improvement in 6-minute walk distance, or 6MWD, and consistent improvement of approximately 80 m% in composite endpoints of 6MWD and oxygen saturation with four weeks of treatment. The study assessed both the iNO 75 and iNO 30 dose, supporting iNO 30 as a potentially safe and effective dose. During August 2017, we announced FDA acceptance of our investigation new drug application for our Phase 2b study using INOpulse therapy in a broad population of patients with pulmonary fibrosis, or PF, both with and without PH.

In addition, other opportunities for the application of our INOpulse platform include the following indications: chronic thromboembolic PH, or CTEPH, PH associated with sarcoidosis and PH associated with pulmonary edema from high altitude sickness.

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

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

## Financial Operations Overview

### Revenue

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

### Research and Development Expenses

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

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 and allocated expenses;

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

- device development and drug manufacturing engineering;
- license fees related to in-licensed products and technology; and
- costs associated with non-clinical activities and regulatory approvals.

We expense research and development costs as incurred.

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

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

#### INOpulse for PAH

We completed a randomized, placebo-controlled, double-blind Phase 2 clinical trial of INOpulse for PAH in October 2014. In February 2016, we performed the final analysis of our Phase 2 long-term extension clinical trial of INOpulse for PAH, which is Part 2 of our Phase 2 clinical trial of INOpulse for PAH. After reaching agreement with the FDA and the EMA on our Phase 3 protocol, we moved forward with Phase 3 development.

#### INOpulse for PH-COPD

We completed a randomized, placebo-controlled, double-blind, dose-confirmation Phase 2 clinical trial of INOpulse for PH-COPD in July 2014. We received results from this trial, and have initiated Phase 2 testing for the use of the INOpulse device for PH-COPD patients to evaluate the potential benefit of chronic use on exercise capacity, with the first patient enrolled in October 2016.

#### INOpulse for interstitial lung disease

We initiated our clinical program in interstitial lung disease, or ILD, in 2016. During May 2017, we announced completion of our Phase 2 study using INOpulse therapy to treat PH associated with idiopathic pulmonary fibrosis, or PH-IPF.

#### BCM

In December 2011, we initiated a clinical trial of BCM and completed enrollment in December 2014. Top-line results from the clinical trial were announced in July 2015. Following the results, we are considering further exploratory work but we do not intend to proceed with further clinical development of BCM at this point until and unless we can determine an alternative path forward.

### Research and Development Infrastructure

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

#### INOpulse Engineering

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

It is difficult to determine with certainty the duration and completion costs of our current or any future pre-clinical programs and any of our current or future clinical trials and any future product candidates we may advance, or if,

when or to what extent we will generate revenue from the commercialization and sale of any of our product candidates that obtain regulatory approval. We may never succeed in achieving regulatory approval for any of our product candidates. The duration, costs and timing of clinical trials and development of our product candidates will depend on a variety of factors, including the uncertainties of any future clinical trials and pre-clinical studies, uncertainties in clinical trial enrollment rate and significant and changing government regulation. In addition, the probability of success for each product candidate will depend on numerous factors, including competition, manufacturing capability and commercial viability. A change in the outcome of any of

these variables with respect to the development of a product candidate could change significantly the costs and timing associated with the development of that product candidate. For example, if the FDA or other regulatory authority were to require us to conduct clinical trials beyond those that we currently anticipate will be required for the completion of clinical development of a product candidate, or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time with respect to the development of that product candidate. We will determine which programs to pursue and how much to fund each program in response to the scientific and clinical success of each product candidate, as well as an assessment of each product candidate's commercial potential, including the likelihood of regulatory approval on a timely basis.

#### General and Administrative Expenses

General and administrative expenses include salaries and costs related to executive, finance, and administrative support functions, patent filing, patent prosecution, professional fees for legal, insurance, consulting, investor relations, human resources, information technology and auditing and tax services not otherwise included in research and development expenses.

#### Results of Operations

##### Comparison of Three Months Ended June 30, 2017 and 2016

The following table summarizes our results of operations for the three months ended June 30, 2017 and 2016.

(Dollar amounts in thousands)	Three Months Ended June 30,		\$ Change	% Change
	2017	2016		
Research and development expenses:				
PAH	\$3,236	\$2,382	\$854	36 %
BCM	13	35	(22 )	(63 )%
PH-COPD and ILD	8	40	(32 )	(80 )%
Clinical programs	3,257	2,457	800	33 %
Research and development infrastructure	1,179	1,222	(43 )	(4 )%
INOpulse engineering	253	275	(22 )	(8 )%
Total research and development expenses	4,689	3,954	735	19 %
General and administrative expenses	1,634	1,205	429	36 %
Total operating expenses	6,323	5,159	1,164	23 %
Loss from operations	(6,323 )	(5,159 )	(1,164 )	23 %
Change in fair value of common stock warrant liability	2,367	—	2,367	n.a.
Interest and other income	26	22	4	18 %
Net loss	\$(3,930)	\$(5,137)	\$1,207	(23 )%

**Total Operating Expenses.** Total operating expenses for the three months ended June 30, 2017 were \$6.3 million compared to \$5.2 million for the three months ended June 30, 2016, an increase of \$1.2 million, or 23%. This increase was primarily due to increased research and development expenses pertaining to our development of INOpulse for PAH and an increase in general and administrative expenses.

**Research and Development Expenses.** Total research and development expenses for the three months ended June 30, 2017 were \$4.7 million compared to \$4.0 million for the three months ended June 30, 2016, an increase of \$0.7 million, or 19%. Total research and development expenses consisted of the following:



- PAH research and development expenses were \$3.2 million for the three months ended June 30, 2017, compared to \$2.4 million for the three months ended June 30, 2016, an increase of \$0.9 million, or 36%. The increase was primarily driven by a bulk purchase of cartridges in the three months ended June 30, 2017.
- BCM research and development expenses for the three months ended June 30, 2017 were \$13.0 thousand compared to \$35.0 thousand for the three months ended June 30, 2016.

- PH-COPD and ILD research and development expenses were \$8.0 thousand and \$40.0 thousand for the three months ended June 30, 2017 and 2016, respectively.
- Research and development infrastructure expenses for both the three months ended June 30, 2017 and June 30, 2016 were \$1.2 million.
- INOpulse engineering expenses for both the three months ended June 30, 2017 and June 30, 2016 were \$0.3 million.

**General and Administrative Expenses.** General and administrative expenses for the three months ended June 30, 2017 were \$1.6 million compared to \$1.2 million for the three months ended June 30, 2016, an increase of \$0.4 million, or 36%. The increase was primarily due to the reversal of a restructuring accrual in the three months ended June 30, 2016 pursuant to resolution of certain matters that resulted in cessation of severance payments.

**Change in fair value of common stock warrant liability.** Change in fair value of common stock warrant liability for the three months ended June 30, 2017 was \$2.4 million and we had no change in fair value of common stock warrant liability for the three months ended June 30, 2016 as the warrants were issued in November 2016 and May 2017.

#### Comparison of Six Months Ended June 30, 2017 and 2016

The following table summarizes our results of operations for the six months ended June 30, 2017 and 2016.

(Dollar amounts in thousands)	Six Months Ended June 30,		\$ Change	% Change
	2017	2016		
Research and development expenses:				
PAH	\$4,877	\$5,411	\$(534)	(10)%
BCM	39	355	(316)	(89)%
PH-COPD and ILD	37	54	(17)	(31)%
Clinical programs	4,953	5,820	(867)	(15)%
Research and development infrastructure	2,534	2,240	294	13%
INOpulse engineering	539	1,007	(468)	(46)%
Total research and development expenses	8,026	9,067	(1,041)	(11)%
General and administrative expenses	3,080	3,181	(101)	(3)%
Total operating expenses	11,106	12,248	(1,142)	(9)%
Loss from operations	(11,106)	(12,248)	1,142	(9)%
Change in fair value of common stock warrant liability	(12,020)	—	(12,020)	n.a.
Interest and other income	53	52	1	2%
Net loss	\$(23,073)	\$(12,196)	\$(10,877)	89%

**Total Operating Expenses.** Total operating expenses for the six months ended June 30, 2017 were \$11.1 million compared to \$12.2 million for the six months ended June 30, 2016, a decrease of \$1.1 million, or 9%. This decrease was primarily due to decreases in research and development expenses pertaining to our development of INOpulse for PAH and INOpulse engineering costs.

**Research and Development Expenses.** Total research and development expenses for the six months ended June 30, 2017 were \$8.0 million compared to \$9.1 million for the six months ended June 30, 2016, a decrease of \$1.0 million,

or 11%. Total research and development expenses consisted of the following:

- PAH research and development expenses were \$4.9 million for the six months ended June 30, 2017, compared to \$5.4 million for the six months ended June 30, 2016, a decrease of \$0.5 million, or 10%. The decrease

25

---

was primarily driven by reduced costs due to the completion of the Phase 2 clinical trial in 2016 offset in part by an increase in costs associated with the Phase 3 clinical trial and a bulk purchase of cartridges in 2017.

- BCM research and development expenses for the six months ended June 30, 2017 were \$39.0 thousand compared to \$0.4 million for the six months ended June 30, 2016, a decrease of \$0.3 million, or 89%. The decrease was driven by a reduction in spend on manufacturing costs.
- PH-COPD and ILD research and development expenses were \$37 thousand and \$54 thousand for the six months ended June 30, 2017 and 2016, respectively.
- Research and development infrastructure expenses for the six months ended June 30, 2017 were \$2.5 million compared to \$2.2 million for the six months ended June 30, 2016, an increase of \$0.3 million, or 13%. The increase was primarily due to increased personnel costs.
- INOpulse engineering expenses for the six months ended June 30, 2017 were \$0.5 million compared to \$1.0 million for the six months ended June 30, 2016, a decrease of \$0.5 million, or 46%. The decrease was primarily the result of a reduction in development costs for the INOpulse device and triple-lumen cannula.

**General and Administrative Expenses.** General and administrative expenses for the six months ended June 30, 2017 were \$3.1 million compared to \$3.2 million for the six months ended June 30, 2016, a decrease of \$0.1 million, or 3%. The decrease was primarily due to reduction in personnel costs and consulting costs offset in part by the reversal of a restructuring accrual in the prior year pursuant to resolution of certain matters that resulted in cessation of severance payments.

**Change in fair value of common stock warrant liability.** Change in fair value of common stock warrant liability for the six months ended June 30, 2017 was \$(12.0) million and we had no change in fair value of common stock warrant liability for the six months ended June 30, 2016 as the warrants were issued in November 2016 and May 2017.

## Liquidity and Capital Resources

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

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

We had cash and cash equivalents of \$11.0 million and marketable securities of \$3.9 million as of June 30, 2017. Our existing cash and cash equivalents and marketable securities as of June 30, 2017 will be used primarily to fund the first of two INOpulse for PAH Phase 3 trials and to a lesser extent for the Phase 2 trials for PH-COPD and ILD. As of June 30, 2017, we had \$4.7 million prepayments of research and development expenses related to our amended drug supply agreement with Ikaria and the clinical research organization we have partnered with for the first of the two Phase 3 clinical trials for INOpulse for PAH. The corresponding prepayments balance as of December 31, 2016 was \$7.2 million.

On May 5, 2016, we filed a shelf registration statement with the SEC on Form S-3, which as amended became effective on May 23, 2016. The shelf registration will allow the Company to issue, from time to time at prices and on terms to be determined prior to the time of any such offering, up to \$30.0 million of any combination of the Company's

common stock, preferred stock, debt securities, warrants, rights, purchase contracts or units, either individually or in units. As of June 30, 2017, the Company had sold 1,025,793 shares for gross and net proceeds of \$2.2 million and \$2.1 million, respectively, under the Company's effective shelf registration statement on Form S-3 and the related prospectus supplement dated May 27, 2016 and filed with the SEC on May 27, 2016.

On October 25, 2016, we filed a registration statement on Form S-1 with the SEC which as amended became effective on November 22, 2016. On November 29, 2016, we completed the sale of 17,142,858 Class A Units consisting of an aggregate of 17,142,858 shares of our common stock and warrants exercisable for up to 17,142,858 shares of our common stock at a price of \$0.70 per Unit, or the Secondary Offering, resulting in net proceeds of \$10.9 million, after deducting placement fees of \$0.8 million and offering costs of \$0.3 million. Each warrant has an exercise price per full share of common stock equal to \$0.80, is

immediately exercisable and expires five years from the date on which such warrant becomes exercisable. The warrants require cash settlement by us under certain situations. During the six months ended June 30, 2017, we received proceeds of \$0.5 million for the exercise of 648,586 warrants.

On May 9, 2017, we entered into a Securities Purchase Agreement, or the Purchase Agreement, with a single institutional investor for the sale of 2,000,000 shares of our common stock at a purchase price of \$1.50 per share and warrants to purchase up to an aggregate of 1,000,000 shares of our common stock, or the Direct Offering. The warrants are initially exercisable commencing six months from the issuance date at an exercise price equal to \$1.50 per full share of common stock, subject to adjustments as provided under the terms of the warrants. The warrants are exercisable for five years from the initial exercise date. In addition, the Company issued the placement agent of the Direct Offering, warrants to purchase up to 60,000 shares. The placement agent warrants have substantially the same terms as the warrants issued to the investor, except that the placement agent warrants have an exercise price equal to \$1.875 and will be exercisable for five years from the date of the closing of this offering. The closing of the sales of these securities under the Purchase Agreement occurred on May 15, 2017. The aggregate gross and net proceeds for the Direct Offering were \$3.0 million and \$2.7 million, respectively.

We have evaluated whether there are any conditions and events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern within one year beyond the filing of this Quarterly Report on Form 10-Q.

Based on such evaluation, we believe that our existing cash and cash equivalents and marketable securities as of June 30, 2017 and proceeds that will become available to us upon sale of our state net operating losses (NOL) and R&D tax credits under the State of New Jersey's Technology Business Tax Certificate Transfer Program will not be sufficient to satisfy our operating cash needs for at least one year after the filing of this Quarterly Report on Form 10-Q. These factors raise substantial doubt about our ability to continue as a going concern. We continue to pursue potential sources of funding, including equity financing.

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

- progress and cost of our clinical trials and other research and development activities;
- our ability to manufacture sufficient supply of our product candidates and the costs thereof;
- the cost and timing of seeking regulatory approvals;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution for any of our product candidates for which we receive marketing approval;
- the number and development requirements of any other product candidates we pursue;
- our ability to enter into collaborative agreements and achieve milestones under those agreements;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the cost of filing, prosecuting, defending and enforcing patent applications, claims, patents and other intellectual property rights; and
- the extent to which we acquire or in-license other products and technologies.

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

may include liquidation or other preferences or rights such as anti-dilution rights that adversely affect the rights of our existing stockholders. If we raise additional funds through strategic partnerships in the future, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

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

#### Cash Flows

The following table summarizes our cash flows for the six months ended June 30, 2017 and 2016:

(Dollar amounts in thousands)	Six Months Ended	
	June 30,	
	2017	2016
Operating activities	\$(8,170)	\$(11,470)
Investing activities	1,670	5,863
Financing activities	3,015	651
Net change in cash and cash equivalents	\$(3,485)	\$(4,956 )

#### Net Cash Used in Operating Activities

Cash used in operating activities for the six months ended June 30, 2017 was \$8.2 million compared to \$11.5 million for the six months ended June 30, 2016, a decrease of \$3.3 million, or 29%. The decrease in cash used in operating activities was primarily due to reduced operating expenses.

#### Net Cash Provided by Investing Activities

Cash provided by investing activities for the six months ended June 30, 2017 was \$1.7 million compared to \$5.9 million for the six months ended June 30, 2016 primarily due to reduced proceeds from the sale of marketable securities offset by the purchase of marketable securities.

#### Net Cash Provided by Financing Activities

Cash provided by financing activities for the six months ended June 30, 2017 was \$3.0 million which included the proceeds from the Director Offering and warrant exercises offset by the payment of issuance costs related to the 2016 secondary offering. For the six months ended June 30, 2016 the Company received \$0.7 million representing proceeds from the sale of common stock in ATM offering.

#### Contractual Obligations and Commitments

There were no material changes, outside the ordinary course of business, in our outstanding contractual obligations from those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2016.

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

#### Off-Balance Sheet Arrangements

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



Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to research and development expense, and

stock-based compensation. We base our estimates on historical experience, known trends and events and various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

During the six months ended June 30, 2017, 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, 2016.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risk related to changes in interest rates. As of June 30, 2017, we had cash and cash equivalents of \$11.0 million, consisting primarily of demand deposits with U.S. banking institutions and marketable securities of \$3.9 million. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in cash and cash equivalents, federally insured certificates of deposit and corporate or agency bonds rated A or better. Due to the nature of our deposits and the low risk profile of our investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our deposits.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2017. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of June 30, 2017, 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 June 30, 2017 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

We are currently not a party to any material legal proceedings.

Item 1A. Risk Factors.

There have been no material changes to our risk factors contained in our Annual Report on Form 10-K for the year ended December 31, 2016. 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, 2016.

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

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

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

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

BELLEROPHON  
THERAPEUTICS, INC.

Date: August 7, 2017 By: /s/ Fabian Tenenbaum  
Fabian Tenenbaum  
Chief Executive Officer  
(Principal Executive Officer)

Date: August 7, 2017 By: /s/ Megan Schoeps  
Megan Schoeps  
Controller  
(Principal Financial Officer)

Exhibit Index

Exhibit Number	Description
<u>31.1</u>	<u>Certification of Principal Executive Officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended</u>
<u>31.2</u>	<u>Certification of Principal Financial Officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended</u>
<u>32</u>	<u>Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</u>
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