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Bellerophon Therapeutics, Inc.
Form 10-Q
November 07, 2018

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 September 30, 2018

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 every Interactive Data File required to be submitted 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 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", "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer Accelerated filer
Non-accelerated filer 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 November 6, 2018: 58,679,492

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REFERENCES TO BELLEROPHON

In this Quarterly Report on Form 10-Q, unless otherwise stated or the context otherwise requires references to the “Company,” “Bellerophon,” “we,” “us” and “our” refer to Bellerophon Therapeutics, Inc. and its consolidated subsidiaries.

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FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Quarterly Report on Form 10-Q, including statements regarding our future results of operations and financial position, business strategy and plans and objectives of management for future operations, are forward-looking statements. The words “may,” “will,” “should,” “expects,” “plans,” “anticipates,” “could,” “intends,” “target,” “projects,” “contemplates,” “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;

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;

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, 2017, 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.

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

| | As of September 30, 2018 (Unaudited) | As of December 31, 2017 |
|--|---|-------------------------------|
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 19,552 | \$ 28,823 |
| Restricted cash | 255 | 402 |
| Marketable securities | 998 | 2,996 |
| Prepaid expenses and other current assets | 1,738 | 3,359 |
| Total current assets | 22,543 | 35,580 |
| Restricted cash, non-current | 300 | 150 |
| Other non-current assets | 44 | 54 |
| Property and equipment, net | 755 | 1,026 |
| Total assets | \$ 23,642 | \$ 36,810 |
| Liabilities and Stockholders' Equity (Deficiency in Assets) | | |
| Current liabilities: | | |
| Accounts payable | \$ 4,371 | \$ 3,853 |
| Accrued research and development | 3,823 | 1,785 |
| Accrued expenses | 880 | 1,441 |
| Total current liabilities | 9,074 | 7,079 |
| Common stock warrant liability | 10,641 | 32,325 |
| Total liabilities | 19,715 | 39,404 |
| Commitments and contingencies | | |
| Stockholders' equity (deficiency in assets): | | |
| Common stock, \$0.01 par value per share; 200,000,000 and 125,000,000 shares authorized and 58,679,492 and 56,899,353 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively, 289,269 shares paid for and to be issued at December 31, 2017 | 587 | 569 |
| Preferred stock, \$0.01 par value per share; 5,000,000 shares authorized, zero shares issued and outstanding at September 30, 2018 and December 31, 2017 | — | — |
| Additional paid-in capital | 178,925 | 176,151 |
| Accumulated other comprehensive loss | (1) | (4) |
| Accumulated deficit | (175,584) | (179,310) |
| Total stockholders' equity (deficiency in assets) | 3,927 | (2,594) |
| Total liabilities and stockholders' equity (deficiency in assets) | \$ 23,642 | \$ 36,810 |

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 | | Nine Months Ended | |
|--|--------------------|-------------|-------------------|--------------|
| | September 30, | | September 30, | |
| | 2018 | 2017 | 2018 | 2017 |
| Operating expenses: | | | | |
| Research and development | \$5,247 | \$ 4,438 | \$17,442 | \$ 12,464 |
| General and administrative | 1,584 | 1,746 | 5,754 | 4,826 |
| Total operating expenses | 6,831 | 6,184 | 23,196 | 17,290 |
| Loss from operations | (6,831) | (6,184) | (23,196) | (17,290) |
| Change in fair value of common stock warrant liability | 17,840 | (1,435) | 21,201 | (13,455) |
| Interest and other income, net | 92 | 33 | 282 | 86 |
| Pre-tax income (loss) | 11,101 | (7,586) | (1,713) | (30,659) |
| Income tax benefit | — | — | 5,439 | — |
| Net income (loss) | \$11,101 | \$ (7,586) | \$3,726 | \$ (30,659) |
| Weighted average shares outstanding: | | | | |
| Basic | 57,710,251 | 44,989,831 | 57,356,443 | 33,505,444 |
| Diluted | 64,544,504 | 44,989,831 | 65,854,903 | 33,505,444 |
| Net income (loss) per share: | | | | |
| Basic | \$0.19 | \$ (0.22) | \$0.06 | \$ (0.92) |
| Diluted | \$ (0.10) | \$ (0.22) | \$ (0.27) | \$ (0.92) |

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

BELLEROPHON THERAPEUTICS, INC.

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

| | Three Months | | Nine Months | |
|--|-----------------|-----------|-----------------|------------|
| | Ended September | | Ended September | |
| | 30, | 30, | 30, | 30, |
| | 2018 | 2017 | 2018 | 2017 |
| Net income (loss) | \$11,101 | \$(7,586) | \$3,726 | \$(30,659) |
| Other comprehensive income | | | | |
| Unrealized gains on available-for-sale marketable securities | 2 | — | 3 | — |
| Total other comprehensive income | 2 | — | 3 | — |
| Comprehensive income (loss) | \$11,103 | \$(7,586) | \$3,729 | \$(30,659) |

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

BELLEROPHON THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY (UNAUDITED)

(in thousands except share data)

| | Common Stock | | Additional | Accumulated Other Comprehensive | Accumulated | Total Stockholders' |
|----------------------------|--------------|--------|-----------------|---------------------------------------|---------------|------------------------|
| | Shares | Amount | Paid in Capital | Loss | Deficit | Equity |
| December 31, 2017 | 56,899,353 | \$ 569 | \$ 176,151 | \$ (4) | \$ (179,310) | \$ (2,594) |
| Net income | — | — | — | — | 3,726 | 3,726 |
| Other comprehensive income | — | — | — | 3 | — | 3 |
| Warrant exercises | 529,093 | 5 | 668 | — | — | 673 |
| Exercise of stock options | 5,875 | — | 4 | — | — | 4 |
| Stock-based compensation | 1,245,171 | 13 | 2,102 | — | — | 2,115 |
| September 30, 2018 | 58,679,492 | \$ 587 | \$ 178,925 | \$ (1) | \$ (175,584) | \$ 3,927 |

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

~BELLEROPHON THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)

(in thousands)

| | Nine Months Ended September 30, | |
|--|------------------------------------|------------|
| | 2018 | 2017 |
| Cash flows from operating activities: | | |
| Net income (loss) | \$3,726 | \$(30,659) |
| Adjustments to reconcile net income (loss) to net cash used in operating activities: | | |
| Change in fair value of common stock warrant liability | (21,201) | 13,455 |
| Stock based compensation | 2,115 | 2,134 |
| Depreciation | 271 | 283 |
| Issuance costs attributable to common stock warrant liability | — | 111 |
| Changes in operating assets and liabilities: | | |
| Prepaid expenses and other current assets | 1,621 | 2,397 |
| Other non-current assets | 10 | 1,432 |
| Accounts payable, accrued research and development, and accrued expenses | 2,023 | (552) |
| Net cash used in operating activities | (11,435) | (11,399) |
| Cash flows from investing activities: | | |
| Purchase of marketable securities | — | (2,982) |
| Proceeds from sale of marketable securities | 2,001 | 5,375 |
| Net cash provided by investing activities | 2,001 | 2,393 |
| Cash flows from financing activities: | | |
| Proceeds from sale of Units in PIPE Offering, net of offering expenses | (28) | 23,437 |
| Proceeds from sale of Units in Direct Offering, net of commissions and offering expenses | — | 2,730 |
| Proceeds received from exercise of warrants | 190 | 747 |
| Proceeds received from exercise of stock options | 4 | — |
| Payment of offering expenses related to the secondary offering | — | (235) |
| Net cash provided by financing activities | 166 | 26,679 |
| Net change in cash, cash equivalents and restricted cash | (9,268) | 17,673 |
| Cash, cash equivalents and restricted cash at beginning of period | 29,375 | 14,910 |
| Cash, cash equivalents and restricted cash at end of period | \$20,107 | \$32,583 |
| Non-cash financing activities: | | |
| Unpaid expenses related to offerings | \$— | \$720 |
| Conversion of warrant liability to common stock upon exercise of warrants | \$483 | \$1,005 |

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. 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 income (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, 2017, included in the Company's Annual Report on Form 10-K for the year ended December 31, 2017. The results of operations for the three and nine months ended September 30, 2018 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

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 applicable accounting guidance 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, less estimated forfeitures, 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, estimated forfeitures and expected term. For restricted stock, the fair value is the closing market price per share on the grant date. See Note 7 - Stock-Based Compensation for a description of these assumptions.

(d) Common Stock Warrants and Warrant Liability

The Company accounts for common stock warrants issued as freestanding instruments in accordance with applicable accounting guidance 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 based on the warrants' terms 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 liability. Certain assumptions used in the model include expected volatility, dividend yield and risk-free interest rate. 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 applicable accounting guidance, 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.

(f) Marketable Securities

Unrealized gains and losses are reported as accumulated other comprehensive income (loss), 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 and other income, net, 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 is included in interest and other income, net.

(g) Research and Development Expense

Research and development costs are expensed as incurred. These expenses include the costs of the Company's proprietary research and development efforts, as well as costs incurred in connection with certain licensing arrangements.

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

(i) Recently Issued Accounting Pronouncements

Adopted

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. The Company adopted ASU 2016-01 during the quarter ended March 31, 2018. The adoption of this standard did not have an impact on the Company's financial statements.

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 provides for retrospective application for all periods presented. The Company adopted ASU 2016-15 during the quarter ended March 31, 2018. The adoption of this standard did not have an impact on the Company's financial statements.

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. The Company retrospectively adopted ASU 2016-18 during the quarter ended March 31, 2018 by including restricted cash with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows.

Not Yet Adopted

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 2018, the FASB issued ASU 2018-13, "Fair Value Measurement (Topic 820) - Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement", which eliminates, modifies and adds certain disclosure on fair value measurements. This standard will be effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. The Company is assessing ASU 2018-03's impact and will adopt it when effective.

(3) Liquidity

In the course of its development activities, the Company has sustained operating losses and expects such losses to continue over the next several years. The Company 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 \$19.6 million and marketable securities of \$1.0 million as of September 30, 2018.

The Company's existing cash and cash equivalents and marketable securities as of September 30, 2018 will be used primarily to complete the first cohort and partially complete additional cohorts of the Company's ongoing Phase 2b trial of INOpulse for PH associated with Interstitial Lung Disease, or PH-ILD, and to fund the closeout activities, expected to be completed in the fourth quarter of 2018, of the Phase 3 trial for PAH following our discontinuation of the trial based on the Data Monitoring Committee's recommendation in August 2018.

On May 9, 2017, the Company entered into a Securities Purchase Agreement, or the Purchase Agreement, under the shelf registration statement, with a single institutional 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 became 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 to 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 the Direct 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.

On September 26, 2017, the Company entered into a Securities Purchase Agreement, or the PIPE Purchase Agreement, pursuant to which the Company sold an aggregate of 19,449,834 shares of its common stock at a purchase price of \$1.205 per share and warrants to purchase up to an aggregate of 19,449,834 shares of its common stock, or the PIPE Offering. The warrants became exercisable commencing six months from the issuance date at an exercise price equal to \$1.2420 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. The closing of the sales of these securities under the PIPE Purchase Agreement occurred on September 29, 2017. The aggregate gross and net proceeds for the PIPE Offering were \$23.4 million and \$22.8 million, respectively.

The shelf registration statement that was filed in May 2016 was replaced by a new shelf registration statement with the SEC on Form S-3 which became effective on July 6, 2018. The new shelf registration statement allows 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 \$100 million of any combination of the Company's common stock, preferred stock, debt securities, warrants and rights, either individually or in units.

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 September 30, 2018 may 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's ability to access funding in any form is not

assured and is likely to be influenced by the results of its ongoing Phase 2b trial of INOpulse for PH-ILD and our other ongoing and planned clinical trials.

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 may not be able to accurately 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.

(4) Marketable Securities

The Company considers all of its investments to be available-for-sale. Marketable securities were as follows at September 30, 2018 and December 31, 2017 (in thousands):

| | September 30, 2018 | | | December 31, 2017 | | |
|---------------------|--------------------|-------------------------------|---------------|-------------------|-------------------------------|---------------|
| | Amortized Cost | Gross Unrealized Losses | Fair Value | Amortized Cost | Gross Unrealized Losses | Fair Value |
| US Government bonds | \$999 | \$ (1) | \$ 998 | \$3,000 | \$ (4) | \$2,996 |
| Total | \$999 | \$ (1) | \$ 998 | \$3,000 | \$ (4) | \$2,996 |

Maturities of marketable securities classified as available-for-sale were as follows at September 30, 2018 and December 31, 2017 (in thousands):

| | September 30, 2018 | | December 31, 2017 | |
|---------------------|--------------------|---------------|-------------------|---------------|
| | Amortized Cost | Fair Value | Amortized Cost | Fair Value |
| Due within one year | \$999 | \$ 998 | \$3,000 | \$2,996 |
| Total | \$999 | \$ 998 | \$3,000 | \$2,996 |

(5) Common Stock Warrants and 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 are classified as liabilities and recorded at estimated fair value using a Black-Scholes-Merton pricing model. As of September 30, 2018, warrants to purchase 13,741,180 shares were outstanding.

On May 15, 2017, the Company issued to an investor a warrant to purchase 1,000,000 shares that became 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 to 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. As of September 30, 2018, all of these warrants were outstanding.

On September 29, 2017, the Company issued warrants to purchase 19,449,834 shares that became exercisable commencing six months from their issuance and will expire five years from the initial exercise date at an exercise price of \$1.2420 per share. As the warrants could not require cash settlement, the warrants were classified as equity. As of September 30, 2018, all of these warrants were outstanding.

The following table summarizes warrant activity for the nine months ended September 30, 2018 (fair value amount in thousands):

| | Equity Classified | Liability Classified | Estimated Fair Value |
|---|-------------------|----------------------|----------------------|
| | Warrants | Warrants | |
| Warrants outstanding as of December 31, 2017 | 19,449,834 | 15,041,004 | \$32,325 |
| Exercises | — | (239,824) | (483) |
| Change in fair value of common stock warrant liability recognized in consolidated statement of operations | — | — | (21,201) |
| Warrants outstanding as of September 30, 2018 | 19,449,834 | 14,801,180 | \$10,641 |

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

| | Equity Classified | Liability Classified | Estimated Fair Value |
|---|-------------------|----------------------|----------------------|
| | Warrants | Warrants | |
| Warrants outstanding as of December 31, 2016 | — | 17,142,858 | \$5,215 |
| Exercises | — | (934,300) | (1,005) |
| Additions | 19,449,834 | 1,060,000 | 1,119 |
| Change in fair value of common stock warrant liability recognized in consolidated statement of operations | — | — | 13,455 |
| Warrants outstanding as of September 30, 2017 | 19,449,834 | 17,268,558 | \$18,784 |

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

(6) Fair Value Measurements

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

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

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

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

The following table summarizes fair value measurements by level at September 30, 2018 for assets and liabilities measured at fair value on a recurring basis (in thousands):

| | Level 1 | Level 2 | Level 3 | Total |
|-----------------------|---------|---------|---------|---------|
| Marketable securities | \$ | —\$ 998 | \$ | —\$ 998 |

Common stock warrant liability — — 10,641 10,641

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The following table summarizes fair value measurements by level at December 31, 2017 for assets and liabilities measured at fair value on a recurring basis (in thousands):

| | Level 1 | Level 2 | Level 3 | Total |
|----------------------------------|---------|----------|---------|----------|
| Marketable securities | \$ | —\$2,996 | \$ | —\$2,996 |
| Common stock warrant liabilities | — | — | 32,325 | 32,325 |

The Company uses a Black-Scholes-Merton option pricing model to value its liability classified 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 changes in the inputs 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 outstanding as of September 30, 2018 and December 31, 2017:

| | September 30, 2018 | | December 31, 2017 | |
|--------------------------|--------------------|---|-------------------|---|
| Valuation assumptions: | | | | |
| Risk-free interest rate | 2.87 | % | 2.08 | % |
| Expected volatility | 93.50 | % | 96.24 | % |
| Expected term (in years) | 3.2 | | 4.0 | |
| Dividend yield | — | % | — | % |

(7) Stock-Based Compensation

Bellerophon 2015 and 2014 Equity Incentive Plans

During 2014, the Company adopted the 2014 Equity Incentive Plan, or the 2014 Plan, which provided for the grant 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 between one to four years.

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 September 30, 2018, the Company had 2,051,395 shares available for grant under the 2015 plan.

As of September 30, 2018, there was approximately \$3.4 million of total unrecognized compensation expense related to unvested stock awards. This expense is expected to be recognized over a weighted-average period of 1.9 years.

No tax benefit was recognized during the three and nine months ended September 30, 2018 and 2017 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

The weighted average grant-date fair value of options issued during the nine months ended September 30, 2018 and 2017 were \$1.55 and \$0.84, respectively. The following are the weighted average assumptions used in estimating the fair values of options issued during the nine months ended September 30, 2018 and 2017.

| | Nine Months Ended September 30, 2018 | Nine Months Ended September 30, 2017 | | |
|------------------------|--|--|---|---|
| Valuation assumptions: | | | | |
| Risk-free rate | 2.50 | 1.98 | % | % |
| Expected volatility | 89.13 | 90.98 | % | % |
| Expected term (years) | 5.98 | 6.0 | | |
| Dividend yield | — | — | | |

A summary of option activity under the 2015 and 2014 Plans for the nine months ended September 30, 2018 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, 2017 | 3,269,883 | \$0.49-13.28 | \$ 3.04 | 8.4 |
| Granted | 1,508,228 | 2.03 -2.92 | 2.09 | |
| Exercised | (5,875) | 0.49 -1.94 | 0.52 | |
| Expired | (7,983) | 13.28 | 13.28 | |
| Forfeited | (45,525) | 0.49 -4.12 | 2.20 | |
| Options outstanding as of September 30, 2018 | 4,718,728 | \$0.49-13.28 | \$ 2.73 | 8.2 |
| Options vested and exercisable as of September 30, 2018 | 1,324,010 | \$0.49-13.28 | \$ 6.17 | 7.1 |

The intrinsic value of options outstanding, vested and exercisable as of September 30, 2018 was \$1.1 million.

Restricted Stock

All restricted stock awards granted under the 2015 Plan during the nine months ended September 30, 2018 were in relation to 2017 and 2018 incentives for employees or director compensation and vest in full less than one year from the grant date.

A summary of restricted stock activity under the 2015 Plan for the nine months ended September 30, 2018 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) |

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| | | | | |
|---|------------|---------|--------|-----|
| Restricted stock outstanding as of December 31, 2017 | 328,530 | \$ 1.42 | \$ 0.5 | 0.2 |
| Granted | 1,245,171 | 1.41 | 1.8 | |
| Vested | (608,083) | (1.70) | (1.0) | |
| Restricted stock outstanding as of September 30, 2018 | 965,618 | \$ 1.23 | \$ 1.2 | 0.6 |

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Ikaria Equity Incentive Plans prior to February 12, 2014

Options

A summary of option activity under Ikaria incentive plans assumed in 2014 for the nine months ended September 30, 2018, is presented below:

| | Ikaria Equity Incentive Plans | | | Weighted Average Contractual Life (in years) |
|---|-------------------------------|-------------------------|------------------------|--|
| | Options | Range of Exercise Price | Weighted Average Price | |
| Options outstanding as of December 31, 2017 | 72,209 | \$7.77-17.92 | \$ 9.21 | 4.0 |
| Forfeited | (2,590) | 11.65 | 11.65 | — |
| Options outstanding as of September 30, 2018 | 69,619 | \$7.77-17.92 | \$ 9.12 | 3.4 |
| Options vested and exercisable as of September 30, 2018 | 69,619 | \$7.77-17.92 | \$ 9.12 | 3.4 |

The intrinsic value of options outstanding, vested and exercisable as of September 30, 2018 was zero.

Stock-Based Compensation Expense, Net of Estimated Forfeitures

The following table summarizes the stock-based compensation expense by the unaudited condensed consolidated statement of operations line items for the three and nine months ended September 30, 2018 and 2017 (in thousands):

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|----------------------------|----------------------------------|-------|---------------------------------|---------|
| | 2018 | 2017 | 2018 | 2017 |
| Research and development | \$87 | \$188 | \$469 | \$661 |
| General and administrative | 416 | 568 | 1,646 | 1,473 |
| Total expense | \$503 | \$756 | \$2,115 | \$2,134 |

(8) Income Taxes

Excluding the impact of the sale of state net operating losses and research and development credits during the first quarter of 2018, the effective tax rate for each of the three and nine months ended September 30, 2018 and 2017 was 0.0% which was lower than the federal statutory rates primarily due to the losses incurred and the full valuation allowance on deferred tax assets.

The Company's estimated tax rate for 2018 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 valuation allowance is required until the Company has sufficient positive evidence of taxable income necessary to support realization of its deferred tax assets. In addition, the Company may be subject to certain limitations in its annual utilization of NOL carry forwards to offset future taxable income (and of tax credit carry forwards to offset future tax expense) pursuant to Section 382 of the Internal

Revenue Code, which could result in tax attributes expiring unused.

In February 2018, the Company has sold \$61.5 million of state NOLs and \$0.2 million of research and development credits under the State of New Jersey's Technology Business Tax Certificate Transfer Program for net proceeds of \$5.3 million which resulted in the reversal of the valuation allowance and a tax benefit of \$5.4 million for the nine months ended September 30, 2018 and, subject to state approval, plans to sell additional NOLs and credits under the same program in 2018 as well.

As of September 30, 2018, 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.

(9) Net Income (Loss) Per Share

| | Three months ended | | Nine months ended | |
|--------------------------------|--------------------|-------------|-------------------|--------------|
| | September 30, | | September 30, | |
| | 2018 | 2017 | 2018 | 2017 |
| Net income (loss) | \$11,101 | \$ (7,586) | \$3,726 | \$ (30,659) |
| Weighted-average shares: | | | | |
| Basic | 57,710,254 | 44,989,831 | 57,356,444 | 43,505,444 |
| Effect of dilutive securities: | | | | |
| Warrants | 6,834,253 | — | 8,498,458 | — |
| Diluted | 64,544,507 | 44,989,831 | 65,854,902 | 43,505,444 |
| Net income (loss) per share: | | | | |
| Basic | \$0.19 | \$ (0.22) | \$0.06 | \$ (0.92) |
| Diluted | \$(0.10) | \$(0.22) | \$(0.27) | \$(0.92) |

For the nine months ended September 30, 2018, the total number of potential shares of common stock excluded from the diluted earnings per share computation because their inclusion would have been anti-dilutive was 31.6 million which included 4.8 million options to purchase shares, 1.0 million restricted shares and 25.8 million warrants to purchase shares.

For the three months ended September 30, 2018, the total number of potential shares of common stock excluded from the diluted earnings per share computation because their inclusion would have been anti-dilutive was 33.2 million which included 4.8 million options to purchase shares, 1.0 million restricted shares and 27.4 million warrants to purchase shares.

As of September 30, 2017, the Company had 3.3 million options to purchase shares, 0.7 million restricted shares and 36.7 million warrants to purchase 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.

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

(10) Commitments and Contingencies

Legal Proceedings

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

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

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, 2017 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 pulsatile nitric oxide delivery platform, INOpulse.

We began our clinical program in interstitial lung disease in 2016, based on feedback from the medical community and the large unmet medical need. During May 2017, we announced completion of our Phase 2 trial using INOpulse therapy to treat PH associated with idiopathic pulmonary fibrosis, or PH-IPF. The 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 trial was a proof of concept study (n=4) designed to evaluate the ability of pulsed inhaled nitric oxide, or 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 trial also showed consistent benefit in hemodynamics with a clinically meaningful average reduction of 14% in systolic pulmonary arterial pressure, or sPAP, with acute exposure to iNO. An assessment of the chronic effects of iNO on exercise capacity showed an average 75 meter improvement in six-minute walk distance, or 6MWD, and consistent improvement of approximately 75 meter% 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 investigational new drug application, or IND, for our Phase 2b clinical trial, iNO-PF, using INOpulse therapy in a broad population of patients with pulmonary fibrosis, or PF, at both low and intermediate/high risk of PH. In January 2018, we announced the first patient enrollment in our iNO-PF Phase 2b trial. In October 2018, we announced the enrollment completion of the planned 40 subjects, or cohort 1, in our iNO-PF study. In addition, we announced the expansion of the trial with the addition of cohort 2 and cohort 3, to evaluate a higher iNO 45 and iNO 75 dose as well as a longer 16 week evaluation period. We expect to report top-line results for cohort 1 of this Phase 2b trial during the first quarter of 2019.

We completed a randomized, placebo-controlled, double-blind, dose-confirmation Phase 2 clinical trial of INOpulse for pulmonary hypertension associated with chronic obstructive pulmonary disease, or PH-COPD, in July 2014. We received results from this trial, and completed 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 entitled “Pulmonary vascular effects of pulsed inhaled nitric oxide in COPD patients with pulmonary hypertension.” In September 2017, we disclosed results of our Phase 2 PH-COPD study that was designed to evaluate the acute effects of pulsed inhaled nitric oxide, or iNO, on vasodilation as well as the chronic effect on hemodynamics and exercise tolerance. The results showed a statistically significant and clinically meaningful increase in 6MWD, and a statistically significant and clinically meaningful decrease in sPAP. The therapy was well tolerated with no related safety concerns. In May 2018, we announced that we reached agreement with the FDA on all key aspects of our planned Phase 2b study of INOpulse for treatment of PH-COPD.

We initiated a Phase 3 clinical trial of INOpulse for PAH in June 2016. As agreed upon with the FDA, a pre-specified interim analysis was conducted by the Data Monitoring Committee, or DMC, in August 2018, after half of the planned subjects completed 16 weeks of blinded treatment. The data showed improvement in pulmonary vascular resistance, cardiac output and NT Pro-BNP (a peptide bio marker for right ventricular function), however, the DMC determined that the overall change in

6MWD, the primary endpoint of the trial, was insufficient to support the continuation of the study. Accordingly, based on the DMC's recommendation, we have discontinued the trial. We are in the process of performing analyses of the cumulative unblinded data from the study. The results also showed that the decline in 6 minute walk distance was improved when subjects were on less background therapies. INOpulse was well tolerated and there were no safety concerns.

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

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

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

Financial Operations Overview

Revenue

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

Research and Development Expenses

Research and development expenses consist of costs incurred in connection with the development of our product candidates, 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.

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

We initiated our clinical program in PH-ILD in 2016. During May 2017, we announced completion of our Phase 2 study using INOpulse therapy to treat PH-IPF. After reaching agreement with the FDA, we initiated and are currently conducting our Phase 2b trial in PH-ILD. In January 2018, we announced the first patient enrollment in our iNO-PF Phase 2b trial. In October 2018, we announced the enrollment completion of the planned 40 subjects, or cohort 1, in our iNO-PF study. In addition, we announced the expansion of the trial with the addition of cohort 2 and cohort 3, to evaluate higher doses of iNO as well as a longer 16 week evaluation period.

INOpulse for PH-COPD

We completed and received results from a randomized, placebo-controlled, double-blind, dose-confirmation Phase 2a clinical trial of INOpulse for PH-COPD in July 2014. During September 2017, we shared results of our Phase 2a PH-COPD study designed to evaluate the acute effects of pulsed inhaled nitric oxide, or iNO, on vasodilation as well as the chronic effect on hemodynamics and exercise tolerance. In May 2018, we announced that we reached agreement with the FDA on all key aspects of our planned Phase 2b study of INOpulse for treatment of PH-COPD.

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 initiated the first of two Phase 3 trials. As agreed upon with the FDA, a pre-specified interim analysis was conducted by the DMC, in August 2018, after half of the planned subjects completed 16-weeks of blinded treatment. The data showed improvement in pulmonary vascular resistance, cardiac output and NT Pro-BNP (a peptide marker for right ventricular function), however, the DMC deemed the overall change in 6MWD, the primary endpoint of the trial, was insufficient to support the continuation of the study. Accordingly, based on the DMC's recommendation, we have discontinued the trial. We are in the process of performing analyses of the cumulative unblinded data from the study. The results also showed that the decline in 6 minute walk distance was improved when subjects were on less background therapies. INOpulse was well tolerated and there were no safety concerns.

Drug and Delivery System Costs

Drug and delivery system costs include cartridge procurement, cartridge filling, delivery system manufacturing and delivery system servicing. These costs relate to all indications that utilize the INOpulse delivery system. During the three months ended September 2017, we began to incur drug and delivery system costs for our Phase 2b study using INOpulse therapy in a broad population of patients with PF. Historically, drug and delivery system costs were primarily for our studies of INOpulse for PAH.

BCM

In December 2011, we initiated a clinical trial of BCM and completed enrollment in December 2014. Top-line results from the clinical trial, announced in July 2015. In July 2018, we informed BioLineRx Ltd., from whom we in-licensed the

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BCM technology, on our decision to discontinue further development and terminate the License and Commercialization Agreement.

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/DS-C device. We believe our second generation INOpulse device, as well as a custom triple-lumen cannula, have significantly improved 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 PH-ILD and PH-COPD.

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

General and Administrative Expenses

General and administrative expenses 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 September 30, 2018 and 2017

The following table summarizes our results of operations for the three months ended September 30, 2018 and 2017.

| (Dollar amounts in thousands) | Three Months Ended September 30, | | \$ Change | % Change | |
|--|----------------------------------|-----------|-----------|----------|---|
| | 2018 | 2017 | | | |
| Research and development expenses: | | | | | |
| PAH | \$1,979 | \$1,608 | \$371 | 23 | % |
| BCM | 10 | 7 | 3 | 43 | % |
| PH-ILD and PH-COPD | 622 | 48 | 574 | 1,196 | % |
| Drug and delivery system costs | 1,177 | 1,271 | (94) | (7) | % |
| Clinical programs | 3,788 | 2,934 | 854 | 29 | % |
| Research and development infrastructure | 1,056 | 1,232 | (176) | (14) | % |
| INOpulse engineering | 403 | 272 | 131 | 48 | % |
| Total research and development expenses | 5,247 | 4,438 | 809 | 18 | % |
| General and administrative expenses | 1,584 | 1,746 | (162) | (9) | % |
| Total operating expenses | 6,831 | 6,184 | 647 | 10 | % |
| Loss from operations | (6,831) | (6,184) | (647) | 10 | % |
| Change in fair value of common stock warrant liability | 17,840 | (1,435) | 19,275 | (1,343) | % |
| Interest and other income, net | 92 | 33 | 59 | 179 | % |
| Net loss | \$11,101 | \$(7,586) | \$18,687 | (246) | % |

Total Operating Expenses. Total operating expenses for the three months ended September 30, 2018 were \$6.8 million compared to \$6.2 million for the three months ended September 30, 2017, an increase of \$0.6 million, or 10%. This increase was primarily due to increased research and development expenses pertaining to our PAH and PH-ILD clinical trials.

Research and Development Expenses. Total research and development expenses for the three months ended September 30, 2018 were \$5.2 million compared to \$4.4 million for the three months ended September 30, 2017, an increase of \$0.8 million, or 18%. Total research and development expenses consisted of the following:

- PAH research and development expenses were \$2.0 million for the three months ended September 30, 2018, compared to \$1.6 million for the three months ended September 30, 2017, an increase of \$0.4 million, or 23%. The increase was primarily driven by increased spending and closeout costs in our PAH Phase 3 trial following the DMC's interim analysis and our subsequent discontinuation of the trial in August 2018.
- PH-ILD and PH-COPD expenses for the three months ended September 30, 2018 were \$0.6 million. The expenses for the three months ended September 30, 2017 were de minimis. The increase was primarily due to increased spending on the PH-ILD Phase 2b trial.
- Drug and delivery system costs were \$1.2 million for the three months ended September 30, 2018, compared to \$1.3 million for the three months ended September 30, 2017, a decrease of \$0.1 million, or (7)%. Drug and delivery system costs are recorded at the time of procurement from our suppliers.

General and Administrative Expenses. General and administrative expenses were \$1.6 million for the three months ended September 30, 2018, compared to \$1.7 million for the three months ended September 30, 2017, a decrease of \$0.1 million, or (9)%. The decrease was primarily due to stock based compensation expenses.

Change in fair value of common stock warrant liability. Change in fair value of common stock warrant liability for the three months ended September 30, 2018 was an income of \$17.8 million, compared to an expense of \$(1.4) million for the

three months ended September 30, 2017. The warrants were issued in November 2016 and May 2017 and the change in the liability fair value was primarily due to a change in our stock price.

Comparison of Nine Months Ended September 30, 2018 and 2017

The following table summarizes our results of operations for the nine months ended September 30, 2018 and 2017.

| (Dollar amounts in thousands) | Nine Months Ended September 30, 2018 | | \$ Change | % Change | |
|--|--------------------------------------|------------|-----------|----------|----|
| | 2018 | 2017 | | | |
| Research and development expenses: | | | | | |
| PAH | \$6,356 | \$4,333 | \$2,023 | 47 | % |
| BCM | 26 | 46 | (20) | (43) |)% |
| PH-ILD and PH-COPD | 1,516 | 85 | 1,431 | 1,684 | % |
| Drug and delivery system costs | 4,625 | 3,423 | 1,202 | 35 | % |
| Clinical programs | 12,523 | 7,887 | 4,636 | 59 | % |
| Research and development infrastructure | 3,877 | 3,766 | 111 | 3 | % |
| INOpulse engineering | 1,042 | 811 | 231 | 28 | % |
| Total research and development expenses | 17,442 | 12,464 | 4,978 | 40 | % |
| General and administrative expenses | 5,754 | 4,826 | 928 | 19 | % |
| Total operating expenses | 23,196 | 17,290 | 5,906 | 34 | % |
| Loss from operations | (23,196) | (17,290) | (5,906) | 34 | % |
| Change in fair value of common stock warrant liability | 21,201 | (13,455) | 34,656 | (258) |)% |
| Interest and other income, net | 282 | 86 | 196 | 228 | % |
| Pre-tax loss | (1,713) | (30,659) | 28,946 | (94) |)% |
| Income tax benefit | \$5,439 | \$— | 5,439 | n.a. | |
| Net loss | \$3,726 | \$(30,659) | \$34,385 | (112) |)% |

Total Operating Expenses. Total operating expenses for the nine months ended September 30, 2018 were \$23.2 million compared to \$17.3 million for the nine months ended September 30, 2017, an increase of \$5.9 million, or 34%. This increase was primarily due to increased research and development expenses pertaining to our drug and delivery system expenses and to our PAH and PH-ILD clinical trials.

Research and Development Expenses. Total research and development expenses for the nine months ended September 30, 2018 were \$17.4 million compared to \$12.5 million for the nine months ended September 30, 2017, an increase of \$5.0 million, or 40%. Total research and development expenses consisted of the following:

- PAH research and development expenses were \$6.4 million for the nine months ended September 30, 2018, compared to \$4.3 million for the nine months ended September 30, 2017, an increase of \$2.0 million, or 47%. The increase was primarily driven by increased spending and closeout cost in the PAH Phase 3 trial.
- PH-ILD and PH-COPD expenses were \$1.5 million for the nine months ended September 30, 2018, compared to \$0.1 million for the nine months ended September 30, 2017, an increase of \$1.4 million, or 1,684%. The increase was primarily due to start up fees associated with these programs and due to increased spending on the PH-ILD Phase 2b trial.

•Drug and delivery system costs were \$4.6 million for the nine months ended September 30, 2018, compared to \$3.4 million for the nine months ended September 30, 2017, an increase of \$1.2 million, or 35%. The increase was driven by the utilization of additional cartridges for the PAH Phase 3 and our PH-ILD Phase 2b trials.

General and Administrative Expenses. General and administrative expenses were \$5.8 million for the nine months ended September 30, 2018, compared to \$4.8 million for the nine months ended September 30, 2017, an increase of \$0.9

million, or 19%. The increase was primarily due to commercial, intellectual property and financial consulting expenses and stock based compensation expenses.

Income Tax Benefit. Income tax benefit for the nine months ended September 30, 2018 was \$5.4 million compared to zero for the nine months ended September 30, 2017. The benefit in the nine months ended September 30, 2018 was from the sale of \$61.5 million of state NOLs and \$0.2 million of research and development credits under the State of New Jersey's Technology Business Tax Certificate Transfer Program for net proceeds of \$5.3 million.

Change in fair value of common stock warrant liability. Change in fair value of common stock warrant liability for the nine months ended September 30, 2018 was income of \$21.2 million, compared to an expense of \$(13.5) million for the nine months ended September 30, 2017. The warrants were issued in November 2016 and May 2017 and the change in the liability fair value was primarily due to a change in our stock price and the timing of the warrants' issuance.

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 \$19.6 million and marketable securities of \$1.0 million as of September 30, 2018. Our existing cash and cash equivalents and marketable securities as of September 30, 2018 will be used primarily to complete the first cohort and partially complete additional cohorts of the ongoing Phase 2b trial of INOpulse for PH-ILD and to fund the closeout activities, expected to be completed in the fourth quarter of 2018, of the Phase 3 trial for PAH following our discontinuation of the trial based on the DMC's recommendation in August 2018. We expect to report top-line results for cohort 1 of the Phase 2b trial of INOpulse for PH-ILD during the first quarter of 2019.

On May 9, 2017, we entered into a Securities Purchase Agreement, or the Purchase Agreement, under the shelf registration statement, with a single institutional 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 became 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, we issued to 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.

On September 26, 2017, we entered into a Securities Purchase Agreement, or the PIPE Purchase Agreement, pursuant to which we sold an aggregate of 19,449,834 shares of our common stock at a purchase price of \$1.205 per share and warrants to purchase up to an aggregate of 19,449,834 shares of our common stock, or the PIPE Offering. The warrants became exercisable commencing six months from the issuance date at an exercise price equal to \$1.2420 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. The closing of the sales of these securities under the PIPE Purchase Agreement occurred on September 29, 2017. The aggregate gross and net proceeds for the PIPE Offering were \$23.4 million and \$22.8 million, respectively.

The shelf registration statement that was filed in May 2016 was replaced by a new shelf registration statement on Form S-3 which became effective on July 6, 2018. The new shelf registration allows us to issue, from time to time at prices and on terms to be determined prior to the time of any such offering, up to \$100 million of any combination of common stock, preferred stock, debt securities, warrants and rights, either individually or in units.

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 September 30, 2018 may 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. Our ability to continue as a going concern is related to the further implementation of our current business plan. Advances and changes in our business plans and clinical programs may offer alternative utilization of our capital resources including shifting resources between programs as well as various strategic financing opportunities. We continue to pursue potential sources of funding, including equity financing. Our ability to access funding in any form is not assured and is likely to be influenced by the results of our ongoing Phase 2b trial of INOpulse for PH-ILD and our other ongoing and planned clinical trials.

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 may not be able to accurately 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.

Cash Flows

The following table summarizes our cash flows for the nine months ended September 30, 2018 and 2017:

| (Dollar amounts in thousands) | Nine Months Ended | |
|--|--------------------|--------------------|
| | September 30, 2018 | September 30, 2017 |
| Operating activities | \$(11,436) | \$(11,399) |
| Investing activities | 2,000 | 2,393 |
| Financing activities | 168 | 26,679 |
| Net change in cash, cash equivalents and restricted cash | \$(9,268) | \$17,673 |

Net Cash Used in Operating Activities

Cash used in operating activities for the nine months ended September 30, 2018 and September 30, 2017 was \$11.4 million. The cash used in operating activities was primarily used to fund our PAH Phase 3 and PH-ILD Phase 2b clinical trials.

Net Cash Provided by Investing Activities

Cash provided by investing activities for the nine months ended September 30, 2018 was \$2.0 million compared to \$2.4 million for the nine months ended September 30, 2017 due to reduced proceeds from the sale of marketable securities partially offset by purchases of marketable securities for the nine months ended September 30, 2017.

Net Cash Provided by Financing Activities

Cash provided by financing activities for the nine months ended September 30, 2018 was \$0.2 million compared to \$26.7 million for the nine months ended September 30, 2017 which included the proceeds from the September 2017 PIPE Offering, the May 2017 Direct Offering and warrant exercises partially offset by the payment of issuance costs related to the 2016 secondary offering.

Contractual Obligations and Commitments

There were no material changes in our outstanding contractual obligations from those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2017.

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

During the nine months ended September 30, 2018, 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, 2017.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risk related to changes in interest rates. As of September 30, 2018, we had cash and cash equivalents of \$19.6 million, consisting primarily of demand deposits with U.S. banking institutions and marketable securities of \$1.0 million. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in cash and cash equivalents, federally insured certificates of deposit and corporate or agency bonds rated A or better. Due to the nature of our deposits and the low risk profile of our investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our deposits.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2018. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2018, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal quarter ended September 30, 2018 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 5. Other Information.

None.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

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

Item 1A. Risk Factors.

Other than as set forth below, there have been no material changes to our risk factors contained in our Annual Report on Form 10-K for the year ended December 31, 2017. 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, 2017.

We are currently dependent on the results of INOpulse for PH-ILD, PH-COPD and PH-Sarcoidosis, which are the subject of our ongoing and planned clinical trials. We cannot be certain that we will be able to successfully develop or obtain regulatory approval for INOpulse for PH-ILD or any other product candidate.

Because we recently discontinued our Phase 3 clinical trial of INOpulse for PAH, we are currently dependent on the results of INOpulse for PH-ILD, PH-COPD and PH-Sarcoidosis which are the subject of our ongoing and planned clinical trial. In the event that our ongoing and planned clinical trials results are not positive, we may have to cease all further development's activities for our product candidates and implement operating cost reductions and organizational restructuring to preserve our cash resources while we seek a strategic alternative. We currently have no drug products for sale and may never be able to develop marketable drug products. Our ability to access funding in any form is likely to be influenced by the results of our ongoing Phase 2b trial of INOpulse for PH-ILD and our other ongoing and planned clinical trials, which are not under our control. If access to additional funding is not achieved on a timely basis or at all, it would materially harm our business and financial condition.

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.

Exhibit Index

| Exhibit Number | Description |
|----------------|---|
| <u>3.1</u> | <u>Restated Certificate of Incorporation of Bellerophon Therapeutics, Inc., as amended, dated July 30, 2018.</u> |
| <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 |

SIGNATURES

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

BELLEROPHON
THERAPEUTICS, INC.

Date: November 7, 2018 By: /s/ Fabian Tenenbaum
Fabian Tenenbaum
Chief Executive Officer
(Principal Executive Officer)

Date: November 7, 2018 By: /s/ Assaf Korner
Assaf Korner
Chief Financial Officer
(Principal Financial Officer)