

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, 2019**

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

(State or other jurisdiction of
incorporation or organization)

47-3116175

(I.R.S. Employer
Identification No.)

184 Liberty Corner Road, Suite 302
Warren, New Jersey

(Address of principal executive offices)

07059

(Zip Code)

(908) 574-4770

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.01 par value per share	BLPH	The Nasdaq Capital Market

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, a smaller reporting company, or an emerging growth 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.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

If an emerging growth company, indicate by 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 5, 2019: 68,906,765

TABLE OF CONTENTS

	<u>Page No.</u>
PART I. FINANCIAL INFORMATION	<u>6</u>
Item 1. Financial Statements	<u>6</u>
Condensed Consolidated Balance Sheets as of September 30, 2019 (Unaudited) and December 31, 2018	<u>6</u>
Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2019 and 2018 (Unaudited)	<u>7</u>
Condensed Consolidated Statements of Comprehensive (Loss) Income for the three and nine months ended September 30, 2019 and 2018 (Unaudited)	<u>8</u>
Condensed Consolidated Statement of Changes in Stockholders' Equity for the three and nine months ended September 30, 2019 and 2018 (Unaudited)	<u>9</u>
Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2019 and 2018 (Unaudited)	<u>10</u>
Notes to Condensed Consolidated Financial Statements (Unaudited)	<u>11</u>
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	<u>22</u>
Item 3. Quantitative and Qualitative Disclosures About Market Risk	<u>32</u>
Item 4. Controls and Procedures	<u>32</u>
PART II. OTHER INFORMATION	<u>33</u>
Item 1. Legal Proceedings	<u>33</u>
Item 1A. Risk Factors	<u>33</u>
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	<u>33</u>
Item 3. Defaults Upon Senior Securities	<u>33</u>
Item 4. Mine Safety Disclosures	<u>33</u>
Item 5. Other Information	<u>33</u>
Item 6. Exhibits	<u>33</u>
Signatures	<u>34</u>

REFERENCES TO BELLEROPHON

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

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Quarterly Report on Form 10-Q, including statements regarding our future results of operations and financial position, business strategy and plans and objectives of management for future operations, are forward-looking statements. The words “may,” “will,” “should,” “expects,” “plans,” “anticipates,” “could,” “intends,” “target,” “projects,” “contemplates,” “believes,” “estimates,” “predicts,” “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, 2018, particularly in the “Risk Factors” section, that could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

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

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

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements.

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

	As of September 30, 2019	As of December 31, 2018
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 12,838	\$ 16,645
Restricted cash	102	101
Prepaid expenses and other current assets	712	650
Total current assets	13,652	17,396
Restricted cash, non-current	300	300
Right of use assets, net	2,256	—
Property and equipment, net	401	664
Total assets	\$ 16,609	\$ 18,360
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 2,264	\$ 2,755
Accrued research and development	2,581	3,771
Accrued expenses	1,488	1,013
Current portion of operating lease liabilities	647	—
Total current liabilities	6,980	7,539
Long term operating lease liabilities	\$ 1,828	\$ —
Common stock warrant liability	452	6,965
Total liabilities	9,260	14,504
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.01 par value per share; 200,000,000 shares authorized and 68,906,765 and 58,679,492 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	689	587
Preferred stock, \$0.01 par value per share; 5,000,000 shares authorized, zero shares issued and outstanding at September 30, 2019 and December 31, 2018	—	—
Additional paid-in capital	192,343	179,765
Accumulated deficit	(185,683)	(176,496)
Total stockholders' equity	7,349	3,856
Total liabilities and stockholders' equity	\$ 16,609	\$ 18,360

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

BELLEROPHON THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)

(in thousands except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Operating expenses:				
Research and development	\$ 3,259	\$ 5,247	\$ 8,193	\$ 17,442
General and administrative	1,332	1,584	4,965	5,754
Total operating expenses	4,591	6,831	13,158	23,196
Loss from operations	(4,591)	(6,831)	(13,158)	(23,196)
Change in fair value of common stock warrant liability	215	17,840	2,504	21,201
Warrant amendment charge	—	—	(674)	—
Interest and other income, net	89	92	340	282
Pre-tax (loss) income	(4,287)	11,101	(10,988)	(1,713)
Income tax benefit	—	—	1,801	5,439
Net (loss) income	\$ (4,287)	\$ 11,101	\$ (9,187)	\$ 3,726
Weighted average shares outstanding:				
Basic	68,303,027	57,710,251	67,229,585	57,356,445
Diluted	68,303,027	64,544,504	67,229,585	65,854,903
Net (loss) income per share:				
Basic	\$ (0.06)	\$ 0.19	\$ (0.14)	\$ 0.06
Diluted	\$ (0.06)	\$ (0.10)	\$ (0.14)	\$ (0.27)

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

BELLEROPHON THERAPEUTICS, INC.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Net (loss) income	\$ (4,287)	\$ 11,101	\$ (9,187)	\$ 3,726
Other comprehensive income				
Unrealized gain on available-for-sale marketable securities	—	2	—	3
Total other comprehensive income	—	2	—	3
Comprehensive (loss) income	<u>\$ (4,287)</u>	<u>\$ 11,103</u>	<u>\$ (9,187)</u>	<u>\$ 3,729</u>

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)

For the three and nine months ended September 30, 2019:

	Common Stock		Additional Paid in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
June 30, 2019	68,906,765	\$ 689	\$ 192,169	\$ (181,396)	\$ 11,462
Net loss	—	—	—	(4,287)	(4,287)
Stock-based compensation	—	—	174	—	174
September 30, 2019	68,906,765	\$ 689	\$ 192,343	\$ (185,683)	\$ 7,349
December 31, 2018	58,679,492	\$ 587	\$ 179,765	\$ (176,496)	\$ 3,856
Net loss	—	—	—	(9,187)	(9,187)
Warrant amendment	—	—	4,683	—	4,683
Public offering	10,000,000	100	6,136	—	6,236
Stock-based compensation	227,273	2	1,759	—	1,761
September 30, 2019	68,906,765	\$ 689	\$ 192,343	\$ (185,683)	\$ 7,349

For the three and nine months ended September 30, 2018:

	Common Stock		Additional Paid in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
June 30, 2018	57,765,304	\$ 578	\$ 178,335	\$ (3)	\$ (186,685)	\$ (7,775)
Net income	—	\$ —	\$ —	\$ —	\$ 11,101	\$ 11,101
Other comprehensive income	—	\$ —	\$ —	\$ 2	\$ —	\$ 2
Warrant exercises	33,333	\$ —	\$ 95	—	—	\$ 95
Stock-based compensation	880,855	\$ 9	\$ 495	\$ —	\$ —	\$ 504
September 30, 2018	58,679,492	\$ 587	\$ 178,925	\$ (1)	\$ (175,584)	\$ 3,927
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,	
	2019	2018
Cash flows from operating activities:		
Net (loss) income	\$ (9,187)	\$ 3,726
Adjustments to reconcile net (loss) income to net cash used in operating activities:		
Change in fair value of common stock warrant liability	(2,504)	(21,201)
Warrant amendment charge	674	—
Stock based compensation	1,761	2,115
Depreciation	263	271
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(62)	1,621
Other non-current assets	—	10
Accounts payable, accrued research and development, and accrued expenses	(987)	2,023
Net cash used in operating activities	(10,042)	(11,435)
Cash flows from investing activities:		
Proceeds from sale of marketable securities	—	2,001
Net cash provided by investing activities	—	2,001
Cash flows from financing activities:		
Proceeds from sale of Units in PIPE Offering, net of offering expenses	—	(28)
Proceeds received from exercise of warrants	—	190
Proceeds from issuance of common stock in Public Offering	6,236	—
Proceeds received from exercise of stock options	—	4
Net cash provided by financing activities	6,236	166
Net change in cash, cash equivalents and restricted cash	(3,806)	(9,268)
Cash, cash equivalents and restricted cash at beginning of period	17,046	29,375
Cash, cash equivalents and restricted cash at end of period	<u>\$ 13,240</u>	<u>\$ 20,107</u>
Non-cash financing activities:		
Conversion of warrant liability to common stock upon exercise of warrants	\$ —	\$ 483
Reclassification of warrant liability to equity on amendment of warrant agreements	\$ 4,009	\$ —
New right of use asset and operating lease	\$ 322	\$ —

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 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 (loss) income 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, 2018, included in the Company's Annual Report on Form 10-K for the year ended December 31, 2018. The results of operations for the three and nine months ended September 30, 2019 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 right of use assets and operating lease liabilities, 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) Research and Development Expense

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

(g) Recently Issued Accounting Pronouncements

Adopted

In February 2016, the FASB issued ASU No. 2016-02, "Leases" (ASU 2016-02) which along with subsequent ASUs, was codified as Accounting Standards Codification 842 (ASC 842) and provides accounting guidance for both lessee and lessor accounting models. The new standard became effective for the Company on January 1, 2019. The Company adopted the standard using the effective date method at the beginning of the year in which the new lease standard is adopted, rather than to the earliest comparative period presented in their financial statements. The recognition of lease liabilities and corresponding ROU assets had a material impact on our consolidated balance sheet. Upon adoption, as of January 1, 2019, we recognized a \$2.6 million operating lease liability and a \$2.3 million ROU asset. The adoption of this standard did not have a material impact on the Company's consolidated statements of operations, stockholders' equity or cash flows.

Not Yet Adopted

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. The Company expects to continue to incur significant expenses and operating losses for the foreseeable future as it continues to develop, conduct clinical trials and seek regulatory approval for, its product candidates. The Company's primary uses of capital are, and it expects will continue to be, compensation and related expenses, third-party clinical research and development services, contract manufacturing services, laboratory and related supplies, clinical costs, legal and other regulatory expenses and general overhead costs.

The Company had cash and cash equivalents of \$12.8 million as of September 30, 2019. The Company's existing cash and cash equivalents as of September 30, 2019 will be used primarily to complete the Phase 2b trial of INOpulse for PH-ILD and to complete the dose escalation study for PH-Sarc. The Company expects to complete these trials during the fourth quarter of 2019.

On June 25, 2018, the Company filed a shelf registration statement on Form S-3 with the SEC, which became effective on July 6, 2018. The shelf registration 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 common stock, preferred stock, debt securities, warrants and rights, either individually or in units.

On January 25, 2019, the Company completed the sale of 10,000,000 shares of its common stock at a public offering price of \$0.70 per share, resulting in net proceeds of \$6.2 million, after deducting placement fees of \$0.5 million and other offering costs of \$0.3 million. Such shares were sold pursuant to the Company's effective shelf registration statement on Form S-3.

The Company has 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 and the Company's current plans, management believes that the Company's existing cash and cash equivalents as of September 30, 2019 and proceeds expected to become available upon the sale of state net operating losses, or NOLs, and research and development (R&D) tax credits under the State of New Jersey's Technology Business Tax Certificate Transfer Program 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 continue as a going concern is related to the further implementation of its current business plan. Advances and changes in the Company's business plans and clinical programs may offer alternative utilization of its capital resources including shifting resources between programs as well as various strategic financing opportunities. The Company continues to pursue potential sources of funding, including equity financing.

The State of New Jersey's Technology Business Tax Certificate Transfer Program enables qualified, unprofitable New Jersey based technology or biotechnology companies to sell a percentage of NOL and R&D tax credits to unrelated profitable corporations, subject to meeting certain eligibility criteria. Based on consideration of various factors, including application processing time and past trend of benefits made available under the program, the Company believes that it is probable that its plans to sell its NOLs can be effectively implemented to address its short term financial needs. The Company has sold \$61.5 million of its 2015 and 2016 state NOLs and \$0.2 million of its 2016 Research and Development credits under the State of New Jersey's Technology Business Tax Certificate Transfer Program in February 2018 for net proceeds of \$5.3 million and has sold an additional \$20.0 million of its 2017 state NOLs for net proceeds of \$1.7 million in January 2019. Subject to state approval and program availability, the Company plans to sell additional NOLs and credits under the same program later in 2019 or early 2020. The proceeds from such sales are recorded as Income tax benefit when sales occur or proceeds are received.

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, sales of state NOLs and R&D credits subject to program availability and approval, 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 its 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 or is unable to sell its state NOLs and R&D credits, 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) Leases

The Company has two operating leases in Warren, NJ, one for the use of an office and research facility and a second for the use of a laboratory. The office and research facility lease is for a term of four years with a term date of March 31, 2023, with the Company's right to extend the original term for one period of five years. The laboratory lease is for a term of three years and nine months with a term date of April 30, 2023, with the Company's right to extend the original term for one period of 90 days. The office and research facility as well as the laboratory operating leases are included in "Right of use assets, net" on the Company's September 30, 2019 consolidated balance sheet and represents the Company's right to use the underlying assets for the respective lease term. The Company's obligation to make lease payments are included in "Current portion of operating lease liabilities" and "Long term operating lease liabilities" on the Company's September 30, 2019 consolidated balance sheet. Operating lease expense is recognized on a straight-line basis over the respective lease term.

We do not recognize right of use assets or related lease liabilities with a lease term of twelve months or less on our consolidated balance sheet. Short-term lease costs are recorded in our consolidated statements of operations in the period in which the obligation for those payments was incurred. Short-term lease costs for the three and nine months ended September 30, 2019 were de minimis.

Information related to the Company's right-of-use assets and related lease liabilities were as follows (\$ amounts in thousands):

	Three Months Ended September 30, 2019	Nine Months Ended September 30, 2019
Cash paid for operating lease liability	\$ 171	\$ 496
Operating lease expenses	160	465
Weighted average remaining lease term		3.51 years
Weighted average discount rate		4.94%
Maturities of lease liabilities as of September 30, 2019 were as follows :		
2019		\$ 187
2020		757
2021		770
2022		783
2023		205
		<u>2,702</u>
Less imputed interest		(227)
Total operating lease liabilities		<u>2,475</u>

Rent expense for the three and nine months ended September 30, 2018 were \$0.2 million and \$0.5 million, respectively.

(5) Common Stock Warrants and Warrant Liability

On November 29, 2016, the Company issued warrants to purchase 17,142,858 shares (the "2016 Warrants") that were immediately exercisable and set to expire five years from issuance at an exercise price of \$0.80 per share. On June 28, 2019, the Company entered into a warrant amendment (the "Warrant Amendment") with certain holders (the "Holders") of 12,598,572 of the 2016 Warrants to purchase shares. Pursuant to the Warrant Amendment, the Company and the Holders have agreed to eliminate provisions that had previously precluded equity classification treatment on the Company's balance sheets. In consideration of such amendment, the 2016 Warrants were extended by two (2) additional years (until November 29, 2023). The difference in fair market value of the warrants before and after the amendment, of \$0.7 million, was recorded in the statement of operations as a warrant amendment charge. The fair market value of the amended warrants was reclassified from warrant liability to stockholders' equity. The balance of the 2016 Warrants that were not amended could require cash settlement under certain circumstances, and therefore continue to be classified as liabilities and to be recorded at estimated fair value using a Black-Scholes-Merton pricing model. As of September 30, 2019, 13,741,180 2016 Warrants were outstanding, of which 12,598,572 were equity classified and 1,142,608 were liability classified.

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, 2019, 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, 2019, all of these warrants were outstanding.

The following table summarizes warrant activity for the nine months ended September 30, 2019 (fair value amount in thousands):

	Equity Classified	Liability Classified	
	Warrants	Warrants	Estimated Fair Value
Warrants outstanding as of December 31, 2018	19,449,834	14,801,180	\$ 6,965
Reclassification of warrants to equity on amendment of warrant agreements	12,598,572	(12,598,572)	(4,009)
Change in fair value of common stock warrant liability recognized in consolidated statement of operations	—	—	(2,504)
Warrants outstanding as of September 30, 2019	32,048,406	2,202,608	\$ 452

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

	Equity Classified	Liability Classified	
	Warrants	Warrants	Estimated Fair Value
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

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, 2019 for liabilities measured at fair value on a recurring basis (in thousands):

	Level 1	Level 2	Level 3	Total
Common stock warrant liability	—	—	452	452

The following table summarizes fair value measurements by level at December 31, 2018 for liabilities measured at fair value on a recurring basis (in thousands):

	Level 1	Level 2	Level 3	Total
Common stock warrant liabilities	—	—	6,965	6,965

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 considers comparable public companies as a basis for its expected volatility to calculate the fair value of common stock warrants and transitions to its own volatility as the Company develops sufficient appropriate 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, 2019 and December 31, 2018:

	September 30, 2019	December 31, 2018
Valuation assumptions:		
Risk-free interest rate	1.58%	2.45%
Expected volatility	101.55%	93.61%
Expected term (in years)	2.6	3.0
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 of options. Following the effectiveness of the Company's registration statement filed in connection with its initial public offering, no options may be granted under the 2014 plan. The awards granted under the 2014 Plan generally have a vesting period of 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. On May 14, 2019, the Company's stockholders approved an additional amendment to the 2015 Plan to increase the aggregate number of shares reserved for issuance under the 2015 plan from 5,000,000 to 12,500,000.

As of September 30, 2019, the Company had 7,081,719 shares available for grant under the 2015 Plan.

As of September 30, 2019, there was approximately \$3.3 million of total unrecognized compensation expense related to unvested stock awards. This expense is expected to be recognized over a weighted-average period of 2.8 years.

No tax benefit was recognized during the three and nine months ended September 30, 2019 and 2018 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 values of options issued during the nine months ended September 30, 2019 and 2018 were \$0.52 and \$1.55, respectively. The following are the weighted average assumptions used in estimating the fair values of options issued during the nine months ended September 30, 2019 and 2018:

	Nine Months Ended September 30, 2019	Nine Months Ended September 30, 2018
Valuation assumptions:		
Risk-free rate	1.67%	2.50%
Expected volatility	86.02%	89.13%
Expected term (years)	6.0	5.98
Dividend yield	—	—

A summary of option activity under the 2015 and 2014 Plans for the nine months ended September 30, 2019 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, 2018	6,769,232	\$ 0.49	-	13.28	\$ 2.16	8.6
Granted	3,323,813	0.50	-	0.88	0.52	
Expired	(1,995)	12.00	-	12.00	12.00	
Forfeited	(129,919)	0.49	-	12.00	2.39	
Options outstanding as of September 30, 2019	9,961,131	\$ 0.49	-	13.28	\$ 1.61	8.5
Options vested and exercisable as of September 30, 2019	3,020,986	\$ 0.49	-	13.28	\$ 3.48	7.2

The intrinsic value of options outstanding, vested and exercisable as of September 30, 2019 was zero.

Restricted Stock

All restricted stock awards granted under the 2015 Plan during the nine months ended September 30, 2019 were in relation to director compensation and vested in full on the grant date.

A summary of restricted stock activity under the 2015 Plan for the nine months ended September 30, 2019 is presented below:

	Bellerophon 2015 Equity Incentive Plan			
	Shares	Weighted Average Fair Value	Aggregate Grant Date Fair Value (in millions)	Weighted Average Remaining Contractual Life (in years)
Restricted stock outstanding as of December 31, 2018	965,618	\$ 1.23	\$ 1.2	0.3
Granted	227,273	0.88	0.2	
Vested	(589,153)	(1.26)	(0.7)	
Restricted stock outstanding as of September 30, 2019	603,738	\$ 1.07	\$ 0.6	0.1

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, 2019, is presented below:

	Ikaria Equity Incentive Plans			
	Options	Range of Exercise Price	Weighted Average Price	Weighted Average Remaining Contractual Life (in years)
Options outstanding as of December 31, 2018	69,619	\$ 7.77 - 17.92	\$ 9.12	3.2
Expired	(5,588)	17.92 - 17.92	17.92	
Forfeited	(11,055)	7.77 - 14.91	8.66	
Options outstanding as of September 30, 2019	<u>52,976</u>	<u>\$ 7.77 - 14.91</u>	<u>\$ 8.28</u>	<u>2.6</u>
Options vested and exercisable as of September 30, 2019	<u>52,976</u>	<u>\$ 7.77 - 14.91</u>	<u>\$ 8.28</u>	<u>2.6</u>

The intrinsic value of options outstanding, vested and exercisable as of September 30, 2019 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, 2019 and 2018 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Research and development	\$ 84	\$ 87	\$ 591	\$ 469
General and administrative	90	417	1,170	1,646
Total expense	<u>\$ 174</u>	<u>\$ 504</u>	<u>\$ 1,761</u>	<u>\$ 2,115</u>

(8) Income Taxes

Excluding the impact of the sale of state net operating losses and research and development credits during the first quarter of 2019 and 2018, the effective tax rate for each of the three and nine months ended September 30, 2019 and 2018 was 0.0% which was lower than the federal statutory rate primarily due to the losses incurred and the full valuation allowance on deferred tax assets.

The Company's estimated tax rate for 2019 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 January 2019, the Company sold \$20.0 million of its 2017 state NOLs for net proceeds of \$1.7 million under the State of New Jersey's Technology Business Tax Certificate Transfer Program, which resulted in the reversal of the valuation allowance and a tax benefit of \$1.8 million for the nine months ended September 30, 2019. In February 2018, the Company sold \$61.5 million of its 2015 and 2016 state NOLs and \$0.2 million of its 2016 research and development credits under the same 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. Subject to state approval, the Company plans to sell additional

NOLs and credits under the same program in 2019 as well. The proceeds from such sales are recorded as Income tax benefit when sales occur or proceeds are received.

As of September 30, 2019, 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 (Loss) Income Per Share

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Net (loss) income	\$ (4,287)	\$ 11,101	\$ (9,187)	\$ 3,726
Weighted-average shares:				
Basic	68,303,027	57,710,251	67,229,585	57,356,445
Effect of dilutive securities:				
Warrants	—	6,834,253	—	8,498,458
Diluted	68,303,027	64,544,504	67,229,585	65,854,903
Net (loss) income per share:				
Basic	\$ (0.06)	\$ 0.19	\$ (0.14)	\$ 0.06
Diluted	\$ (0.06)	\$ (0.10)	\$ (0.14)	\$ (0.27)

For the three and nine months ended September 30, 2019, 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 44.9 million which include 10.0 million options to purchase shares, 0.6 million restricted shares and 34.3 million warrants to purchase shares.

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.

Basic net (loss) income per share is calculated by dividing net (loss) income by the weighted average number of shares outstanding during the period, as applicable. Diluted net loss per share is calculated by dividing net (loss) income, 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, 2018 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 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.

In 2016, we began developing INOpulse for the treatment of pulmonary hypertension associated with interstitial lung disease (PH-ILD), which includes PH associated with idiopathic pulmonary fibrosis (PH-IPF) as well as other pulmonary fibrosing diseases. During May 2017, we announced the completion of our Phase 2 clinical trial using INOpulse therapy to treat PH-IPF. The clinical data showed that INOpulse was associated with clinically meaningful improvements in hemodynamics and exercise capacity in difficult-to-treat PH-IPF patients. The PH-IPF 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 clinical trial 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 showed consistent benefit in hemodynamics with a clinically meaningful average reduction of 14% in systolic pulmonary arterial pressure (sPAP) with acute exposure to iNO. The study assessed both the iNO 75 and iNO 30 dose, supporting iNO 30 as a potentially safe and efficacious dose. During August 2017, we announced Food and Drug Administration ("FDA") acceptance of our IND for our Phase 2b (iNO-PF) clinical trial 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 higher doses as well as a longer 16 week evaluation period.

In January 2019, we announced top-line results from cohort 1 of our iNO-PF study. The results showed statistically significant improvements in multiple clinically meaningful activity parameters as measured by a wearable medical-grade activity monitor:

- subjects on iNO demonstrated an increase of 8% in moderate activity versus a 26% decrease for subjects on placebo ($p=0.04$);
- subjects on iNO showed no decline in their overall activity levels versus a 12% decline for subjects on placebo ($p=0.05$);

Clinically meaningful improvements were also demonstrated in the following key areas:

- subjects on iNO showed an increase of 15% in NT-ProBNP versus a 42% increase for subjects on placebo (NT-ProBNP is a peptide marker of right ventricular failure, with higher levels indicative of disease worsening);
- subjects on iNO demonstrated improved oxygen saturation by 9% versus a worsening of 11% for placebo.

In addition, iNO was well-tolerated with no safety concerns supporting the continuation into cohort 2.

In April 2019, we announced that we reached an agreement with the FDA on modifying the ongoing Phase 2b trial into a Phase 2/3 trial, with cohort 3 serving as the pivotal study, as well as an agreement on the primary endpoint of change in moderate to vigorous activity from baseline to week 16, measured by Actigraphy. Actigraphy (medical wearable continuous activity monitoring) provides highly sensitive objective real-world physical activity data that correlates to clinically meaningful patient functional abilities and health outcomes. In addition to the primary endpoint, we are currently utilizing Actigraphy to evaluate multiple clinically meaningful activity parameters in the iNO-PF study. Actigraphy is currently being utilized as the primary endpoint in multiple late-stage clinical programs in various cardiopulmonary diseases such as heart failure and COPD.

In May 2019, we presented additional positive data from cohort 1 at the American Thoracic Society 115th International Conference:

- 23% of subjects on iNO had a clinically significant improvement in Moderate to Vigorous Physical Activity (MVPA), compared to 0% of subjects on placebo. This represents a placebo corrected difference of 23% - a clinically significant improvement is > 15% increase in MVPA from baseline;
- 39% of subjects on iNO had a clinically significant decline in MVPA, compared to 71% of subjects on placebo. This represents a placebo corrected difference of 32% - a clinically significant improvement is >15% decrease in MVPA from baseline;
- Proportion of awake time spent in MVPA improved by 38% (16% increase on iNO vs. 22% decrease on placebo; p=0.04);
- Calorie expenditure improved by 12% (6% decrease on iNO vs. 18% decrease on placebo; p=0.05);
- Subjects on open-label extension demonstrated consistent improvements in MVPA and overall activity, with subjects transitioning from placebo to open-label experiencing a reversal from worsening to improving.

In August 2019, we announced that we completed enrollment of 44 patients and randomized the last patient into cohort 2 of our iNO-PF study. We anticipate to complete cohort 2 in the fourth quarter of 2019 and to initiate the phase 3 cohort in the first quarter of 2020.

In September 2019, we announced that that we received an Orphan Drug Designation for nitric oxide for the treatment of IPF. Orphan drug designation provides us access to various development incentives, including tax credits for qualified clinical trial expenditures and waivers for certain FDA user fees. Orphan Drug Designation also provides up to seven years of marketing exclusivity if regulatory approval is received.

In October 2019, we presented additional positive responder analysis data from cohort 1, as well as new long-term results for subjects on open-label extension (OLE) at the American College of Chest Physicians Conference:

- Responder analysis:
 - 85% of subjects on placebo declined in MVPA, overall activity and non-sedentary activity;
 - 46% of subjects on INOpulse improved in MVPA, 62% in overall activity and 39% in non-sedentary activity (compared to only 15% of subjects on placebo in each category).
- OLE:
 - Collectively, subjects (with an average of 27 weeks of OLE data) demonstrated maintenance of MVPA, overall activity and non-sedentary activity;
 - Subjects randomized to active treatment in the blinded portion of the trial continued to maintain their activity levels when transitioning to OLE over 27 weeks of open-label treatment;
 - Subjects randomized to placebo in the blinded portion of the trial transitioned from a decline during blinded treatment to stabilization of activity levels (MVPA, overall activity and non-sedentary activity) over 27 weeks of open-label treatment.

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. The results from this trial showed that iNO 30 was a potentially safe and effective dose for treatment of PH-COPD. Based on the results of this trial, we completed further Phase 2 testing to assess the targeted vasodilation provided by INOpulse in this patient population. We presented the results of this trial in September 2015 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." During September 2017, we shared the 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. The trial showed a statistically significant increase (average 4.2%) in blood vessel volume on iNO compared to baseline (p=0.03), and a statistically significant correlation in Ventilation-Vasodilation (p=0.01). The chronic results demonstrated a statistically significant and clinically meaningful increase in 6MWD of 50.7m (p=0.04) as well as a decrease of 19.9% in systolic pulmonary arterial pressure (p=0.02), as compared to baseline. The therapy was well tolerated with no related safety concerns. In May 2018, we announced that the FDA concurred with the design of our planned Phase 2b study of INOpulse for treatment of PH-COPD. The study will assess the effect of INOpulse on various parameters including exercise capacity, right ventricular function and oxygen saturation, as well as other composite endpoints. We are currently evaluating alternatives for the funding and timing of this program.

We also initiated development of INOpulse for the treatment of PH associated with Sarcoidosis (PH-Sarc). The study is a Phase 2a dose escalation design that will utilize right heart catheterization to assess the hemodynamic effect of INOpulse from a dose of iNO 30 to iNO 125 in PH-Sarc subjects, with results expected in the fourth quarter of 2019.

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 INOpulse provided clinically meaningful improvements in pulmonary vascular resistance (18%), cardiac output (0.7 L/min) and NT Pro-BNP. In addition, subjects on PAH background mono-therapy showed a 23 meter improvement in 6MWD, while subjects that were not on prostanoid background therapy showed a 17 meter improvement in 6MWD. 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. The trial results showed 6MWD was improved when subjects were on less background therapies and more patients deteriorated in 6MWD on placebo as compared to iNO. In addition, 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 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.

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 a Phase 3 trial for PH-ILD, potentially advance INOpulse for PH-COPD and PH-Sarc, 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.

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 significantly change the costs and timing associated with the development of that product candidate. For example, if the FDA or another 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 make an assessment of each product candidate's commercial potential, including the likelihood of regulatory approval on a timely basis.

INOpulse for PH-ILD

We initiated our clinical program in PH-ILD in 2016. During May 2017, we announced the completion of our Phase 2 study using INOpulse therapy to treat PH-IPF. After reaching an 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. In January 2019, we announced top-line results from cohort 1 of our iNO-PF study. The results showed statistically significant improvements in multiple clinically meaningful activity parameters as measured by a wearable medical-grade activity monitor. In April 2019, we announced that we reached an agreement with the FDA on modifying the ongoing Phase 2b trial into a Phase 2/3 trial. In August 2019, we announced that we completed enrollment and randomized the last patient into cohort 2 of our iNO-PF study. We anticipate to complete cohort 2 in the fourth quarter of 2019 and to initiate the phase 3 cohort in the first quarter of 2020.

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 an agreement with the FDA on the design of our planned Phase 2b study of INOpulse for treatment of PH-COPD. We are currently evaluating alternatives for the funding and timing of this program.

INOpulse for PH-Sarc

We initiated the development of INOpulse for the treatment of PH-Sarc. The study is a Phase 2a dose escalation design that will utilize right heart catheterization to assess the hemodynamic effect of INOpulse from a dose of iNO 30 to iNO 125 in PH-Sarc subjects, with results expected in the fourth quarter of 2019.

INOpulse for PAH

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 INOpulse provided clinically meaningful improvements in pulmonary vascular resistance (18%), cardiac output (0.7 L/min) and NT Pro-BNP. In addition, subjects on PAH background mono-therapy showed a 23 meter improvement in 6MWD, while subjects that were not on prostanoid background therapy showed a 17 meter improvement in 6MWD. 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 discontinued the trial in August 2018. The trial results showed 6MWD was improved when subjects were on less background therapies and more patients deteriorated in 6MWD on placebo as compared to iNO. In addition, 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.

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. We manufacture and service the INOpulse devices that we are using in our ongoing clinical trials of INOpulse for PH-ILD and PH-Sarc by third party turnkey manufacturers.

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, 2019 and 2018

The following table summarizes our results of operations for the three months ended September 30, 2019 and 2018.

(Dollar amounts in thousands)	Three Months Ended September 30,		\$ Change	% Change
	2019	2018		
Research and development expenses:				
PH-ILD, PH-Sarc and PH-COPD	\$ 1,045	\$ 622	\$ 423	68 %
PAH	3	1,979	(1,976)	(100)%
BCM	—	10	(10)	(100)%
Drug and delivery system costs	501	1,177	(676)	(57)%
Clinical programs	1,549	3,788	(2,239)	(59)%
Research and development infrastructure	1,381	1,056	325	31 %
INOpulse engineering	329	403	(74)	(18)%
Total research and development expenses	3,259	5,247	(1,988)	(38)%
General and administrative expenses	1,332	1,584	(252)	(16)%
Total operating expenses	4,591	6,831	(2,240)	(33)%
Loss from operations	(4,591)	(6,831)	2,240	(33)%
Change in fair value of common stock warrant liability	215	17,840	(17,625)	(99)%
Interest and other income, net	89	92	(3)	(3)%
Net loss (income)	\$ (4,287)	\$ 11,101	\$ (15,388)	(139)%

Total Operating Expenses. Total operating expenses for the three months ended September 30, 2019 were \$4.6 million compared to \$6.8 million for the three months ended September 30, 2018, a decrease of \$2.2 million, or (33)%. This decrease was primarily due to decreased research and development expenses pertaining to our PAH clinical trial, drug and delivery system costs, as well as general and administrative expenses.

Research and Development Expenses. Total research and development expenses for the three months ended September 30, 2019 were \$3.3 million compared to \$5.2 million for the three months ended September 30, 2018, a decrease of \$1.9 million, or (38)%. Total research and development expenses consisted of the following:

- PH-ILD, PH-Sarc and PH-COPD expenses for the three months ended September 30, 2019 were \$1.0 million, compared to \$0.6 million for the three months ended September 30, 2018, an increase of \$0.4 million, or 68%. The increase was primarily due to increased spending on the PH-ILD Phase 2b trial.
- PAH research and development expenses for the three months ended September 30, 2019 were de minimis, compared to \$2.0 million for the three months ended September 30, 2018. The decrease was driven by the discontinuation of our PAH Phase 3 trial in August 2018.
- Drug and delivery system costs were \$0.5 million for the three months ended September 30, 2019, compared to \$1.2 million for the three months ended September 30, 2018, a decrease of \$0.7 million, or (57)%. Drug and delivery system costs are recorded at the time of procurement from our suppliers.
- Research and development infrastructure expenses were \$1.4 million for the three months ended September 30, 2019, compared to \$1.1 million for the three months ended September 30, 2018, an increase of \$0.3 million, or 31%. The increase was primarily driven by clinical operations contractor costs to support our PH-ILD Phase 2b trial, as well as increases in labor cost.
- INOpulse engineering expenses were \$0.3 million for the three months ended September 30, 2019, compared to \$0.4 million for the three months ended September 30, 2018, a decrease of \$0.1 million, or (18)%. The decrease was primarily driven by reduction in consulting expenses.

General and Administrative Expenses. General and administrative expenses were \$1.3 million for the three months ended September 30, 2019, compared to \$1.6 million for the three months ended September 30, 2018, a decrease of \$0.3 million or (16)%. The decrease was primarily due to a reversal of prior year consulting expenses, as well as a decrease in stock based compensation expenses that was partially offset by increases in labor cost.

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, 2019 was a gain of \$0.2 million, compared to a gain of \$17.8 million for the three months ended September 30, 2018. The warrants were issued in November 2016 and May 2017 and the change in the liability fair value was primarily due to fewer liability classified warrants and the change in our stock price.

Comparison of Nine Months Ended September 30, 2019 and 2018

The following table summarizes our results of operations for the nine months ended September 30, 2019 and 2018.

(Dollar amounts in thousands)	Nine Months Ended September 30,			
	2019	2018	\$ Change	% Change
Research and development expenses:				
PH-ILD, PH-Sarc and PH-COPD	\$ 2,436	\$ 1,516	\$ 920	61 %
PAH	98	6,356	(6,258)	(98)%
BCM	—	26	(26)	(100)%
Drug and delivery system costs	1,168	4,625	(3,457)	(75)%
Clinical programs	3,702	12,523	(8,821)	(70)%
Research and development infrastructure	3,627	3,877	(250)	(6)%
INOpulse engineering	864	1,042	(178)	(17)%
Total research and development expenses	8,193	17,442	(9,249)	(53)%
General and administrative expenses	4,965	5,754	(789)	(14)%
Total operating expenses	13,158	23,196	(10,038)	(43)%
Loss from operations	(13,158)	(23,196)	10,038	(43)%
Change in fair value of common stock warrant liability	2,504	21,201	(18,697)	(88)%
Warrant amendment charge	(674)	—	(674)	N/A
Interest and other income, net	340	282	58	21 %
Pre-tax loss	\$ (10,988)	\$ (1,713)	(9,275)	541 %
Income tax benefit	\$ 1,801	\$ 5,439	(3,638)	(67)%
Net loss (income)	\$ (9,187)	\$ 3,726	(12,913)	(347)%

Total Operating Expenses. Total operating expenses for the nine months ended September 30, 2019 were \$13.2 million compared to \$23.2 million for the nine months ended September 30, 2018, a decrease of \$10.0 million, or (43)%. This decrease was primarily due to decreased research and development expenses pertaining to our PAH clinical trial, drug and delivery system costs, as well as general and administrative expenses.

Research and Development Expenses. Total research and development expenses for the nine months ended September 30, 2019 were \$8.2 million compared to \$17.4 million for the nine months ended September 30, 2018, a decrease of \$9.2 million, or (53)%. Total research and development expenses consisted of the following:

- PH-ILD, PH-Sarc and PH-COPD expenses for the nine months ended September 30, 2019 were \$2.4 million, compared to \$1.5 million for the nine months ended September 30, 2018, an increase of \$0.9 million, or 61%. The increase was primarily due to increased spending on the PH-ILD Phase 2b trial.

- PAH research and development expenses for the nine months ended September 30, 2019 were \$0.1 million, compared to \$6.4 million for the nine months ended September 30, 2018, a decrease of \$6.3 million, or (98)%. The decrease was driven by the discontinuation of our PAH Phase 3 trial in August 2018.

- Drug and delivery system costs for the nine months ended September 30, 2019 were \$1.2 million, compared to \$4.6 million for the nine months ended September 30, 2018, a decrease of \$3.4 million, or (75)%. Drug and delivery system costs are recorded at the time of procurement from our suppliers.

- Research and development infrastructure expenses were \$3.6 million for the nine months ended September 30, 2019, compared to \$3.9 million for the nine months ended September 30, 2018, a decrease of \$0.3 million, or (6)%. The decrease was driven primarily by reduction in consulting expenses.

- INOpulse engineering expenses were \$0.9 million for the nine months ended September 30, 2019, compared to \$1.0 million for the nine months ended September 30, 2018, a decrease of \$0.1 million, or (17)%. The decrease was driven primarily by reduction in consulting expenses.

General and Administrative Expenses. General and administrative expenses for the nine months ended September 30, 2019 were \$5.0 million, compared to \$5.8 million for the nine months ended September 30, 2018, a decrease of \$0.8 million, or (14)%. The decrease was primarily due to lower consulting expenses as well as a decrease in stock based compensation expenses.

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, 2019 was a gain of \$2.5 million, compared to a gain of \$21.2 million for the nine months ended September 30, 2018. The warrants were issued in November 2016 and May 2017 and the change in the liability fair value was primarily due to fewer liability classified warrants and the change in our stock price.

Warrant amendment charge. On June 28, 2019, we entered into a warrant amendment (the “Warrant Amendment”) with certain holders (the “Holders”) of the November 2016 warrants to purchase 12,598,572 shares. Pursuant to the Warrant Amendment, we and the Holders agreed to eliminate provisions that had previously precluded equity classification treatment on our balance sheets. In consideration of such amendment, the November 2016 warrants were extended by two (2) additional years (or until November 29, 2023). The difference in fair market value of the warrants before and after the amendment, of \$0.7 million, was recorded in our statement of operations as a warrant amendment charge.

Income Tax Benefit. Income tax benefit for the nine months ended September 30, 2019 was \$1.8 million, compared to \$5.4 million for the nine months ended September 30, 2018, a decrease of \$3.6 million, or (67)%. The benefit for the nine months ended September 2019 was from the sale of \$20.0 million of our 2017 state NOLs under the State of New Jersey’s Technology Business Tax Certificate Transfer Program for net proceeds of \$1.7 million. The benefit for the nine months ended September 30, 2018 was from the sale of \$61.5 million of our 2015 and 2016 state NOLs and \$0.2 million of our 2016 research and development credits under the same program for net proceeds of \$5.3 million.

Liquidity and Capital Resources

In the course of our development activities, we have sustained operating losses. 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 \$12.8 million as of September 30, 2019. Our existing cash and cash equivalents as of September 30, 2019 will be used primarily to complete the Phase 2b trial of INOpulse for PH-ILD and to complete the dose escalation study for PH-Sarc. We expect to complete these trials during the fourth quarter of 2019.

On June 25, 2018, we filed a shelf registration statement on Form S-3 with the SEC, which became effective on July 6, 2018. The 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.

On January 25, 2019, we completed the sale of 10,000,000 shares of our common stock at a public offering price of \$0.70 per share, resulting in net proceeds of \$6.2 million, after deducting placement fees of \$0.5 million and other offering costs of \$0.3 million. Such shares were sold pursuant to our effective shelf registration statement on Form S-3.

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 and our current plans, which are subject to change as discussed below, we believe that our existing cash and cash equivalents as of September 30, 2019 and proceeds expected to become available upon the sale of our state net operating losses, or NOLs, and research and development (R&D) tax credits under the State of New Jersey's Technology Business Tax Certificate Transfer Program 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.

The State of New Jersey's Technology Business Tax Certificate Transfer Program enables qualified, unprofitable New Jersey based technology or biotechnology companies to sell a percentage of NOL and R&D tax credits to unrelated profitable corporations, subject to meeting certain eligibility criteria. Based on consideration of various factors, including application processing time and past trend of benefits made available under the program, we believe that it is probable that our plans to sell our NOLs can be effectively implemented to address our short term financial needs. We have sold \$61.5 million of our 2015 and 2016 state NOLs and \$0.2 million of our 2016 Research and Development credits under the State of New Jersey's Technology Business Tax Certificate Transfer Program in February 2018 for net proceeds of \$5.3 million and have sold an additional \$20.0 million of our 2017 state NOLs for net proceeds of \$1.7 million in January 2019. Subject to state approval and program availability, we plan to sell additional NOLs and credits under the same program later in 2019 or early 2020. The proceeds from such sales are recorded as Income tax benefit when sales occur or proceeds are received.

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 NOLs and R&D credits, subject to program availability and approval, 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 or are unable to sell our state NOLs and R&D credits, 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, 2019 and 2018:

(Dollar amounts in thousands)	Nine Months Ended September 30,	
	2019	2018
Operating activities	\$ (10,042)	\$ (11,435)
Investing activities	—	2,001
Financing activities	6,236	166
Net change in cash, cash equivalents and restricted cash	\$ (3,806)	\$ (9,268)

Net Cash Used in Operating Activities

Cash used in operating activities for the nine months ended September 30, 2019 was \$10.0 million compared to \$11.4 million for the nine months ended September 30, 2018. The decrease in cash used in operating activities was primarily due to a decrease in our operating expenses that was offset by the change in operating assets and liabilities.

Net Cash Provided by Investing Activities

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

Net Cash Provided by Financing Activities

Cash provided by financing activities for the nine months ended September 30, 2019 was \$6.2 million, which included the proceeds from the January 2019 Public Offering. Cash provided by financing activities for the nine months ended September 30, 2018 was \$0.2 million and mainly included proceeds from warrant exercises.

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, 2018.

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 U.S. generally accepted accounting principles. 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, 2019, 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, 2018.

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, 2019, we had cash and cash equivalents of \$12.8 million, consisting primarily of demand deposits with U.S. banking institutions. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in cash and cash equivalents. Due to the 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, 2019. 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, 2019, 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, 2019 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.

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, 2018. 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, 2018.

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

<u>Exhibit Number</u>	<u>Description</u>
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended
32	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

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 6, 2019

By: /s/ Fabian Tenenbaum
Fabian Tenenbaum
Chief Executive Officer
(Principal Executive Officer)

Date: November 6, 2019

By: /s/ Assaf Korner
Assaf Korner
Chief Financial Officer
(Principal Financial Officer)

CERTIFICATION

I, Fabian Tenenbaum, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Bellerophon Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 6, 2019

By: /s/ Fabian Tenenbaum

Fabian Tenenbaum

Chief Executive Officer

(Principal Executive Officer)

CERTIFICATION

I, Assaf Korner, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Bellerophon Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 6, 2019

By: /s/ Assaf Korner
Assaf Korner
Chief Financial Officer
(Principal Financial Officer)

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code), each of the undersigned officers of Bellerophon Therapeutics, Inc., a Delaware corporation (the "Company"), does hereby certify, to such officer's knowledge, that:

- (1) the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2019 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 6, 2019

By: /s/ Fabian Tenenbaum

Fabian Tenenbaum

Chief Executive Officer

(Principal Executive Officer)

Date: November 6, 2019

By: /s/ Assaf Korner

Assaf Korner

Chief Financial Officer

(Principal Financial Officer)