

**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, 2020

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
<b>Common Stock, \$0.01 par value per share</b>	<b>BLPH</b>	<b>The Nasdaq Capital Market</b>

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

Non-accelerated filer

Accelerated filer

Smaller reporting company

Emerging growth company

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 4, 2020: 9,497,777

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## REFERENCES TO BELLEROPHON

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

## 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;
- INOpulse® may prove not to be an effective treatment for COVID-19 or approved for marketing by the FDA;
- 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, 2019, 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, 2020 (Unaudited)	As of December 31, 2019
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 53,970	\$ 9,874
Restricted cash	103	103
Prepaid expenses and other current assets	633	405
<b>Total current assets</b>	<b>54,706</b>	<b>10,382</b>
Restricted cash, non-current	300	300
Right of use assets, net	1,659	2,110
Property and equipment, net	198	316
Other non-current assets	177	—
<b>Total assets</b>	<b>\$ 57,040</b>	<b>\$ 13,108</b>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 3,820	\$ 3,106
Accrued research and development	3,097	2,117
Accrued expenses	1,380	1,703
Current portion of operating lease liabilities	692	658
<b>Total current liabilities</b>	<b>8,989</b>	<b>7,584</b>
Long term operating lease liabilities	1,136	1,659
Common stock warrant liability	1,042	274
<b>Total liabilities</b>	<b>11,167</b>	<b>9,517</b>
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.01 par value per share; 200,000,000 shares authorized and 9,497,777 and 4,580,127 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	95	46
Preferred stock, \$0.01 par value per share; 5,000,000 shares authorized, zero shares issued and outstanding at September 30, 2020 and December 31, 2019	—	—
Additional paid-in capital	252,264	193,308
Accumulated deficit	(206,486)	(189,763)
<b>Total stockholders' equity</b>	<b>45,873</b>	<b>3,591</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 57,040</b>	<b>\$ 13,108</b>

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,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	\$ 6,065	\$ 3,259	\$ 11,754	\$ 8,193
General and administrative	2,196	1,332	6,376	4,965
Total operating expenses	8,261	4,591	18,130	13,158
Loss from operations	(8,261)	(4,591)	(18,130)	(13,158)
Change in fair value of common stock warrant liability	319	215	(768)	2,504
Warrant amendment charge	—	—	—	(674)
Interest and other income, net	9	89	50	340
Pre-tax loss	(7,933)	(4,287)	(18,848)	(10,988)
Income tax benefit	—	—	2,125	1,801
Net loss	\$ (7,933)	\$ (4,287)	\$ (16,723)	\$ (9,187)
Weighted average shares outstanding:				
Basic	9,491,111	4,553,535	7,228,349	4,481,972
Diluted	9,491,111	4,553,535	7,228,349	4,481,972
Net loss per share:				
Basic	\$ (0.84)	\$ (0.94)	\$ (2.31)	\$ (2.05)
Diluted	\$ (0.84)	\$ (0.94)	\$ (2.31)	\$ (2.05)

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, 2020:

	Common Stock		Additional Paid in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
June 30, 2020	9,497,777	\$ 95	\$ 251,858	\$ (198,553)	\$ 53,400
Net loss	—	—	—	(7,933)	(7,933)
Stock-based compensation	—	—	406	—	406
September 30, 2020	9,497,777	\$ 95	\$ 252,264	\$ (206,486)	\$ 45,873
December 31, 2019	4,580,127	\$ 46	\$ 193,308	\$ (189,763)	\$ 3,591
Net loss	—	—	—	(16,723)	(16,723)
Reverse stock split adjustment	(826)	—	—	—	—
Warrant exercises	254,760	3	3,054	—	3,057
Direct offerings	2,428,846	24	28,178	—	28,202
Public offering	2,211,538	22	26,472	—	26,494
Stock-based compensation	23,332	—	1,252	—	1,252
September 30, 2020	9,497,777	\$ 95	\$ 252,264	\$ (206,486)	\$ 45,873

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	4,593,674	\$ 46	\$ 192,812	\$ (181,396)	\$ 11,462
Net loss	—	—	—	(4,287)	(4,287)
Stock-based compensation	—	—	174	—	174
September 30, 2019	4,593,674	\$ 46	\$ 192,986	\$ (185,683)	\$ 7,349
December 31, 2018	3,911,857	\$ 39	\$ 180,313	\$ (176,496)	\$ 3,856
Net loss	—	—	—	(9,187)	(9,187)
Warrant amendment	—	—	4,683	—	4,683
Public offering	666,666	7	6,229	—	6,236
Stock-based compensation	15,151	—	1,761	—	1,761
September 30, 2019	4,593,674	\$ 46	\$ 192,986	\$ (185,683)	\$ 7,349

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,	
	2020	2019
<b>Cash flows from operating activities:</b>		
Net loss	\$ (16,723)	\$ (9,187)
Adjustments to reconcile net loss to net cash used in operating activities:		
Change in fair value of common stock warrant liability	768	(2,504)
Warrant amendment charge	—	674
Stock based compensation	1,252	1,761
Depreciation	118	263
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(228)	(62)
Accounts payable, accrued research and development, and accrued expenses	1,333	(987)
Net cash used in operating activities	<u>(13,480)</u>	<u>(10,042)</u>
<b>Cash flows from financing activities:</b>		
Proceeds from issuance of common stock in Direct Offerings, net of offering expenses	28,202	—
Proceeds received from exercise of warrants	3,057	—
Proceeds from issuance of common stock in Public Offering, net of offering expenses	26,494	6,236
Payment of expenses related to the ATM Offering	(177)	—
Net cash provided by financing activities	<u>57,576</u>	<u>6,236</u>
Net change in cash, cash equivalents and restricted cash	44,096	(3,806)
Cash, cash equivalents and restricted cash at beginning of period	10,277	17,046
Cash, cash equivalents and restricted cash at end of period	<u>\$ 54,373</u>	<u>\$ 13,240</u>
<b>Non-cash financing activities:</b>		
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 and infectious 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® ("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.
- There are many uncertainties regarding the novel coronavirus ("COVID-19") pandemic, and the Company is closely monitoring the impact of the pandemic on all aspects of its business, including how the pandemic will impact its clinical trials, employees and suppliers. While the pandemic did not materially affect the Company's financial results and business operations in the Company's nine months ended September 30, 2020, the extent to which the coronavirus impacts the Company's results will depend on future developments, which are highly uncertain and cannot be predicted. Further, should COVID-19 continue to spread, the Company's business operations could be delayed or interrupted. For instance, the Company's clinical trials may suffer from lower than anticipated patient recruitment or enrollment and the Company may be forced to temporarily delay ongoing trials.

**(2) Summary of Significant Accounting Policies**

***(a) Basis of Presentation***

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

The Company is responsible for the unaudited condensed consolidated financial statements. The condensed consolidated financial statements include all normal and recurring adjustments that are considered necessary for the fair presentation of the Company's financial position, results of operations, comprehensive income (loss) and its cash flows for the periods presented. These condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements for the year ended December 31, 2019, included in the Company's Annual Report on Form 10-K for the year ended December 31, 2019. The results of operations for the three and nine months ended September 30, 2020 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 asset and operating lease liability, accrued expenses, accrued research and development expenses, stock-based compensation, common stock warrant liabilities and income taxes. Actual results could differ from those estimates.

On February 5, 2020, the Company filed a certificate of amendment to its amended and restated Certificate of Incorporation to effect a 1-for-15 reverse stock split of the Company's outstanding shares of common stock which became effective on February 7, 2020. The shares of common stock underlying the Company's outstanding options and warrants were also proportionately adjusted for the reverse stock split. In addition, the number of shares of common stock available for issuance under the Company's equity incentive plans and employee stock purchase plan were proportionately adjusted for the reverse stock split. Further, the per share exercise prices for options granted under such plans and warrants were proportionately adjusted for the reverse stock split. There was no change to the Company's authorized number of shares or to its par value per share. The reverse stock split reduced the number of shares of the Company's common stock that were outstanding at February 10, 2020 from 69,053,548 to 4,603,460, after the cancellation of fractional shares. No fractional shares were issued in connection with the reverse stock split. Stockholders who otherwise held fractional shares of the Company's common stock as a result of the reverse stock split received a de minimis cash payment in lieu of such fractional shares. These condensed consolidated financial statements give retroactive effect to such reverse stock split and all share and per share amounts have been adjusted accordingly.

***(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 the 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) Leases***

A lease is a contract, or part of a contract, that conveys the right to control the use of explicitly or implicitly identified property, plant or equipment in exchange for consideration. Control of an asset is conveyed to the Company if the Company obtains the right to obtain substantially all of the economic benefits of the asset or the right to direct the use of the asset. The Company recognizes ROU assets and lease liabilities at the lease commencement date based on the present value of future, fixed lease payments over the term of the arrangement. ROU assets are amortized on a straight-line basis over the term of the lease. Lease liabilities accrete to yield and are reduced at the time when the lease payment is payable to the vendor. Variable lease payments are recognized at the time when the event giving rise to the payment occurs and are recognized in the statement of operations in the same line item as expenses arising from fixed lease payments.

Leases are measured at present value using the rate implicit in the lease or, if the implicit rate is not determinable, the lessee's implicit borrowing rate. As the implicit rate is not typically available, the Company uses its implicit borrowing rate based on the information available at the lease commencement date to determine the present value of future lease payments. The implicit borrowing rate approximates the rate the Company would pay to borrow on a collateralized basis over a similar term an amount equal to the lease payments.

The Company does not recognize right of use assets or related lease liabilities with a lease term of twelve months or less on its consolidated balance sheet. Short-term lease costs are recorded in the Company's 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, 2020 and 2019 were de minimis.

### ***(h) Recently Issued Accounting Pronouncements***

#### *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, adds and modifies certain disclosure requirements for fair value measurements. The standard requires the disclosure of the range and weighted average used to develop significant unobservable inputs and how weighted average is calculated for recurring and nonrecurring Level 3 fair value measurements. The amendment is effective for fiscal years beginning after December 15, 2019 and interim periods within those fiscal years with early adoption permitted. The Company adopted ASU 2018-13 during the nine months ended September 30, 2020 by including disclosure on the range of inputs used to calculate the Company's Level 3 fair value measurements.

### **(3) Liquidity**

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

The Company had unrestricted cash and cash equivalents of \$54.0 million as of September 30, 2020. The Company's existing cash and cash equivalents as of September 30, 2020 will be used primarily to fund the Phase 3 trial of INOpulse for PH-ILD, to complete the dose escalation study for PH-Sarc and to fund a portion of the Phase 3 trial of INOpulse for the treatment of patients infected with COVID-19.

On June 26, 2020, the Company filed a shelf registration statement on Form S-3 with the SEC, which became effective on July 2, 2020. 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 \$150 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 666,666 shares of its common stock at a public offering price of \$10.50 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.

On April 1, 2020, the Company completed the sale of 1,275,000 shares of its common stock in a registered direct offering at an offering price of \$12.00 per share, resulting in net proceeds of approximately \$14.1 million, after deducting agent fees of \$1.1 million and offering costs of \$0.1 million. Such shares were sold pursuant to the Company's prior shelf registration statement on Form S-3.

On May 22, 2020, the Company completed the sale of 3,365,384 shares of its common stock in a public offering and concurrent registered direct offering including a full exercise of an option to purchase additional shares at a price of \$13.00 per share, resulting in net proceeds of approximately \$40.6 million, after deducting agent fees of \$2.9 million, and offering costs of \$0.3 million. The agent fees included a financial advisory fee of \$900,000 to Angel Pond Capital LLC, a company affiliated with Theodore Wang, a member of the Company's board of directors. Such shares were sold pursuant to the Company's prior shelf registration statement on Form S-3.

In July 2020, the Company entered into an Open Market Sale Agreement<sup>SM</sup> with Jefferies LLC, as sales agent, pursuant to which the Company may offer and sell shares of its common stock, from time to time, for an aggregate sales price of up to \$40.0 million through an "at the market offering" program under a shelf registration statement on Form S-3. To date, the Company has not sold any shares under this agreement.

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. The Company has sold \$21.2 million of state NOLs and \$0.2 million of Research and Development credit under the State of New Jersey's Technology Business Tax Certificate Transfer Program in May 2020 for net proceeds of \$2.0 million and has sold \$20.0 million of 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 in the future. The proceeds from such sales are recorded as income tax benefit when sales occur or proceeds are received.

The Company evaluated whether there are any remaining conditions and events, considered in the aggregate, that raise substantial doubt about the Company's 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, 2020 will be sufficient to satisfy its operating cash needs for at least one year after the filing of this Quarterly Report on Form 10-Q.

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, funding from federal programs subject to approval, 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, is unable to sell its state NOLs and R&D credits or obtain federal funding for the Investigational New Drug (“IND”) to study the iNO delivery system for the treatment of patients infected with COVID-19, 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) Right of Use Assets and 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. Operating lease expense is recognized on a straight-line basis over the respective lease term.

The Company does 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 nine months ended September 30, 2020 and 2019 were de minimis.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Cash paid for operating lease liability	\$ 190	\$ 171	\$ 567	\$ 496
Operating lease expenses	\$ 177	\$ 160	\$ 529	\$ 465
Weighted average remaining lease term			2.5 years	3.5 years
Weighted average discount rate			4.93 %	4.94 %

Maturities of the lease liability as of September 30, 2020 were as follows:

2020	\$ 190
2021	770
2022	783
2023	205
	<u>1,948</u>
Less imputed interest	(120)
Total operating lease liability	<u>\$ 1,828</u>

#### (5) Common Stock Warrants and Warrant Liability

On November 29, 2016, the Company issued 1,142,838 warrants that were immediately exercisable and will expire 5 years from issuance at an exercise price of \$12.00 per share (the “2016 Warrants”). On June 28, 2019, the Company entered into a warrant amendment (the “Warrant Amendment”) with certain holders (the “Holders”) of 839,899 of the 2016 Warrants to purchase shares. Pursuant to the Warrant Amendment, the Company and the Holders agreed to eliminate provisions that had previously precluded equity classification treatment on the Company’s consolidated 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 consolidated statement of

operations as a warrant amendment charge. The fair market value of the amended warrants was reclassified from common stock 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, 2020, 661,310 of the 2016 Warrants were outstanding, of which 585,139 were equity classified and 76,171 were liability classified. During the nine months ended September 30, 2020, 254,760 of the 2016 Warrants were exercised for net proceeds of \$3.1 million.

On May 15, 2017, the Company issued to an investor a warrant to purchase 66,666 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 \$22.50 per share. In addition, the Company issued to the placement agent warrants to purchase 4,000 shares that were immediately exercisable and will expire five years from issuance at an exercise price of \$28.125 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, 2020, all of these warrants were outstanding.

On September 29, 2017, the Company issued warrants to purchase 1,296,650 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 \$18.63 per share. As the warrants could not require cash settlement, the warrants were classified as equity. As of September 30, 2020, all of these warrants were outstanding.

The following table summarizes warrant activity for the nine months ended September 30, 2020 (fair value amount in thousands):

	Equity Classified	Liability Classified	
	Warrants	Warrants	Estimated Fair Value
Warrants outstanding as of December 31, 2019	2,136,549	146,837	\$ 274
Exercises	(254,760)	—	—
Change in fair value of common stock warrant liability recognized in consolidated statement of operations	—	—	768
Warrants outstanding as of September 30, 2020	1,881,789	146,837	\$ 1,042

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	1,296,650	986,736	\$ 6,965
Reclassification of warrants to equity on amendment of warrant agreements	839,899	(839,899)	(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	2,136,549	146,837	\$ 452

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, 2020 for liabilities measured at fair value on a recurring basis (in thousands):

	Level 1	Level 2	Level 3	Total
Common stock warrant liability	—	—	1,042	1,042

The following table summarizes fair value measurements by level at December 31, 2019 for liabilities measured at fair value on a recurring basis (in thousands):

	Level 1	Level 2	Level 3	Total
Common stock warrant liabilities	—	—	274	274

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 historically considered comparable public companies as a basis for its expected volatility to calculate the fair value of common stock warrants and transitioned to its own volatility as the Company developed 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 and the range of assumptions used in estimating the fair value of warrants outstanding (weighted average calculated based on the number of outstanding warrants on each issuance) as of September 30, 2020 and December 31, 2019:

Valuation assumptions:	September 30, 2020			December 31, 2019		
	Range		Weighted Average	Range		Weighted Average
Risk-free interest rate	0.12 %	- 0.13 %	0.13 %	1.57 %	- 1.61 %	1.59 %
Expected volatility	166.31 %	- 209.61 %	189.14 %	104.74 %	- 109.05 %	107.00 %
Expected term (in years)	1.2	- 2.1	1.6	1.9	- 2.9	2.4
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 IPO, no options may be granted under the 2014 Plan. The awards granted under the 2014 Plan generally have a vesting period of between one to four years.

During 2015, the Company adopted the 2015 Equity Incentive Plan, or the 2015 Plan, which provides for the grant of options, restricted stock and other forms of equity compensation. On May 4, 2017, the Company's stockholders approved an amendment to the 2015 Plan to increase the aggregate number of shares available for the grant of awards to 333,333 and to increase the maximum number of shares available under the annual increase to 200,000 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 333,333 to 833,333. As of September 30, 2020, the Company had 386,030 shares available for grant under the 2015 Plan.

As of September 30, 2020, there was approximately \$2.7 million of total unrecognized compensation expense related to unvested stock awards. This expense is expected to be recognized over a weighted-average period of 2.1 years.

No tax benefit was recognized during the three and nine months ended September 30, 2020 and 2019 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, 2020 and 2019 were \$10.12 and \$7.80, respectively. The following are the weighted average assumptions used in estimating the fair values of options issued during the nine months ended September 30, 2020 and 2019:

	Nine Months Ended September 30, 2020	Nine Months Ended September 30, 2019
Valuation assumptions:		
Risk-free rate	0.33 %	1.67 %
Expected volatility	144.33 %	86.02 %
Expected term (years)	5.7	6.0
Dividend yield	—	—

A summary of option activity under the 2015 and 2014 Plans for the nine months ended September 30, 2020 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, 2019	663,501	\$ 7.35 - 199.20	\$ 24.15	8.3
Granted	77,263	10.12 - 12.58	10.12	—
Forfeited	(325)	7.35 - 199.20	32.41	—
Options outstanding as of September 30, 2020	740,439	\$ 7.35 - 199.20	\$ 22.69	7.8
Options vested and exercisable as of September 30, 2020	370,418	\$ 7.35 - 199.20	\$ 33.96	7.0

The intrinsic value of options outstanding, vested and exercisable as of September 30, 2020 was \$0.4 million.

## Restricted Stock

All restricted stock awards granted under the 2015 Plan during the nine months ended September 30, 2020 were in relation to director compensation and vest in full by December 31, 2020, subject to certain terms and conditions.

A summary of restricted stock activity under the 2015 Plan for the nine months ended September 30, 2020 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, 2019	—	\$ —	\$ —	—
Granted	23,332	6.00	0.1	—
Vested	(16,666)	6.00	—	—
Restricted stock outstanding as of September 30, 2020	6,666	\$ 6.00	\$ —	0.25

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

### Options

A summary of option activity under Ikaria equity incentive plans assumed in 2014 for the nine months ended September 30, 2020, 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, 2019	3,463	\$ 116.55 - 223.65	\$ 124.21	2.3
Expired	(63)	208.65	208.65	—
Forfeited	(814)	116.55 - 124.05	118.71	—
Options outstanding as of September 30, 2020	2,586	\$ 116.55 - 223.65	\$ 123.88	1.8
Options vested and exercisable as of September 30, 2020	2,586	\$ 116.55 - 223.65	\$ 123.88	1.8

The intrinsic value of options outstanding, vested and exercisable as of September 30, 2020 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, 2020 and 2019 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Research and development	\$ 94	\$ 84	\$ 265	\$ 591
General and administrative	312	90	987	1,170
Total expense	\$ 406	\$ 174	\$ 1,252	\$ 1,761

## **(8) Income Taxes**

Excluding the impact of the sale of state net operating losses and research and development credits during the second quarter of 2020 and the first quarter of 2019, the effective tax rate for each of the three and nine months ended September 30, 2020 and 2019 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 2020 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 May 2020, the Company sold \$21.2 million of state NOLs and \$0.2 million of Research and Development credits under the State of New Jersey's Technology Business Tax Certificate Transfer Program for net proceeds of \$2.0 million, which resulted in the reversal of the valuation allowance and a tax benefit of \$2.1 million for the nine months ended September 30, 2020. In January 2019, the Company sold \$20.0 million of state NOLs for net proceeds of \$1.7 million under the same 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. Subject to state approval, the Company plans to sell additional NOLs and credits under the same program in the future. The proceeds from such sales are recorded as income tax benefit when sales occur or proceeds are received.

As of September 30, 2020, 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 Per Share**

Basic net loss 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.

The Company reported a net loss for the three and nine months ended September 30, 2020 and 2019, therefore diluted net loss per share is the same as the basic net loss per share.

As of September 30, 2020, the Company had 743,025 options to purchase shares, 6,666 restricted shares and 2,028,626 warrants to purchase shares outstanding that have been excluded from the computation of diluted weighted average shares outstanding, because such securities had an anti-dilutive impact due to the loss reported.

As of September 30, 2019, the Company had 667,607 options to purchase shares, 40,249 restricted shares and 2,283,386 warrants to purchase shares outstanding that have been excluded from the computation of diluted weighted average shares outstanding, because such securities had an anti-dilutive impact due to the loss reported.

## **(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 the date 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, 2019 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 and infectious 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 August 2017, we announced acceptance by the U.S. Food and Drug Administration (the “FDA”) of our Investigational New Drug (“IND”) application 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 trial. In addition, we announced the expansion of the trial with the addition of cohort 2 and cohort 3, to evaluate a higher iNO 45 and iNO 75 dose as well as a longer 16 week evaluation period. In January 2019, we announced top-line results from cohort 1 of our iNO-PF trial. The results showed statistically significant improvements in multiple clinically meaningful activity parameters as measured by a wearable medical-grade activity monitor. 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 seamless 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 (“MVPA”) from baseline to month 4, 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 chronic obstructive pulmonary disease (“COPD”). In December 2019, we announced top-line results from cohort 2 of the iNO-PF trial. Cohort 2 of iNO-PF demonstrated statistically significant placebo corrected improvement in MVPA, in subjects treated with iNO45 (45 mcg/kg IBW/hr) versus placebo. The improvements in MVPA were underscored by benefits in other Actigraphy parameters, as well as multiple patient reported outcomes. In March 2020, we announced that in consultation with the FDA, we had finalized the key elements of our planned pivotal Phase 3 study for PH-PF, including the use of MVPA as the primary endpoint for approval, the patient population of pulmonary fibrosis subjects at risk of PH, as well as the dose of iNO45. The first research site in the Phase 3 study has been initiated, allowing us to begin recruiting patients into the trial. We are expecting to enroll the first patient in the fourth quarter of 2020.

In 2018, we initiated an ancillary Phase 2 intra-patient dose escalation study that utilizes right heart catheterization to assess the hemodynamic effect of INOpulse from a dose of iNO 30 to iNO 125 in PH-ILD subjects. In February 2020, we announced the completion of the study and that the top-line results demonstrated that INOpulse achieved clinically and statistically significant improvements in pulmonary vascular resistance and mean pulmonary arterial pressure. Inhaled nitric oxide was well-tolerated with no safety concerns across doses.

On March 19, 2020, the FDA granted emergency expanded access (“EA”) to allow for our INOpulse system to immediately be used as supportive treatment for a patient with COVID-19 under the care and supervision of the patient’s physician. The clinical goal of this experimental treatment was to avert the hospitalized patient’s disease progression and avoid the need to perform intubation. Under the recently completed emergency access program, 180 hospitalized patients with COVID-19 from 18 hospitals across the United States received treatment with INOpulse. In April 2020, we submitted an IND application to the FDA to study the iNO delivery system for the treatment of patients infected with COVID-19. The proposed

randomized, placebo controlled study called COViNOX, will evaluate the efficacy and safety of INOpulse in patients diagnosed with COVID-19 who require supplemental oxygen before the disease progresses to necessitate mechanical ventilation support. The COViNOX protocol utilizes an adaptive design and aims to enroll up to 500 patients with COVID-19 who will be treated with either INOpulse or placebo. The primary endpoint will assess the proportion of subjects that had respiratory failure or mortality, which should allow the trial to serve as a registrational study for approval. The IND application was accepted by the FDA in May 2020, and the trial was initiated with the first patient treated in July 2020. The first 100 patients have completed their 28 days assessment period in October 2020 and the results of the planned interim analysis are expected in the fourth quarter of 2020. In parallel, we have submitted for federal funding, through multiple federal agencies including Operation Warp Speed (“OWS”), Department of Defense (“DOD”), Biomedical Advanced Research and Development Authority (“BARDA”), and National Institutes of Health (“NIH”), to support the study. We may not receive federal funding, and if we do, any funding may not be sufficient to fund the trial. In addition, we may be obligated to grant access rights, such as march-in rights, to the U.S. government in connection with such funding.

In 2018, we initiated development of INOpulse for the treatment of PH associated with Sarcoidosis (“PH-Sarc”). Sarcoidosis is a multi-system disease which is characterized by the growth of granulomas (inflammatory cells) in one or more organs. The most frequent organs involved are the lungs and lymph nodes within the chest. Pulmonary hypertension may be present in as many as 74% of patients depending on how the pulmonary hypertension (“PH”) is defined. The presence of PH in sarcoidosis is associated with a poor prognosis. There are a number of different mechanisms linking PH with sarcoidosis. The primary treatment for sarcoidosis is corticosteroids; however, the outcome of this treatment on the PH is unclear. There is no approved therapy for PH associated with sarcoidosis. Various PAH treatments have been tried including iNO and IV prostacyclin with some clinical and functional improvement. 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. We have completed the process of initiating sites and enrolled our first subject in 2019, with results expected around the end of 2020.

In July 2014, 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. 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 continue to evaluate alternatives for the funding and timing of this program.

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 may 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 Phase 3 trials for PH-ILD, COVID-19, 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.

### *INOpulse for PH-ILD*

We initiated our clinical program in PH-ILD in 2016. In March 2020, we announced that in consultation with the FDA, we had finalized the key elements of our planned pivotal Phase 3 study for PH-PF, including the use of MVPA as the primary endpoint for approval, the patient population of pulmonary fibrosis subjects at risk of PH, as well as the dose of iNO45.

### *INOpulse for COVID-19*

In April 2020, we submitted an IND application to the FDA to study the iNO delivery system for the treatment of patients infected with COVID-19. The proposed randomized, placebo controlled study called COViNOX, will evaluate the efficacy and safety of INOpulse in patients diagnosed with COVID-19 who require supplemental oxygen before the disease progresses to necessitate mechanical ventilation support. The COViNOX protocol utilizes an adaptive design and aims to enroll up to 500 patients with COVID-19 who will be treated with either INOpulse or placebo. The primary endpoint will assess the proportion of subjects that had respiratory failure or mortality, which should allow the trial to serve as a registrational study for approval. The IND was accepted by the FDA in May 2020, and the trial was initiated with the first patient treated in July. In parallel, we have submitted for federal funding, through multiple federal agencies to support the study.

### *INOpulse for PH-Sarcoidosis*

In 2018, we 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. We have completed the process of initiating sites and enrolled our first subject in 2019, with results expected around the end of 2020.

### *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 long-term oxygen therapy, or 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, PH-Sarc and COVID-19 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, 2020 and 2019

The following table summarizes our results of operations for the three months ended September 30, 2020 and 2019.

(Dollar amounts in thousands)	Three Months Ended September 30,		\$ Change	% Change
	2020	2019		
Research and development expenses:				
PH-ILD, PH-Sarc and PH-COPD	\$ 789	\$ 1,045	\$ (256)	(24)%
COVID-19	2,164	—	2,164	—
Other clinical trials	33	3	30	1,000 %
Drug and delivery system costs	1,461	501	960	192 %
Clinical programs	4,447	1,549	2,898	187 %
Research and development infrastructure	1,334	1,381	(47)	(3)%
INOpulse engineering	284	329	(45)	(14)%
Total research and development expenses	6,065	3,259	2,806	86 %
General and administrative expenses	2,196	1,332	864	65 %
Total operating expenses	8,261	4,591	3,670	80 %
Loss from operations	(8,261)	(4,591)	(3,670)	80 %
Change in fair value of common stock warrant liability	319	215	104	48 %
Interest and other income, net	9	89	(80)	(90)%
Net loss	\$ (7,933)	\$ (4,287)	\$ (3,646)	85 %

**Total Operating Expenses.** Total operating expenses for the three months ended September 30, 2020 were \$8.3 million compared to \$4.6 million for the three months ended September 30, 2019, an increase of \$3.7 million, or 80%. This increase was primarily due to an increase in clinical program expenditures attributable to the commencement of the COVID-19 trial in the current period as well as an increase in general and administrative expenses.

**Research and Development Expenses.** Total research and development expenses for the three months ended September 30, 2020 were \$6.1 million compared to \$3.3 million for the three months ended September 30, 2019, an increase of \$2.8 million, or 86%. Total research and development expenses consisted of the following:

- PH-ILD, PH-Sarc and PH-COPD expenses for the three months ended September 30, 2020 were \$0.8 million compared to \$1.0 million for the three months ended September 30, 2019, a decrease of \$0.2 million, or 24%. The decrease is primarily due to the timing of the Phase 2 PH-ILD trial which was ongoing during the three months ended September 30, 2019 and completed prior to the three months ended September 30, 2020.
- COVID-19 expenses for the three months ended September 30, 2020 were \$2.2 million. COVID-19 expenses in the third quarter of 2020 included costs related to the commencement of our Phase 3 clinical trial as well as the EA program.
- Drug and delivery system costs for the three months ended September 30, 2020 were \$1.5 million, compared to \$0.5 million for the three months ended September 30, 2019, an increase of \$1.0 million, or 192%. Drug and delivery system costs are recorded at the time of procurement from our suppliers. The increase in the drug and delivery system costs is attributable to the requirements to support the ongoing COVID-19 trial and preparation for Phase 3 trial activities of PH-ILD.

**General and Administrative Expenses.** General and administrative expenses for the three months ended September 30, 2020 were \$2.2 million, compared to \$1.3 million for the three months ended September 30, 2019, an increase of \$0.9 million, or 65%. The increase was primarily due to stock based compensation, consulting fees as well as legal expenses.



**Change in fair value of common stock warrant liability.** Change in fair value of common stock warrant liability for the three months ended September 30, 2020 was income of \$0.3 million, compared to income of \$0.2 million for the three months ended September 30, 2019. The warrants were issued in November 2016 and May 2017 and the change in the liability fair value was primarily due to a change in our stock price and volatility.

**Comparison of Nine Months Ended September 30, 2020 and 2019**

The following table summarizes our results of operations for the nine months ended September 30, 2020 and 2019.

(Dollar amounts in thousands)	Nine Months Ended September 30,		\$ Change	% Change
	2020	2019		
Research and development expenses:				
PH-ILD, PH-Sarc and PH-COPD	\$ 2,236	\$ 2,436	\$ (200)	(8)%
COVID-19	2,709	—	2,709	—
Other clinical trials	104	98	6	6 %
Drug and delivery system costs	2,340	1,168	1,172	100 %
Clinical programs	7,389	3,702	3,687	100 %
Research and development infrastructure	3,545	3,627	(82)	(2)%
INOpulse engineering	820	864	(44)	(5)%
Total research and development expenses	11,754	8,193	3,561	43 %
General and administrative expenses	6,376	4,965	1,411	28 %
Total operating expenses	18,130	13,158	4,972	38 %
Loss from operations	(18,130)	(13,158)	(4,972)	38 %
Change in fair value of common stock warrant liability	(768)	2,504	(3,272)	(131)%
Warrant amendment charge	—	(674)	674	(100)%
Interest and other income, net	50	340	(290)	(85)%
Pre-tax loss	(18,848)	(10,988)	(7,860)	72 %
Income tax benefit	2,125	1,801	324	18 %
Net loss	\$ (16,723)	\$ (9,187)	\$ (7,536)	82 %

**Total Operating Expenses.** Total operating expenses for the nine months ended September 30, 2020 were \$18.1 million compared to \$13.2 million for the nine months ended September 30, 2019, an increase of \$4.9 million, or 38%. This increase was primarily due to an increase in clinical programs as well as general and administrative expenses.

**Research and Development Expenses.** Total research and development expenses for the nine months ended September 30, 2020 were \$11.8 million compared to \$8.2 million for the nine months ended September 30, 2019, an increase of \$3.6 million, or 43%. Total research and development expenses consisted of the following:

- PH-ILD, PH-Sarc and PH-COPD expenses for the nine months ended September 30, 2020 were \$2.2 million compared to \$2.4 million for the nine months ended September 30, 2019, a decrease of \$0.2 million, or 8%. The decrease is primarily due to the timing of the Phase 2 PH-ILD trial which was ongoing during the nine months ended September 30, 2019 and completed during the nine months ended September 30, 2020.
- COVID-19 expenses for the nine months ended September 30, 2020 were \$2.7 million. COVID-19 expenses in the first nine months of 2020 included costs related to the commencement of our Phase 3 clinical trial as well as the EA program.
- Drug and delivery system costs for the nine months ended September 30, 2020 were \$2.3 million, compared to \$1.2 million for the nine months ended September 30, 2019, an increase of \$1.1 million, or

100%. Drug and delivery system costs are recorded at the time of procurement from our suppliers. The increase in the drug and delivery system costs is attributable to the requirements to support the ongoing COVID-19 trial and preparation for Phase 3 trial activities of PH-ILD.

- Research and development infrastructure expenses for the nine months ended September 30, 2020 were \$3.5 million, essentially flat as compared to the nine months ended September 30, 2019.

**General and Administrative Expenses.** General and administrative expenses for the nine months ended September 30, 2020 were \$6.4 million, compared to \$5.0 million for the nine months ended September 30, 2019, an increase of \$1.4 million, or 28%. The increase was primarily due to consulting fees as well as legal expenses.

**Income Tax Benefit.** Income tax benefit was \$2.1 million for the nine months ended September 30, 2020, compared to \$1.8 million for the nine months ended September 30, 2019, an increase of \$0.3 million, or 18%. In May 2020, we sold \$21.2 million of state NOLs and \$0.2 million of Research and Development credit under the State of New Jersey's Technology Business Tax Certificate Transfer Program for net proceeds of \$2.0 million. In March 2019, we sold \$20.0 million of state NOLs under the same program for net proceeds of \$1.7 million. The proceeds from such sales are recorded as income tax benefit when sales occur or proceeds are received.

**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, 2020 was an expense of \$0.8 million, compared to income of \$2.5 million for the nine months ended September 30, 2019. The warrants were issued in November 2016 and May 2017 and the change in the liability fair value was primarily due to a change in our stock price and volatility.

**Warrant amendment charge.** On June 28, 2019, we entered into the Warrant Amendment with Holders of the November 2016 warrants to purchase 839,899 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.

## Liquidity and Capital Resources

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

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

We had unrestricted cash and cash equivalents of \$54.0 million as of September 30, 2020. Our existing cash and cash equivalents as of September 30, 2020 will be used primarily to fund the Phase 3 trial of INOpulse for PH-ILD, to complete the dose escalation study for PH-Sarc and to fund a portion of the Phase 3 trial of INOpulse for the treatment of patients infected with COVID-19.

On June 26, 2020, we filed a shelf registration statement on Form S-3 with the SEC, which became effective on July 2, 2020. 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 \$150 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 666,666 shares of our common stock at a public offering price of \$10.50 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.

On April 1, 2020, we completed the sale of 1,275,000 shares of our common stock in a registered direct offering at an offering price of \$12.00 per share, resulting in net proceeds of approximately \$14.1 million, after deducting agent fees of \$1.1 million and offering costs of \$0.1 million. Such shares were sold pursuant our effective shelf registration statement on Form S-3.

On May 22, 2020, we completed the sale of 3,365,384 shares of our common stock in a public offering and concurrent registered direct offering including a full exercise of an option to purchase additional shares at a price of \$13.00 per share, resulting in net proceeds of approximately \$40.6 million, after deducting agent fees of \$2.9 million and offering costs of \$0.3 million. The agent fees included a financial advisory fee of \$900,000 to Angel Pond Capital LLC, a company affiliated with Theodore Wang, a member of our board of directors. Such shares were sold pursuant to our prior shelf registration statement on Form S-3.

In July 2020, we entered into an Open Market Sale Agreement<sup>SM</sup> with Jefferies LLC, as sales agent, pursuant to which we may offer and sell shares of its common stock, from time to time, for an aggregate sales price of up to \$40.0 million through an “at the market offering” program under a shelf registration statement on Form S-3. To date, we have not sold any shares under this agreement.

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 its short term financial needs. We have sold \$21.2 million of state NOLs and \$0.2 million of Research and Development credit under the State of New Jersey's Technology Business Tax Certificate Transfer Program in May 2020 for net proceeds of \$2.0 million and have sold \$20.0 million of 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 in the future. The proceeds from such sales are recorded as income tax benefit when sales occur or proceeds are received.

We evaluated whether there are any remaining 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, we believe that our existing cash and cash equivalents as of September 30, 2020 will be sufficient to satisfy our operating cash needs for at least one year after the filing of this Quarterly Report on Form 10-Q.

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

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

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity and debt offerings, sales of state NOL and R&D credits, existing working capital, funding from federal programs subject to approvals, 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, are unable to sell our state NOLs and R&D credits or obtain federal funding for the IND to study the iNO delivery system for the treatment of patients infected with COVID-19, 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, 2020 and 2019:

(Dollar amounts in thousands)	Nine Months Ended September 30,	
	2020	2019
Operating activities	\$ (13,480)	\$ (10,042)
Financing activities	\$ 57,576	\$ 6,236
Net change in cash, cash equivalents and restricted cash	\$ 44,096	\$ (3,806)

#### *Net Cash Used in Operating Activities*

Cash used in operating activities for the nine months ended September 30, 2020 was \$13.5 million, as compared to \$10.0 million for the nine months ended September 30, 2019. The change in cash used in operating activities was primarily due to an increase in our operating expenses partially offset by changes in our operating assets and liabilities.

#### *Net Cash Provided by Financing Activities*

Cash provided by financing activities for the nine months ended September 30, 2020 was \$57.6 million, which included proceeds from the direct and public offerings in the second quarter of 2020 as well as warrant exercises in the first quarter of 2020. 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.

### **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, 2019.

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, 2020, 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, 2019.

### **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, 2020, we had unrestricted cash and cash equivalents of \$54.0 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, 2020. 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, 2020, 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 nine months ended September 30, 2020 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## PART II. OTHER INFORMATION

### Item 1. Legal Proceedings.

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

### Item 1A. Risk Factors.

Except as set forth below, there have been no material changes to our risk factors contained in our Annual Report on Form 10-K for the year ended December 31, 2019. 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, 2019.

*Although the FDA has granted us emergency expanded access to allow for INOpulse to be used as treatment for certain patients with COVID-19 under the care and supervision of such patient’s physician, and has accepted our application to initiate a Phase 3 study of INOpulse therapy in patients with COVID-19, we cannot assure you that INOpulse will prove to be a safe or effective treatment for COVID-19 or approved for marketing by the FDA.*

On March 19, 2020, the FDA granted emergency expanded access to allow for our proprietary iNO delivery system, INOpulse to immediately be used as supportive treatment for single patients with COVID-19 under the care and supervision of the patient’s physician. This emergency expanded access from the FDA was granted on a named patient basis and subsequently expanded to allow for additional COVID-19 patients as necessary. On May 11, 2020, we announced that the FDA had accepted our IND application, allowing us to initiate a Phase 3 study of iNO therapy in up to 500 patients infected with COVID-19. The Phase 3 trial was initiated with the first patient treated in July 2020. As there is no history of using iNO for this purpose, there can be no assurance that our product will be safe or effective when used to treat COVID-19 patients. In addition, there are still regulatory and product development steps to be taken before INOpulse is approved for marketing by FDA and can be fully commercialized in the United States. Accordingly, there can be no assurance that INOpulse will prove to be a safe or effective treatment for COVID-19 or that it will be approved for marketing by the FDA or that it can be successfully commercialized.

*Our business may be adversely affected by the COVID-19 pandemic.*

The COVID-19 pandemic has affected our operations and may materially affect our business. In response to the pandemic, we have limited operations, including implemented work from home and social distancing policies. For instance, our clinical trials may suffer from lower than anticipated patient recruitment or enrollment and we may be forced to temporarily delay ongoing trials in PH. In addition, we risk a delay, default and/or nonperformance under our existing agreements arising from force majeure. The extent to which COVID-19 impacts our results will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of COVID-19 and the actions to contain it or treat its impact, among others.

In addition, COVID-19 has resulted in significant governmental measures being implemented to control the spread of the virus, including quarantines, travel restrictions, social distancing and business shutdowns. We have taken temporary precautionary measures intended to help minimize the risk of the virus to our employees, including temporarily allowing all employees to work remotely. We have already suspended non-essential travel worldwide for our employees and are discouraging employee attendance at other gatherings. These measures could negatively affect our business. For instance, temporarily requiring all employees to work remotely may induce absenteeism, disrupt our operations or increase the risk of a cybersecurity incident. COVID-19 has also caused volatility in the global financial markets and threatened a slowdown in the global economy, which may negatively affect our ability to raise additional capital on attractive terms or at all.

The extent to which COVID-19 may impact our business will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the pandemic, the severity of COVID-19 or the effectiveness of actions to contain and treat COVID-19, particularly in the geographies where we or our third party suppliers, contract manufacturers, or contract research organizations operate. We cannot presently predict the scope and severity of any potential business shutdowns or disruptions. If we or any of the third parties with whom we engage, however, were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively affected, which could have a material adverse impact on our business and our results of operations and financial condition.

*We currently rely on Ikaria, as our single source supplier, for our supply of nitric oxide for the clinical trials of INOpulse. Ikaria's inability to continue manufacturing adequate supplies of nitric oxide, or its refusal to supply us with commercial quantities of nitric oxide on commercially reasonable terms, or at all, due to the bankruptcy filing of Ikaria's parent company Mallinckrodt plc or otherwise could result in a disruption in the supply of, or impair our ability to market, INOpulse.*

We have a drug clinical supply agreement with Ikaria, pursuant to which Ikaria will manufacture and supply our requirements for nitric oxide for inhalation and corresponding placebo for use in clinical trials of INOpulse. Ikaria manufactures pharmaceutical-grade nitric oxide at its facility in Port Allen, Louisiana. Ikaria's Port Allen facility is subject to the risks of a natural disaster or other business disruption, including the widespread outbreak of infectious diseases as the outbreak of the coronavirus known as COVID-19. We maintain under controlled storage conditions a two- to three-month supply of clinical trial drug product, but there can be no assurance that we would be able to meet our requirements for INOpulse if there were a catastrophic event or failure of Ikaria's manufacturing system. Because Ikaria's Port Allen facility is one of the few FDA-inspected sites that can manufacture nitric oxide for INOpulse and because the manufacture of a pharmaceutical gas requires specialized equipment and expertise, there are few third-party manufacturers to which we could contract this work in a short period of time. Therefore, any disruption in Ikaria's Port Allen facility, or the failure by Ikaria for any other reason to provide us with nitric oxide, could materially and adversely affect supplies of nitric oxide for INOpulse and our ongoing and planned clinical trials. In addition, Ikaria's parent company Mallinckrodt plc filed for Chapter 11 bankruptcy protection in October 2020. While we have been assured by Ikaria and believe that there will be no disruption in Ikaria's ability to fulfill its supply obligations to us, there can be no assurance that there will not be a disruption or delay in such manufacture and supply of nitric oxide for our use. Any such disruption would force us to seek nitric oxide from an alternative source, which may not be available on commercially reasonable terms. In addition, we do not currently have any arrangements with Ikaria to provide us with commercial quantities of nitric oxide. If we are unable to arrange for Ikaria to provide such quantities on commercially reasonable terms, or at all, we may not be able to successfully produce and market INOpulse or may be delayed in doing so.

**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>
<a href="#">10.1</a>	<a href="#">Open Market Sale Agreement, dated July 17, 2020, by and between Bellerophon Therapeutics, Inc. and Jefferies LLC (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-36845) filed with the SEC on July 17, 2020).</a>
<a href="#">31.1</a>	<a href="#">Certification of Principal Executive Officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended</a>
<a href="#">31.2</a>	<a href="#">Certification of Principal Financial Officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended</a>
<a href="#">32</a>	<a href="#">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</a>
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 5, 2020

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

Date: November 5, 2020

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 5, 2020

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 5, 2020

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, 2020 (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 5, 2020

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

Date: November 5, 2020

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