
**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, 2021

or

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

For the transition period from _____ to
Commission File Number 001-36845

Bellerophon Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

47-3116175

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

**184 Liberty Corner Road, Suite 302
Warren, New Jersey**

(Address of principal executive offices)

07059

(Zip Code)

(908) 574-4770

(Registrant's telephone number, including area code)

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

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

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

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

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

The number of shares outstanding of the registrant's common stock as of November 12, 2021: 9,506,419

TABLE OF CONTENTS

	<u>Page No.</u>
<u>PART I. FINANCIAL INFORMATION</u>	6
<u>Item 1. Financial Statements</u>	6
<u>Condensed Consolidated Balance Sheets as of September 30, 2021 (Unaudited) and December 31, 2020</u>	6
<u>Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2021 and 2020 (Unaudited)</u>	7
<u>Condensed Consolidated Statement of Changes in Stockholders' Equity for the three and nine months ended September 30, 2021 and 2020 (Unaudited)</u>	8
<u>Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2021 and 2020 (Unaudited)</u>	9
<u>Notes to Condensed Consolidated Financial Statements (Unaudited)</u>	10
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	21
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	32
<u>Item 4. Controls and Procedures</u>	32
<u>PART II. OTHER INFORMATION</u>	33
<u>Item 1. Legal Proceedings</u>	33
<u>Item 1A. Risk Factors</u>	33
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	33
<u>Item 3. Defaults Upon Senior Securities</u>	33
<u>Item 4. Mine Safety Disclosures</u>	33
<u>Item 5. Other Information</u>	33
<u>Item 6. Exhibits</u>	33
<u>Signatures</u>	35

REFERENCES TO BELLEROPHON

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

FORWARD-LOOKING STATEMENTS

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

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

- the timing of the ongoing and expected clinical trials of our product candidates, including statements regarding the timing of completion of the trials and the respective periods during which the results of the trials will become available;
- our ability to obtain adequate financing to meet our future operational and capital needs;
- the timing of and our ability to obtain marketing approval of our product candidates, and the ability of our product candidates to meet existing or future regulatory standards;
- our ability to comply with government laws and regulations;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our estimates regarding the potential market opportunity for our product candidates;
- the timing of or our ability to enter into partnerships to market and commercialize our product candidates;
- the rate and degree of market acceptance of any product candidate for which we receive marketing approval;
- our intellectual property position;
- our estimates regarding expenses, future revenues, capital requirements and needs for additional funding;
- the success of competing treatments; and
- our competitive position.

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, 2020, 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.

[Table of Contents](#)

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, 2021 (Unaudited)	As of December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 28,714	\$ 47,557
Restricted cash	103	103
Prepaid expenses and other current assets	898	420
Total current assets	29,715	48,080
Restricted cash, non-current	300	300
Right of use assets, net	1,026	1,504
Property and equipment, net	88	169
Other non-current assets	186	186
Total assets	\$ 31,315	\$ 50,239
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 1,278	\$ 3,725
Accrued research and development	1,314	3,699
Accrued expenses	1,795	2,305
Current portion of operating lease liabilities	740	704
Total current liabilities	5,127	10,433
Long term operating lease liabilities	396	956
Common stock warrant liability	1	601
Total liabilities	5,524	11,990
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.01 par value per share; 200,000,000 shares authorized and 9,506,419 and 9,491,111 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	95	95
Preferred stock, \$0.01 par value per share; 5,000,000 shares authorized, zero shares issued and outstanding at September 30, 2021 and December 31, 2020	—	—
Additional paid-in capital	253,671	252,645
Accumulated deficit	(227,975)	(214,491)
Total stockholders' equity	25,791	38,249
Total liabilities and stockholders' equity	\$ 31,315	\$ 50,239

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,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	\$ 3,030	\$ 6,065	\$ 9,853	\$ 11,754
General and administrative	1,773	2,196	6,035	6,376
Total operating expenses	4,803	8,261	15,888	18,130
Loss from operations	(4,803)	(8,261)	(15,888)	(18,130)
Change in fair value of common stock warrant liability	167	319	600	(768)
Interest and other income, net	2	9	4	50
Pre-tax loss	(4,634)	(7,933)	(15,284)	(18,848)
Income tax benefit	—	—	1,800	2,125
Net loss	\$ (4,634)	\$ (7,933)	\$ (13,484)	\$ (16,723)
Weighted average shares outstanding:				
Basic	9,506,419	9,491,111	9,501,428	7,228,349
Diluted	9,506,419	9,491,111	9,501,428	7,228,349
Net loss per share:				
Basic	\$ (0.49)	\$ (0.84)	\$ (1.42)	\$ (2.31)
Diluted	\$ (0.49)	\$ (0.84)	\$ (1.42)	\$ (2.31)

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, 2021:

	Common Stock		Additional Paid in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at June 30, 2021	9,506,419	\$ 95	\$ 253,343	\$ (223,341)	\$ 30,097
Net loss	—	—	—	(4,634)	(4,634)
Stock-based compensation	—	—	328	—	328
Balance at September 30, 2021	<u>9,506,419</u>	<u>\$ 95</u>	<u>\$ 253,671</u>	<u>\$ (227,975)</u>	<u>\$ 25,791</u>
Balance at December 31, 2020	9,491,111	\$ 95	\$ 252,645	\$ (214,491)	\$ 38,249
Net loss	—	—	—	(13,484)	(13,484)
Stock-based compensation	15,308	—	1,026	—	1,026
Balance at September 30, 2021	<u>9,506,419</u>	<u>\$ 95</u>	<u>\$ 253,671</u>	<u>\$ (227,975)</u>	<u>\$ 25,791</u>

For the three and nine months ended September 30, 2020:

	Common Stock		Additional Paid in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at June 30, 2020	9,497,777	\$ 95	\$ 251,858	\$ (198,553)	\$ 53,400
Net loss	—	—	—	(7,933)	(7,933)
Stock-based compensation	—	—	406	—	406
Balance at September 30, 2020	<u>9,497,777</u>	<u>\$ 95</u>	<u>\$ 252,264</u>	<u>\$ (206,486)</u>	<u>\$ 45,873</u>
Balance at 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
Balance at September 30, 2020	<u>9,497,777</u>	<u>\$ 95</u>	<u>\$ 252,264</u>	<u>\$ (206,486)</u>	<u>\$ 45,873</u>

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,	
	2021	2020
Cash flows from operating activities:		
Net loss	\$ (13,484)	\$ (16,723)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	81	118
Stock-based compensation	1,026	1,252
Change in fair value of common stock warrant liability	(600)	768
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(478)	(228)
Accounts payable, accrued research and development, accrued expenses and other liabilities	(5,388)	1,333
Net cash used in operating activities	<u>(18,843)</u>	<u>(13,480)</u>
Cash flows from financing activities:		
Proceeds received from exercise of warrants	—	3,057
Proceeds from issuance of common stock in Public Offering, net of offering expenses	—	26,494
Payment of expenses related to the ATM sale agreement	—	(177)
Proceeds from issuance of common stock in Direct Offerings, net of offering expenses	—	28,202
Net cash provided by financing activities	<u>—</u>	<u>57,576</u>
Net change in cash, cash equivalents and restricted cash	(18,843)	44,096
Cash, cash equivalents and restricted cash at beginning of period	47,960	10,277
Cash, cash equivalents and restricted cash at end of period	<u>\$ 29,117</u>	<u>\$ 54,373</u>

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

BELLEROPHON THERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

(1) Organization and Nature of the Business

Bellerophon Therapeutics, Inc., or the Company, is a clinical-stage therapeutics company focused on developing innovative products that address significant unmet medical needs in the treatment of cardiopulmonary diseases. The focus of the Company's clinical program is the continued development of its nitric oxide therapy for patients with or at risk of 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 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 impacts its clinical trials, employees and suppliers. While the pandemic did not materially affect the Company's financial results and business operations in the three and nine months ended September 30, 2021, site activation and patient enrollment in the Company's clinical trials have been affected by COVID-19. 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 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 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, 2020, included in the Company's Annual Report on Form 10-K for the year ended December 31, 2020. The results of operations for the three and nine months ended September 30, 2021 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 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 right of use ("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 ROU 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, 2021 and 2020 were de minimis.

(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.

If the Company obtains regulatory approval for any of its product candidates, the Company expects to incur significant commercialization expenses. The Company does not have a sales, marketing, manufacturing or distribution infrastructure for a pharmaceutical product. To develop a commercial infrastructure, the Company will have to invest financial and management resources, some of which would have to be deployed prior to having any certainty of marketing approval.

The Company had unrestricted cash and cash equivalents of \$28.7 million as of September 30, 2021. The Company's existing cash and cash equivalents as of September 30, 2021 will be used primarily to fund the Phase 3 trial of INOpulse for fILD and to complete the dose escalation study for PH-Sarc.

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.

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.

In July 2020, the Company entered into an Open Market Sale AgreementSM 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 research and development ("R&D") tax credits to unrelated profitable corporations, subject to meeting certain eligibility criteria. Based on consideration of various factors, including application processing time and past trend of benefits made available under the program, the Company believes that it is probable that its plans to sell its NOLs can be effectively implemented to address its short term financial needs. The Company has sold \$16.4 million of state NOLs and \$0.3 million of Research and Development credits under the State of New Jersey's Technology Business Tax Certificate Transfer Program in June 2021 for net proceeds of \$1.7 million and has sold an additional \$21.2 million of state NOLs and \$0.2 million of Research and Development credits for net proceeds of \$2.0 million in May 2020. The Company plans to sell additional NOLs and R&D tax credits under the same program in the future subject to program availability and state approval. The proceeds from such sales are recorded as income tax benefit when sales occur or proceeds are received. The Company's estimates and assumptions may prove to be wrong, and the Company may exhaust its capital resources sooner than expected. The process of testing product candidates in clinical trials is costly, and the timing of progress in clinical trials is uncertain. Because the Company's product candidates are in clinical development and the outcome of these efforts is uncertain, the Company may not be able to accurately estimate the actual amounts that will be necessary to successfully complete the development and commercialization, if approved, of its product candidates or whether, or when, the Company may achieve profitability.

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, 2021 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.

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 financings, sales of state NOLs and R&D credits subject to program availability and approval, existing working capital and funding from potential future collaboration arrangements. To the extent that the Company raises additional capital through the future sale of equity or convertible debt, the ownership interest of its existing stockholders may be diluted, and the terms of such securities may include liquidation or other preferences or rights such as anti-dilution rights that adversely affect the rights of its existing stockholders. If the Company raises additional funds through strategic partnerships in the future, it may have to relinquish valuable rights to its technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to it. If the Company is unable to raise additional funds through equity or debt financings when needed, or unable to sell its state NOLs and R&D credits, it may be required to delay, limit, reduce or terminate its product development or future commercialization efforts or grant rights to develop and market product candidates that it would otherwise prefer to develop and market itself. In addition, there are many uncertainties regarding the COVID-19 pandemic, and the Company is closely monitoring the impact of the pandemic on all aspects of its business, including how the pandemic impacts its clinical trials, employees and suppliers. While the pandemic did not materially affect the Company's business operations, site activation and patient enrollment in its clinical trials have been affected by the COVID-19 pandemic. Further, should COVID-19 continue to spread, the Company's business operations could be delayed or interrupted which could result in the use of more funds than anticipated in completing such trials.

(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 three and nine months ended September 30, 2021 and 2020 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,	
	2021	2020	2021	2020
Cash paid for operating lease liability	\$ 193	\$ 190	\$ 577	\$ 567
Operating lease expenses	\$ 177	\$ 177	\$ 530	\$ 529
Weighted average remaining lease term			1.5 years	2.5 years
Weighted average discount rate			4.93 %	4.93 %

Maturities of the lease liability as of September 30, 2021 were as follows:

2021	\$ 193
2022	783
2023	205
	1,181
Less imputed interest	(45)
Total operating lease liability	<u>\$ 1,136</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, 2021, there were 661,310 of the 2016 Warrants outstanding, of which 585,139 were equity classified and 76,171 were liability classified. No warrants were exercised during the nine months ended September 30, 2021. During the nine months ended September 30, 2020, there were 254,760 of the 2016 Warrants exercised for net proceeds of \$3.1 million.

On May 15, 2017, the Company issued to an investor warrants 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, 2021, all of these warrants were outstanding.

[Table of Contents](#)

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, 2021, all of these warrants were outstanding.

The following table summarizes warrant activity for the nine months ended September 30, 2021 (fair value amount in thousands):

	<u>Equity Classified</u>	<u>Liability Classified</u>	
	<u>Warrants</u>	<u>Warrants</u>	<u>Estimated Fair Value</u>
Warrants outstanding as of December 31, 2020	1,881,789	146,837	\$ 601
Change in fair value of common stock warrant liability recognized in consolidated statement of operations	—	—	(600)
Warrants outstanding as of September 30, 2021	<u>1,881,789</u>	<u>146,837</u>	<u>\$ 1</u>

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

	<u>Equity Classified</u>	<u>Liability Classified</u>	
	<u>Warrants</u>	<u>Warrants</u>	<u>Estimated Fair Value</u>
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	<u>1,881,789</u>	<u>146,837</u>	<u>\$ 1,042</u>

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, 2021 for liabilities measured at fair value on a recurring basis (in thousands):

	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>	<u>Total</u>
Common stock warrant liability	\$ —	\$ —	\$ 1	\$ 1

The following table summarizes fair value measurements by level at December 31, 2020 for liabilities measured at fair value on a recurring basis (in thousands):

	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>	<u>Total</u>
Common stock warrant liabilities	\$ —	\$ —	\$ 601	\$ 601

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, 2021 and December 31, 2020:

Valuation assumptions:	September 30, 2021		December 31, 2020		
	Range	Weighted Average	Range	Weighted Average	
Risk-free interest rate	0.09 % - 0.11 %	0.10 %	0.10 % - 0.13 %	0.11 %	
Expected volatility	47.31 % - 68.84 %	56.83 %	169.63 % - 231.10 %	202.21 %	
Expected term (in years)	0.2 - 1.1	0.6	0.9 - 1.9	1.4	
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, 2021, the Company had 677,343 shares available for grant under the 2015 Plan.

As of September 30, 2021, there was approximately \$0.9 million of total unrecognized compensation expense related to unvested stock awards. This expense is expected to be recognized over a weighted-average period of 1.5 years.

No tax benefit was recognized during the three and nine months ended September 30, 2021 and 2020 related to stock-based compensation expense since the Company incurred operating losses and has established a full valuation allowance to offset all the potential tax benefits associated with its deferred tax assets.

Options

The weighted average grant-date fair value of options issued during the nine months ended September 30, 2021 and 2020 were \$4.06 and \$12.58, respectively. The following are the weighted average assumptions used in estimating the fair values of options issued during the nine months ended September 30, 2021 and 2020:

	<u>Nine Months Ended September 30, 2021</u>	<u>Nine Months Ended September 30, 2020</u>
Valuation assumptions:		
Risk-free rate	1.16 %	0.33 %
Expected volatility	134.72 %	144.33 %
Expected term (years)	6.1	5.7
Dividend yield	—	—

A summary of option activity under the 2015 and 2014 Plans for the nine months ended September 30, 2021 is presented below:

	<u>Bellerophon 2015 and 2014 Equity Incentive Plans</u>			
	<u>Options</u>	<u>Range of Exercise Price</u>	<u>Weighted Average Price</u>	<u>Weighted Average Remaining Contractual Life (in years)</u>
Options outstanding as of December 31, 2020	740,257	\$ 7.35 - 199.20	\$ 22.69	7.5
Granted	1,500	4.06	4.06	
Forfeited	(101,373)	7.50 - 199.20	74.60	
Options outstanding as of September 30, 2021	<u>640,384</u>	<u>\$ 4.06 - 199.20</u>	<u>\$ 14.43</u>	<u>6.8</u>
Options vested and exercisable as of September 30, 2021	<u>496,415</u>	<u>\$ 4.06 - 199.20</u>	<u>\$ 15.49</u>	<u>6.6</u>

The intrinsic value of options outstanding, vested and exercisable as of September 30, 2021 was zero.

Restricted Stock

All restricted stock awards granted under the 2015 Plan during the nine months ended September 30, 2021 were in relation to director compensation and vested in full during the six months ended June 30, 2021.

A summary of restricted stock activity under the 2015 Plan for the nine months ended September 30, 2021 is presented below:

	<u>Bellerophon 2015 Equity Incentive Plan</u>			
	<u>Shares</u>	<u>Weighted Average Fair Value</u>	<u>Aggregate Grant Date Fair Value (in millions)</u>	<u>Weighted Average Remaining Contractual Life (in years)</u>
Restricted stock outstanding as of December 31, 2020	—	\$ —	\$ —	—
Granted	15,308	5.19	0.1	
Vested	<u>(15,308)</u>	<u>5.19</u>	<u>(0.1)</u>	
Restricted stock outstanding as of September 30, 2021	<u>—</u>	<u>\$ —</u>	<u>\$ —</u>	<u>—</u>

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, 2021, 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, 2020	2,508	\$116.55 - 223.65	\$ 123.87	1.5
Expired	(907)	116.55	116.55	
Forfeited	(451)	124.05 - 131.55	131.12	
Options outstanding, vested and exercisable as of September 30, 2021	<u>1,150</u>	<u>\$124.05 - 223.65</u>	<u>\$ 126.81</u>	<u>1.4</u>

The intrinsic value of options outstanding, vested and exercisable as of September 30, 2021 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 nine months ended September 30, 2021 and 2020 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Research and development	\$ 88	\$ 94	\$ 238	\$ 265
General and administrative	240	312	788	987
Total expense	<u>\$ 328</u>	<u>\$ 406</u>	<u>\$ 1,026</u>	<u>\$ 1,252</u>

(8) Income Taxes

Excluding the impact of the sale of state net operating losses (“NOL”) and research and development tax credits during the nine months ended September 30, 2021 and 2020, the effective tax rate for each of the nine months ended September 30, 2021 and 2020 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 2021 excluding any benefits from any sales of net operating losses 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 June 2021, the Company sold \$16.4 million of state NOLs and \$0.3 million of R&D tax credits under the State of New Jersey’s Technology Business Tax Certificate Transfer Program for net proceeds of \$1.7 million, which resulted in the reversal of the valuation allowance and a tax benefit of \$1.8 million for the nine months ended September 30, 2021. In May 2020, the Company sold \$21.2 million of state NOLs and \$0.2 million of R&D tax 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. The proceeds from such sales are recorded as income tax benefit when sales occur or proceeds are received.

In May 2021 the Company received a Final Determination letter from the New Jersey Division of Taxation (the “Final Determination Letter”) related to the deduction of expenses, disallowed for federal income tax purposes, used in calculating the Orphan Drug Credit for tax years 2015 and 2016. The aggregate claim of tax liabilities owed by the Company was approximately \$1.6 million, inclusive of interest. The Company opted to formally amend the 2015 and 2016 federal income tax returns to forgo the federal Orphan Drug Credit and fully claimed the deduction for the previously disallowed operating expenses. On August 25, 2021 the Company received an additional letter from the New Jersey Division of Taxation notifying the Company of the acceptance of the amended returns and the cancellation of its assessment as communicated in the Final Determination Letter with no liability due for either year.

As of September 30, 2021, 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 by the weighted average number of shares outstanding during the period, as applicable. Diluted net loss per share is calculated by dividing net loss, adjusted to reflect the impact of dilutive warrants, by the weighted average number of shares outstanding, adjusted to reflect potentially dilutive securities using the treasury stock method, except when the effect would be anti-dilutive.

The Company reported a net loss for the nine months ended September 30, 2021 and 2020, therefore diluted net loss per share is the same as the basic net loss per share.

As of September 30, 2021, the Company had 641,534 options to purchase 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, 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.

(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, 2020 for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

Business

We are a clinical-stage therapeutics company focused on developing innovative products that address significant unmet medical needs in the treatment of cardiopulmonary diseases. Our focus is the continued development of our nitric oxide therapy for patients with or at risk of 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 fibrotic interstitial lung disease (“fILD”), which includes PH associated with idiopathic pulmonary fibrosis (“PH-IPF”) as well as other pulmonary fibrosing diseases. During May 2017, we announced the completion of our Phase 2 clinical trial using INOpulse therapy to treat PH-IPF. The clinical data showed that INOpulse was associated with clinically meaningful improvements in hemodynamics and exercise capacity in difficult-to-treat PH-IPF patients. The PH-IPF trial was a proof of concept study (n=4) designed to evaluate the ability of pulsed inhaled nitric oxide, or iNO, to provide selective vasodilation as well as to assess the potential for improvement in hemodynamics and exercise capacity in PH-IPF patients. The clinical trial met its primary endpoint showing an average of 15.3% increase in blood vessel volume ($p < 0.001$) during acute inhalation of iNO as well as showing a significant association between ventilation and vasodilation, demonstrating the ability of INOpulse to provide selective vasodilation to the better ventilated areas of the lung. The trial showed consistent benefit in hemodynamics with a clinically meaningful average reduction of 14% in systolic pulmonary arterial pressure (“sPAP”) with acute exposure to iNO. The study assessed both the iNO 75 and iNO 30 dosage.

In January 2019, we announced top-line results from cohort 1 of our iNO-PF trial. The results suggested directional improvements in multiple clinically meaningful exploratory endpoints as measured by a wearable medical-grade activity monitor. In addition, these results suggested that iNO may have a favorable safety profile, 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 in cohort 3 of change in moderate to vigorous activity (“MVPA”) from baseline to month 4, measured by Actigraphy. Actigraphy (medical wearable continuous activity monitoring) has the potential to provide highly sensitive objective real-world physical activity data that we expect to correlate with clinically meaningful patient functional abilities and health outcomes. 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 suggested directionally favorable and potentially clinically meaningful placebo corrected improvement in MVPA, in subjects treated with iNO45 (45 mcg/kg IBW/hr) versus placebo. The improvement in MVPA was underscored by benefits in overall activity, as well as multiple patient reported outcomes. In March 2020, we announced that in consultation with the FDA, we had finalized some of the key elements of our planned pivotal Phase 3 study for fILD, 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. In December 2020, we announced the first patient enrollment in this Phase 3 study called REBUILD.

In 2018, we initiated an ancillary Phase 2 open-label 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-PF subjects. In February 2020, we announced the completion of the study and that the top-line results demonstrated that INOpulse achieved clinically and statistically meaningful cardiopulmonary improvements in pulmonary vascular resistance and mean pulmonary arterial pressure. The data suggested that inhaled nitric oxide was generally well tolerated and may yield a favorable risk-benefit profile across doses.

In 2018, we also 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 the disease severity and 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 2 open-label dose escalation design that utilizes right heart catheterization to assess the acute hemodynamic effect of INOpulse from a dose of iNO 30 to iNO 125 in PH-Sarc subjects. We have completed the process of initiating clinical sites and enrolling patients into the trial, with results expected in 2021.

We completed a randomized, placebo-controlled, double-blind, dose-confirmation Phase 2 clinical trial of INOpulse for pulmonary hypertension associated with chronic obstructive pulmonary disease, or PH-COPD, in July 2014. The results from this trial showed that iNO 30 was a potentially safe and effective dose for treatment of PH-COPD. Based on the results of this trial, we completed further Phase 2 testing to assess the targeted vasodilation provided by INOpulse in this patient population. We presented the results of this trial in September 2015 at the European Respiratory Society International Congress 2015 in Amsterdam. The data showed that INOpulse improved vasodilation in patients with PH-COPD. In July 2016, the results were published in the International Journal of COPD in an article entitled “Pulmonary vascular effects of pulsed inhaled nitric oxide in COPD patients with pulmonary hypertension.” During September 2017, we shared the results of our Phase 2a PH-COPD trial that was designed to evaluate the acute effects of 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 six minute walk distance, or 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 data suggested that the dose may have a favorable safety profile. 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.

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 mitigate the hospitalized patient’s disease progression and avoid the need to perform intubation. Under the 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 with COVID-19. The proposed randomized, placebo controlled study, called COViNOX, was designed to 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 aimed to enroll up to 500 patients with COVID-19 who were to be treated with either INOpulse or placebo. The primary endpoint of the study required an assessment of the proportion of subjects who experienced respiratory failure or mortality during the 28-day study period, which would 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 completed their 28-day assessment periods in October 2020. In November 2020, we announced that the independent Data Monitoring Committee (“DMC”) had completed its pre-specified interim analysis from the first 100 patients. Based on the finding of futility, we placed the COViNOX study on a clinical hold. Although new enrollment of subjects into the study was halted, the remaining 91

subjects already enrolled at the time the clinical hold was announced were allowed to complete the treatment course. Upon completion of the protocol defined monitoring period, the pre-specified efficacy and safety analysis of these 191 patients was reviewed by the DMC and the DMC concluded that there were no safety concerns that were attributed to INOpulse for COVID-19. Based on the COViNOX results, we put the trial on a permanent clinical hold and we are not planning additional studies for INOpulse for the treatment of COVID-19. In May 2021, we submitted notification of withdrawal of the COViNOX IND to the FDA.

We initiated a Phase 3 clinical trial of INOpulse for PAH in June 2016. As agreed upon with the FDA, a pre-specified interim analysis was conducted by the DMC in August 2018, after half of the planned subjects completed 16 weeks of blinded treatment. The data showed INOpulse provided clinically meaningful improvements in pulmonary vascular resistance (18%), cardiac output (0.7 L/min) and NT Pro-BNP. In addition, subjects on PAH background monotherapy showed a 23 meter improvement in 6MWD, while subjects that were not on prostanoid background therapy showed a 17 meter improvement in 6MWD. However, the DMC determined that the overall change in 6MWD, the primary endpoint of the trial, was insufficient to support the continuation of the study. Accordingly, based on the DMC's recommendation, we discontinued the trial in August 2018. The trial results showed 6MWD was improved when subjects were on fewer background therapies and more patients deteriorated in 6MWD on placebo as compared to iNO. During the trial, however, the data suggested that INOpulse may have a favorable safety profile.

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

Prior to February 2014, we were a wholly-owned subsidiary of Ikaria, Inc. (a subsidiary of Mallinckrodt plc), or Ikaria. As part of an internal reorganization of Ikaria in October 2013, Ikaria transferred to us exclusive worldwide rights, with no royalty obligations, to develop and commercialize pulsed nitric oxide in PAH, PH-COPD and PH-IPF. Following the internal reorganization, in February 2014, Ikaria distributed all of our then outstanding units to its stockholders through the payment of a special dividend on a pro rata basis based on each stockholder's ownership of Ikaria capital stock, which we refer to as the Spin-Out, and as a result we became a stand-alone company. In November 2015, we entered into an amendment to our exclusive cross-license, technology transfer and regulatory matters agreement with Ikaria that included a royalty equal to 3% of net sales of any commercial products for PAH. In April 2018, we expanded the scope of our license from PH-IPF to PH in patients with Pulmonary Fibrosis ("PH-PF"), which includes idiopathic interstitial pneumonias, chronic hypersensitivity pneumonitis, occupational and environmental lung disease, with a royalty equal to 1% of net sales of any commercial products for PH-PF.

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 to potentially advance INOpulse for PH-COPD 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 fILD

We initiated our clinical program in fILD 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. In December 2020, we announced the first patient enrollment in this Phase 3 study.

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 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 completed their 28 days assessment period in October 2020. In November 2020, we announced that the independent DMC had completed its pre-specified interim analysis from the first 100 patients. Based on the finding of futility, we placed the COViNOX study on a clinical hold. Although new enrollment of subjects into the study was halted, the remaining 91 subjects already enrolled at the time the clinical hold was announced were allowed to complete the treatment course. Upon completion of the protocol defined monitoring period, the pre-specified efficacy and safety analysis of these 191 patients was reviewed by the DMC and the DMC concluded that there were no safety concerns that were attributed to INOpulse for COVID-19. Based on the COViNOX results, we put the trial on a permanent clinical hold and we are not planning additional studies for INOpulse for the treatment of COVID-19.

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 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 that 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 fILD and PH-Sarc by third party turnkey manufacturers.

General and Administrative Expenses

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

Results of Operations**Comparison of Three Months Ended September 30, 2021 and 2020**

The following table summarizes our results of operations for the three months ended September 30, 2021 and 2020.

(Dollar amounts in thousands)	Three Months Ended September 30,		\$ Change	% Change
	2021	2020		
Research and development expenses:				
fILD, PH-Sarc and PH-COPD	\$ 871	\$ 789	\$ 82	10 %
COVID-19	(7)	2,164	(2,171)	(100)%
Other clinical trials	3	33	(30)	(91)%
Drug and delivery system costs	207	1,461	(1,254)	(86)%
Clinical programs	1,074	4,447	(3,373)	(76)%
Research and development infrastructure	1,472	1,334	138	10 %
INOpulse engineering	484	284	200	70 %
Total research and development expenses	3,030	6,065	(3,035)	(50)%
General and administrative expenses	1,773	2,196	(423)	(19)%
Total operating expenses	4,803	8,261	(3,458)	(42)%
Loss from operations	(4,803)	(8,261)	3,458	(42)%
Change in fair value of common stock warrant liability	167	319	(152)	(48)%
Interest income and financing expenses, net	2	9	(7)	(78)%
Net loss	\$ (4,634)	\$ (7,933)	\$ 3,299	(42)%

Total Operating Expenses. Total operating expenses for the three months ended September 30, 2021 were \$4.8 million compared to \$8.3 million for the three months ended September 30, 2020, a decrease of \$3.5 million, or 42%. This decrease was primarily due to a decrease in clinical program expenses.

Research and Development Expenses. Total research and development expenses for the three months ended September 30, 2021 were \$3.0 million compared to \$6.1 million for the three months ended September 30, 2020, a decrease of \$3.1 million, or 50%. Total research and development expenses consisted of the following:

- fILD, PH-Sarc and PH-COPD expenses for the three months ended September 30, 2021 were essentially flat as compared to the three months ended September 30, 2020.
- COVID-19 expenses for the three months ended September 30, 2020 included costs related to the Phase 3 clinical trial as well as the EA program. Completion and close-out activities were performed during the three months ended March 31, 2021.
- Drug and delivery system costs for the three months ended September 30, 2021 were \$0.2 million, compared to \$1.5 million for the three months ended September 30, 2020, a decrease of \$1.3 million, or 86%. Drug and delivery system costs are recorded at the time of procurement from our suppliers. The decrease in the drug and delivery system costs was attributable to the close-out of the COVID-19 trial prior to the three months ended September 30, 2021 compared to the activities to support the COVID-19 trial and the Phase 3 trial activities of fILD during the three months ended September 30, 2020.

- Research and development infrastructure for the three months ended September 30, 2021 were \$1.5 million compared to \$1.3 million for the three months ended September 30, 2020, an increase of \$0.2 million, or 10%. The increase was primarily due to an increase in contractor costs associated with the Phase 3 clinical trial for fILD during the three months ended September 30, 2021.
- INOpulse engineering expenses for the three months ended September 30, 2021 were \$0.5 million compared to \$0.3 million for the three months ended September 30, 2020, an increase of \$0.2 million, or 70%. The increase was primarily due to additional consulting expenses related to improvement of the delivery system manufacturing process.

General and Administrative Expenses. General and administrative expenses for the three months ended September 30, 2021 were \$1.8 million compared to \$2.2 million for the three months ended September 30, 2020, a decrease of \$0.4 million, or 19%. The decrease was primarily due to a decrease in consulting and stock-based compensation costs.

Change in Fair Value of Common Stock Warrant Liability. The change in fair value of the common stock warrant liability for the three months ended September 30, 2021 was income of \$0.2 million compared to income of \$0.3 million for the three months ended September 30, 2020, a decrease of \$0.1 million, or 48%. The warrants were issued in November 2016 and May 2017 and the change in the liability fair value was due to a change in our stock price, volatility, and a shorter remaining term.

Comparison of Nine Months Ended September 30, 2021 and 2020

The following table summarizes our results of operations for the nine months ended September 30, 2021 and 2020.

(Dollar amounts in thousands)	Nine Months Ended September 30,		\$ Change	% Change
	2021	2020		
Research and development expenses:				
fILD, PH-Sarc and PH-COPD	\$ 2,599	\$ 2,236	\$ 363	16 %
COVID-19	411	2,709	(2,298)	(85)%
Other clinical trials	9	104	(95)	(91)%
Drug and delivery system costs	966	2,340	(1,374)	(59)%
Clinical programs	3,985	7,389	(3,404)	(46)%
Research and development infrastructure	4,375	3,545	830	23 %
INOpulse engineering	1,493	820	673	82 %
Total research and development expenses	9,853	11,754	(1,901)	(16)%
General and administrative expenses	6,035	6,376	(341)	(5)%
Total operating expenses	15,888	18,130	(2,242)	(12)%
Loss from operations	(15,888)	(18,130)	2,242	(12)%
Change in fair value of common stock warrant liability	600	(768)	1,368	(178)%
Interest income and financing expenses, net	4	50	(46)	(92)%
Pre-tax loss	(15,284)	(18,848)	3,564	(19)%
Income tax benefit	1,800	2,125	(325)	(15)%
Net loss	\$ (13,484)	\$ (16,723)	\$ 3,239	(19)%

Total Operating Expenses. Total operating expenses for the nine months ended September 30, 2021 were \$15.9 million compared to \$18.1 million for the nine months ended September 30, 2020, a decrease of \$2.2 million, or 12%. This decrease was primarily due to a decrease in clinical program expenditures attributable to the completion of the COVID-19 trial in the current period, partially offset by an increase in research and development expenses.

Research and Development Expenses. Total research and development (“R&D”) expenses for the nine months ended September 30, 2021 were \$9.9 million compared to \$11.8 million for the nine months ended September 30, 2020, a decrease of \$1.9 million, or 16%. Total research and development expenses consisted of the following:

- fILD, PH-Sarc and PH-COPD expenses for the nine months ended September 30, 2021 were \$2.6 million, compared to \$2.2 million for the nine months ended September 30, 2020, an increase of \$0.4 million, or 16%. The increase was primarily due to the timing of the Phase 3 fILD trial which was ongoing during the nine months ended September 30, 2021 and the Phase 2 fILD trial during the nine months ended September 30, 2020.
- COVID-19 expenses for the nine months ended September 30, 2021 were \$0.4 million, compared to \$2.7 million for the nine months ended September 30, 2020, a decrease of \$2.3 million, or 85%. The decrease is due to the timing of the completion of the trial and close-out activities during the first quarter of 2021.
- Drug and delivery system costs for the nine months ended September 30, 2021 were \$1.0 million, compared to \$2.3 million for the nine months ended September 30, 2020, a decrease of \$1.3 million, or 59%. Drug and delivery system costs are recorded at the time of procurement from our suppliers. The decrease in the drug and delivery system costs was attributable to the close-out of the COVID-19 trial during the first quarter in 2021 compared to the commencement requirements to support the COVID-19 trial and the Phase 3 trial activities of fILD during the nine months ended September 30, 2020.
- Research and development infrastructure for the nine months ended September 30, 2021 were \$4.4 million compared to \$3.5 million for the nine months ended September 30, 2020, an increase of \$0.9 million, or 23%. The increase was primarily due to an increase in contractor costs associated with the Phase 3 clinical trial for fILD during the nine months ended September 30, 2021.
- INOpulse engineering expenses for the nine months ended September 30, 2021 were \$1.5 million compared to \$0.8 million for the nine months ended September 30, 2020, an increase of \$0.7 million, or 82%. The increase was primarily due to additional consulting expenses related to improvement of the delivery system manufacturing process.

General and Administrative Expenses. General and administrative expenses for the nine months ended September 30, 2021 were \$6.0 million compared to \$6.4 million for the nine months ended September 30, 2020, a decrease of \$0.4 million, or 5%. The decrease was primarily due to a decrease in consulting and stock-based compensation costs.

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, 2021 was income of \$0.6 million compared to expense of \$0.8 million for the nine months ended September 30, 2020. The warrants were issued in November 2016 and May 2017 and the change in the liability fair value was due to a change in our stock price, volatility, and a shorter remaining term.

Income Tax Benefit. Income tax benefit was \$1.8 million for the nine months ended September 30, 2021, compared to \$2.1 million for the nine months ended September 30, 2020, a decrease of \$0.3 million, or 15%. In June 2021, we sold \$16.4 million of state NOLs and \$0.3 million of research and development tax credits under the State of New Jersey's Technology Business Tax Certificate Transfer Program for net proceeds of \$1.7 million. In May 2020, we sold \$21.2 million of state NOLs and \$0.2 million of research and development tax credits under the State of New Jersey's Technology Business Tax Certificate Transfer Program for net proceeds of \$2.0 million. The proceeds from such sales are recorded as income tax benefit when sales occur or proceeds are received.

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 \$28.7 million as of September 30, 2021. Our existing cash and cash equivalents as of September 30, 2021 will be used primarily to fund the Phase 3 trial of INOpulse for fILD and to complete the dose escalation study for PH-Sarc.

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.

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.

In July 2020, we entered into an Open Market Sale AgreementSM 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 our short term financial needs. We have sold \$16.3 million of state NOLs and \$0.3 million of research and development tax credits under the State of New Jersey’s Technology Business Tax Certificate Transfer Program in June 2021 for net proceeds of \$1.7 million and has sold an additional \$21.2 million of state NOLs and \$0.2 million of research and development tax credits for net proceeds of \$1.7 million in May 2020. We plan to sell additional NOLs and R&D credits under the same program in the future subject to program availability and state approval. The proceeds from such sales are recorded as Income tax benefit when sales occur or proceeds are received.

In May 2021 we received a Final Determination letter from the New Jersey Division of Taxation (the “Final Determination Letter”) related to the deduction of expenses, disallowed for federal income tax purposes, used in calculating the Orphan Drug Credit for tax years 2015 and 2016. The aggregate claim of tax liabilities owed by us was approximately \$1.6 million, inclusive of interest. We opted to formally amend our 2015 and 2016 federal income tax returns to forgo the federal Orphan Drug Credit and fully claim the deduction for the previously disallowed operating expenses. On August 25, 2021, we received an additional letter from the New Jersey Division of Taxation notifying us of the acceptance of the amended returns and the cancellation of its assessment as communicated in the Final Determination Letter with no liability due for either year.

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, 2021 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 financings, sales of state NOLs and R&D credits subject to program availability and approval, existing working capital and funding from potential future collaboration arrangements. To the extent that we raise additional capital through the future sale of equity or convertible debt, the ownership interest of our existing stockholders may 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, it may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, or unable to sell our state NOLs and R&D credits, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or

grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. In addition, there are many uncertainties regarding the COVID-19 pandemic, and we are closely monitoring the impact of the pandemic on all aspects of our business, including how the pandemic impact our clinical trials, employees and suppliers. While the pandemic did not materially affect our business operations, site activation and patient enrollment in our clinical trials have been affected by the COVID-19 pandemic. Further, should COVID-19 continue to spread, our business operations could be delayed or interrupted which could result in the use of more funds than anticipated in completing such trials.

Cash Flows

The following table summarizes our cash flows for the nine months ended September 30, 2021 and 2020:

(Dollar amounts in thousands)	Nine Months Ended September 30,	
	2021	2020
Operating activities	\$ (18,843)	\$ (13,480)
Financing activities	—	57,576
Net change in cash, cash equivalents and restricted cash	\$ (18,843)	\$ 44,096

Net Cash Used in Operating Activities

Cash used in operating activities for the nine months ended September 30, 2021 was \$18.8 million, as compared to \$13.5 million for the nine months ended September 30, 2020. The change in cash used in operating activities was primarily due to a decrease in our operating expenses combined with the 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 the proceeds from the registered direct and public offerings in the nine months ended September 30, 2020 as well as warrant exercises in the three months ended March 31, 2020.

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, 2020.

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, 2021, 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, 2020.

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, 2021, we had unrestricted cash and cash equivalents of \$28.7 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, 2021. 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, 2021, 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 three and nine months ended September 30, 2021 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, 2020. 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, 2020.

Recent and pending management changes could disrupt our operations and impair our ability to attract and retain key personnel.

We have experienced a number of recent changes to our senior management team, including the departure of our Chief Executive Officer on October 24, 2021 and our Chief Financial Officer on September 10, 2021. We appointed Peter Fernandes, our Chief Regulatory and Safety Officer, to serve as our Interim Principal Executive Officer, effective as of November 11, 2021 while our Board of Directors conducts a search for a permanent Chief Executive Officer. We appointed Nicholas Laccona, our Controller, to serve as our Principal Financial Officer and Principal Accounting Officer of the Company, effective as of September 30, 2021. Changes in our senior management and uncertainty regarding pending changes may disrupt our operations, impact partner relationships, and impair our ability to recruit and retain other needed personnel. Any such disruption or impairment could have an adverse effect on our business.

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

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

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

Exhibit Index

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

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 15, 2021

By: /s/ Peter Fernandes

Peter Fernandes

Interim Principal Executive Officer

(Principal Executive Officer)

Date: November 15, 2021

By: /s/ Nicholas Laccona

Nicholas Laccona

Principal Financial & Accounting Officer

(Principal Financial Officer)

CERTIFICATION

I, Peter Fernandes, 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 15, 2021

By: /s/ Peter Fernandes
Peter Fernandes
Interim Principal Executive Officer
(Principal Executive Officer)

CERTIFICATION

I, Nicholas Laccona, 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 15, 2021

By: /s/ Nicholas Laccona
Nicholas Laccona
Principal Finance & Accounting 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, 2021 (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 15, 2021

By: /s/ Peter Fernandes

Peter Fernandes
Interim Principal Executive Officer
(Principal Executive Officer)

Date: November 15, 2021

By: /s/ Nicholas Laccona

Nicholas Laccona
Principal Finance & Accounting Officer
(Principal Financial Officer)
