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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2023

or

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

For the transition period from to

Commission File Number 001-36845

Bellerophon Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**47-3116175**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

20 Independence Boulevard, Suite 402
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	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

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

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

The number of shares outstanding of the registrant's common stock as of August 11, 2023: 12,232,648

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REFERENCES TO BELLEROPHON

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

FORWARD-LOOKING STATEMENTS

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

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

- our recently announced plan to review strategic alternatives and significantly reduce our operations and workforce;
- our ability to fund our planned operations for the next twelve months and our ability to continue to operate as a going concern;
- the timing of any future clinical trials and impact on the workforce;
- 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 estimates regarding the potential market opportunity for 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;
- our competitive position; and
- our ability to maintain the listing of our common stock on the Nasdaq Capital Market.

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, 2022, particularly in the “Risk Factors” section, that could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

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

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

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements.

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

	As of June 30, 2023 (Unaudited)	As of December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 10,575	$ 6,924
Restricted cash	107	405
Prepaid expenses and other current assets	563	234
Total current assets	11,245	7,563
Right of use assets, net	—	184
Property and equipment, net	—	2
Other non-current assets	—	186
Total assets	$ 11,245	$ 7,935
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,887	$ 1,230
Accrued research and development	2,391	2,655
Accrued expenses	1,344	1,313
Current portion of operating lease liabilities	—	203
Total current liabilities	5,622	5,401
Total liabilities	5,622	5,401
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.01 par value per share; 200,000,000 shares authorized and 12,232,648 and 9,645,711 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	122	96
Preferred stock, $0.01 par value per share; 5,000,000 shares authorized, zero shares issued and outstanding at June 30, 2023 and December 31, 2022	—	—
Additional paid-in capital	259,895	254,516
Accumulated deficit	(254,394)	(252,078)
Total stockholders' equity	5,623	2,534
Total liabilities and stockholders' equity	$ 11,245	$ 7,935

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

BELLEROPHON THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
AND COMPREHENSIVE LOSS (UNAUDITED)
(in thousands except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Revenues:				
Licensing revenue	$ —	$ —	$ 5,640	$ —
Operating expenses:				
Research and development	2,895	4,488	5,447	8,897
General and administrative	2,364	2,053	3,973	3,286
Total operating expenses	5,259	6,541	9,420	12,183
Loss from operations	(5,259)	(6,541)	(3,780)	(12,183)
Interest and other income, net	121	19	187	20
Pre-tax loss	(5,138)	(6,522)	(3,593)	(12,163)
Income tax benefit	—	2,417	1,277	2,417
Net loss and comprehensive loss	$ (5,138)	$ (4,105)	$ (2,316)	$ (9,746)
Weighted average shares outstanding:				
Basic	12,231,726	9,545,451	11,300,529	9,545,451
Diluted	12,231,726	9,545,451	11,300,529	9,545,451
Net loss per share:				
Basic	$ (0.42)	$ (0.43)	$ (0.20)	$ (1.02)
Diluted	$ (0.42)	$ (0.43)	$ (0.20)	$ (1.02)

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 six months ended June 30, 2023:

	Common Stock		Additional Paid in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at March 31, 2023	10,448,185	$ 104	$ 259,754	$ (249,256)	$ 10,602
Net loss	—	—	—	(5,138)	(5,138)
Stock-based compensation	—	—	133	—	133
Exercise of pre-funded warrants	1,781,526	18	—	—	18
Exercise of stock options	1,288	—	10	—	10
Issuance of common stock, restricted stock vesting	2,500	—	—	—	—
Surrender of shares to the Company for the payment of tax withholding obligations	(851)	—	(2)	—	(2)
Balance at June 30, 2023	12,232,648	$ 122	$ 259,895	$ (254,394)	$ 5,623
Balance at December 31, 2022	9,645,711	$ 96	$ 254,516	$ (252,078)	$ 2,534
Net loss	—	—	—	(2,316)	(2,316)
Direct offering of common stock	718,474	7	1,430	—	1,437
Direct offering of pre-funded warrants	—	—	3,545	—	3,545
Stock-based compensation	—	—	397	—	397
Exercise of pre-funded warrants	1,781,526	18	—	—	18
Exercise of stock options	1,288	—	10	—	10
Issuance of common stock, restricted stock vesting	86,500	1	(1)	—	—
Surrender of shares to the Company for the payment of tax withholding obligations	(851)	—	(2)	—	(2)
Balance at June 30, 2023	12,232,648	$ 122	$ 259,895	$ (254,394)	$ 5,623

For the three and six months ended June 30, 2022:

	Common Stock		Additional Paid in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at March 31, 2022	9,545,451	$ 95	$ 253,963	$ (237,888)	$ 16,170
Net loss	—	—	—	(4,105)	(4,105)
Stock-based compensation	—	—	215	—	215
Balance at June 30, 2022	9,545,451	$ 95	$ 254,178	$ (241,993)	$ 12,280
Balance at December 31, 2021	9,545,451	$ 95	$ 253,771	$ (232,247)	$ 21,619
Net loss	—	—	—	(9,746)	(9,746)
Stock-based compensation	—	—	407	—	407
Balance at June 30, 2022	9,545,451	$ 95	$ 254,178	$ (241,993)	$ 12,280

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

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

	Six Months Ended June 30,	
	2023	2022
Cash flows from operating activities:		
Net loss	$ (2,316)	$ (9,746)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	2	40
Stock-based compensation	397	407
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(329)	363
Other non-current assets	186	—
Accounts payable, accrued research and development, lease liabilities and other accrued expenses	405	528
Net cash used in operating activities	(1,655)	(8,408)
Cash flows from financing activities:		
Proceeds from issuance of common stock in Direct Offering	1,437	—
Proceeds from exercise of pre-funded warrants in Direct Offering	3,545	—
Proceeds received from exercise of pre-funded warrants	18	—
Proceeds received from exercise of stock options	10	—
Tax withholding payments for stock compensation	(2)	—
Net cash provided by financing activities	5,008	—
Net change in cash, cash equivalents and restricted cash	3,353	(8,408)
Cash, cash equivalents and restricted cash at beginning of period	7,329	25,139
Cash, cash equivalents and restricted cash at end of period	$ 10,682	$ 16,731

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 has been the development of its nitric oxide therapy for patients with pulmonary hypertension, or PH, using its proprietary delivery system, INOpulse®**.** The Company has three wholly-owned subsidiaries: Bellerophon BCM LLC, a Delaware limited liability company; Bellerophon Pulse Technologies LLC, a Delaware limited liability company; and Bellerophon Services, Inc., a Delaware corporation. On June 5, 2023, the Company announced top-line results from its Phase 3 REBUILD clinical trial evaluating the safety and efficacy of INOpulse® for the treatment of Interstitial Lung Disease. The trial did not meet its primary endpoint and the secondary endpoints demonstrated minimal difference between the two groups with none approaching statistical significance. Overall, INOpulse® was well-tolerated with no safety concerns, consistent with what had been observed in the prior Phase 2 studies. Based on these findings, the Company decided to terminate the REBUILD Phase 3 clinical study and withdraw patients from all of the Company's ongoing INOpulse® development programs. These conditions and events raise substantial doubt about the Company's ability to continue as a going concern.

The Company intends to explore a range of strategic alternatives to maximize stockholder value. Strategic alternatives that may be evaluated include, but are not limited to, a merger, a business combination, a sale of assets or other strategic transaction or a liquidation and dissolution. There is no set timetable for this process and there can be no assurance that this process will result in the Company pursuing a transaction or that any transaction, if pursued, will be completed on attractive terms. In connection with the termination of the clinical study, the Company approved a reduction-in-force of substantially all of the Company's employees, including officers. The workforce reduction is designed to reduce the Company's operating expenses while the Company explores a range of strategic alternatives. The Company expects that the implementation of the workforce reduction will be substantially completed by the end of the third quarter of 2023. The Company's Chief Executive Officer has agreed to remain employed by the Company until November 15, 2023 or such later date if extended by the Company in its discretion.

The Company recorded approximately $0.8 million in separation costs during the six months ended June 30, 2023 as a component of general and administrative expenses.

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

- On July 19, 2023, the Company was notified by the Listing Qualifications Department (the "Staff") of The Nasdaq Stock Market LLC ("Nasdaq") that in light of the Company's previously disclosed workforce reduction plan and focus on exploring strategic alternatives, based upon the Staff's belief that the Company is a "public shell" as that term is defined in Nasdaq Listing Rule 5101 and the Company's non-compliance with the $1.00 bid price requirement set forth in Nasdaq Listing Rule 5550(a)(2), the Company would be delisted from The Nasdaq Capital Market at the opening of business on July 28, 2023 unless the Company timely requested a hearing before a Nasdaq Hearings Panel (the "Panel") to address the deficiencies and present a plan to regain compliance. The Company timely requested a hearing before the Panel, which request has stayed any further delisting action by the Staff pending the ultimate outcome of the hearing and the expiration of any extension that may be granted by the Panel. The hearing is currently scheduled for September 21, 2023 and a decision by the Panel is typically not rendered for several weeks after such hearing. The Company's common stock will remain listed and eligible for trading on Nasdaq at least pending the ultimate conclusion of the hearing process.

- The Company is exploring strategic alternatives that could significantly impact its future operations and financial position.

- The outcome of the Company's recent REBUILD Phase 3 clinical study and resulting impact on the Company's access to capital indicate substantial doubt exists related to its ability to continue as a going concern.

- If the Company does not successfully consummate a strategic transaction, the board of directors may decide to pursue a liquidation and dissolution.

- The expectation that the Company will continue to experience operating losses for the foreseeable future.

- The risk that the Company will fail to obtain adequate financing to meet its future operational and capital needs, for which the Company may be required to further reduce or cease operations.

- The risk that the Company will be unable to obtain adequate funds to alleviate the substantial doubt about its ability to continue as a going concern.

(2) Summary of Significant Accounting Policies

(a) Basis of Presentation

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

The Company is responsible for the unaudited condensed consolidated financial statements. The condensed consolidated financial statements include all normal and recurring adjustments that are considered necessary for the fair presentation of the Company's financial position, results of operations and comprehensive loss and its cash flows for the periods presented. These condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements for the year ended December 31, 2022, included in the Company's Annual Report on Form 10-K for the year ended December 31, 2022. The results of operations for the three and six months ended June 30, 2023 for the Company are not necessarily indicative of the results expected for the full year.

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

(b) Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity date of three months or less to be cash equivalents. All investments with maturities of greater than three months from 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 is recognized on a straight-line basis over the requisite service period or sooner if the awards immediately vest. The Company determines the fair value of stock options issued using a Black-Scholes-Merton option pricing model. Certain assumptions used in the model include expected volatility, dividend yield, risk-free interest rate and expected term. For restricted stock, the fair value is the closing market price per share on the grant date. See Note 7 - *Stock-Based Compensation* for a description of these assumptions.

(d) Common Stock Warrants

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 historically classified warrant liabilities on the consolidated balance sheet based on the warrants' terms as long-term liabilities, which were revalued at each balance sheet date subsequent to the initial issuance. Changes in the fair value of the liability-classified warrants were historically reflected in the consolidated statement of operations as "Change in fair value of common stock warrant liability." The Company used the Black-Scholes-Merton pricing model to value the related warrant liability. There were no remaining liability-classified warrants as of June 30, 2023 and December 31, 2022.

(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. Lease expense is recognized on a straight-line basis over the term of the lease. Lease liabilities 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 for leases 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 six months ended June 30, 2023 and 2022 were de minimis.

(h) Revenue from Contracts with Customers

To date the Company's only revenue has consisted of license revenue. The Company has not generated any revenue from product sales and does not expect to generate any revenue from product sales for the foreseeable future.

The Company recognizes revenue in accordance with ASC 606, *Revenue from Contracts with Customers* ("ASC 606"). ASC 606 applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under ASC 606, the Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration the Company expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that are within the scope of ASC 606, the Company performs the following five steps:

(i) identify the contract(s) with a customer;

(ii) identify the performance obligations in the contract;

(iii) determine the transaction price;

(iv) allocate the transaction price to the performance obligations in the contract; and

(v) recognize revenue when (or as) the Company satisfies a performance obligation.

If a contract is determined to be within the scope of ASC 606 at inception, the Company assesses the goods or services promised within such contract, determines which of those goods and services are performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Specifically, license revenue relates to license fees from the Company's license agreement granting a customer with the right to use the Company's intellectual property for development and commercialization activities within an authorized territory. The Company must first assess whether the license is distinct, which depends upon whether the customer can benefit from the license and whether the license is separate from other performance obligations in the agreement. If the license is distinct, the Company must further assess whether the customer has a right to access or a right to use the license depending on whether the functionality of the license is expected to substantively change over time. If the license is not expected to substantively change, the revenue is recognized at a point in time when the license is provided. If the license is expected to substantively change, the revenue is recognized over the license period. The Company's license agreement entered into during the six months ended June 30, 2023 was determined to be a right to use license and accordingly, the revenue was recognized at a point in time.

(i) New Accounting Pronouncements

Not Yet Adopted

In June 2022, the FASB issued ASU No. 2022-03: ASC Subtopic 820 - Value Measurement of Equity Securities Subject to Contractual Sale Restrictions ("ASU 2022-03"). ASU 2022-03 amends ASC 820 to clarify that a contractual sales restriction is not considered in measuring an equity security at fair value and to introduce new disclosure requirements for equity securities subject to contractual sale restrictions that are measured at fair value. ASU 2022-03 applies to both holders and issuers of equity and equity-linked securities measured at fair value. The amendments in ASU 2022-03 are effective for the Company for fiscal years beginning after December 15, 2023, and the interim periods within those fiscal years. Early adoption is permitted for both interim and annual financial statements that have not yet been issued or made available for issuance. The Company is evaluating the impact of this pronouncement on its consolidated financial statements and related disclosures.

(3) Liquidity

In the course of its development activities, the Company has sustained operating losses and expects such losses to continue for the foreseeable future. The Company's primary uses of capital have been compensation and related expenses, third-party clinical research and development services, contract manufacturing services, laboratory and related supplies, clinical costs, legal and other regulatory expenses and general overhead costs.

The Company had unrestricted cash and cash equivalents of $10.6 million as of June 30, 2023. The Company's existing cash and cash equivalents as of June 30, 2023 will be used primarily to fund the termination of the Phase 3 trial of INOpulse for fILD and explore a range of strategic alternatives to maximize stockholder value. Strategic alternatives that may be evaluated include, but are not limited to, a merger, a business combination, a sale of assets or other strategic transaction or a liquidation and dissolution. There is no set timetable for this process and there can be no assurance that this process will result in the Company pursuing a transaction or that any transaction, if pursued, will be completed on attractive terms.

The Company evaluated whether there are any 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 June 30, 2023 are not sufficient to satisfy its operating cash needs for at least one year after the filing of this Quarterly Report on Form 10-Q. Accordingly, substantial doubt about the Company's ability to continue as a going concern exists.

Until such time, if ever, as the Company can generate substantial revenues, it expects to finance its cash needs through a combination of equity and debt financings, existing working capital and funding from potential future collaboration or licensing arrangements, licensing agreements or strategic alternative. Strategic alternatives that may be evaluated include, but are not limited to, a merger, business combination, sale of assets or other strategic transaction or a liquidation and dissolution. 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, it may be required to cease operations.

(4) Right of Use Assets and Leases

The Company historically maintained 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 was for a term of four years with an expiration date of March 31, 2023, with the Company's right to extend the original term for one period of five years. During the six months ended June 30, 2023, the Company decided not to renew the lease associated with its corporate headquarters and decided to vacate the premises upon the expiration of the existing lease.

The laboratory lease was for a term of three years and nine months with an expiration date of April 30, 2023. During the six months ended June 30, 2023, the Company agreed to a short-term lease extension of the existing laboratory space through August 2023. Upon expiration of the lease, the Company intends to operate remotely or in temporary flexible office workspace locations on demand. The existing laboratory space and future remote workspace locations are deemed adequate to meet the Company's needs. 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 for leases with a term of twelve months or less on its 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 six months ended June 30, 2023 and 2022 were de minimis.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Cash paid for operating lease liability	$ 8	$ 196	$ 205	$ 390
Operating lease expenses	$ 8	$ 177	$ 185	$ 354
Weighted average remaining lease term			— years	0.8 years
Weighted average discount rate			— %	4.93 %

There are no right-of-use assets or lease liabilities recognized as of June 30, 2023.

(5) Common Stock Warrants and Warrant Liability

On November 29, 2016, the Company issued 1,142,838 warrants to purchase shares of common stock to investors that were immediately exercisable with an original expiration date five years from issuance at an exercise price of $12.00 per share (the "2016 Warrants"). Of the 2016 Warrants issued, 557,699 warrants were either previously exercised or expired unexercised, leaving 585,139 warrants outstanding as of June 30, 2023, all of which are equity classified. None of the 2016 Warrants were exercised during the six months ended June 30, 2023 or 2022.

On May 15, 2017, the Company issued, to an investor, warrants to purchase 66,666 shares of common stock that became exercisable commencing six months from their issuance with an expiration date 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 of common stock that were immediately exercisable with an expiration date 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 June 30, 2023, all of the warrants have expired, unexercised.

On September 29, 2017, the Company issued warrants to purchase 1,296,650 shares of common stock that became exercisable commencing six months from their issuance with an expiration date 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 June 30, 2023, all of these warrants have expired, unexercised.

On March 3, 2023, the Company entered into a subscription agreement with an institutional investor, pursuant to which the Company agreed to issue and sell in a registered direct offering (i) an aggregate of 718,474 shares of common stock, $0.01 par value per share and (ii) 1,781,526 pre-funded warrants (the “Pre-Funded Warrants”) to purchase shares of common stock. The Pre-Funded Warrants were sold at an offering price of $1.99 per Pre-Funded Warrant, which represents the per share offering price for the common stock less a $0.01 per share exercise price for each such Pre-Funded Warrant. The Pre-Funded Warrants are exercisable at any time after the date of issuance. A holder of Pre-Funded Warrants may not exercise the warrant if the holder, together with its affiliates, would beneficially own more than 9.99% of the number of shares of common stock outstanding immediately after giving effect to such exercise. A holder of Pre-Funded Warrants may increase or decrease this percentage, but not in excess of 19.99%, by providing at least 61 days prior notice to the Company. The Pre-Funded Warrants cannot not require cash settlement, are freestanding financial instruments that are legally detachable and separately exercisable from the shares of common stock with which they were issued, are immediately exercisable, and do not embody an obligation for the Company to repurchase its shares and permit the holders to receive a fixed number of shares of common stock upon exercise. Additionally, the Pre-Funded Warrants do not provide any guarantee of value or return. Accordingly, the Pre-Funded Warrants were classified as a component of permanent equity. During the three months ended June 30, 2023, all of the Pre-Funded Warrants were exercised.

The following table summarizes warrant activity for the six months ended June 30, 2023 (fair value amount in thousands):

	Equity Classified	Liability Classified	
	Warrants	Warrants	Estimated Fair Value
Warrants outstanding as of December 31, 2022	1,881,789	—	$ —
Expired	(1,296,650)	—	—
Issued	1,781,526	—	—
Exercised	(1,781,526)	—	—
Warrants outstanding as of June 30, 2023	585,139	—	$ —

The following table summarizes warrant activity for the six months ended June 30, 2022 (fair value amount in thousands):

	Equity Classified	Liability Classified	
	Warrants	Warrants	Estimated Fair Value
Warrants outstanding as of December 31, 2021	1,881,789	70,666	$ 1
Expired	—	(4,000)	—
Warrants outstanding as of June 30, 2022	1,881,789	66,666	$ 1

(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.

There were no liabilities measured at fair value as of June 30, 2023 or December 31, 2022.

There were no outstanding liability classified warrants as of June 30, 2023 and December 31, 2022.

(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 June 7, 2023, the Company's stockholders approved an amendment to the 2015 Plan to increase the number of shares authorized for the issuance of awards from 833,333 to 1,443,318 shares. As of June 30, 2023, the Company had 422,966 shares available for grant with an aggregate of 2,089,637 shares of common stock authorized under the 2015 Plan.

As of June 30, 2023, 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 2.7 years.

No tax benefit was recognized during the three and six months ended June 30, 2023 and 2022 related to stock-based compensation expense since the Company incurred operating losses and has established a full valuation allowance to offset all of the potential tax benefits associated with its deferred tax assets.

Options

The weighted average grant-date fair value of options issued during the six months ended June 30, 2023 was $1.22. There were no options issued during the six months ended June 30, 2022. The following are the weighted average assumptions used in estimating the fair values of the options issued during the six months ended June 30, 2023:

	Six Months Ended June 30, 2023
Valuation assumptions:	
Risk-free rate	3.86 %
Expected volatility	147.39 %
Expected term (years)	6.0
Dividend yield	—

A summary of option activity under the 2015 and 2014 Plans for the six months ended June 30, 2023 is presented below:

	Bellerophon 2015 and 2014 Equity Incentive Plans			
	Options	Range of Exercise Price	Weighted Average Price	Weighted Average Remaining Contractual Life (in years)
Options outstanding as of December 31, 2022	322,038	$ 3.10 - 199.20	$ 12.58	6.7
Granted	904,428	0.83 - 1.52	1.22	
Exercised	(1,288)	7.35 - 7.50	7.47	
Forfeited	(155,330)	0.83 - 10.12	1.96	—
Options outstanding as of June 30, 2023	1,069,848	$ 0.83 - 199.20	$ 4.53	8.7
Options vested and exercisable as of June 30, 2023	312,444	$ 0.83 - 199.20	$ 12.47	6.2

The intrinsic value of options outstanding, vested and exercisable as of June 30, 2023 was zero.

Restricted Stock

Compensation expense is measured based on the fair value of the restricted stock on the grant date and is recognized on a straight-line basis over the requisite service period. Restricted stock are forfeited if the employee ceases to be employed by the Company prior to vesting.

A summary of restricted stock activity under the 2015 Plan for the six months ended June 30, 2023 is presented below:

	Bellerophon 2015 Equity Incentive Plan			
	Shares	Weighted Average Fair Value	Aggregate Grant Date Fair Value (in millions)	Weighted Average Remaining Contractual Life (in years)
Restricted stock outstanding as of December 31, 2022	165,500	$ 2.23	$ 0.4	0.9
Granted	131,578	1.27	0.2	
Vested	(86,500)	1.53	(0.1)	
Forfeited	(48,000)	1.95	(0.1)	
Restricted stock outstanding as of June 30, 2023	162,578	$ 1.91	$ 0.3	0.5

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 six months ended June 30, 2023, 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, 2022	864	$ 124.05 - 131.55	$ 124.50	0.2
Expired	(864)	124.05 - 131.55	124.50	—
Options outstanding as of June 30, 2023	—	$ -	$ —	—
Options vested and exercisable as of June 30, 2023	—	$ -	$ —	—

The intrinsic value of options outstanding, vested and exercisable as of June 30, 2023 was zero.

Stock-Based Compensation Expense, Net of Estimated Forfeitures

The following table summarizes the stock-based compensation expense by the unaudited condensed consolidated statement of operations line items for the three and six months ended June 30, 2023 and 2022 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Research and development	$ 92	$ 133	$ 193	$ 246
General and administrative	41	82	204	161
Total expense	$ 133	$ 215	$ 397	$ 407

(8) Revenue

Licensing Revenue

The Company's sources of revenue are detailed in Note 2, *Summary of Significant Accounting Policies*.

Performance Obligations

A performance obligation is a promise in a contract to transfer a distinct good or service to the customer and is the unit of account in ASC 606. A contract's transaction price is allocated to each distinct performance obligation and recognized as revenue when, or as, the performance obligation is satisfied.

At contract inception, the Company assesses the goods or services promised in its contracts with customers and identifies a performance obligation for each promise to transfer to the customer a good or service that is distinct. When identifying individual performance obligations, the Company considers all goods or services promised in the contract regardless of whether explicitly stated in the customer contract or implied by customary business practices. The Company's license agreement with Baylor BioSciences, Inc. ("Baylor"), requires the Company to grant the right of use of its intellectual property to Baylor within China, Hong Kong, Macau and Taiwan (collectively, the "Territory"), which represents a single performance obligation. The Company's performance obligation with respect to the license agreement with Baylor is satisfied at a point in time, when Baylor was first able to use the license provided, which occurred during the six months ended June 30, 2023. Net cash receipts of $5.0 million, consisting of gross license fees of $6.0 million less VAT and withholding taxes of $1.0 million, were received in full as of June 30, 2023. The VAT expenses are accounted for as a pass-through expense similar to that of sales tax and the withholding taxes are accounted for as income tax expenses incurred by the Company during the six months ended June 30, 2023. The contract also

contains a provision for future royalties based on Baylor's future net sales and any related revenues earned by the Company are recognized at the time of Baylor's sale.

(9) Income Taxes

Excluding the impact of the sale of state net operating losses ("NOL") and research and development tax credits, the effective tax rate for the six months ended June 30, 2023 and 2022 was (16.7%) and zero, respectively. The effective tax rate for the six months ended June 30, 2023 was lower than the federal statutory rate due to the impact of the $0.6 million paid to the Chinese tax authorities for required withholding taxes applicable under Chinese tax regulations. The $0.6 million payment of withholdings taxes are eligible for a credit under the U.S. income tax regulations and as such are recorded as an income tax expense for the period. The effective tax rate for the six months ended June 30, 2022 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 2023 excluding any benefits from any sales of net operating losses or research and development, or R&D, tax credits is expected to be less than zero because of the impact of the withholding taxes paid to the Chinese tax authorities described above, however, the Company expects to generate additional losses and currently has maintained 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.

During January 2023, the Company completed the sale of $19.7 million of state NOLs and $0.1 million of R&D credits under the State of New Jersey's Technology Business Tax Certificate Transfer Program for net proceeds of $1.7 million. During April 2022, the Company completed the sale of $25.1 million of state NOLs and $0.2 million of R&D credits under the State of New Jersey's Technology Business Tax Certificate Transfer Program for net proceeds of $2.2 million.

As of June 30, 2023, there were no material uncertain tax positions. There are no tax positions for which a material change in any unrecognized tax benefit liability is reasonably possible in the next 12 months.

(10) Net Loss Per Share

Basic net loss per share is calculated by dividing net loss by the weighted average number of shares outstanding during the period, as applicable. Included in the calculation of the weighted average number of shares outstanding for the basic net loss per share calculation for the three and six months ended June 30, 2023 are the 1,781,526 pre-funded warrants, as described in Note 5 – *Common Stock Warrants and Warrant Liability*, as they were issuable in exchange for a nominal cash consideration and are therefore treated as issued for basic net loss per share purposes. Diluted net loss per share is calculated by dividing net loss by the weighted average number of shares outstanding, adjusted to reflect potentially dilutive securities using the treasury stock method, except when the effect would be anti-dilutive.

The Company reported a net loss for the three and six months ended June 30, 2023 and 2022, therefore diluted net loss per share is the same as the basic net loss per share.

The following table sets forth the computation of basic and diluted net loss per common share for the three and six months ended June 30, 2023 (in thousands, except share and per share amounts):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Net loss	$ (5,138)	$ (4,105)	$ (2,316)	$ (9,746)
Weighted-average shares:				
Basic	12,231,726	9,545,451	11,300,529	9,545,451
Effect of dilutive securities:				
Options	—	—	—	—
Restricted Stock	—	—	—	—
Diluted	12,231,726	9,545,451	11,300,529	9,545,451
Net loss per share:				
Basic	$ (0.42)	$ (0.43)	$ (0.20)	$ (1.02)
Diluted	$ (0.42)	$ (0.43)	$ (0.20)	$ (1.02)

As of June 30, 2023, the Company had 1,069,848 options to purchase shares, 585,139 warrants to purchase shares, and 162,578 restricted stock units 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 June 30, 2022, the Company had 686,162 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.

(11) Commitments and Contingencies

Legal Proceedings

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

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, 2022 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 has primarily been the 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.

During August 2017, we announced acceptance by the U.S. Food and Drug Administration (the "FDA") of our Investigational New Drug ("IND") application for our Phase 2b ("iNO-PF") clinical trial using INOpulse therapy in a broad population of patients with pulmonary fibrosis, or PF, at both low and intermediate/high risk of PH. In January 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 September 2022, the FDA informed us that it had no objection to our proposal to reduce the study size to 140 subjects which does not impact the trial's principal objective or endpoints and maintains power of >90% (p-value <0.01) for the primary endpoint of MVPA based on the effect size observed in our Phase 2 study. The FDA did note that since our proposal to reduce the sample size was based on Phase 2b cohort 2 actigraphy data, there is always a concern that such sample size reduction may further limit the acquisition of information on other important clinical endpoints in the trial. During January 2023, we completed enrollment of the REBUILD study with a total of 145 patients enrolled. In May 2023, the last subject completed blinded treatment in the REBUILD study.

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 was a Phase 2 open-label dose escalation design that utilized right heart catheterization to assess the acute hemodynamic effect of INOpulse from a dose of iNO 30 to iNO 125 in PH-Sarc subjects. In December 2021, we announced the completion of the acute dose escalation phase of the study and that the top-line results demonstrated that INOpulse provided clinically meaningful improvements in pulmonary vascular resistance. Supported by the results from this study, on June 21, 2022, we submitted to the FDA an exploratory Phase 2 double-blinded placebo-controlled study to investigate the safety and efficacy of inhaled nitric oxide/INOpulse dosed chronically for six months in patients with PH-Sarc. Subsequently, on July 28, 2022, we received an FDA letter indicating that the FDA completed its review of our study protocol, with a minor recommendation to include safety stopping rules. We have agreed to incorporate this recommendation into our periodic safety reviews. We do not currently have the resources to initiate this Phase 2 study.

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 pulsed inhaled nitric oxide, or iNO, on vasodilation as well as the chronic effect on hemodynamics and exercise tolerance. The trial showed a statistically significant increase (average 4.2%) in blood vessel volume on iNO compared to baseline (p=0.03), and a statistically significant correlation in Ventilation-Vasodilation (p=0.01). The chronic results demonstrated a statistically significant and clinically meaningful increase in 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 do not currently have the resources to initiate this Phase 2b study.

We have devoted all of our resources to our therapeutic discovery and development efforts, including performance of IND-enabling studies, 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.

On June 5, 2023, we announced top-line results from our Phase 3 REBUILD clinical trial evaluating the safety and efficacy of INOpulse® for the treatment of Interstitial Lung Disease. The trial did not meet its primary endpoint and the secondary endpoints demonstrated minimal difference between the two groups with none approaching statistical significance. Overall, INOpulse® was well-tolerated with no safety concerns, consistent with what has been observed in the prior Phase 2 studies. Based on these findings, we decided to terminate the REBUILD Phase 3 clinical study and withdraw patients from all of our ongoing INOpulse development programs. We intend to explore a range of strategic alternatives to maximize stockholder value. Strategic alternatives that may be evaluated include, but are not limited to, a merger, a business combination, a sale of assets or other strategic transaction or a liquidation and dissolution. There is no set timetable for this process and there can be no assurance that this process will result in us pursuing a transaction or that any transaction, if pursued, will be completed on attractive terms. In connection with the termination of the clinical study, we approved a reduction-in-force of substantially all of our employees, including officers. The workforce reduction is designed to reduce our operating expenses while we explore a range of strategic alternatives. We expect that the implementation of the workforce reduction will be substantially completed by the end of the third quarter of 2023. Affected employees were offered separation benefits, including severance payments along with temporary healthcare coverage assistance. Severance and termination-related costs of approximately $0.8 million were recorded in the second quarter of 2023, as a component of general and administrative expenses. We expect to record additional severance and termination-related costs of approximately $0.7 million in the second half of 2023. Our Chief Executive Officer has agreed to remain employed by the Company until November 15, 2023 or such later date if extended by us in our discretion.

On July 19, 2023, we were notified by the Listing Qualifications Department (the “Staff”) of The Nasdaq Stock Market LLC (“Nasdaq”) that in light of our previously disclosed workforce reduction plan and focus on exploring strategic alternatives, based upon the Staff’s belief that we are a “public shell” as that term is defined in Nasdaq Listing Rule 5101 and our non-compliance with the $1.00 bid price requirement set forth in Nasdaq Listing Rule 5550(a)(2), we would be delisted from The Nasdaq Capital Market at the opening of business on July 28, 2023 unless we timely requested a hearing before a Nasdaq Hearings Panel (the “Panel”) to address the deficiencies and present a plan to regain compliance. We timely requested a hearing before the Panel, which request stayed any further delisting action by the Staff pending the ultimate outcome of the hearing and the expiration of any extension that may be granted by the Panel. The hearing is currently scheduled for September 21, 2023 and a decision by the Panel is typically not rendered for several weeks after such hearing. Our common stock will remain listed and eligible for trading on Nasdaq at least pending the ultimate conclusion of the hearing process.

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.

License Agreement with Baylor BioSciences, Inc.

In January 2023, we entered into a License Agreement with Baylor BioSciences, Inc. ("Baylor"), pursuant to which Baylor received exclusive rights to develop and commercialize INOpulse within Greater China for diseases associated with pulmonary hypertension, including the lead indication of fibrotic interstitial lung disease ("fILD"), as well as PAH, PH-Sarcodosis, and PH-COPD, CTEPH and PH associated with pulmonary edema from high altitude sickness. Under the terms of the License Agreement, we received a license payment of $5 million, which was net of VAT and withholding taxes of approximately $1.0 million, from Baylor. Additionally, we are entitled to royalties of 5% on net sales by Baylor resulting from all of the licensed INOpulse indications within Greater China.

Registered Direct Offering

On March 3, 2023, we entered into a subscription agreement with an institutional investor, pursuant to which we agreed to issue and sell in a registered direct offering (the "Offering") (i) an aggregate of 718,474 shares (the "Shares") of our common stock and (ii) pre-funded warrants (the "Pre-Funded Warrants") to purchase up to 1,781,526 shares of common stock. We closed the Offering on March 7, 2023 with the Shares sold to the purchaser at a price per share of $2.00 per share. The Pre-Funded Warrants were sold at an offering price of $1.99 per Pre-Funded Warrant, which represents the per share offering price for the common stock less a $0.01 per share exercise price for each such Pre-Funded Warrant. No underwriter or placement agent participated in the Offering and the proceeds from the Offering were approximately $5 million.

The Pre-Funded Warrants are exercisable at any time after the date of issuance. A holder of Pre-Funded Warrants may not exercise the warrant if the holder, together with its affiliates, would beneficially own more than 9.99% of the number of shares of common stock outstanding immediately after giving effect to such exercise. A holder of Pre-Funded Warrants may increase or decrease this percentage, but not in excess of 19.99%, by providing at least 61 days prior notice to us. During the three months ended June 30, 2023, all of the Pre-Funded Warrants were exercised.

The Offering was made pursuant to the Company's shelf registration statement previously filed with the Securities and Exchange Commission (the "SEC"), originally filed on June 26, 2020 (File No. 333-239473), which the SEC declared effective on July 2, 2020, and a related prospectus supplement.

Completion of Sale under the State of New Jersey's Technology Business Tax Certificate Transfer Program

During January 2023, we completed a sale of our NOLs and R&D credits under the State of New Jersey's Technology Business Tax Certificate Transfer Program. We sold $19.7 million of state NOLs and $0.1 million of R&D credits for net proceeds of approximately $1.7 million.

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. Our ability to pursue clinical development activities discussed in this report will require significant funding, which is unlikely to be available, or may only be pursued if we are able to successfully complete a strategic alternative. We are currently exploring strategic alternatives that could significantly impact our future operations and financial position.

We recognize revenue in accordance with ASC 606, *Revenue from Contracts with Customers* ("ASC 606"). ASC 606 applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under ASC 606, we recognize revenue when our customer obtains control of promised goods or services, in an amount that reflects the consideration we expect to receive in exchange for those goods or services. To determine revenue recognition for arrangements that are within the scope of ASC 606, we perform the following five steps:

(i) identify the contract(s) with a customer;

(ii) identify the performance obligations in the contract;

(iii) determine the transaction price;

(iv) allocate the transaction price to the performance obligations in the contract; and

(v) recognize revenue when (or as) we satisfy a performance obligation.

If a contract is determined to be within the scope of ASC 606 at inception, we assess the goods or services promised within such contract, determines which of those goods and services are performance obligations, and assesses whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Specifically, license revenue relates to license fees from our license agreement granting a customer with the right to use our intellectual property for development and commercialization activities within an authorized territory. We must first assess whether the license is distinct, which depends upon whether the customer can benefit from the license and whether the license is separate from other performance obligations in the agreement. If the license is distinct, we must further assess whether the customer has a right to access or a right to use the license depending on whether the functionality of the license is expected to substantively change over time. If the license is not expected to substantively change, the revenue is recognized at a point in time when the license is provided. If the license is expected to substantively change, the revenue is recognized over the license period. Our license agreement with Baylor entered into during the six months ended June 30, 2023 was determined to be a right to use license and accordingly, the revenue was recognized at a point in time.

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 has been 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.

We have tracked external research and development expenses and personnel expenses on a program-by-program basis. We used 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 have also not been 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.

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 invested in regulatory, quality, clinical development and clinical operations activities, which have been expensed as incurred. These activities have primarily supported 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 have manufactured and serviced the INOpulse devices that we have used in our 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 June 30, 2023 and 2022

The following table summarizes our results of operations for the three months ended June 30, 2023 and 2022.

(Dollar amounts in thousands)	Three Months Ended June 30, 2023	2022	$ Change	% Change
Revenues:				
Licensing revenue	$ —	$ —	$ —	— %
Research and development expenses:				
fILD, PH-Sarc and PH-COPD	1,162	1,185	(23)	(2)%
Drug and delivery system costs	176	1,040	(864)	(83)%
Clinical programs	1,338	2,225	(887)	(40)%
Research and development infrastructure	1,186	1,808	(622)	(34)%
INOpulse engineering	371	455	(84)	(18)%
Total research and development expenses	2,895	4,488	(1,593)	(35)%
General and administrative expenses	2,364	2,053	311	15 %
Total operating expenses	5,259	6,541	(1,282)	(20)%
Loss from operations	(5,259)	(6,541)	1,282	(20)%
Interest income	121	19	102	537 %
Pre-tax loss	(5,138)	(6,522)	1,384	(21)%
Income tax benefit	—	2,417	(2,417)	(100)%
Net loss	$ (5,138)	$ (4,105)	$ (1,033)	25 %

Total Operating Expenses. Total operating expenses for the three months ended June 30, 2023 were $5.3 million compared to $6.5 million for the three months ended June 30, 2022, a decrease of $1.2 million, or 20%. This decrease was due to decreases in clinical program expenses and general and administrative expenses.

Research and Development Expenses. Total research and development expenses for the three months ended June 30, 2023 were $2.9 million compared to $4.5 million for the three months ended June 30, 2022, a decrease of $1.6 million, or 35%. Total research and development expenses consisted of the following:

- fILD, PH-Sarc and PH-COPD expenses remained relatively flat for the three months ended June 30, 2023 and 2022.

- Drug and delivery system costs for the three months ended June 30, 2023 were $0.2 million, compared to $1.0 million for the three months ended June 30, 2022, a decrease of $0.8 million, or 83%. Drug and delivery system costs are recorded at the time of procurement from our suppliers. The decrease is primarily attributable to the requisite lead times to support trial related activities along with the termination of the Phase 3 clinical trial for fILD during the three months ended June 30, 2023.

- Research and development infrastructure costs for the three months ended June 30, 2023 were $1.2 million compared to $1.8 million for the three months ended June 30, 2022, a decrease of $0.6 million, or 34%. The decrease was primarily due to a decrease in contractor costs associated with the termination of the Phase 3 clinical trial for fILD during the three months ended June 30, 2023.

General and Administrative Expenses. General and administrative expenses for the three months ended June 30, 2023 were $2.4 million compared to $2.1 million for the three months ended June 30, 2022, an increase of $0.3 million, or 15%. The increase is due to the one-time separation benefits costs associated with the reduction-in-force partially offset by the reduction in rent expenses related to the vacated office space combined with additional reductions in legal and consulting costs in connection with the termination of the Phase 3 clinical trial for fILD during the three months ended June 30, 2023.

Comparison of Six Months Ended June 30, 2023 and 2022

The following table summarizes our results of operations for the six months ended June 30, 2023 and 2022.

	Six Months Ended June 30,			
(Dollar amounts in thousands)	**2023**	**2022**	**$ Change**	**% Change**
Revenues:				
Licensing revenue	$ 5,640	$ —	$ 5,640	>100 %
Research and development expenses:				
fILD, PH-Sarc and PH-COPD	2,141	2,512	(371)	(15)%
Other clinical trials	—	1	(1)	(100)%
Drug and delivery system costs	190	1,839	(1,649)	(90)%
Clinical programs	2,331	4,352	(2,021)	(46)%
Research and development infrastructure	2,424	3,655	(1,231)	(34)%
INOpulse engineering	692	890	(198)	(22)%
Total research and development expenses	5,447	8,897	(3,450)	(39)%
General and administrative expenses	3,973	3,286	687	21 %
Total operating expenses	9,420	12,183	(2,763)	(23)%
Loss from operations	(3,780)	(12,183)	8,403	(69)%
Interest income	187	20	167	835 %
Pre-tax loss	(3,593)	(12,163)	8,570	(70)%
Income tax benefit	1,277	2,417	(1,140)	(47)%
Net loss	$ (2,316)	$ (9,746)	$ 7,430	(76)%

Licensing Revenue. Total licensing revenue for the six months ended June 30, 2023 was $5.6 million which directly relates to the upfront payment received in relation to the licensing agreement with Baylor BioSciences, Inc. We did not earn any revenue during the six months ended June 30, 2022.

Total Operating Expenses. Total operating expenses for the six months ended June 30, 2023 were $9.4 million compared to $12.2 million for the six months ended June 30, 2022, a decrease of $2.8 million, or 23%. This decrease was primarily due to a decrease in clinical program expenses and research and development infrastructure expenses.

Research and Development Expenses. Total research and development expenses for the six months ended June 30, 2023 were $5.4 million compared to $8.9 million for the six months ended June 30, 2022, a decrease of $3.5 million, or 39%. Total research and development expenses consisted of the following:

- fILD, PH-Sarc and PH-COPD expenses for the six months ended June 30, 2023 were $2.1 million, compared to $2.5 million for the six months ended June 30, 2022, a decrease of $0.4 million, or 15%. The decrease was primarily due to the termination of the Phase 3 clinical trial for fILD during the six months ended June 30, 2023.

- Drug and delivery system costs for the six months ended June 30, 2023 were $0.2 million, compared to $1.8 million for the six months ended June 30, 2022, a decrease of $1.6 million, or 90%. Drug and delivery system costs are recorded at the time of procurement from our suppliers. The decrease is primarily attributable to the requisite lead times to support trial related activities along with the termination of the Phase 3 clinical trial for fILD during the six months ended June 30, 2023.

- Research and development infrastructure costs for the six months ended June 30, 2023 were $2.4 million compared to $3.6 million for the six months ended June 30, 2022, a decrease of $1.2 million, or 34%. The decrease was primarily due to a reduction in consulting and labor costs associated with the termination of the Phase 3 clinical trial for fILD during the six months ended June 30, 2023.

General and Administrative Expenses. General and administrative expenses for the six months ended June 30, 2023 were $4.0 million compared to $3.3 million for the six months ended June 30, 2022, an increase of $0.7 million, or 21%. The increase is due to the one-time separation benefits costs associated with the reduction-in-force combined with increases in legal and consulting costs associated with various SEC filings and costs associated with the termination of the Phase 3 clinical trial. These increases were partially offset by a reduction in rent expenses related to the vacated office space during the six months ended June 30, 2023.

Liquidity and Capital Resources

In the course of our development activities, we have sustained operating losses and expect such losses to continue for the foreseeable future based on our current operations.

On June 5, 2023, we announced top-line results from our Phase 3 REBUILD clinical trial evaluating the safety and efficacy of INOpulse® for the treatment of Interstitial Lung Disease. The trial did not meet its primary endpoint and the secondary endpoints demonstrated minimal difference between the two groups with none approaching statistical significance. Based on these findings, we decided to terminate the REBUILD Phase 3 clinical study and withdraw patients from all of our ongoing INOpulse development programs. We intend to explore a range of strategic alternatives to maximize stockholder value. Strategic alternatives that may be evaluated include, but are not limited to, a merger, a business combination, a sale of assets or other strategic transaction or a liquidation and dissolution. There is no set timetable for this process and there can be no assurance that this process will result in us pursuing a transaction or that any transaction, if pursued, will be completed on attractive terms. In connection with the termination of the clinical study, we approved a reduction-in-force of substantially all of our employees, including officers. The workforce reduction is designed to reduce our operating expenses while we explore a range of strategic alternatives. We expect that the implementation of the workforce reduction will be substantially completed by the end of the third quarter of 2023. Affected employees were offered separation benefits, including severance payments along with temporary healthcare coverage assistance. Severance and termination related-costs of approximately $0.8 million were recorded in the second quarter of 2023, as a component of general and administrative expenses. We expect to record additional severance and termination-related costs of approximately $0.7 million in the second half of 2023.

We had unrestricted cash and cash equivalents of $10.6 million as of June 30, 2023. Our existing cash and cash equivalents as of June 30, 2023 will be used primarily to fund the termination of the Phase 3 trial of INOpulse for fILD and explore a range of strategic alternatives to maximize shareholder value. Strategic alternatives that may be evaluated include, but are not limited to, a merger, business combination, sale of assets or other strategic transaction or liquidation and dissolution.

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 June 30, 2023 will not be sufficient to satisfy our operating cash needs for at least one year after the filing of this Quarterly Report on Form 10-Q. Accordingly, substantial doubt about our ability to continue as a going concern exists.

Cash Flows

The following table summarizes our cash flows for the six months ended June 30, 2023 and 2022:

(Dollar amounts in thousands)	Six Months Ended June 30, 2023	2022
Operating activities	$ (1,655)	$ (8,408)
Financing activities	5,008	—
Net change in cash, cash equivalents and restricted cash	$ 3,353	$ (8,408)

Net Cash Used in Operating Activities

Cash used in operating activities for the six months ended June 30, 2023 was $1.7 million, as compared to $8.4 million for the six months ended June 30, 2022. 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 six months ended June 30, 2023 was $5.0 million which was directly attributable to cash raised under the direct offering of common stock and pre-funded warrants in March 2023. There were no financing activities conducted during the six months ended June 30, 2022.

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, 2022.

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

During the six months ended June 30, 2023, 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, 2022.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risk related to changes in interest rates. As of June 30, 2023, we had unrestricted cash and cash equivalents of $10.6 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 June 30, 2023. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of June 30, 2023, 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 six months ended June 30, 2023 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, 2022. 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, 2022.

We are exploring strategic alternatives that could significantly impact our future operations and financial position.

In June 2023, we announced that we are exploring strategic alternatives with the goal of maximizing shareholder value. Potential strategic alternatives that may be considered as part of this process include a merger, a business combination, a sale of assets or other strategic transaction or a liquidation and dissolution. There can be no assurance that the exploration of strategic alternatives will result in any agreements or transactions, or that, if completed, any agreements or transactions will be successful or on attractive terms. No timetable has been established for the completion of this process, and we do not expect to disclose developments unless and until the Board of Directors has concluded that disclosure is appropriate or required. If we determine to change our business strategy or to seek to engage in a strategic transaction, our future business, prospects, financial position and operating results could be significantly different than those in historical periods or projected by our management. Because of the significant uncertainty regarding our future plans, we are not able to accurately predict the impact of a potential change in our business strategy and future funding requirements. Until the review process is concluded, perceived uncertainties related to our future may result in the loss of potential business opportunities and volatility in the market price of our common stock and may make it more difficult for us to attract and retain qualified personnel and business partners.

The outcome of our recent REBUILD Phase 3 clinical study and resulting impact on our access to capital indicate substantial doubt exists related to our ability to continue as a going concern. Our financial statements have been prepared assuming that we will continue as a going concern.

We have incurred net losses and used significant cash in operating activities since inception, and we expect to continue to generate operating losses for the foreseeable future. As of June 30, 2023, we have an accumulated deficit of $254.4 million and cash and cash equivalents of $10.6 million. These factors raise substantial doubt about our ability to continue as a going concern and to satisfy our estimated liquidity needs for twelve months from the issuance of the financial statements.

If we continue to experience operating losses, and we are not able to generate additional liquidity through a capital raise or other cash infusion, we might need to secure additional sources of funds, which may or may not be available to us. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to further reduce our operations or initiate steps to cease operations.

If we do not successfully consummate a strategic transaction, our board of directors may decide to pursue a dissolution and liquidation of our company. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities.

There can be no assurance that the process to identify a strategic transaction will result in a successfully consummated transaction. If no transaction is completed, our board of directors may decide to pursue a dissolution and liquidation of our company. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such decision and, ultimately, such liquidation, since the amount of cash available for distribution continues to decrease as we fund our operations while we evaluate our strategic alternatives. In addition, if our board of directors were to approve and recommend, and our stockholders were to approve, a dissolution and liquidation of our company, we would be required under Delaware corporate law to pay our outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions in

liquidation to our stockholders. Our commitments and contingent liabilities may include, among other things, (i) obligations under our employment and related agreements with certain employees that provide for severance and other payments following a termination of employment occurring for various reasons; (ii) obligations under our license agreement with Baylor Biosciences, Inc., (iii) potential litigation against us, and other various claims and legal actions arising in the ordinary course of business; and (iv) non-cancelable contractual obligations. As a result of this requirement, a portion of our assets may need to be reserved pending the resolution of such obligations. In addition, we may be subject to litigation or other claims related to a dissolution and liquidation of our company. If a dissolution and liquidation were pursued, our board of directors, in consultation with its advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of our common stock could lose all or a significant portion of their investment in the event of a liquidation, dissolution or winding up of our company.

If we fail to maintain the listing of our common stock on the Nasdaq Capital Market or another national securities exchange, the liquidity of our common stock could be adversely affected.

On July 19, 2023, we were notified by the Staff of Nasdaq that in light of our previously disclosed workforce reduction plan and focus on exploring strategic alternatives, based upon the Staff's belief that we are a "public shell" as that term is defined in Nasdaq Listing Rule 5101 and our non-compliance with the $1.00 bid price requirement set forth in Nasdaq Listing Rule 5550(a)(2), we would be delisted from The Nasdaq Capital Market at the opening of business on July 28, 2023 unless we timely requested a hearing before a Nasdaq Hearings Panel to address the deficiencies and present a plan to regain compliance. We timely requested a hearing before the Panel, which request stayed any further delisting action by the Staff pending the ultimate outcome of the hearing and the expiration of any extension that may be granted by the Panel. The hearing is currently scheduled for September 21, 2023 and a decision by the Panel is typically not rendered for several weeks after such hearing. Our common stock will remain listed and eligible for trading on Nasdaq at least pending the ultimate conclusion of the hearing process.

If our common stock is delisted by Nasdaq, our common stock may be eligible to trade on the OTC Bulletin Board or another over-the-counter market. Any such alternative would likely result in it being more difficult for us to raise additional capital through the public or private sale of equity securities and for investors to dispose of, or obtain accurate quotations as to the market value of, our common stock. In addition, we may become less desirable for a potential strategic transaction. There can be no assurance that our common stock would be eligible for trading on any such alternative exchange or markets.

Until we hire a permanent principal financial & accounting officer, our Chief Executive Officer will also be serving as our principal financial and accounting officer, which could have an adverse impact on our business.

Following the previously-announced resignation of our principal financial & accounting officer, Nicholas Laccona on April 19, 2023 (with transitional support through May 15, 2023), Peter Fernandes, our Chief Executive Officer, has assumed the role of our principal financial and accounting officer. As a result of this change, Mr. Fernandes has taken on substantially more responsibility for the management of our business and of our financial reporting, which has resulted in greater workload demands and could divert his attention away from certain key areas of our business. Mr. Fernandes's serving in a temporary dual capacity of Chief Executive Officer and principal financial and accounting officer may have a disruptive impact on our ability to implement our strategy and could adversely affect our business, internal controls, financial condition and results of operations. Our lack of a principal financial & accounting officer is likely to affect our internal control over financial reporting. Until we find and integrate a principal financial & accounting officer, we may be unable to successfully manage our business, and our results of operations, internal controls and financial condition could be adversely affected as a result.

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

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

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

Exhibit Index

Exhibit Number	Description
10.1+	Separation Agreement, dated as of May 4, 2023, by and between Bellerophon Therapeautics, Inc. and Nicholas Laccona (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on May 5, 2023).
10.2+	Amended and Restated 2015 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on June 9, 2023).
31.1	Certification of Principal Executive Officer and 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 Date File (Formatted as Inline XBRL and contained in Exhibit 101)

+ Management contract or compensatory plan or arrangement.

SIGNATURES

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

BELLEROPHON THERAPEUTICS, INC.

Date: August 14, 2023

By: /s/ Peter Fernandes

Peter Fernandes
Chief Executive Officer
(Principal Executive Officer and
Principal Financial and Accounting Officer)

Exhibit 31.1

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: August 14, 2023

By: /s/ Peter Fernandes
Peter Fernandes
Chief Executive Officer
(Principal Executive Officer and
Principal Financial and Accounting Officer)

Exhibit 32

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 June 30, 2023 (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: August 14, 2023

By: /s/ Peter Fernandes
Peter Fernandes
Chief Executive Officer
(Principal Executive Officer and
Principal Financial and Accounting Officer)