
**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 March 31, 2023

or

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

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

Bellerophon Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

47-3116175

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

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

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

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

The number of shares outstanding of the registrant's common stock as of May 12, 2023: 10,449,834

TABLE OF CONTENTS

	<u>Page No.</u>
<u>PART I. FINANCIAL INFORMATION</u>	6
<u>Item 1. Financial Statements</u>	6
<u>Condensed Consolidated Balance Sheets as of March 31, 2023 (Unaudited) and December 31, 2022</u>	6
<u>Condensed Consolidated Statements of Operations and Comprehensive Income (Loss) for the three months ended March 31, 2023 and 2022 (Unaudited)</u>	7
<u>Condensed Consolidated Statement of Changes in Stockholders' Equity for the three months ended March 31, 2023 and 2022 (Unaudited)</u>	8
<u>Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2023 and 2022 (Unaudited)</u>	9
<u>Notes to Condensed Consolidated Financial Statements (Unaudited)</u>	10
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	22
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	32
<u>Item 4. Controls and Procedures</u>	32
<u>PART II. OTHER INFORMATION</u>	33
<u>Item 1. Legal Proceedings</u>	33
<u>Item 1A. Risk Factors</u>	33
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	33
<u>Item 3. Defaults Upon Senior Securities</u>	33
<u>Item 4. Mine Safety Disclosures</u>	33
<u>Item 5. Other Information</u>	33
<u>Item 6. Exhibits</u>	33
<u>Signatures</u>	35

REFERENCES TO BELLEROPHON

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

FORWARD-LOOKING STATEMENTS

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

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

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

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K for the year ended December 31, 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.

[Table of Contents](#)

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

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

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements.

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

	As of March 31, 2023 (Unaudited)	As of December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	\$ 15,172	\$ 6,924
Restricted cash	405	405
Prepaid expenses and other current assets	194	234
Total current assets	<u>15,771</u>	<u>7,563</u>
Right of use assets, net	8	184
Property and equipment, net	1	2
Other non-current assets	186	186
Total assets	<u>\$ 15,966</u>	<u>\$ 7,935</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 1,070	\$ 1,230
Accrued research and development	2,858	2,655
Accrued expenses	1,428	1,313
Current portion of operating lease liabilities	8	203
Total liabilities	<u>5,364</u>	<u>5,401</u>
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.01 par value per share; 200,000,000 shares authorized and 10,448,185 and 9,645,711 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively	104	96
Preferred stock, \$0.01 par value per share; 5,000,000 shares authorized, zero shares issued and outstanding at March 31, 2023 and December 31, 2022	—	—
Additional paid-in capital	259,754	254,516
Accumulated deficit	(249,256)	(252,078)
Total stockholders' equity	<u>10,602</u>	<u>2,534</u>
Total liabilities and stockholders' equity	<u>\$ 15,966</u>	<u>\$ 7,935</u>

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

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

	Three Months Ended	
	March 31,	
	2023	2022
Revenues:		
Licensing revenue	\$ 5,640	\$ —
Operating expenses:		
Research and development	2,552	4,409
General and administrative	1,609	1,233
Total operating expenses	4,161	5,642
Income (loss) from operations	1,479	(5,642)
Interest income	66	1
Pre-tax income (loss)	1,545	(5,641)
Income tax benefit	1,277	—
Net income (loss) and comprehensive income (loss)	\$ 2,822	\$ (5,641)
Weighted average shares outstanding:		
Basic	10,358,111	9,545,451
Diluted	10,605,946	9,545,451
Net income (loss) per share:		
Basic	\$ 0.27	\$ (0.59)
Diluted	\$ 0.27	\$ (0.59)

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 months ended March 31, 2023:

	Common Stock		Additional Paid in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at December 31, 2022	9,645,711	\$ 96	\$ 254,516	\$ (252,078)	\$ 2,534
Net income	—	—	—	2,822	2,822
Direct offering of common stock	718,474	7	1,430	—	1,437
Direct offering of pre-funded warrants	—	—	3,545	—	3,545
Issuance of common stock, restricted stock vesting	84,000	1	(1)	—	—
Stock-based compensation	—	—	264	—	264
Balance at March 31, 2023	<u>10,448,185</u>	<u>\$ 104</u>	<u>\$ 259,754</u>	<u>\$ (249,256)</u>	<u>\$ 10,602</u>

For the three months ended March 31, 2022:

	Common Stock		Additional Paid in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at December 31, 2021	9,545,451	\$ 95	\$ 253,771	\$ (232,247)	\$ 21,619
Net loss	—	—	—	(5,641)	(5,641)
Stock-based compensation	—	—	192	—	192
Balance at March 31, 2022	<u>9,545,451</u>	<u>\$ 95</u>	<u>\$ 253,963</u>	<u>\$ (237,888)</u>	<u>\$ 16,170</u>

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

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

	Three Months Ended March 31,	
	2023	2022
Cash flows from operating activities:		
Net income (loss)	\$ 2,822	\$ (5,641)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	1	21
Stock-based compensation	264	192
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	40	207
Accounts payable, accrued research and development, lease liabilities and other accrued expenses	139	485
Net cash provided by (used in) operating activities	<u>3,266</u>	<u>(4,736)</u>
Cash flows from financing activities:		
Proceeds from issuance of common stock in Direct Offering	1,437	—
Proceeds from issuance of pre-funded warrants in Direct Offering	3,545	—
Net cash provided by financing activities	<u>4,982</u>	<u>—</u>
Net change in cash, cash equivalents and restricted cash	8,248	(4,736)
Cash, cash equivalents and restricted cash at beginning of period	7,329	25,139
Cash, cash equivalents and restricted cash at end of period	<u>\$ 15,577</u>	<u>\$ 20,403</u>

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

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

(1) Organization and Nature of the Business

Bellerophon Therapeutics, Inc., or the Company, is a clinical-stage therapeutics company focused on developing innovative products that address significant unmet medical needs in the treatment of cardiopulmonary diseases. The focus of the Company's clinical program is the continued development of its nitric oxide therapy for patients with pulmonary hypertension, or PH, using its proprietary delivery system, INOpulse. The Company has three wholly-owned subsidiaries: Bellerophon BCM LLC, a Delaware limited liability company; Bellerophon Pulse Technologies LLC, a Delaware limited liability company; and Bellerophon Services, Inc., a Delaware corporation.

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

- The risk that the Company will not achieve success in its research and development efforts, including clinical trials conducted by it or its potential collaborative partners.
- The expectation that the Company will experience operating losses for the next several years.
- Decisions by regulatory authorities regarding whether and when to approve the Company's regulatory applications as well as their decisions regarding labeling and other matters which could affect the commercial potential of the Company's products or product candidates.
- The risk that the Company will fail to obtain adequate financing to meet its future operational and capital needs post-top-line results, expected mid-year 2023, for which the Company may be required to significantly 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.
- The risk that key personnel will leave the Company and/or that the Company will be unable to recruit and retain senior level officers to manage its business.
- There are many uncertainties regarding the novel coronavirus ("COVID-19") pandemic, and the Company is closely monitoring the impact of the pandemic on all aspects of its business, including how the pandemic will impact its clinical trials, employees and suppliers. While the pandemic did not materially affect the Company's financial results and business operations in the three months ended March 31, 2023, the extent to which the coronavirus impacts the Company's results will depend on future developments, which are highly uncertain and cannot be predicted. Further, should COVID-19 continue to spread, the Company's business operations could be delayed or interrupted.

(2) Summary of Significant Accounting Policies

(a) Basis of Presentation

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

The Company is responsible for the unaudited condensed consolidated financial statements. The condensed consolidated financial statements include all normal and recurring adjustments that are considered necessary for the fair presentation of the Company's financial position, results of operations, comprehensive loss 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 months ended March 31, 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, common stock warrant liabilities and income taxes. Actual results could differ from those estimates.

(b) Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity date of three months or less to be cash equivalents. All investments with maturities of greater than three months from 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 classifies warrant liabilities on the consolidated balance sheet based on the warrants' terms as long-term liabilities, which are revalued at each balance sheet date subsequent to the initial issuance. Changes in the fair value of the warrants are reflected in the consolidated statement of operations as "Change in fair value of common stock warrant liability." The Company uses the Black-Scholes-Merton pricing model to value the related warrant liability. Certain assumptions used in the model include expected volatility, dividend yield and risk-free interest rate. See Note 6 - *Fair Value Measurements* for a description of these assumptions.

(e) Income Taxes

The Company uses the asset and liability approach to account for income taxes as required by applicable accounting guidance, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Valuation allowances are provided when necessary to reduce deferred tax assets to the amount expected to be realized, on a more likely than not basis. The Company recognizes the benefit of an uncertain tax position that it has taken or expects to take on income tax returns it files if such tax position is more likely than not to be sustained on examination by the taxing authorities, based on the technical merits of the position. These tax benefits are measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate resolution.

(f) Research and Development Expense

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

(g) Leases

A lease is a contract, or part of a contract, that conveys the right to control the use of explicitly or implicitly identified property, plant or equipment in exchange for consideration. Control of an asset is conveyed to the Company if the Company obtains the right to obtain substantially all of the economic benefits of the asset or the right to direct the use of the asset. The Company recognizes right of use ("ROU") assets and lease liabilities at the lease commencement date based on the present value of future, fixed lease payments over the term of the arrangement. 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 months ended March 31, 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 three months ended March 31, 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 over the next several years. The Company expects to continue to incur significant expenses and operating losses for the foreseeable future as it continues the development and clinical trials of, and seeks regulatory approval for, its product candidates. The Company's primary uses of capital are, and it expects will continue to be, compensation and related expenses, third-party clinical research and development services, contract manufacturing services, laboratory and related supplies, clinical costs, legal and other regulatory expenses and general overhead costs.

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

The Company had unrestricted cash and cash equivalents of \$15.2 million as of March 31, 2023. The Company's existing cash and cash equivalents as of March 31, 2023, will be used primarily to fund the Phase 3 trial of INOpulse for FILD.

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 March 31, 2022 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 product revenues, it expects to finance its cash needs through a combination of equity and debt financings, sales of state net operating losses ("NOLs") and research and development ("R&D") tax credits subject to program availability and approval, existing working capital and funding from potential future collaboration or licensing arrangements. To the extent that the Company raises additional capital through the future sale of equity or convertible debt, the ownership interest of its existing stockholders may be diluted, and the terms of such securities may include liquidation or other preferences or rights such as anti-dilution rights that adversely affect the rights of its existing stockholders. If the Company raises additional funds through strategic partnerships in the future, it may have to relinquish valuable rights to its technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to it. If the Company is unable to raise additional funds through equity or debt financings when needed, or unable to sell its state NOLs and R&D credits, it may be required to delay, limit, reduce or terminate its product development or future commercialization efforts or grant rights to develop and market product candidates that it would otherwise prefer to develop and market itself.

(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 three months ended March 31, 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 is for a term of three years and nine months with an expiration date of April 30, 2023, with the Company's right to extend the original term for one period of 90 days. During the three months ended March 31, 2023, the Company agreed to a short-term lease extension of the existing laboratory space through August 2023. The existing laboratory space is deemed to have adequate office space to meet the Company's needs and will serve as the Company's corporate headquarters. Operating lease expense is recognized on a straight-line basis over the respective lease term.

[Table of Contents](#)

The Company does not recognize right of use assets or related lease liabilities for leases with a lease term of twelve months or less on our consolidated balance sheet. Short-term lease costs are recorded in our consolidated statements of operations in the period in which the obligation for those payments was incurred. Short-term lease costs for the three months ended March 31, 2023 and 2022 were de minimis.

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

	Three Months Ended March 31,	
	2023	2022
Cash paid for operating lease liability	\$ 197	\$ 193
Operating lease expenses	\$ 177	\$ 177
Weighted average remaining lease term	0.1 years	1.0 years
Weighted average discount rate	4.57 %	4.93 %

Maturities of the lease liability as of March 31, 2023 were as follows:

2023	\$	8
Less imputed interest		—
Total operating lease liability	\$	<u>8</u>

(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 of 5 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 March 31, 2023, all of which are equity classified. None of the 2016 Warrants were exercised during the three months ended March 31, 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 March 31, 2023 all of these 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 (March 29, 2023) 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 March 31, 2023, all of these warrants 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 are classified as a component of permanent equity.

The following table summarizes warrant activity for the three months ended March 31, 2023 (fair value amount in thousands):

	<u>Equity Classified</u>	<u>Liability Classified</u>	
	<u>Warrants</u>	<u>Warrants</u>	<u>Estimated Fair Value</u>
Warrants outstanding as of December 31, 2022	1,881,789	—	\$ —
Expired	(1,296,650)	—	—
Issued	1,781,526	—	—
Warrants outstanding as of March 31, 2023	<u>2,366,665</u>	<u>—</u>	<u>\$ —</u>

The following table summarizes warrant activity for the three months ended March 31, 2022 (fair value amount in thousands):

	<u>Equity Classified</u>	<u>Liability Classified</u>	
	<u>Warrants</u>	<u>Warrants</u>	<u>Estimated Fair Value</u>
Warrants outstanding as of December 31, 2021	1,881,789	70,666	\$ 1
Change in fair value of common stock warrant liability recognized in consolidated statement of operations	—	—	—
Warrants outstanding as of March 31, 2022	<u>1,881,789</u>	<u>70,666</u>	<u>\$ 1</u>

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

(6) Fair Value Measurements

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

- Level 1 — Values are based on unadjusted quoted prices for identical assets or liabilities in an active market which the Company has the ability to access at the measurement date.
- Level 2 — Values are based on quoted market prices in markets where trading occurs infrequently or whose values are based on quoted prices of instruments with similar attributes in active markets.
- Level 3 — Values are based on prices or valuation techniques that require inputs that are both unobservable and significant to the overall fair value measurement. These inputs reflect management's own assumptions about the assumptions a market participant would use in pricing the asset.

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

The Company uses a Black-Scholes-Merton option pricing model to value its liability classified common stock warrants. The significant unobservable inputs used in calculating the fair value of common stock warrants represent management's best estimates and involve inherent uncertainties and the application of management's judgment. For volatility, the Company historically considered comparable public companies as a basis for its expected volatility to calculate the fair value of common stock warrants and transitioned to its own volatility as the Company developed sufficient appropriate history as a public company. The risk-free interest rate is based on U.S. Treasury notes with a term approximating the expected term of the common stock warrant. Any significant changes in the inputs may result in significantly higher or lower fair value measurements.

There were no outstanding liability classified warrants as of March 31, 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. As of March 31, 2023, the Company had 65,834 shares available for grant with an aggregate of 1,479,652 shares of common stock authorized under the 2015 Plan.

As of March 31, 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 2.5 years.

No tax benefit was recognized during the three months ended March 31, 2023 and 2022 related to stock-based compensation expense since the Company expects to incur and has 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 values of options issued during the three months ended March 31, 2023 was \$1.52. There were no options issued during the three months ended March 31, 2022. The following are the weighted average assumptions used in estimating the fair values of options issued during the three months ended March 31, 2023:

	<u>Three Months Ended March 31, 2023</u>
Valuation assumptions:	
Risk-free rate	3.86 %
Expected volatility	136.83 %
Expected term (years)	6.0
Dividend yield	—

A summary of option activity under the 2015 and 2014 Plans for the three months ended March 31, 2023 is presented below:

	<u>Bellerophon 2015 and 2014 Equity Incentive Plans</u>			
	<u>Options</u>	<u>Range of Exercise Price</u>	<u>Weighted Average Price</u>	<u>Weighted Average Remaining Contractual Life (in years)</u>
Options outstanding as of December 31, 2022	322,038	\$ 3.10 - 199.20	\$ 12.58	6.7
Granted	516,000	1.52	1.52	
Forfeited	(5,177)	4.06 - 180.00	23.40	
Options outstanding as of March 31, 2023	<u>832,861</u>	<u>\$ 1.52 - 199.20</u>	<u>\$ 5.66</u>	<u>8.6</u>
Options vested and exercisable as of March 31, 2023	<u>311,210</u>	<u>\$ 1.52 - 199.20</u>	<u>\$ 12.49</u>	<u>6.5</u>

The intrinsic value of options outstanding, vested and exercisable as of March 31, 2023 was \$0.5 million.

Restricted Stock

All restricted stock awards granted under the 2015 Plan during the three months ended March 31, 2023 were in relation to director compensation and vested in full by the three months ended March 31, 2023.

A summary of restricted stock activity under the 2015 Plan for the three months ended March 31, 2023 is presented below:

	<u>Bellerophon 2015 Equity Incentive Plan</u>			
	<u>Shares</u>	<u>Weighted Average Fair Value</u>	<u>Aggregate Grant Date Fair Value (in millions)</u>	<u>Weighted Average Remaining Contractual Life (in years)</u>
Restricted stock outstanding as of December 31, 2022	165,500	\$ 2.23	\$ 0.7	0.9
Granted	84,000	1.52	0.1	
Vested	(86,500) ⁽¹⁾	1.53	(0.1)	
Forfeited	(15,000)	1.11	—	
Restricted stock outstanding as of March 31, 2023	<u>148,000</u>	<u>\$ 2.35</u>	<u>\$ 0.7</u>	<u>0.7</u>

(1) 2,500 restricted stock units vested during the three months ended March 31, 2023, however, the common stock was subsequently issued in April 2023.

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 three months ended March 31, 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	(812)	124.05	124.05	
Options outstanding as of March 31, 2023	<u>52</u>	<u>\$ 131.55</u>	<u>\$ 131.55</u>	<u>0.1</u>
Options vested and exercisable as of March 31, 2023	<u>52</u>	<u>\$ 131.55</u>	<u>\$ 131.55</u>	<u>0.1</u>

The intrinsic value of options outstanding, vested and exercisable as of March 31, 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 months ended March 31, 2023 and 2022 (in thousands):

	Three Months Ended March 31,	
	2023	2022
Research and development	\$ 101	\$ 113
General and administrative	163	79
Total expense	<u>\$ 264</u>	<u>\$ 192</u>

(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 three months ended March 31, 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 March 31, 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 three months ended March 31, 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 the state net operating losses (“NOL”) and research and development tax credits during the three months ended March 31, 2023, the effective tax rate for each of the three months ended March 31, 2023 and 2022 was 38.8% and zero, respectively. The effective tax rate for the three months ended March 31, 2023 exceeded 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 U.S. income tax regulations and as such are recorded as an income tax expense for the period. The effective tax rate for the three months ended March 31, 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 (“R&D”), tax credits is expected to be greater 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.

Subject to state approval, the Company plans to sell NOLs and Research and Development credits under the State of New Jersey’s Technology Business Tax Certificate Transfer Program in the future. The proceeds from such sales are recorded as income tax benefit when sales occur and proceeds are received.

During January 2023, the Company completed the sale of \$19.7 million of state NOLs and \$0.1 million of R&D tax credit under the State of New Jersey’s Business Tax Certificate Transfer Program for net proceeds of \$1.7 million.

As of March 31, 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 Income (Loss) Per Share

Basic net income (loss) per share is calculated by dividing net income (loss) by the weighted average number of shares outstanding during the period, as applicable. Included in the calculation of the weighted average number of shares outstanding for the basic net income per share calculation for the three months ended March 31, 2023 is the 1,781,526 pre-funded warrants, as described in Note 5 – *Common Stock Warrants and Warrant Liability*, as they are issuable in exchange for a nominal cash consideration and are therefore treated as issued for basic net income per share purposes. Diluted net income (loss) per share is calculated by dividing net income (loss), adjusted to reflect the impact of dilutive warrants, by the weighted average number of shares outstanding, adjusted to reflect potentially dilutive securities using the treasury stock method, except when the effect would be anti-dilutive.

[Table of Contents](#)

The following table sets forth the computation of basic and diluted net income (loss) per common share for the three months ended March 31, 2023 and 2022 (in thousands, except per share amounts):

	Three months ended March 31,	
	2023	2022
Net income (loss)	\$ 2,822	\$ (5,641)
Weighted-average shares:		
Basic	10,358,111	9,545,451
Effect of dilutive securities:		
Options	168,844	—
Restricted Stock	78,991	—
Diluted	<u>10,605,946</u>	<u>9,545,451</u>
Net income (loss) per share:		
Basic	\$ 0.27	\$ (0.59)
Diluted	\$ 0.27	\$ (0.59)

As of March 31, 2023, the Company had 220,930 options to purchase shares and 585,139 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.

As of March 31, 2022, the Company had 326,315 options to purchase shares and 1,952,455 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 is the continued development of our nitric oxide therapy for patients with or at risk of pulmonary hypertension, or PH, using our proprietary pulsatile nitric oxide delivery platform, INOpulse.

In 2016, we began developing INOpulse for the treatment of pulmonary hypertension associated with fibrotic interstitial lung disease (“fILD”), which includes PH associated with idiopathic pulmonary fibrosis (“PH-IPF”) as well as other pulmonary fibrosing diseases. During May 2017, we announced the completion of our Phase 2 clinical trial using INOpulse therapy to treat PH-IPF. The clinical data showed that INOpulse was associated with clinically meaningful improvements in hemodynamics and exercise capacity in difficult-to-treat PH-IPF patients. The PH-IPF trial was a proof of concept study (n=4) designed to evaluate the ability of pulsed inhaled nitric oxide, or iNO, to provide selective vasodilation as well as to assess the potential for improvement in hemodynamics and exercise capacity in PH-IPF patients. The clinical trial met its primary endpoint showing an average of 15.3% increase in blood vessel volume (p<0.001) during acute inhalation of iNO as well as showing a significant association between ventilation and vasodilation, demonstrating the ability of INOpulse to provide selective vasodilation to the better ventilated areas of the lung. The trial showed consistent benefit in hemodynamics with a clinically meaningful average reduction of 14% in systolic pulmonary arterial pressure with acute exposure to iNO. The study assessed both the iNO 75 and iNO 30 dose.

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. The FDA agreement was based on its review of:

- Analysis conducted on cohort 2 (Phase 2) data utilizing the statistical analysis methodology to be used in REBUILD, including bi-weekly analysis of MVPA data and mixed models for repeated measures ("MMRM") assessment of the last half of the blinded treatment period, which showed the trial would be >90% powered for $p < 0.05$ at 80 total patients and >90% powered for a $p < 0.01$ at 114 patients based on the effect size determined from cohort 2;
- Similar baseline MVPA distribution between cohort 2 and the first 80 randomized patients in REBUILD based on a blinded assessment; and
- Independent Data Monitoring Committee unblinded safety review of the first 85 randomized patients in REBUILD indicating no safety concern with regards to reduction of REBUILD to 140 patients.

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. We expect to report pivotal top-line data results in mid-2023.

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 are positioned to initiate this Phase 2 study and are currently assessing the next steps for the 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 continue to evaluate alternatives for the funding and timing of this program.

In addition, other potential indications for our INOpulse platform include: chronic thromboembolic PH, or CTEPH and PH associated with pulmonary edema from high altitude sickness. However, we have not yet commenced any studies of the INOpulse platform with respect to such other indications.

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. We expect that it may be several years before we commercialize a product candidate, if ever.

Financial Operations Overview

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

License Agreement with Baylor BioSciences, Inc.

In January 2023, we entered into a License Agreement with 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-Sarcoidosis, 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.

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. We expect that any revenue we may generate will fluctuate from quarter to quarter as a result of the timing and amount of any payments we may receive under future partnerships, if any, and from sales of any products we successfully develop and commercialize, if any. If we fail to complete the development of any of our product candidates currently in clinical development or any future product candidates in a timely manner, or to obtain regulatory approval for such product candidates, our ability to generate future revenue, and our business, results of operations, financial condition and cash flows and future prospects would be materially adversely affected.

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 entered into during the three months ended March 31, 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;

[Table of Contents](#)

- lab supplies, reagents, active pharmaceutical ingredients and other direct and indirect costs in support of our pre-clinical and clinical activities;
- device development and drug manufacturing engineering;
- license fees related to in-licensed products and technology; and
- costs associated with non-clinical activities and regulatory approvals.

We expense research and development costs as incurred.

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

We track external research and development expenses and personnel expenses on a program-by-program basis. We use our employee and infrastructure resources, including regulatory, quality, clinical development and clinical operations, across our clinical development programs and have included these expenses in research and development infrastructure. Research and development laboratory expenses are also not allocated to a specific program and are included in research and development infrastructure. Engineering activities related to INOpulse and the manufacture of cylinders related to INOpulse are included in INOpulse engineering.

Drug and Delivery System Costs

Drug and delivery system costs include cartridge procurement, cartridge filling, delivery system manufacturing and delivery system servicing. These costs relate to all indications that utilize the INOpulse delivery system.

Research and Development Infrastructure

We invest in regulatory, quality, clinical development and clinical operations activities, which are expensed as incurred. These activities primarily support our clinical development programs.

INOpulse Engineering

We have invested a significant amount of funds in INOpulse, which is configured to be highly portable and compatible with available modes of long-term oxygen therapy via nasal cannula delivery. Our Phase 2 clinical trials of INOpulse for PAH and INOpulse for PH-COPD utilized the first generation INOpulse DS/DS-C device. We believe that our second generation INOpulse device, as well as a custom triple-lumen cannula, have significantly improved several characteristics of our INOpulse delivery system. We have also invested in design and engineering technology, through Ikaria, for the manufacture of our drug cartridges. We manufacture and service the INOpulse devices that we are using in our ongoing clinical trials of INOpulse for FiLD and PH-Sarc by third party turnkey manufacturers.

General and Administrative Expenses

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

Results of Operations

Comparison of Three Months Ended March 31, 2023 and 2022

The following table summarizes our results of operations for the three months ended March 31, 2023 and 2022.

(Dollar amounts in thousands)	Three Months Ended March 31,		\$ Change	% Change
	2023	2022		
Revenues:				
Licensing revenue	\$ 5,640	\$ —	\$ 5,640	>100 %
Research and development expenses:				
fILD, PH-Sarc and PH-COPD	979	1,327	(348)	(26)%
Other clinical trials	—	1	(1)	(100)%
Drug and delivery system costs	14	799	(785)	(99)%
Clinical programs	993	2,127	(1,134)	(53)%
Research and development infrastructure	1,238	1,846	(608)	(33)%
INOpulse engineering	321	436	(115)	(26)%
Total research and development expenses	2,552	4,409	(1,857)	(42)%
General and administrative expenses	1,609	1,233	376	30 %
Total operating expenses	4,161	5,642	(1,481)	(26)%
Income (loss) from operations	1,479	(5,642)	7,121	>100 %
Interest income	66	1	65	>100 %
Pre-tax income (loss)	1,545	(5,641)	7,186	(127)%
Income tax benefit	1,277	—	1,277	>100 %
Net income (loss)	\$ 2,822	\$ (5,641)	\$ 8,463	>100 %

Licensing Revenue. Total licensing revenue for the three months ended March 31, 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 have any revenue for the three month period March 31, 2022.

Total Operating Expenses. Total operating expenses for the three months ended March 31, 2023 were \$4.2 million compared to \$5.6 million for the three months ended March 31, 2022, a decrease of \$1.4 million, or 26%. This decrease was primarily due to a decrease in clinical program expenditures attributable to the ongoing REBUILD trial partially offset by an increase in general and administrative expenses.

Research and Development Expenses. Total research and development expenses for the three months ended March 31, 2023 were \$2.6 million compared to \$4.4 million for the three months ended March 31, 2022, a decrease of \$1.8 million, or 42%. Total research and development expenses consisted of the following:

- fILD, PH-Sarc and PH-COPD expenses for the three months ended March 31, 2023 were \$1.0 million compared to \$1.3 million for the three months ended March 31, 2022, a decrease of \$0.3 million, or 26%. The decrease was primarily due to the completion of enrollment in January 2023 resulting in fewer patients in the active trial activities compared to the prior period during which there was an increase in expenditures to support patient enrollment activities related to the Phase 3 fILD trial.
- Drug and delivery system costs for the three months ended March 31, 2023 were de minimis, compared to \$0.8 million for the three months ended March 31, 2022, a decrease of \$0.8 million, or 99%. Drug and delivery system costs are recorded at the time of procurement from our suppliers. The decrease is directly attributable to the requisite lead times to source sufficient clinical materials and supplies to support the Phase 3 fILD trial.

- Research and development infrastructure for the three months ended March 31, 2023 was \$1.2 million compared to \$1.8 million for the three months ended March 31, 2022, a decrease of \$0.6 million, or 33%. The decrease was primarily due to a decrease in contractor costs associated with the Phase 3 clinical trial for fILD combined with a reduction in general labor and bonus costs.

General and Administrative Expenses. General and administrative expenses for the three months ended March 31, 2023 were \$1.6 million compared to \$1.2 million for the three months ended March 31, 2022, an increase of \$0.4 million, or 30%. The increase was due to additional consulting costs for due diligence and legal efforts associated with the Baylor BioSciences, Inc. license transaction combined with an increase in stock-based compensation associated with equity issuances for Board of Directors' compensation.

Liquidity and Capital Resources

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

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

We had unrestricted cash and cash equivalents of \$15.2 million as of March 31, 2023. Our existing cash and cash equivalents as of March 31, 2023 will be used primarily to fund the Phase 3 trial of INOpulse for fILD.

We have evaluated whether there are any conditions and events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern within one year beyond the filing of this Quarterly Report on Form 10-Q. Based on such evaluation and our current plans, we believe that our existing cash and cash equivalents as of March 31, 2023 are not 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.

We may continue to pursue potential sources of funding, including equity financing and previously were able to obtain funding from the sale of tax attributes during 2023 and 2022, including the sale of NOLs and R&D credits described below.

- The Technology Business Tax Certificate Transfer Program enables qualified, unprofitable New Jersey based technology or biotechnology companies to sell a percentage of NOL and R&D tax credits to unrelated profitable corporations, subject to meeting certain eligibility criteria. We have sold \$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 in January 2023 for net proceeds of \$1.7 million. We have also sold an additional \$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 in April 2022. We plan to sell additional NOLs and R&D credits under the same program in the future subject to program availability and state approval. The proceeds from such sales are recorded as income tax benefit when sales occur or proceeds are received.
- In January 2023, we entered into a license agreement (the "License Agreement") with Baylor BioSciences, Inc. ("Baylor"), pursuant to which Baylor received exclusive rights to develop and commercialize INOpulse within mainland China, Taiwan, Hong Kong and Macau (collectively, "Greater China") for diseases associated with pulmonary hypertension, including the lead indication of fibrotic interstitial lung

disease (ILD), as well as PAH, PH-Sarcoidosis, and PH-COPD, CTEPH and PH associated with pulmonary edema from high altitude sickness. Under the terms of the License Agreement, a license payment of \$5 million, which was net of VAT and withholding taxes of approximately \$1.0 million, was received in full from Baylor by March 31, 2023. Additionally, we are entitled to royalties of 5% on net sales by Baylor resulting from all of the licensed INOpulse indications within Greater China.

- 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 (the “Offering”) (i) an aggregate of 718,474 shares (the “Shares”) of the Company’s common stock, \$0.01 par value per share (“Common Stock”) and (ii) pre-funded warrants (the “Pre-Funded Warrants”) to purchase up to 1,781,526 shares of Common Stock. The Company 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 the Company.

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.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity and debt financings, sales of state NOLs and R&D credits subject to program availability and approval, existing working capital and funding from potential future collaboration or licensing arrangements. To the extent that we raise additional capital through the future sale of equity or convertible debt, the ownership interest of our existing stockholders may be diluted, and the terms of such securities may include liquidation or other preferences or rights such as anti-dilution rights that adversely affect the rights of our existing stockholders. If we raise additional funds through strategic partnerships in the future, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, or are unable to sell our state NOLs and R&D credits, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Cash Flows

The following table summarizes our cash flows for the three months ended March 31, 2023 and 2022:

(Dollar amounts in thousands)	Three Months Ended	
	March 31,	
	2023	2022
Operating activities	\$ 3,266	\$ (4,736)
Financing activities	4,982	—
Net change in cash, cash equivalents and restricted cash	\$ 8,248	\$ (4,736)

Net Cash Provided by (Used in) Operating Activities

Cash provided by operating activities for the three months ended March 31, 2023 was \$3.3 million, as compared to \$4.7 million used in operating activities for the three months ended March 31, 2022. The change in cash used in operating activities was primarily due to the net income from the licensing revenue earned and reduction in operating expenses during the current period combined with the changes in our operating assets and liabilities.

Net Cash Provided by Financing Activities

Cash provided by financing activities for the three months ended March 31, 2023 was \$5.0 million which was directly attributable to cash raised under the direct offering of common stock and pre-funded warrants during March 2023. There were no financing activities conducted during the three months ended March 31, 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 also enter into agreements with contract service providers and others to assist in the performance of our research and development and manufacturing activities. We can elect to discontinue the work under these contracts and purchase orders at any time with notice, and such contracts and purchase orders do not contain minimum purchase obligations.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under applicable SEC rules.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to research and development expense, stock-based compensation and common stock warrants. We base our estimates on historical experience, known trends and events and various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

During the three months ended March 31, 2023, we modified our critical accounting policies to include disclosures related to revenues with customers recognized under ASC 606, which is described under the Management's Discussion and Analysis of Financial Condition and Results of Operations herein this Form 10-Q. There were no other 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 March 31, 2023, we had unrestricted cash and cash equivalents of \$15.2 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. At times, our deposits held at financial institutions exceeds the \$250,000 limit insured by the Federal Deposit Insurance Corporation (“FDIC”).

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 March 31, 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 officer and principal financial officer, 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 March 31, 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 months ended March 31, 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.

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. Leadership transitions can be inherently difficult to manage and may cause uncertainty and decreased productivity among our employees and increase the likelihood of turnover, which could result in significant disruptions to our operations. We could be adversely affected if we fail to adequately plan for the succession of members of our management team should we have additional departures.

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

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

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

Exhibit Index

<u>Exhibit Number</u>	<u>Description</u>
4.1	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8 K filed with the SEC on March 6, 2023).
10.1*	License Agreement, dated as of January 4, 2023, by and between Bellerophon Therapeutics, Inc. and Baylor BioSciences, Inc.
10.2	Subscription Agreement, dated as of March 3, 2023, by and among Bellerophon Therapeutics, Inc. and the purchaser identified on the signature pages thereto (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8 K filed with the SEC on March 6, 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 Data File (Formatted as Inline XBRL and contained in Exhibit 101)

* Schedules to this agreement have been omitted pursuant to Items 601(a)(5) of Regulation S-K. A copy of any omitted schedules will be furnished supplementally to the SEC upon request; provided, however, that the parties may request confidential treatment pursuant to Rule 24b-2 of the Exchange Act for any document so furnished.

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: May 15, 2023

By: /s/ Peter Fernandes

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

TECHNOLOGY LICENSE AGREEMENT

This TECHNOLOGY LICENSE AGREEMENT (this “**Agreement**”) is made as of January 4, 2023 (the “**Effective Date**”) by and between **Baylor Biosciences, Inc.**, a company organized and existing under the laws of the People’s Republic of China (“**Baylor**”), Bellerophon Pulse Technologies LLC, a limited liability company organized and existing under the laws of Delaware, the United States (“**Bellerophon**”), and Bellerophon Therapeutics, Inc., a company organized and existing under the laws of Delaware, the United States (“**BTI**”). Bellerophon and Baylor shall hereinafter be referred to collectively as the “**Parties**” and individually as a “**Party**” (and for the purposes of Sections 17.3 through 17.12, inclusive, a “**Party**” or “**Parties**” shall be read as including BTI).

RECITALS

- A. Bellerophon owns or Controls certain Intellectual Property Rights (defined below) relating to the Bellerophon’s product known as *INOpulse*® therapy.
- B. Baylor desires to obtain an exclusive license to such Intellectual Property Rights from Bellerophon to Develop and Commercialize the *INOpulse*® therapy in the Territory, and Bellerophon is willing to grant such a license to Baylor, all on the terms and conditions set forth herein.
- C. BTI agrees to assume certain responsibility and liability in relation to the compliance (or non-compliance) of, and the performance (or non-performance) of certain obligations under, this Agreement by Bellerophon.

NOW THEREFORE, in consideration of the mutual promises and covenants contained herein, and other good and valuable consideration contained herein, the receipt and sufficiency of which are hereby duly acknowledged, the Parties and BTI hereby agree as follows:

1. DEFINITIONS

Terms used herein with initial capital letters shall have the respective meanings set forth below in this Section 1 or other Sections herein where such terms are defined. The definitions of terms herein shall apply equally to the singular and plural forms of the terms defined. Whenever the context may require, any pronoun shall include the corresponding masculine, feminine and neuter forms. Except where expressly limited or otherwise stated to the contrary, the words “include,” “includes” and “including” shall be deemed to be followed by the phrase “without limitation.” The word “will” shall be construed to have the same meaning and effect as the word “shall,” and vice versa.

1.1 “**Additional Indications**” means CTEPH, High Altitude Sickness, and Sarcoidosis.

1.2 “**Affiliate**” means a Person that controls, is controlled by or is under common control with a Party, but only for so long as such control exists. For the purposes of this definition, the word “control” (including, with correlative meaning, the terms “controlled by” or “under common control with”) means the actual power, either directly or indirectly through one or more intermediaries, to direct the management and policies of such Person, whether by the ownership of more than fifty percent (50%) of the voting stock of such entity, or by contract or otherwise. The Parties and BTI acknowledge that in the case of certain entities organized under the laws of certain countries outside of the United States, the maximum percentage ownership permitted by law for a foreign investor may be equal to or less than fifty percent (50%), and that in such case such lower percentage shall be substituted in the preceding sentence, provided that such foreign investor has the power to direct

the management or policies of such entity. For the avoidance of doubt, as of the Effective Date, Bellerophon shall be treated as an Affiliate of BTI, and *vice versa*. BTI, Bellerophon and their respective Affiliates shall collectively be referred to herein as the “**Bellerophon Group**”.

- 1.3 “**Anti-Corruption Laws**” means all local and foreign anti-corruption laws, rules and regulations, including the provisions of the United States Foreign Corrupt Practices Act of 1977, as amended, and the UK Bribery Act of 2010, as amended.
- 1.4 “**Applicable Laws**” means all applicable laws, statutes, rules, regulations, orders, judgments, or ordinances having the effect of law of any national, multinational, federal, state, provincial, county, city, or other political subdivision, including, to the extent applicable, GCP, GLP, GMP, and those governing pharmaceutical and medical device products, as well as all applicable data protection and privacy laws, rules, and regulations, including, to the extent applicable, the United States Department of Health and Human Services privacy rules under the Health Insurance Portability and Accountability Act and the Health Information Technology for Economic and Clinical Health Act, the EU Data Protection Directive (Council Directive 95/46/EC), applicable laws implementing the EU Data Protection Directive, and the General Data Protection Regulation (2016/679), the PRC Personal Information Protection Law, the PRC Data Security Law, the PRC Biosecurity Law, the PRC Cybersecurity Law, the Hong Kong Personal Data (Privacy) Ordinance, the Macau Personal Data Protection Act, the Taiwan Personal Data Protection Act, and their respective implementing regulations and rules, as well as all applicable laws, regulations, orders, judicial decisions, conventions, and international financial institution rules regarding corruption, bribery, ethical business conduct, money laundering, political contributions, gifts and gratuities, or lawful expenses to public officials, healthcare professionals, and private persons, agency relationships, commissions, lobbying, books and records, and financial controls, including Anti-Corruption Laws, that, in each case, govern or otherwise apply to the applicable Person.
- 1.5 “**Approvals**” means the regulatory approvals, registrations, filings and authorizations required under any Applicable Laws for the Development, marketing and Commercialization of the Product in a region or country within the Territory.
- 1.6 “**Background Intellectual Property Rights**” means any and all Intellectual Property Rights: (a) which are Controlled by a Party or any of its Affiliates at the Effective Date; and (b) which are Controlled by a Party or any of its Affiliates after the Effective Date and during the Term as a result of activities conducted, directly and indirectly, outside the framework of this Agreement.
- 1.7 “**Bellerophon IND**” means IND number 135,076.
- 1.8 “**Best Endeavors**” means such efforts to accomplish an objective that a prudent, determined and reasonable Person, acting in such Person’s interest and desiring to achieve that result.
- 1.9 “**Business Day**” means a day, other than a Saturday, a Sunday, or a public holiday in New York, New York or any jurisdiction within the Territory, on which banking institutions in each such jurisdiction are open for business.
- 1.10 “**Clinical Trial**” means any human clinical trial of a Product, including any Phase 1 clinical trial, Phase 2 clinical trial, Phase 3 clinical trial, Phase 4 clinical trial bridging study, and any post-marketing clinical trial commenced after Approval of a Product.
- 1.11 “**Commercialization**” means the conduct of any and all activities, whether before or after Approvals have been obtained, directed to the promotion, marketing, commercial sale, distribution, or importation for commercial sale of the Product, including pricing, reimbursement, order processing, invoicing, sales, detailing (in person or by digital media), scientific and medical affairs,
-

inventory management, handling, delivery, and customer support. “**Commercialize**” means to engage in Commercialization.

- 1.12 “**Commercially Reasonable Efforts**” means such efforts to accomplish an objective that are substantially equivalent to those efforts and resources commonly used by a similarly situated company in the life sciences industry in the Territory for another drug or medical device product that is at a similar stage in its development or product life and is of similar market potential as the Product, taking into account efficacy, safety, approved labeling, and the patent and other proprietary position of the product.
- 1.13 “**Confidential Information**” means all information, including trade secrets, processes, formulae, data, Know-How, improvements, inventions, chemical or biological materials, assays, techniques, marketing plans, business plans, strategies, customer lists, financial information, or other information that has been disclosed by or on behalf of one Party to the other Party under this Agreement, regardless of whether any of the foregoing are marked “confidential” or “proprietary” or communicated in oral, written, graphic, or electronic form, or by visual inspection. This Agreement shall be the Confidential Information of each Party, and the Know-How disclosed by Bellerophon to Baylor constitutes the Confidential Information of Bellerophon.
- 1.14 “**Control**” or “**Controlled**” means, with respect to any Intellectual Property Rights, the possession by a Party, whether by ownership or license (other than a license granted to such Party under this Agreement), of the right to grant access to or a license (or sublicense) under such Intellectual Property Rights to the other Party on the terms and conditions set forth in this Agreement without requiring the consent of any Third Party or violating the terms of any agreement or other arrangement with any Third Party and without requiring payment to any Third Party unless the other Party agrees in writing to be responsible for such payment. Notwithstanding anything to the contrary set forth in this Agreement, Bellerophon and its Affiliates will not be deemed to Control any Intellectual Property Rights that are owned or in-licensed or controlled by a Third Party that becomes an Affiliate of Bellerophon after the Effective Date.
- 1.15 “**COPD**” means pulmonary hypertension secondary to chronic obstructive pulmonary disease.
- 1.16 “**Cost of Goods**” means (a) with respect to any Product that is manufactured and supplied by a Third Party, the actual price paid by a Party or its Affiliate to such Third Party for such Product; and (b) to the extent any Product is manufactured and supplied by a Party or its Affiliates, the fully-burdened cost of all direct materials and labor and fully-allocated manufacturing overhead directly attributable to the manufacture, storage, packaging and shipping of such Product, including all testing and yield loss costs, quality control, quality assurance, or other testing of such Product, together with all reasonably allocated indirect costs and overhead applicable to the manufacturing of such Product (including internal FTE costs associated with supply thereof), or technical operational functions, less cost of goods returned in accordance with such Party’s or its Affiliates’ or suppliers’ return policy.
- 1.17 “**Cover**” and “**Covered**” means, as to the Product and a claim of a Patent Right within the Licensed IP, that, in the absence of the license granted to Baylor in this Agreement under such Patent Right, the making, using, selling, offering for sale, or importation of such Product would infringe such claim of such Patent Right.
- 1.18 “**Creation**” means any Know-How, software, invention or discovery, whether or not patentable, that is conceived, discovered, generated, developed, collected, acquired, conceived, or reduced to practice, in whole or in part, by or on behalf of a Party or its Affiliate in the performance of its activities under this Agreement.
-

- 1.19 “**CTEPH**” means chronic thromboembolic pulmonary hypertension in patients who are (a) not candidates for surgical treatment or (b) are surgical treatment failures for chronic, out-of-hospital treatment.
- 1.20 “**Data Security and Privacy Laws**” means any Applicable Law relating to the privacy, data protection, integrity, Processing and security of Personal Data, including but not limited to the General Data Protection Regulation (EU) 2016/679, the PRC Personal Information Protection Law, the PRC Data Security Law, the PRC Biosecurity Law, the PRC Cybersecurity Law, the Hong Kong Personal Data (Privacy) Ordinance, the Macau Personal Data Protection Act, the Taiwan Personal Data Protection Act, and any related Applicable Law implementing the foregoing.
- 1.21 “**Development**” means, with respect to a drug product or medical device, all processes and activities that are reasonably required to seek, obtain and maintain Approval of such drug product or device, including, without limitation, toxicology, pharmacology and other pre-clinical efforts, test method development and stability testing, statistical analysis, clinical studies and regulatory activities. When used as a verb, “**Develop**” means to engage in Development.
- 1.22 “**Development Activities**” means any activity or undertaking to be performed by one Party or the Parties for the Development of the Product hereunder.
- 1.23 “**First Commercial Sale**” means, with respect to any Product in a region in the Territory, the first arm’s length sale of such Product in such region in the Territory by Baylor, its Affiliates, or Sublicensees to a Third Party after any final, conditional, or special Approvals required for marketing and selling such Product in any part of such region have been granted. First Commercial Sale does not include any sale or other distribution for use in a Clinical Trial or other Development Activities, promotional use (including a reasonable number of samples), or compassionate or named-patient use, where such sale or distribution is made at or below cost.
- 1.24 “**Foreground Intellectual Property Rights**” means any and all Intellectual Property Rights, other than Background Intellectual Property Rights, in any Creation.
- 1.25 “**GCP**” means the applicable then-current ethical and scientific quality standards for designing, conducting, recording, and reporting Clinical Trials as are required by applicable Regulatory Authorities or Applicable Law in the relevant jurisdiction, including Guidelines for Good Clinical Practice - ICH Harmonized Tripartite Guideline (ICH E6).
- 1.26 “**GLP**” means the applicable then-current good laboratory practice standards as are required by applicable Regulatory Authorities or Applicable Law in the relevant jurisdiction.
- 1.27 “**GMP**” means all applicable then-current good manufacturing practice standards for fine chemicals, intermediates, bulk products, or finished pharmaceutical products, as are required by applicable Regulatory Authorities or Applicable Law in the relevant jurisdiction, including, as applicable, all Applicable Law promulgated by any Governmental Authority having jurisdiction over the manufacture of the applicable device drug substance or drug product.
- 1.28 “**Governmental Authority**” means any court, agency, department, authority or other instrumentality of any national, state, provincial, county, city or other political subdivision, including any entity authorized or delegated by the foregoing to exercise any administrative authority or function.
- 1.29 “**HGRAC Approvals**” means any and all necessary record filings with, notification to, and approvals, licenses or permits issued by, the Human Genetics Resources Administration of the People’s Republic of China or any other Governmental Authority in the People’s Republic of China
-

required for any activities, including Development Activities and data sharing, under this Agreement.

- 1.30 “**High Altitude Sickness**” means pulmonary hypertension associated with pulmonary edema from high altitude sickness.
- 1.31 “**Ikaria**” means INO Therapeutics LLC and its successor(s)-in-interest.
- 1.32 “**Ikaria Competitor**” means any Person that is in any way anywhere in the world, directly or indirectly, engaged in the Ikaria NO Business.
- 1.33 “**Ikaria IP**” means Intellectual Property Rights, including Patent Rights and Know-How, licensed from Ikaria to Bellerophon pursuant to the Upstream License Agreement.
- 1.34 “**Ikaria NO Business**” means the business of the development, manufacture, commercialization, promotion, sale, import, export, servicing, repair, training, storage, distribution, transportation, licensing, or other handling or disposition of any product or service (including any product or service that utilizes, contains, or includes nitric oxide for inhalation, a device intended to deliver nitric oxide, or a service that delivers or supports the delivery of nitric oxide), bundled or unbundled, for or used in connection with (a) the diagnosis, prevention, or treatment, in both adult and/or pediatric populations, and whether in or out patient, of: (i) hypoxic respiratory failure associated with pulmonary hypertension, (ii) pulmonary hypertensive episodes and right heart failure associated with cardiovascular surgery, (iii) bronchopulmonary dysplasia, (iv) the management of ventilation — perfusion mismatch in acute lung injury, (v) the management of ventilation — perfusion mismatch in acute respiratory distress syndrome, (vi) the management of pulmonary hypertension episodes and right heart failure in congestive heart failure, (vii) pulmonary edema from high altitude sickness, (viii) the management of pulmonary hypertension episodes and right heart failure in pulmonary or cardiac surgery, (ix) the management of pulmonary hypertension episodes and right heart failure in organ transplant, (x) sickle cell vaso-occlusive crisis, (xi) hypoxia associated with pneumonia, or (xii) ischemia-reperfusion injury; or (b) the use of nitric oxide to treat or prevent conditions that are primarily managed in the hospital.
- 1.35 “**INO Business**” means the development, manufacture, sale, lease, distribution or provision, directly or indirectly, of (i) any inhaled nitric-oxide based therapy that uses a pulsatile delivery mechanism, or (ii) any pulsed and inhaled nitric-oxide therapy, or (iii) any nitric-oxide therapy that competes with or is substitutable for Bellerophon’s proprietary *INOpulse*® therapy that is the subject of the Bellerophon IND.
- 1.36 “**Intellectual Property Rights**” means Patent Rights, Know-How, utility certificates, utility models, industrial design rights, trademarks, copyrights, software, database rights, rights in data, trade secrets, and Know-How, and any other worldwide statutory, non-statutory, and common law rights applicable to creations and inventions, and all registrations, applications, renewals, extensions, combinations, divisions, continuations or reissues of any of the foregoing.
- 1.37 “**Knowledge**” means, with respect to any person, the actual knowledge of such person, without a duty of investigation.
- 1.38 “**Know-How**” means all information, results and data of any type, in any tangible or intangible form, including trade secrets, databases, ideas, discoveries, inventions, trade secrets, practices, methods, tests, assays, techniques, specifications, processes, formulations, formulae, knowledge, know-how (including Manufacturing Know-How), skill, experience, materials, including pharmaceutical, chemical and biological materials, products and compositions, pre-clinical, clinical, scientific, technical or test data (including pharmacological, biological, chemical, biochemical, toxicological and clinical test data), analytical and quality control data, stability data,
-

studies, procedures, drawings, plans, designs, diagrams, sketches, technology, documentation or descriptions.

- 1.39 “**Licensed Field**” means the R&D Business.
- 1.40 “**Licensed IP**” means any and all Background Intellectual Property Rights that are necessary to Develop and Commercialize the Product within the Licensed Field and which are Controlled by Bellerophon and/or its Affiliates. A list of the Licensed IP is attached hereto as Annex 1, which shall be promptly updated by Bellerophon or deemed so updated immediately in case of any additional Intellectual Property Rights that should be supplemented into the Licensed IP according to this Agreement.
- 1.41 “**Manufacturing Know-How**” means all Know-How that is reasonably useful to manufacture the Product.
- 1.42 “**Material Breach**” means a substantial failure in the performance of this Agreement, which would give the affected Party the right to terminate this Agreement (in addition to its right to sue for damages) in accordance with Section 12.5 or Section 12.6, as well as release the affected Party from its obligations under this Agreement; and for the avoidance of doubt, with respect to Baylor, failure to perform its obligation(s) under Sections 2, 3.2, 4.1(d), 4.1(e), 4.5, 4.6, 4.7, 4.8, 6.2(c), 6.3(l), 7.1, 7.2, 7.3, 7.4, 8.1, 8.3, 9.1, 9.2, and 9.3 of this Agreement, or Baylor’s breach of the License, would constitute a Material Breach under this Agreement, and with respect to Bellerophon, failure to perform its obligation(s) under Sections 2, 3.3, 8.2, 9.1, 9.2, and 9.3 of this Agreement would constitute a Material Breach under this Agreement.
- 1.43 “**NDA**” means a New Drug Application submitted to the United States Food and Drug Administration (and any successor governmental authority having substantially the same function) as more fully defined in United States 21 C.F.R. § 314.50 et. seq.
- 1.44 “**Net Sales**” means Baylor’s and its Sublicensees’ and Affiliates’ (each a “**Selling Party**”) gross receipts for the sale, lease, or transfer of any Product (in respect of which a payment is owed under this Agreement) to any Third Party, less the sum of the following:
- (a) discounts, credits, refunds, and rebates actually allowed in amounts customary in the trade;
 - (b) sales and value added taxes, tariffs, duties and use taxes directly imposed on the sale of an applicable Product and actually paid by a Selling Party;
 - (c) reasonable and customary rebates and similar payments made with respect to sales paid for by any governmental or Regulatory Authority;
 - (d) amounts allowed or credited on returns of sales of any applicable Products;
 - (e) amounts that are written off as non-collectible after the Selling Party’s Commercially Reasonable Efforts to collect such amounts, exclusive of costs of collection; and
 - (f) postage, freight, shipping, insurance, and other transportation-related charges actually incurred directly by the Selling Party in shipping Products.

No deductions may be made for commissions paid to individuals for the sale of an applicable Product, whether they are independent sales agents or regularly employed by the Selling Party, nor for any other cost incurred in the

manufacture, marketing, sale, distribution, shipment (other than as permitted under clause (f) above), promotion, advertisement, exploitation, or commercialization of an applicable Product.

Applicable Products will be considered “sold” when delivered, billed out, or invoiced, whichever comes first. For all applicable Products used by the Selling Party as premiums to promote, market, sell, or lease products or processes other than applicable Products, the applicable Products will be deemed to have been sold at the amount of cash consideration that the Selling Party would receive if they were sold to an unrelated, unaffiliated Third Party in an arm’s length sale of the same product in similar quantities at the same time and place.

In the case of an applicable Product transferred by a Selling Party to another Selling Party or to a Third Party where (i) such transferee is using such applicable Product for the purposes of selling products or creating products for sale or for services in the commercial market (other than under a written agreement pursuant to which the transferee’s use of the applicable Product is limited to research purposes internal to such transferee only for which such transferee does not derive a commercial or other economic benefit) and (ii) such transferee has, in connection with such transfer, paid consideration to the Selling Party in a form other than cash for an applicable Product, the Net Sales for such Product shall mean the cash consideration that the Selling Party would receive if the Product were sold to an unrelated, unaffiliated Third Party in an arm’s length sale of the same Product in similar quantities at the same time and place.

A “sale” shall not include transfers or dispositions in a region in the Territory for bona fide charitable purposes or when applicable Products are distributed alone, prior to receiving final, non-conditional Approval for marketing or sale of such applicable Products generally in such region in the Territory, for pre-clinical, clinical, regulatory or governmental regulatory purposes for which no compensation or financial or economic benefit is received by, or accrued to the Selling Party. A “sale” shall include transfers or dispositions in a region in the Territory prior to receiving final, non-conditional Approval for marketing and sale of such applicable Products generally in such region in the Territory for compensation or financial or economic benefit received by, or accrued to the Selling Party.

Individual samples of applicable Products that are provided by the Selling Party in reasonable and industry-standard quantities free of charge and with no direct or indirect benefit to the Selling Party in a bona fide effort to promote sales of the applicable Product only shall not be considered Net Sales.

With respect to an applicable Product that is sold as part of a combination product with one or more other functional products or functional product enhancements which are not applicable Products, the Net Sales of such applicable Product, for the purposes of determining the amounts due and payable under Section 4.6 and Section 4.7, shall be determined by multiplying the Net Sales of the combination product by the fraction $A/(A+B)$ where A is the average published sale price of such applicable Product when sold separately in finished form in like quantities and B is the average published sale price of the other products in the combined product sold separately in finished form in like quantities. In the event such average published sale price of the other products in the combined product cannot be determined, Net Sales for the purposes of determining royalty payments for the combination product shall be calculated by multiplying the Net Sales of the combination product by the fraction A/C where A is the average published sale price of such applicable Product when sold separately in finished form and C is the average published sale price of the combined product.

- 1.45 “**PAH**” means primary or idiopathic pulmonary arterial hypertension.
 - 1.46 “**PAH Net Sales**” shall have the same meaning as Net Sales but with PAH Product replacing Product in every instance.
 - 1.47 “**PAH Product**” means any product or service that utilizes, contains or includes nitric oxide for the treatment, prevention or diagnosis of PAH as well as all disposables and accessories used with such product. For the avoidance of doubt, a PAH Product may also be an R&D Product if such PAH Product also falls within the definition of R&D Product.
 - 1.48 “**Patent Right**” means any patent, utility model, or certificate of invention, or other indicia of ownership of an invention recognized by any Governmental Authority of competent jurisdiction, any application for any of the foregoing, and any and all pre-grant and post-grant forms of any of
-

the foregoing, including all continuations, continuations-in-part, divisional, provisional, and extensions, and including any counterparts or foreign equivalents of any of the foregoing issued by or filed in any country or other jurisdiction.

- 1.49 **“Person”** means any individual, partnership, joint venture, limited liability company, corporation, firm, trust, association, unincorporated organization, Governmental Authority or agency, or any other entity not specifically listed herein.
- 1.50 **“Personal Data”** means (a) all information identifying, or in combination with other information, identifiable to, an individual, including pseudonymized (key-coded) clinical data containing such information; and (b) any other information that is governed, regulated or protected by one or more Data Security and Privacy Laws.
- 1.51 **“PF”** means pulmonary hypertension in patients with pulmonary fibrosis associated with idiopathic interstitial pneumonias, chronic hypersensitivity pneumonitis or occupational or environmental lung disease.
- 1.52 **“PF Net Sales”** shall have the same meaning as Net Sales but with PF Product replacing Product in every instance.
- 1.53 **“PF Product”** means any product or service that utilizes, contains or includes nitric oxide for the treatment, prevention or diagnosis of PF as well as all disposables and accessories used with such product. For the avoidance of doubt, a PF Product may also be an R&D Product if such PF Product also falls within the definition of R&D Product.
- 1.54 **“Product”** means an R&D Product or any other product that is Covered by the Licensed IP and that is comprised of Bellerophon’s proprietary *INOpulse*® therapy that is the subject of the Bellerophon IND, as well as updates and modifications to such products.
- 1.55 **“Rebuild Trial”** is Bellerophon’s Phase 3 randomized, double-blind, placebo-controlled Clinical Trial designed to assess the safety and efficacy of pulsed inhaled nitric oxide (iNO) [at a dose of 45 mcg/kg ideal body weight (IBW)/hour] versus placebo in fILD patients at risk of pulmonary hypertension (PH) on long-term oxygen therapy.
- 1.56 **“R&D Business”** means the business of the development, manufacture, commercialization, promotion, sale, import, export, servicing, repair, training, storage, distribution, transportation, licensing, or other handling or disposition of (a) nitric oxide, (b) a device intended to deliver nitric oxide, or (c) a service that delivers or supports the delivery of nitric oxide; in each case, solely for or in connection with the outpatient, chronic treatment of patients who have COPD, PF, PAH, CTEPH, High Altitude Sickness, or Sarcoidosis, and even if initiation of therapy occurs in a hospital setting or such treatment occurs as part of episodic treatment or hospitalization of patients with COPD, PF, PAH, CTEPH, High Altitude Sickness, or Sarcoidosis.
- 1.57 **“R&D NO Delivery Device”** means a version (including any existing designs and prototypes) of pulse administering nitric oxide devices (including the “INOpulse” device) for the treatment of COPD and PAH.
- 1.58 **“R&D Payment”** has the meaning ascribed to it in Section 4.6(a).
- 1.59 **“R&D Product”** means (a) any product or service that in any way uses, incorporates, reflects, is based upon, or relies upon any Ikaria IP, or (b) any R&D NO Delivery Device.
- 1.60 **“R&D Product Approval”** means any applications, approvals, clearances, or other government authorizations, foreign or domestic, of any type of or for an R&D Product.
-

- 1.61 **“Regulatory Authority”** means any federal, national, supranational, state, provincial, directly administered municipality or local regulatory agency, department, bureau or other Governmental Authority, that has authority over the manufacture, Development, Commercialization or other use or exploitation (including the granting of Approval) of the Product in any applicable regulatory jurisdiction.
- 1.62 **“Regulatory Materials”** means the regulatory registrations, applications, authorizations, and approvals (including Approvals, supplements and amendments, pre- and post-approvals, pricing and reimbursement approvals, certificates of pharmaceutical product and labeling approvals), and other submissions made to or with, and minutes of meetings with, any Regulatory Authority for research, development (including the conduct of Clinical Trials), manufacture, or commercialization of a pharmaceutical product or medical device in a regulatory jurisdiction, together with all related correspondence to or from any Regulatory Authority and all documents, referenced in the complete regulatory chronology for each such submission including all drug master files (if any).
- 1.63 **“Sarcoidosis”** means pulmonary hypertension associated with the growth of tiny collections of inflammatory cells in the lung.
- 1.64 **“Strategic Transaction”** means, with respect to Bellerophon, the occurrence of any of the following events: (i) the direct or indirect acquisition by any Third Party of more than fifty percent (50%) of the voting stock of Bellerophon; (ii) the sale, transfer, conveyance or other disposition of all or substantially all of Bellerophon’s properties and assets to which this Agreement relates, whether tangible or intangible, to a Third Party; or (iii) the consummation of a merger, acquisition, consolidation or other similar transaction between or involving a Third Party and Bellerophon.
- 1.65 **“Sublicensee”** means (a) any Person to which Baylor or any of its Affiliates grants a sublicense, option to sublicense, or other right or license, under any of the rights licensed or sublicensed hereunder, and (b) any Person granted any further sublicense (at any level) of such rights, directly or indirectly, from any Person described in clause (a).
- 1.66 **“Territory”** means mainland China, Taiwan, Hong Kong and Macau.
- 1.67 **“Third Party”** means any Person other than Baylor, Bellerophon, or an Affiliate of Baylor or Bellerophon.
- 1.68 **“Upstream License Agreement”** means that certain Exclusive Cross-License, Technology Transfer, and Regulatory Matters Agreement, dated as of February 9, 2014, by and between Ikaria and Bellerophon Pulse Technologies LLC, as amended by the parties and/or their successors-in-interest on March 27, 2014, on July 27, 2015, on November 16, 2015, and on April 23, 2018.
- 1.69 **Additional Definitions.** In addition, each of the following definitions shall have the respective meanings set forth in the Section of this Agreement indicated below:

“License” has the meaning set forth in Section 2.1.

“Global Trademark Strategy” has the meaning set forth in Section 4.3.

“Tracking and Reporting Mechanism” has the meaning set forth in Section 4.7(b).

“Manufacture and Supply Agreement” has the meaning set forth in Section 5.1.

“Licensed Foreground IP” has the meaning set forth in Section 6.2(c).

“Breach Inventions” has the meaning set forth in Section 6.2(d).

“**Bellerophon IP**” has the meaning set forth in Section 6.3(i).

“**Ineligible Person**” has the meaning set forth in Section 8.3(d).

“**Term**” has the meaning set forth in Section 12.3.

“**Baylor Indemnified Parties**” has the meaning set forth in Section 15.1.

“**Bellerophon Indemnified Parties**” has the meaning set forth in Section 15.2.

“**Claim**” has the meaning set forth in Section 15.3(a).

“**Indemnified Party**” has the meaning set forth in Section 15.3(a).

“**Indemnifying Party**” has the meaning set forth in Section 15.3(a).

“**ICC**” has the meaning set forth in Section 16.1.

2. LICENSE.

2.1 Exclusive License Grant. Subject to the terms of this Agreement and the Upstream License Agreement, Bellerophon hereby grants to Baylor an exclusive and non-transferable license under (i) the Licensed IP and (ii) Bellerophon’s right, title and interest in and to its Foreground Intellectual Property Rights relating to the INO Business; in each case to Develop, have made, make, and Commercialize Products solely within the Licensed Field within the Territory during the Term (the “**License**”). The License shall be exclusive even as to Bellerophon and its Affiliates; *provided, however,* that Bellerophon and its Affiliates reserve the right to develop and make the Products within the Territory (and to engage Third Party contract service providers to develop and make the Products within the Territory solely for the benefit of Bellerophon) solely for export and use of such Products outside of the Territory.

2.2 Sublicensing. The License is not sub-licensable unless approved by Bellerophon in writing in advance, which shall not be unreasonably withheld, conditioned, or delayed (and Baylor acknowledges that such consent is conditional upon receipt of Ikaria’s consent with respect to the Ikaria IP). Upon request by Baylor, Bellerophon shall use its Best Endeavors to obtain Ikaria’s written consent allowing Baylor to further sub-license the License. Baylor shall be directly responsible for the acts and omissions of its Affiliates and Sublicensees. Any sub-license must be documented in a written sublicense agreement that reflects the requirements of this Agreement and the Upstream License Agreement. Baylor will deliver to Bellerophon a complete and unredacted copy of each sublicense agreement, including all amendments thereto, within thirty (30) days of execution, and Baylor acknowledges that Bellerophon will share such copy(ies) with Ikaria.

2.3 Contract Service Providers. Baylor may engage one or more contract service providers that are not Ikaria Competitors to perform Development Activities, manufacture, or distribute, in each case solely on its behalf and for its sole benefit and pursuant to a written agreement, and such engagement shall not be deemed a sublicense, and is not subject to prior consent by Bellerophon or Ikaria; provided that any agreement entered into by Baylor will not relieve any of its obligations hereunder and Baylor shall be fully responsible for any acts or omissions of its contract service providers, including compliance by such Persons with all Applicable Laws, and for compliance with all provisions of this Agreement. The applicable provisions of each such written agreement between Baylor and a contract service provider shall be consistent in all material respects with the corresponding provisions of this Agreement and shall include confidentiality and non-use provisions at least as stringent as those set forth in Section 9. Baylor shall notify Ikaria and Bellerophon (email shall suffice) of the identity of each contract service provider described in this Section 2.3 within thirty (30) days of engaging such contract service provider.

2.4 **Ikaria as Third Party Beneficiary.** Ikaria is a Third Party beneficiary to this Agreement with the right to enforce its terms against Baylor directly and for Ikaria's own benefit.

2.5 **Reserved Rights.** No Party grants to any other Party any rights or licenses in any Patent Rights, Know-How, Creations, or other Intellectual Property Rights or other proprietary rights of such Party, except as specifically set forth in this Agreement, and there are no implied licenses. All rights not expressly granted by a Party under this Agreement are reserved by such Party and may be used by such Party for any purpose that does not violate the terms of this Agreement.

3. DEVELOPMENT AND REGULATORY

3.1 **Development.** Subject to the terms of this Agreement, Baylor shall solely determine and be responsible for Development Activities in the Licensed Field and in the Territory. Baylor shall use Commercially Reasonable Efforts to Develop and obtain Approval of the Products on an ongoing and diligent basis in the Licensed Field and in the Territory.

3.2 **Regulatory Approvals.** Baylor shall have the exclusive right to file for and hold any and all Approvals for the Products in the Licensed Field in the Territory. Baylor shall not take any action in connection with the Development of Products that could adversely affect Product development or regulatory matters outside of the Territory or outside of the Licensed Field. Notwithstanding anything to the contrary, Baylor may designate any of its Affiliates that are not Ikaria Competitors at its sole discretion to apply for and hold any Approval for a Product in the Territory (or any jurisdiction thereof) as it sees fit. Baylor shall not allow any Third Party to hold any Approval for any Product in the Territory without Bellerophon's prior written consent. Baylor shall notify Bellerophon and Ikaria promptly upon the issuance of each Approval for a Product in the Territory, which notice shall identify the Person that holds such Approval, and Baylor shall notify Bellerophon and Ikaria promptly upon the transfer of any Approval from any Person to any other Person, and shall provide all information relating to such transfer as Bellerophon and Ikaria may reasonably request.

3.3 **Bellerophon Assistance.** Bellerophon shall, and shall cause its Affiliates to, at Baylor's request and expense, reasonably cooperate with and provide reasonable assistance to Baylor's Development Activities, including:

(a) keeping Baylor informed of the status of any Developments relating to the Products outside the Territory relevant to Baylor's Development of the Product, including the safety and efficacy results generated from such Development Activities; and

(b) provide Baylor with reasonable assistance in obtaining the Approvals for the Product in the Territory, including providing, to the extent in Bellerophon's possession and Control, necessary documents or supporting data and materials required by Applicable Law to obtain the Approvals, and attending meetings with Baylor and Regulatory Authorities in the Territory relating to the Products (and any cost or expense incurred by Bellerophon or its Affiliates in traveling at Baylor's request shall be reimbursed by Baylor). Bellerophon shall provide or make available to Baylor copies of all Regulatory Materials submitted or received by Bellerophon or its Affiliates to or from a Regulatory Authority, related to any Product outside the Territory, within a reasonable time after submission of such Regulatory Materials to any applicable Regulatory Authorities. For the avoidance of doubt, Bellerophon has no obligation under this Section 3.3 to commence additional or new Clinical Trials or studies or to generate new data.

3.4 **Access to Data; Rights of Reference.** Baylor hereby grants, and shall cause its Affiliates and Sublicensees to grant to, Bellerophon, Ikaria, and their Affiliates and designees the right to reference any and all Regulatory Materials relating to Products owned or controlled by Baylor or its Affiliates

or Sublicensees (including R&D Product Approvals for R&D Products), at no cost, whether such Regulatory Materials are held by Baylor or its Affiliates or Sublicensees, for any and all purposes relating to the Ikaria NO Business. Baylor shall provide, and shall cause its Affiliates and Sublicensees to provide all documentation and letters of consent to permit such referencing, which documentation and letters may be provided to the applicable Governmental Authorities.

4. COMMERCIALIZATION AND COMPLIANCE; ECONOMIC TERMS

4.1 **Diligence Requirements.**

- (a) Following the first Approval of a Product in any jurisdiction in the Territory, Baylor shall provide to Bellerophon with a Commercialization plan setting forth Baylor's marketing and commercialization strategies, in reasonable detail, for the upcoming twelve (12) months, and will provide updates to the Commercialization plan annually thereafter. Following the first Approval of a Product in any jurisdiction in the Territory, Baylor shall provide to Bellerophon with a written report, and shall provide an updated report not less than once each calendar quarter, that summarizes the Commercialization activities on a Product-by-Product basis in the Territory since the date of the prior report. Such report shall contain reasonably sufficient detail to enable Bellerophon to assess Baylor's compliance with its Commercialization obligations in this Section 4.1. In addition, Baylor shall have a meeting in person, by videoconference, teleconference or other similar communications equipment, with Bellerophon not less than once each calendar year to update Bellerophon as to the status of Baylor's Commercialization activities.
- (b) Baylor shall effect a First Commercial Sale within the Territory within the earlier of (i) twenty four (24) months from approval of NDA for the Product; and (ii) twelve (12) months of obtaining Approval (excluding pricing and reimbursement approvals) to market and sell the Product generally in such region in the Territory.
- (c) Baylor is exclusively responsible for Commercializing the Product in the Territory at its expense, including launching the Product, and shall use Commercially Reasonable Efforts to Commercialize the Product on an ongoing and diligent basis in the Licensed Field and throughout the Territory following Approval and in accordance with the Commercialization plan.
- (d) Baylor shall promptly notify Bellerophon if at any point Baylor is not actively and continuously engaged in the Development or Commercialization (either directly or through an Affiliate or Sublicensee) of an R&D Product for each of the following indications:
 - (a) COPD, (b) PAH, or (c) PF.
- (e) Upon request from Bellerophon from time to time, Baylor shall confirm in writing (within 7 Business Days after receipt of such request from Bellerophon) whether Baylor, its Affiliates or Sublicensees are engaged in such Development and Commercialization and is in compliance with the Commercialization plan.

4.2 Commercialization. For the avoidance of doubt, Baylor retains full rights, powers and discretion in relation to the distribution and Commercialization of the Products in the Licensed Field in the Territory.

4.3 Trademarks. Bellerophon may develop and implement a global trademark strategy (including global positioning, promotional messages, colors, and other visual branding elements) for any Product for use in Commercializing such Products in the Territory and outside the Territory (the "**Global Trademark Strategy**"). Bellerophon shall send the Global Trademark Strategy for any Product to Baylor at least six (6) months before Bellerophon's understanding of the anticipated date

of the First Commercial Sale of such Product hereunder. Baylor has the right to Commercialize the Products in the Territory under trademarks and trade names as is determined by Baylor, so long as such trademarks and trade names do not conflict with the Global Trademark Strategy.

4.4 Compliance with Laws. Baylor shall comply with all Applicable Laws and regulations in the Territory relating to the Development, importation, transportation, storage, handling, advertising, sale, distribution and other Commercialization activities concerning the Product.

4.5 R&D Business Requirements. Baylor shall ensure that all R&D Products are used solely within the scope of the R&D Business. All provision of R&D Products to end users shall be made under an appropriate written agreement. Each such agreement shall include (a) a restriction requiring that such end user use the applicable R&D Product only for a use within the scope of the R&D Business, (b) a mechanism for Baylor to audit and confirm that such restriction is complied with, and (c) a termination right permitting Baylor to terminate that agreement in the event such restriction has been violated. In the event of any such violation, Baylor shall ensure that such violation is promptly remedied, and if it is not, Baylor shall terminate the end user agreement in question. Use of an R&D Product by a Sublicensee or an end user outside of the scope of the R&D Business shall be deemed to be a Material Breach by Baylor of this Agreement. Baylor shall provide (whether doing so directly or through an Affiliate, Sublicensee, or otherwise) the delivery device portion of R&D Products to end users on a loaned or leased-basis only, and shall not transfer title to the delivery device portion of any R&D Product to any end user.

4.6 R&D Payment and Running Royalties.

- (a) Baylor shall pay Bellerophon a payment of six million dollars (\$6,000,000 USD) within ninety (90) days of the Effective Date.
- (b) Baylor shall pay Bellerophon royalties in an amount equal to five percent (5%) of Net Sales. For the avoidance of doubt, such royalties are separate and apart from the royalties payable by Baylor for the benefit of Ikaria pursuant to Section 4.7.

4.7 Royalties Payable for the Benefit of Ikaria, Records, and Audits.

- (a) During the Term and for two (2) years thereafter, Baylor shall maintain (and shall require each Affiliate and Sublicensee to maintain) documentation and records sufficient to demonstrate its compliance with the requirements of this Agreement, and to verify the accuracy of royalties paid and payable hereunder. Upon reasonable notice from Bellerophon or Ikaria, as applicable, Baylor shall provide (and shall require its Affiliates and Sublicensees to provide) to Bellerophon or Ikaria (as applicable) or its agents with access to their premises during normal business hours to examine, audit and copy all records requested by Bellerophon or otherwise relevant to determine whether Baylor (and each Affiliate and Sublicensee) is in compliance with the requirements of this Agreement (including, without limitation, records of sales in the Additional Indications). Without limiting the generality of the foregoing, Bellerophon and Ikaria may review any and all (a) sublicenses granted by Baylor hereunder and (b) agreements with R&D Product end users. If any audit certifies an underpayment made during the audited period, Baylor shall pay Bellerophon or Ikaria (as applicable) the amount of the underpayment within thirty (30) days of receipt of invoice. If such audit **certifies an underpayment of royalties that exceeds either (i) \$100,000 or (ii) 10% of the total royalties owed during the audited period, then Baylor shall pay Bellerophon or Ikaria (as applicable) for the costs of performing the audit.**
 - (b) Baylor shall develop and implement measures reasonably acceptable to Bellerophon and Ikaria such that use in each of the Additional Indication can be tracked by Baylor and reported to Bellerophon (the “**Tracking and Reporting Mechanism**”). If,
-

despite Baylor's Best Endeavors to development and implement the Tracking and Reporting Mechanism, Bellerophon or Ikaria in good faith nonetheless believes that the Tracking and Reporting Mechanism does not meet the requirements of this Section 4.7(b), Bellerophon shall provide written notice thereof, which written notice shall describe each basis for such belief. Promptly following the provision of such notice, the Parties (and Ikaria if it chooses) shall meet to discuss in good faith the content of Bellerophon's notice and to determine whether and how to remedy the issues raised by Bellerophon. If after 30 days from the date of Bellerophon's notice and despite the Parties' good faith efforts to remedy the issues raised by Bellerophon, Bellerophon or Ikaria still believes that Tracking and Reporting Mechanism does not meet the requirements of this Section 4.7(b), the issues shall be escalated to the Chief Executive Officers of each Party and of Ikaria for resolution, provided, that Ikaria shall be entitled to make a final, good faith determination as to whether the Tracking and Reporting Mechanism meets the requirements of this Section 4.7(b).

- (c) Upon the terms and subject to the conditions set forth herein, Baylor shall pay Bellerophon, for the benefit of Ikaria, five percent (5%) of Net Sales of all R&D Products in any of the Additional Indications in the Territory for so long as any such R&D Products for any of the Additional Indications are Commercialized; provided, however, that the foregoing rate of five percent (5%) shall be reduced to three percent (3%) if the royalty rate payable by Bellerophon to Ikaria under the Upstream License Agreement is reduced to three percent (3%). Bellerophon shall notify Baylor of any reduction in the royalty rate within thirty (30) days as of the date of reduction.
- (d) If despite Baylor's Best Endeavors to put in place a Tracking and Reporting Mechanism reasonably acceptable to Bellerophon and Ikaria in respect of the Additional Indications as described in Section 4.7(b), it has not done so, then the sales-based payments on Net Sales required under Section 4.7(c) shall apply to all sales of R&D Products (i.e., not just those Commercialized for an Additional Indication) provided that the royalty rate shall be one percent (1%) rather than five percent (5%) or three percent (3%) (as applicable).
- (e) In addition to any other royalties due by Baylor to Bellerophon for the benefit of Ikaria under this Agreement, Baylor shall pay Bellerophon, for the benefit of Ikaria, three percent (3%) of PAH Net Sales.
- (f) In addition to any other royalties due by Baylor to Bellerophon for the benefit of Ikaria under this Agreement, Baylor shall pay to Bellerophon, for the benefit of Ikaria, one percent (1%) of PF Net Sales.
- (g) For the avoidance of doubt, Baylor is responsible for all amounts payable to Ikaria resulting from this Agreement. Bellerophon shall remit the royalty payments received from Baylor under this Section 4.7 directly to Ikaria.
- (h) Without limiting its applicability to other R&D Products, Section 4.7(a) shall apply with respect to PAH Products and PF Products and shall apply with respect to the documentation, records, and premises of Baylor, its Affiliates and Sublicensees of PAH Products and PF Products.

4.8 Reports; Payment of Royalty.

- (a) Following First Commercial Sale, Baylor shall furnish to Bellerophon (and Bellerophon shall share with Ikaria) a quarterly written report for the prior calendar quarter showing (a) the amount of gross sales and Net Sales of each Product in each region during the applicable calendar quarter, separated into Product Net Sales, R&D Product Net Sales, PF Net Sales, and PAH Net Sales; (b) the applicable royalty rate for Products under this
-

Agreement; (c) the total deductions used to calculate Net Sales, with each specific deduction itemized; (d) a calculation of the amount of royalty payments due to Ikaria on such Net Sales; and (e) a calculation of the amount of royalty payment due to Bellerophon on such Net Sales. Reports shall be due thirty (30) days following the close of each calendar quarter. Royalties shall be due and payable thirty (30) days following the close of each calendar quarter.

(b) All payments by Baylor under this Agreement to Bellerophon shall be made by electronic funds transfer in immediately available funds to such bank account as Bellerophon may from time to time designate by notice to Baylor, and shall be made without withholding, set-off, or deduction. All payments hereunder shall be made in U.S. Dollars. For the purpose of calculating any sums due under, or otherwise reimbursable pursuant to, this Agreement (including the calculation of Net Sales expressed in currencies other than U.S. Dollars), Baylor shall convert any amount expressed in a foreign currency into Dollar equivalents using conversion procedures and methodology in accordance with International Financial Reporting Standards (IFRS), in each case, as generally and consistently applied throughout Baylor's organization. Each Party and Ikaria shall be responsible for any tax obligations of its own due to this Agreement (including income tax). Neither Party nor Ikaria shall have any obligation towards the other Party in case the other Party fails to fully comply with its own tax obligations. Each Party and Ikaria shall bear all taxes for which it is liable under Applicable Law incurred in connection with this Agreement. Any indirect tax, other than Value Added Tax, including but not limited to transfer tax, duties, levies and customs, shall be borne by the payee Party. Any payments or portions thereof due hereunder that are not paid by Baylor when due will accrue interest under this Agreement at a rate of one and one-half percent (1.5%) per annum or the maximum applicable legal rate, if less, calculated on the total number of days payment is delinquent.

(c) This Section 4.8 shall survive any expiration or termination of this Agreement.

5. MANUFACTURE AND SUPPLY

5.1 **Manufacture and Supply Agreement.** Within six (6) months following the Effective Date, the Parties shall negotiate in good faith a separate agreement that sets forth reasonable and customary terms and conditions for (i) the manufacturing and supply of the Products by Bellerophon for Baylor's clinical use, and (ii) the manufacturing and supply of the Products by Baylor to Bellerophon for Bellerophon's commercial use. The transfer price paid by each Party to the other Party for Products will be calculated as the manufacturing Party's Cost of Goods of the Products plus 20% (the "**Manufacture and Supply Agreement**"). The Manufacture and Supply Agreement shall set forth reasonable and customary terms and conditions regarding the quality of the Products supplied to the buying Party, including (a) quality assurance and quality control (and an accompanying Quality Agreement); (b) compliance with any Applicable Laws and standards; and (c) reporting and management of quality defects and quality complaints.

5.2 **Manufacturing Know-How.** Subject to the terms and conditions of the Manufacture and Supply Agreement and the compliance with Applicable Laws, at Baylor's request and at no additional cost to Baylor, Bellerophon shall, and shall cause it Affiliates to, use Commercially Reasonable Efforts to (i) disclose and deliver all Manufacturing Know-How to Baylor or its designated Third Party manufacturer for use in manufacturing the Products in the Territory, and (ii) provide reasonable technical assistance to enable Baylor or its designated Third Party manufacturer to use such Manufacturing Know-How to manufacture the Products in the Territory; all as set forth more particularly in the Manufacture and Supply Agreement.

6. INTELLECTUAL PROPERTY RIGHTS

6.1 Background Intellectual Property. All right, title and interest in and to any and all Background Intellectual Property Rights shall remain solely and exclusively with the respective Party or its Affiliates, as the case may be, except for those granted by Bellerophon to Baylor according to and by virtue of this Agreement.

6.2 Foreground Intellectual Property.

- (a) All right, title and interest in and to any and all Foreground Intellectual Property Rights in any Creation made by or on behalf of Baylor and/or any of its Affiliates under this Agreement shall vest solely and exclusively in Baylor and/or its Affiliates.
- (b) All right, title and interest in and to Foreground Intellectual Property Rights in any Creation made by or on behalf of Bellerophon and/or its Affiliates under this Agreement shall vest solely and exclusively in Bellerophon and/or its Affiliates.
- (c) Baylor hereby grants Bellerophon, Ikaria, and their respective Affiliates, an exclusive, worldwide, royalty-free, fully paid up license to use the Foreground Intellectual Property Rights owned or controlled by Baylor and its Affiliates (“**Licensed Foreground IP**”) (i) to make, have made, use, sell, have sold, offer to sell and import products and services relating to the INO Business in all countries and jurisdictions worldwide other than the Territory and (ii) in case of Ikaria and its Affiliates only, to engage in the Ikaria NO Business in all countries and jurisdictions, and to grant sublicenses under the Licensed Foreground IP to Third Parties or its Affiliates. The license under the Licensed Foreground IP set forth in romanette (i) (1) is not sublicensable unless approved by Baylor in writing in advance, which shall not be unreasonably withheld, conditioned, or delayed. The licenses under the Licensed Foreground IP can be transferred by Bellerophon or Ikaria to a Third Party in case of a Strategic Transaction between Bellerophon or Ikaria and such Third Party. Bellerophon may engage one or more contract service providers to develop, make and have made products and services using the Licensed Foreground IP for Bellerophon’s own interests and such engagement shall not be deemed a sublicense, and is not subject to prior consent by Baylor; provided that any agreement entered into by Bellerophon will not relieve any of its obligations under this Section 6.2(c) and Bellerophon shall be fully responsible for any acts or omissions of its contract service providers, including compliance by such Persons with all Applicable Laws, and for compliance with all provisions of this Agreement. The applicable provisions of each such written agreement between Bellerophon and a contract service provider shall be consistent in all material respects with the corresponding provisions of this Agreement and shall include confidentiality and non-use provisions at least as stringent as those set forth in Section 9. This license to Bellerophon shall become perpetual upon expiration of this Agreement. This license to Ikaria shall become perpetual upon expiration or termination of this Agreement; *provided, however*, that such license shall terminate upon termination of the Upstream License Agreement by Bellerophon or its Affiliate pursuant to the final sentence of Section 9.4 of the Upstream License Agreement, or by Bellerophon or its Affiliate pursuant to Section 11.2.3 of the Upstream License Agreement based on a material uncured breach of the Upstream License Agreement by Ikaria.
- (d) If Baylor uses any Licensed IP in a manner that is not expressly permitted under the terms of this Agreement, all Creations arising from such activities or use, whether patentable or not, will belong solely and exclusively to Bellerophon (“**Breach Inventions**”), and Baylor will and hereby does, and will cause all of its Affiliates and its and their employees, agents and independent contractors to, assign to Bellerophon all of their respective rights, title, and interests in and to all Breach Inventions, and will, and will cause all of its Affiliates and its and their employees, agents and independent contractors to, cooperate with Bellerophon to execute and deliver any and all documents that Bellerophon deems reasonably necessary to perfect and enforce its right hereunder to such Breach Inventions, including by executing consistent confirmatory assignments and by providing good faith testimony by declaration, affidavit, in-person, or otherwise.

6.3 Patent Matters.

- (a) As between the Parties, Bellerophon shall exclusively control all patent and trademark matters relating to the Licensed IP worldwide, including registration, prosecution, defense and maintenance thereof.
- (b) Baylor shall reimburse Bellerophon for the costs and expenses incurred by Bellerophon in registration, prosecution, defense and maintenance of the Licensed IP within the Territory following completion of the Rebuild Trial, provided that Bellerophon shall provide Baylor with reasonable documentation of such costs and expenses.
- (c) During the Term and thereafter, Baylor shall prosecute and maintain patent applications and patents claiming or covering Licensed Foreground IP outside the Territory in accordance with Bellerophon's instructions and requests, and Bellerophon will reimburse Baylor the costs and expenses for such patent prosecution matters. During the Term and thereafter, Bellerophon shall prosecute and maintain patent applications and patents claiming or covering Foreground Intellectual Property Rights licensed to Baylor hereunder within the Territory in accordance with Baylor's instructions and requests, and Baylor will reimburse Bellerophon the costs and expenses for such patent prosecution matters following completion of the Rebuild Trial.
- (d) Each Party shall have the exclusive right at its expense to prepare, file, prosecute, own, maintain, assign, transfer, or license and defend its Foreground Intellectual Property Rights throughout the world; *provided, however*, that during the Term and thereafter Bellerophon shall have the first right, but not the obligation, to defend and enforce Licensed Foreground IP within the INO Business outside of the Territory and in the Ikaria NO Business throughout the world (in each case subject to its obligations to Ikaria, and Ikaria's rights, under Section 9.1.3 of the Upstream License Agreement), and Baylor shall reasonably cooperate with Bellerophon in such efforts, including, at Bellerophon's expense, joining any action as a party-plaintiff if requested by Bellerophon.
- (e) Each Party shall, and shall cause its Affiliates and representatives to, provide all reasonable assistance and cooperation in connection with the other Party's prosecution and maintenance activities under this Section 6.3, including by making its employees, agents, and independent contractors reasonably available and executing any necessary documents or instruments.
- (f) As between the Parties, Bellerophon shall have the sole right, but not the obligation, to defend and control the defense of the validity and/or enforceability of the Licensed IP worldwide, including any inter partes review, post-grant review, and any other post-grant proceedings, including reexamination, reissue, opposition, revocation and other similar proceedings, and Baylor shall not have the right to defend any of the Licensed IP without Bellerophon's prior written consent.
- (g) Baylor shall, as soon as reasonably practicable but in any event within thirty (30) days, provide Bellerophon with written notice reasonably detailing any known or alleged infringement or misappropriation by a Third Party of the Licensed IP, and shall notify Bellerophon of any known filings or submissions within the Territory seeking to challenge or invalidate the Licensed IP and of any declaratory judgment, opposition, or similar action alleging the invalidity, unenforceability or non-infringement of the Licensed IP, in each case, as soon as reasonably practicable but in any event within seven (7) days.
-

- (h) With respect to any actual or suspected infringement of the Ikaria IP by a Third Party, Ikaria shall have the exclusive right, but not the obligation, to initiate a legal action against such Third Party with respect to such infringement, and Baylor may not initiate any such action without Bellerophon and Ikaria's prior written consent. Upon request by Baylor, Bellerophon agrees to use its Best Endeavors to request Ikaria to take legal actions against such actual or suspected infringement of the Ikaria IP; provided that such infringement has or will adversely impact the Development or Commercialization of the Products in the Territory.
- (i) With respect to Licensed IP other than Ikaria IP ("**Bellerophon IP**"), the Parties shall consult and cooperate fully to determine a course of action, including the commencement of legal action by a Party, to terminate infringement or misappropriation of Bellerophon IP in the Territory. Baylor, upon notice to Bellerophon, shall have the first right, but not the obligation, to initiate and prosecute such legal action within the Licensed Field in the Territory at its own expense, or to control the defense of any declaratory judgment action relating to Bellerophon IP. Baylor shall obtain Bellerophon's prior written consent prior to settling or compromising any such defense. Each Party shall have the right to be represented by counsel of its own choice in such action. Baylor shall bear the cost of any such proceedings or claims initiated by itself. Bellerophon shall, at Baylor's expense, provide reasonably necessary assistance that Baylor may reasonably require from time to time in the conduct of such claims or proceedings, but Bellerophon is not required to join as a party plaintiff without its prior written consent. Baylor will keep Bellerophon regularly informed of the status and progress of such enforcement efforts and will reasonably consider Bellerophon's comments on any such efforts, including determination of litigation strategy and filing of material papers, and providing copies of all material documents received, prepared and filed in connection with any such action, and shall consult with to determine a course of action with respect to any defense of the validity and/or enforceability of any Bellerophon IP and shall consider in good faith all reasonable comments, requests, and suggestions provided by with respect thereto. The non-enforcing Party will be entitled to separate representation in such matter by counsel of its own choice and at its own expense. Baylor will not settle any claim, suit, or action in any manner that would limit the rights of Bellerophon or Ikaria or impose any obligation on Bellerophon or Ikaria, without the prior written consent of Bellerophon. Recoveries received by Baylor in such action shall be first used to reimburse Bellerophon's costs and expenses incurred in providing such assistance.
- (j) Each Party shall promptly notify the other Party upon becoming aware of any actual or threatened claim that Baylor's Development, manufacture, or Commercialization of any Product infringes or misappropriates the Intellectual Property Rights of a Third Party in the Territory ("**Third Party IP Claim**"). In all cases, Baylor may defend itself from any such Third Party IP Claim brought against Baylor or its Affiliates or sub-licensees at its own expense and with counsel of its choosing. Each Party shall keep the other Party reasonably informed of all material developments in connection with any Third Party IP Claim, and the other Party shall consult with and offer reasonable assistance to the Party defending against such Third Party IP Claim, at the defending Party's cost and expense.
-

(k) All information exchanged between the Parties regarding the prosecution, maintenance, enforcement and defense of the Licensed IP will be deemed to be Confidential Information of the disclosing Party. In addition, the Parties acknowledge and agree that, with regard to such prosecution, maintenance, enforcement and defense, the interests of the Parties as licensors and/or licensees are to, for their mutual benefit, obtain patent protection and plan patent defense against potential patentability/invalidity challenges or infringement activities by Third Parties, and as such, are aligned and are legal in nature. The Parties agree and acknowledge that they have not waived, and nothing in this Agreement constitutes a waiver of, any legal privilege concerning Patent Rights under this Section 6.3, including privilege under the common interest doctrine and similar or related doctrines. Notwithstanding anything to the contrary in this Agreement, to the extent a Party has a good faith belief that any information required to be disclosed by such Party to the other Party under this Section 6.3 is protected by attorney-client privilege or any other applicable legal privilege or immunity, such Party shall not be required to disclose such information and the Parties shall in good faith cooperate to agree upon a procedure (which may include entering into a specific common interest agreement, disclosing such information on a “for counsel eyes only” basis or similar procedure) under which such information may be disclosed without waiving or breaching such privilege or immunity.

(l) For the avoidance of doubt and notwithstanding anything to the contrary herein, Baylor may not admit invalidity or unenforceability of any of the Licensed IP or take any action that could impair the validity or enforceability of the Licensed IP, or that could impair Bellerophon’s or Ikaria’s rights thereto.

7. NON-COMPETE AND NO CHALLENGE

7.1 **Patent Challenge.** Baylor shall not, and will cause or ensure that its Affiliates and Sublicensees shall not, directly or indirectly challenge or assert, or voluntarily assist any Third Party in challenging or asserting, the patentability, validity, ownership, enforceability, term or scope of the Licensed IP (including in any proceeding before the patent or trademark offices of any jurisdiction). Such challenge includes: (i) filing or pursuing a declaratory judgment action; (ii) citing prior art, filing a request for or pursuing a re-examination, or becoming a party to or pursuing an interference; (iii) filing, or joining in, a petition to institute inter partes review; (iv) filing, or joining in, a petition to institute post-grant review; or (v) filing or pursuing any opposition, cancellation, nullity, or other like proceedings. Without limiting any other rights or remedies that Bellerophon may have, at law or equity, if Baylor or its Affiliate or Sublicensee challenges or supports a challenge to the enforcement or validity of the Licensed IP, Bellerophon may terminate this Agreement upon notice to Baylor.

7.2 **Business Restrictions.** Baylor shall not, directly or indirectly, itself or with or through any Affiliate or Third Party, engage in the Ikaria NO Business, and shall not grant a sublicense hereunder to any Person that is engaged in the Ikaria NO Business, and shall contractually prohibit and prevent each Sublicensee from engaging in the Ikaria NO Business.

7.3 **Non-Compete.** Baylor will not, either directly or indirectly (whether through or with an Affiliate, a Sublicensee, or otherwise), modify, develop, or manufacture, or commercialize (or permit to be modified, developed, manufactured, or commercialized) any long term pulse administering nitric oxide device for COPD or PAH that has any of the following abilities, attributes, capabilities, capacities, functions, or specifications: (i) ability to deliver constant iNO concentration with ventilator(s) on either a continuous or variable flow basis; (ii) ability to deliver iNO in conjunction with NICU/PICU/ICU, Anesthesia and respiratory apparatus applications, including ventilator(s); (iii) ability of controlling, changing, diluting, maintaining iNO concentration to a desired, constant level before delivered to the patients by adding another gas, such as air, oxygen or oxygen enriched gases; (iv) delivery of iNO into an ambu bag application; (v) delivery of continuous NO flow, or

high frequency pulsed approximation of continuous NO flow; (vi) gas concentration monitoring (directly or indirectly taking samples from side stream for analysis); (vii) precision respiratory device flow monitoring (injectable module flow sensor); (viii) ability to communicate to hospital-based electronic medical records systems; (ix) ability to communicate with other medical devices, except the long term oxygen therapy devices; or (x) integrated iNO backup delivery mechanism that is compatible with ventilator devices and ambu bags.

7.4 INO Business. Baylor and its Affiliates and Sublicensees shall not engage in the INO Business in the Territory except with respect to its Development, manufacture and Commercialization of Products in accordance with this Agreement. For clarity, this Section 7.4 does not limit Baylor from developing, manufacturing or commercializing separate devices and products that do not fall within the scope of the foregoing, including distinguishable derivatives developed based on the INOpulse and non-INO Business nitric-oxide therapies.

8. REPRESENTATIONS AND WARRANTIES.

8.1 Mutual. Each Party represents, warrants and covenants to the other that:

- (a) it is duly organized, validly existing, and in good standing under the laws of its jurisdiction of incorporation, organization, or chartering, and has the full power and authority to enter into this Agreement and to perform its obligations;
- (b) when executed and delivered by such Party, this Agreement constitutes the legal, valid, and binding obligation of such Party, enforceable against such Party in accordance with its terms;
- (c) the execution, delivery, and performance of this Agreement by such Party does not violate, conflict with, require consent under, or result in any breach of or default under (i) any Applicable Laws or (ii) the provisions of any contract, instrument, or understanding to which it is a party or by which it is bound;
- (d) no government authorization, consent, approval, license, exemption of or filing or registration with any court or governmental department, commission, board, bureau, agency, or instrumentality, domestic or foreign, under any Applicable Law currently in effect, is or shall be necessary for, or in connection with, the transactions contemplated by this Agreement, or for the performance by it of its obligations under this Agreement, except as may be required to conduct Clinical Trials or to seek or obtain Approvals or applicable Regulatory Materials;
- (e) it has obtained all necessary authorizations, consents, and approvals of any Third Party that is required to be obtained by it for, or in connection with, the transactions contemplated by this Agreement, or for the performance by it of its obligations under this Agreement, except as may be required to conduct Clinical Trials or to seek or obtain Approvals or applicable Regulatory Materials; and
- (f) it has complied and will comply, in all material respects, with all Applicable Laws, rules or regulations regarding the performance of this Agreement.

8.2 By Bellerophon. Bellerophon represents and warrants to Baylor that:

- (a) Subject to the terms of the Upstream License, Bellerophon has the right to grant the rights and licenses granted to Baylor hereunder;
- (b) Bellerophon has not granted and is not under any obligation to grant, to any Third Party any license, lien, option, encumbrance, or other contingent or non-contingent right, title, or interest in or to the Licensed IP that conflicts with the rights and licenses granted to Baylor hereunder;
- (c) Any and all Intellectual Property Rights related to the *INOpulse*® therapy, devices and application software Controlled by Bellerophon and/or its Affiliates at the Effective Date have been included in the Licensed IP as specified under Annex 1 of this Agreement;
- (d) Bellerophon shall use its Best Endeavors to maintain the validity and effectiveness of the Licensed IP, and the validity and effectiveness of Upstream License Agreement; and
- (e) As of the Effective Date, Bellerophon's executives have no Knowledge of any Third Party issued patents within the Territory that will be infringed by the manufacture, use or sale in the Licensed Field of a product comprised solely of Bellerophon's proprietary *INOpulse*® therapy that is the subject of the Bellerophon IND.

8.3 By Baylor. Baylor represents, warrants and covenants to Bellerophon that:

- (a) **Resources.** Baylor has and will continue to have sufficient financial, human and tangible resources necessary to perform its obligations under this Agreement, including to comply with Section 4.1.
- (b) **Anti-Corruption Laws.** Baylor and its Affiliates have not and will not, in the performance of this Agreement, (i) perform any actions that are prohibited by any Anti-Corruption Laws that may be applicable to one or both Parties or (ii) directly or indirectly, make any payment, or offer or transfer anything of value, or agree or promise to make any payment or offer or transfer anything of value, to a government official or government employee, to any political party or any candidate for political office or to any other Third Party with the purpose of influencing decisions related to either Party or its business in a manner that would violate Anti-Corruption Laws.
- (c) **Cooperation.** Upon request, or should Baylor or its Affiliate become the subject of an audit or investigation by a Governmental Authority, including under any anti-boycott regulations, anti-bribery legislation, or related export legislation, Baylor and its Affiliate shall cooperate fully in connection with such investigation and shall provide such information and records to such Person subject to such investigation with respect to Baylor's activities under and in connection with this Agreement as may be requested.
- (d) **Debarment.** Baylor and its Affiliates: (i) are not excluded, debarred, suspended or otherwise ineligible to participate in government healthcare programs or in government procurement or non-procurement programs and no debarment is pending or has been initiated; (ii) have not been charged with or convicted of a criminal offense that requires exclusion from a government healthcare program; and (iii) are not otherwise disqualified or suspended from performing this Agreement or subject to any restrictions or sanctions by any Governmental Authority or professional body (an "**Ineligible Person**"). Baylor further represents, warrants and covenants that Baylor and its Affiliates are not using, and will not in the future use, any employee or agent who is an Ineligible Person in the performance of this Agreement. Baylor shall immediately notify Bellerophon in writing if Baylor or any employee or agent of Baylor or its Affiliates is or becomes an Ineligible Person or if any action, suit, claim, investigation, or other legal or administrative proceeding is pending or, to the best of Baylor's knowledge, threatened, that would make Baylor or its Affiliate or any of their employees or agents an Ineligible Person.

8.4 Disclaimers. Except as expressly provided in this Agreement, each Party makes no representations or warranties of any kind, either express or implied, with respect to the Intellectual Property Rights licensed by such Party under this Agreement, and hereby expressly disclaims any warranties of merchantability, or fitness for a particular purpose. Without limiting the foregoing, Bellerophon disclaim any warranties relating to the validity or enforceability of Patent Rights, that patents will issue upon applications, and non-infringement of Intellectual Property Rights of Third Parties.

8.5 Limitation of Liability. Bellerophon shall not be liable for any indirect, incidental or consequential damages, or for lost profits or lost business, whether such damages are alleged as a result of breach of the Agreement or otherwise, even if the such Party has been advised of the possibility of such damages.

8.6 Ikaria. Baylor acknowledges that Ikaria provides no representations, warranties, or indemnities, nor has any liabilities or responsibilities to Baylor, pursuant to this Agreement.

9. CONFIDENTIALITY

9.1 Nondisclosure and Non-Use. Each Party (for the purposes of this Section 9, a "Party" or "Parties" shall be read as including BTI) acknowledges that it may acquire Confidential Information of the

other Party in connection with its performance of this Agreement. Each Party shall (i) hold all Confidential Information of the other Party in confidence, using the same degree of care to prevent unauthorized disclosure or access that it uses with its own Confidential Information of similar type (but in no event using less than a reasonable degree of care), (ii) shall not disclose such Confidential Information to Third Parties, or allow Third Parties to access it, or (iii) not use the other Party's Confidential Information in any way, commercially or otherwise, except in furtherance of performing its obligations under this Agreement; provided, however, that each Party may disclose Confidential Information to its Affiliates and to its and their attorneys, accountants and other confidential advisors who need to know such information for the purpose of assisting such Party in connection with the activities contemplated herein or the subject matter hereof who are bound by a duty of confidentiality of even scope herewith. Also, the receiving Party may disclose the disclosing Party's Confidential Information to the receiving Party's agents, consultants, or other Third Parties on the condition that such Third Parties have a need to know such Confidential Information so that the receiving Party may exercise its rights and perform its obligations hereunder and agree to be bound by confidentiality and non-use obligations that substantially are no less stringent than those confidentiality and non-use provisions contained in this Agreement (and the receiving Party shall be liable and responsible for such Persons' compliance with the terms of this Section 9). Any Confidential Information transmitted to an employee or agent of the receiving Party shall be considered as transmitted to the receiving Party. Any information disclosed by an employee or agent of the disclosing Party shall be considered to be disclosed by the disclosing Party.

9.2 Exceptions. Confidential Information shall not include information if and to the extent the receiving Party can prove such information:

- (a) is publicly known at the time of disclosure, or becomes known to the public after disclosure other than by breach by the receiving Party of this Agreement;
- (b) was known to the receiving Party previously, without a duty of confidentiality and as evidenced by tangible records of such knowledge;
- (c) was independently developed by the receiving Party outside of this Agreement and without access to or use of any Confidential Information of the disclosing Party; or
- (d) was rightfully obtained by the receiving Party from Third Parties without a duty of confidentiality.

Any combination of features or disclosures shall not be deemed to fall within the foregoing exclusions merely because individual features are published or available to the general public or in the rightful possession of the receiving Party unless the combination itself and principle of operation are published or available to the general public or in the rightful possession of the receiving Party.

9.3 Required Disclosure. If the receiving Party is required to disclose all or any part of any Confidential Information of the disclosing Party under a discovery request, a subpoena, or inquiry issued by a court of competent jurisdiction or by a judicial, administrative, regulatory or governmental agency or legislative body or committee (including Regulatory Authorities, and including any disclosures of Confidential Information in R&D Product Approvals and related Regulatory Materials and communications), the receiving Party so requested may make such disclosure if and to the extent legally required and shall, subject to Applicable Laws, give prompt written notice of such request to the disclosing Party and shall give the disclosing Party the opportunity to seek an appropriate confidentiality agreement, protective order or modification of any disclosure or otherwise intervene, prevent, delay or otherwise affect the response to such request and the receiving Party shall, at the disclosing Party's request and expense, reasonably cooperate in such efforts, to the extent permitted by Applicable Law. Bellerophon may disclose Confidential Information of Baylor to Ikaria to the extent necessary to comply with the Upstream License Agreement.

9.4 Return of Confidential Information. Upon termination or expiration of this Agreement, or upon request by the disclosing Party at any time with respect to particular Confidential Information not required by the receiving Party to perform such receiving Party's obligations under this Agreement, the receiving Party shall (a) return to the disclosing Party all Confidential Information disclosed by such disclosing Party hereunder and all copies thereof that are in the receiving Party's possession or control, and (b) delete from its computers, databases, and servers any electronic copies of all such Confidential Information; provided, however, that (i) each Party may retain one (1) copy of any Confidential Information for its internal legal files or the files of its outside counsel; and (ii) no Party shall be required to disclose or delete automatically created copies of Confidential Information maintained on system back-up media (provided that any retention of such Confidential Information shall not entitle a Party to use or disclose such Confidential Information after termination or expiration of this Agreement).

9.5 Announcements. Promptly following the Effective Date, the Parties shall issue an initial press release having the content specified in Schedule 9.5. The Parties agree that after a press release (including the initial press release or any subsequent press release) or other public announcement has been issued in accordance with this Section 9.5, each Party may make subsequent public disclosures of the information contained in such press release or other public announcement without the further approval of the other Party, so long as the information in such press release or other public announcement remains true and correct. Notwithstanding anything to the contrary set forth in this Agreement, each Party may issue a press release or public announcement as required, in the reasonable judgment of such Party, by Applicable Law, including by the rules or regulations of the United States Securities and Exchange Commission or similar regulatory agency in a country other than the United States or of any stock exchange or listing entity.

9.6 Public Reporting. If any Party is required to disclose the terms of this Agreement in submissions to the U.S. Securities and Exchange Commission or other equivalent Governmental Authority, it will (a) consult with the other Party as to which information to redact from the copy of this Agreement that will be disclosed; and (b) to the extent permitted under Applicable Law, redact all sensitive, material and non-public information, from such copy. The requirements of this Section 9.6 shall not apply if the substance of the description of or reference to this Agreement contained in the proposed filing or disclosure has been included in any previous filing or disclosure made by either Party or otherwise approved by the other Party and such information remains accurate as of such time.

10. EXPORT CONTROLS

10.1 Export Laws. All obligations of the Parties are subject to compliance with any and all Applicable Laws and regulations, including those on export controls and import and export of technologies, and Baylor shall not export any Licensed IP in violation of Applicable Laws.

10.2 Governmental Approvals. The Parties, respectively, shall each use its Commercially Reasonable Efforts to obtain any related approvals or licenses from competent authorities, as applicable, so as to successfully perform its obligations hereunder. Each Party and BTI shall collaborate with the other Party and provide the other Party assistance as reasonably necessary to obtain any required approvals or licenses.

10.3 Intellectual Property Licensing. In the event that any Intellectual Property Rights to be licensed under this Agreement are prohibited from import or export in accordance with Applicable Laws so that such licensing cannot be made, the Parties and BTI undertake to take all necessary and legal measures to facilitate the fulfilment of their contractual obligations under the Agreement to the extent permitted by Applicable Laws. If Applicable Laws prevent Bellerophon from licensing any item of Licensed IP to Baylor in accordance with the terms of this Agreement, then Bellerophon may, upon notice to Baylor, terminate the License with respect to such item, in which case the provisions of Section 12.8 with respect to such terminated rights shall apply. Notwithstanding the

foregoing, prior to termination of the License with respect to any specific item, the Parties shall negotiate in good faith to take any necessary remedial measures to the extent permitted by Applicable Laws.

11. FORCE MAJEURE

11.1 **Excuse.** Except with respect to Baylor's payment obligations hereunder, no party hereto shall be in breach of this Agreement for any delay or failure in the performance of this Agreement resulting from an event of Force Majeure, which renders its performance of this Agreement impossible or illegal, provided however that notice of such Force Majeure shall be promptly given to the other parties hereto within ten (10) days as of the occurrence of such event of Force Majeure.

The parties hereto shall use their Best Endeavors to minimize the effects of such failure or delay as far as possible and with all reasonable dispatch and continue the performance of this Agreement whenever such causes are removed. In the event of any such excused delay the time for performance shall be extended for a period equal to the time lost by reason of the delay.

11.2 **Definition.** Force Majeure means any event beyond the reasonable control of a party hereto which was not reasonably foreseeable and not caused by its negligence, and the effects of which are not capable of being overcome, which may include acts of God, wars, riots, embargoes, acts of civil and military authorities, unforeseen restrictions of law, economic sanctions, epidemics, pandemics, fires, explosions floods, earthquakes, other unusually severe weather conditions, accidents, unavailability of resources, or, cyber security breach, or other type of electronic hacking or attack ("**Force Majeure**").

11.3 **Termination.** Should the events of Force Majeure suffered by a Party extend beyond a six (6)-month period, the other Party may then terminate this Agreement by written notice to the non-performing Party and BTI.

12. TERM AND TERMINATION

12.1 **Closing Conditions.** Notwithstanding Section 12.2, the License under Section 2 hereof will only remain (unless and until terminated in accordance with this Agreement) effective as of the day each of the following conditions (each a "**Closing Condition**") has been met, or waived in writing by Bellerophon:

- (a) Baylor has paid the R&D Payment within ninety (90) of the Effective Date;
- (b) Bellerophon notifies Baylor that, as a result of Bellerophon's performance of diligence in matters relating to this Agreement (such activities not to exceed forty-five (45) days from the Effective Date), there are no unresolved diligence issues, or Bellerophon agrees that any unsolved diligence issue (if any) can be solved after the License becomes effective; and
- (c) If requested by Bellerophon by notice, Baylor delivers to Bellerophon a certificate executed by an officer of Baylor certifying the accuracy of the representations and warranties of Baylor in Section 8 as of the Effective Date.

12.2 **Term.** This Agreement shall commence as of the Effective Date, without any prejudice to Section 12.1. This Agreement, unless sooner terminated pursuant to this Section 12, shall be in effect for the longer of: (i) the life of the last to expire Patent Right within the Licensed IP that Cover the Product; and (ii) 15 years from First Commercial Sale of the Product (the "**Term**"). Subject to the Upstream License Agreement, the Parties agree that the License to Baylor as provided hereunder shall become perpetual upon expiration of this Agreement.

12.3 **Termination for Diligence Failures.**

- (a) Bellerophon may terminate this Agreement upon notice to Baylor, on an Product-by-Product and indication-by-indication basis, if Baylor is no longer actively and continuously engaged in the development or commercialization (either directly or through one or more sublicensees) of such Product for such indication.
- (b) Bellerophon may terminate this Agreement upon notice to Baylor, on an R&D Product-by-R&D Product and indication-by-indication basis:
 - (i) *two years after Baylor has obtained Approval in PAH or COPD (whichever is obtained earlier) if Baylor has failed to commence and remain actively and continuously engaged in the development or commercialization (either directly or through one or more Sublicensees) of an R&D Product for the indications of CTEPH, High Altitude Sickness, or Sarcoidosis, respectively, or*
 - (ii) *if Baylor is no longer actively and continuously engaged in the development or commercialization (either directly or through one or more Sublicensees) of an R&D Product for the indications of CTEPH, High Altitude Sickness, or Sarcoidosis, respectively, after having commenced such development and commercialization within two years after Approval in PAH or COPD (whichever is obtained earlier).*

12.4 **Ikaria IP.** Bellerophon may terminate Baylor's license to the Ikaria IP immediately upon termination of the Upstream License Agreement.

12.5 **Termination by Bellerophon.** Bellerophon may terminate this Agreement upon notice to Baylor if Baylor commits a Material Breach of this Agreement and fails to cure such Material Breach within sixty (60) days of receipt of written notice of such breach from Bellerophon.

12.6 **Termination by Baylor.** Baylor may terminate this Agreement upon notice to Bellerophon if Bellerophon commits a Material Breach of this Agreement and fails to cure such Material Breach within sixty (60) days of receipt of written notice of such breach from Baylor.

12.7 **Automatic Termination and Refund.** If the Closing Conditions have not been met, or waived in writing by Bellerophon, by April 4, 2023, then this Agreement shall automatically terminate and Bellerophon shall return the R&D Payment to Baylor within seven (7) Business Days of such termination.

12.8 **Effects of Termination.**

- (a) **Termination of Licenses.** Upon early termination of this Agreement, all licenses and rights granted hereunder will automatically terminate.
- (b) **Return or Destruction of Confidential Information.** Promptly after expiration or termination of this Agreement, each receiving Party will return to the disclosing Party or destroy, at the disclosing Party's election, all Confidential Information of the disclosing Party that is in the possession or control of the receiving Party related to this Agreement. Nothing in this Agreement will prevent a Party retaining any records as required by Applicable Law.
- (c) **Assignment of Regulatory Materials.** In the event of termination of this Agreement:
- (i) *where permitted by Applicable Law, Baylor shall promptly assign and transfer (or cause to be assigned and transferred) to Bellerophon or its designee (and, if in Baylor's or its Affiliate's possession or control, provide copies of) all Approvals and Regulatory Materials relating to Products, or to the extent not so transferrable, Baylor shall promptly take all reasonable actions to make available to Bellerophon or its designee, the benefits of such Regulatory Materials, including upon Bellerophon's request, by providing a right of reference to any Regulatory Materials controlled by Baylor or Affiliate for Products, and providing Bellerophon with copies of all Clinical Data and all material correspondence between Baylor and its Affiliates and Regulatory Authorities relating to such Regulatory Materials; and*
- (ii) *Baylor and Bellerophon will effectuate and coordinate an orderly transition of the relevant obligations and rights to Bellerophon as reasonably necessary for Bellerophon to Develop, Manufacture and Commercialize Products after termination of this Agreement in a manner consistent with Applicable Law and standards of ethical conduct of human Clinical Trials.*
- (d) **Survival.** The rights and obligations of the Parties under this Agreement that by their nature would continue beyond the expiration or termination of this Agreement (including Section 1, 2.4, 2.5, 3.2, 4.6, 4.7, 4.8, 6.1, 6.2, 6.3(c), 6.3(d), 6.3(f), 6.3(k), 7.1, 8, 9, 12.8, 12.9, 13, 15, 16, and 17) shall survive expiration or earlier termination of this Agreement.

12.9 **Cumulative Remedies.** The election by a Party to terminate this Agreement in accordance with the above provisions will not be deemed an election of remedies, and all remedies provided by this Agreement or available at law or in equity shall be cumulative and shall survive any termination or expiration.

13. NOTICES

13.1 Any notice, demand, consent, waiver, and other formal or legal communications made under or in connection with this Agreement (the "**Notice**") shall be made in writing, and shall be delivered by means of international commercial courier directed:

If to Baylor, to:

Attn: Wang Tiefei; Room 1107, Building 8, No. 778, Yatai Road; Daqiao Town, Nanhu District, Jiaxing City, Zhejiang Province

If to Bellerophon, to:

Attn: Peter Fernandes; 184 Liberty Corner Rd, Suite 302; Warren, NJ 07059

If to BTI, to:

Attn: Peter Fernandes; 184 Liberty Corner Rd, Suite 302; Warren, NJ 07059

If to Ikaria, to:

Attn: Mark Tyndall; Mallinckrodt Pharmaceuticals; 901 F Street NW, Suite 550,
Washington DC 20004

or such other address as may be specified in writing by any party hereto to the other parties hereto in advance. Notices shall be considered delivered upon receipt.

14. NO ASSIGNMENT

Baylor shall have no right to assign, delegate or otherwise transfer its rights or obligations under this Agreement, except with the written consent of Bellerophon, not to be unreasonably withheld or delayed. Bellerophon and BTI may each assign or transfer this Agreement or any part thereof in its discretion to an Affiliate or Third Party provided that (i) such Affiliate or Third Party is not an Ikaria Competitor; (ii) such Affiliate or Third Party agrees in writing to assume Bellerophon's or BTI's (respectively) obligations hereunder; and (iii) Bellerophon or BTI, as applicable, delivers to Baylor a certificate duly executed by such Affiliate or Third Party certifying its assumption of Bellerophon's or BTI's (as applicable) obligations hereunder. Any assignment of this Agreement in contravention of this Section 14 shall be null and void. This Agreement binds the Parties' and BTI's successors and permitted assigns.

15. INDEMNIFICATION

15.1 **By Bellerophon.** Bellerophon shall defend, indemnify and hold harmless Baylor and its Affiliates and its and their officers, directors, employees, agents and representatives (collectively, the "**Baylor Indemnified Parties**") from all judgments, damages, liabilities, losses, costs, fines, penalties and expenses, including reasonable attorneys' fees and costs (collectively, "**Losses**"), incurred in connection with any Third Party claim brought against any of the Baylor Indemnified Parties to the extent arising out of or related to: (a) breach of any representation, warranty or provision in this Agreement by Bellerophon; (b) the gross negligence or willful misconduct of any Bellerophon Indemnified Parties; or (c) any violation of Applicable Laws by Bellerophon Indemnified Parties; in each case except to the extent the claims are caused by actions covered by Baylor's indemnification obligations in Section 15.2.

15.2 **By Baylor.** Baylor shall defend, indemnify and hold harmless Ikaria, and Bellerophon, and their respective Affiliates, and their respective officers, directors, employees, agents and representatives (collectively, the "**Bellerophon Indemnified Parties**") from all Losses, incurred in connection with any Third Party claim brought against any of the Bellerophon Indemnified Parties to the extent arising out of or related to: (a) Baylor's breach of any representation, warranty or provision in this Agreement; (b) the gross negligence or willful misconduct of any Baylor Indemnified Parties; (c) any violation of any Applicable Laws by Baylor Indemnified Parties; or (d) Baylor's and its Affiliates' and Sublicensees' Development, Commercialization, manufacture, use, sale or other exploitation of Products; in each case except to the extent the claims are caused by actions covered by Bellerophon's indemnification obligations in Section 15.1.

15.3 **Indemnification Procedure.**

- (a) If a Party or Ikaria is seeking indemnification from a Third Party claim (“**Claim**”) pursuant to Section 15.1 or Section 15.2 (the “**Indemnified Party**”), then it will promptly inform the indemnifying Party (the “**Indemnifying Party**”) (or, in case of Ikaria, the Indemnifying Party or Bellerophon) of the Claim giving rise to the obligation to indemnify pursuant to such Section as soon as reasonably practicable after receiving notice of the Claim, provided, however, that no delay or failure on the part of the Indemnified Party in notifying the Indemnifying Party (or, in case of Ikaria, the Indemnifying Party or Bellerophon) will relieve the Indemnifying Party from any obligation hereunder unless (and then only to the extent that) such delay or failure is prejudicial to or otherwise adversely affects the Indemnifying Party.
- (b) The Indemnifying Party will have the right, exercisable by notice to the Indemnified Party within thirty (30) days after receipt of notice from the Indemnified Party of the commencement of or assertion of the Claim, to assume the direction and control of the defense, litigation, settlement, appeal, or other disposition of such Claim for which it is obligated to indemnify the Indemnified Party (including the right to settle the Claim solely for monetary consideration) with counsel selected by the Indemnifying Party and reasonably acceptable to the Indemnified Party. During such time as the Indemnifying Party is controlling the defense of such Claim, the Indemnified Party will cooperate with the Indemnifying Party, and will cause its Affiliates and agents to cooperate upon request of the Indemnifying Party, in the defense or prosecution of the Claim, including by furnishing such records, information, and testimony and attending such conferences, discovery proceedings, hearings, trials or appeals as may reasonably be requested by the Indemnifying Party. In the event that the Indemnifying Party does not notify the Indemnified Party of the Indemnifying Party’s intent to defend any Claim within thirty (30) days after notice thereof, the Indemnified Party may (without further notice to the Indemnifying Party) undertake the defense thereof with counsel of its choice and at the Indemnifying Party’s expense (including reasonable, out-of-pocket attorneys’ fees and costs and expenses of enforcement or defense). The Indemnifying Party or the Indemnified Party, as the case may be, will have the right to participate (including the right to conduct discovery, interview and examine witnesses and participate in all settlement conferences), but not control, at its own expense and with counsel of its choice, in the defense of any Claim that has been assumed by the other Party or Ikaria (as applicable).
- (c) Notwithstanding any provision to the contrary in this Agreement, the Indemnifying Party will not enter into any settlement, consent judgment, or other voluntary final disposition of any Claim that has an adverse effect on the rights of any Indemnified Party hereunder or on the Licensed IP, or admits any wrongdoing or fault by any Bellerophon Indemnified Parties or Baylor Indemnified Parties, or imposes on any Bellerophon Indemnified Parties or Baylor Indemnified Parties any payment or other liability, without the prior written consent of such Indemnified Party.
- (d) Each Indemnified Party will take and will procure that its Affiliates take all such reasonable steps and action as are reasonably necessary or as the Indemnifying Party may reasonably require in order to mitigate any claims (or potential losses or damages) under this Section 15. Nothing in this Agreement will or will be deemed to relieve any Party or Ikaria of any common law or other duty to mitigate any losses incurred by it.

16. DISPUTE RESOLUTION AND GOVERNING LAW.

- 16.1 The Parties and, as applicable, Ikaria shall use good faith efforts to settle any dispute, controversy or claim arising from or related to this Agreement or the breach (and alleged breach) thereof (a “**Dispute**”). Any Party or Ikaria (if applicable) shall give the other Party and Ikaria (if applicable) notice of any Dispute not resolved in the normal course of business. Within twenty (20)
-

days from the date of delivery of such notice, the receiving entity shall submit to the other entity a written response. The notice and response shall include (a) a statement of that entity's position and a summary of arguments supporting that position, and (b) the name and title of the executive who will represent that entity and of any other person who will accompany the executive. Within thirty (30) days from the date of delivery of the initial notice, the executives of all entities to the Dispute shall meet at a mutually acceptable time and place (in person or virtually), and thereafter as often as they reasonably deem necessary, to attempt to resolve the Dispute. These executives shall have the authority to settle the Dispute. All negotiations pursuant to this paragraph are confidential and shall be treated as compromise and settlement negotiations for purposes of applicable rules of evidence.

16.2 All Disputes that are not resolved following the process set forth in Section 16.1 within [ninety (90)] days from the date of delivery of initial notice of the Dispute (or such longer period as may be mutually agreed by the relevant Parties and Ikaria, as applicable), shall be finally settled by arbitration under the Rules of Arbitration of the International Chamber of Commerce ("ICC"), as applicable from time to time. The arbitration shall be administered under the supervision of the ICC International Court of Arbitration. The number of arbitrators shall be three (3). The seat of the arbitration shall be United States. The arbitration proceedings shall be conducted in English. The governing law of the arbitration proceedings shall be the laws of United States. Notwithstanding anything to the contrary set forth in this Agreement or the ICC rules, the Parties expressly acknowledge and agree that any breach of the provisions of this Agreement concerning Ikaria Competitors would, at minimum, constitute willful misappropriation of and infringement upon Ikaria's Intellectual Property Rights for which the arbitral tribunal is empowered to award exemplary damages. The decision and award of the arbitral tribunal shall be final and binding on the Parties and Ikaria (as applicable) and may be entered and enforced in any court having jurisdiction, and the Parties and Ikaria (as applicable) irrevocably and unconditionally waive any and all rights to any form of appeal, review or recourse to any judicial authority, insofar as such waiver may be validly made.

16.3 Notwithstanding the foregoing, the Parties recognize that a Party may suffer immediate, irreparable harm in certain circumstances, including a breach or threatened or anticipated breach of obligations hereunder; accordingly, each Party is entitled, in addition to any other remedy available at law or in equity, to injunctive relief to specifically enforce the terms of this Agreement in a court of competent jurisdiction.

16.4 This Agreement shall be exclusively governed by and construed and enforced in accordance with the laws of the State of Delaware in the United States of America, excluding the principles of conflicts of laws.

16.5 Notwithstanding any provision to the contrary set forth in this Agreement, any and all issues regarding the scope, construction, validity, and enforceability of any Patent Rights or trademark relating to this Agreement will be determined in a court or other tribunal, as the case may be, of competent jurisdiction under the applicable patent or trademark laws of the country in which such Patent Rights or trademark rights were granted or arose.

17. MISCELLANEOUS

17.1 **Liability.** For so long as Bellerophon is wholly owned by BTI, if Bellerophon materially breaches Sections 2.1, 3.3, 5, 6.3(c), 8.2, or 12.7 of this Agreement, then BTI shall be responsible and liable to Baylor and/or other Baylor Indemnified Parties (as applicable) for such material breach as if such breach were committed directly by BTI.

17.2 **Entire Agreement.** This Agreement contains the entire and only agreement between Baylor and the Bellerophon Group (or any Person thereof) with respect to the subject matter hereof (save for those other agreements and documents expressly mentioned under this Agreement) and supersedes all previous documents and agreements between Baylor and the Bellerophon Group (or

any Person thereof) regarding the subject matter hereof. Any previous representation, promise or condition in connection with this Agreement not incorporated into this Agreement shall not be binding upon Baylor or the Bellerophon Group (or any Person thereof). None of Baylor or the Bellerophon Group (or any Person thereof) has relied on or has been induced to enter into this Agreement in reliance on any representation, warranty or undertaking that is not set out in this Agreement.

- 17.3 **Waiver.** Neither the failure nor the delay of either Party to enforce any provision of this Agreement shall constitute a waiver of such provision or of the right of each Party to enforce each and every provision of this Agreement.
- 17.4 **Severability.** If any provision of this Agreement is or is held to be invalid or unenforceable, then so far as it is invalid or unenforceable it has no effect and is deemed not to be included in this Agreement. This shall not invalidate any of the remaining provisions of this Agreement. The Parties shall then use all reasonable endeavors to agree with each other Party, and replace the invalid or unenforceable provision by a valid provision the effect of which is as close as possible to the intended effect of the invalid or unenforceable provision.
- 17.5 **Amendments.** Any amendment to this Agreement shall be agreed upon in writing by the Parties.
- 17.6 **Headings.** The captions to the several Articles, Sections and subsections hereof are not a part of this Agreement, but are merely for convenience to assist in locating and reading the several Articles and Sections hereof.
- 17.7 **Independent Contractors.** It is expressly agreed that the Parties shall be independent contractors and that the relationship between them hereunder shall not constitute a partnership, joint venture or agency. No Party shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on any other Party, without the prior written consent of the other Party.
- 17.8 **Use of Affiliates.** Each Party shall have the right to exercise its rights and perform its obligations under this Agreement either itself or through any of its Affiliates provided that Baylor may not allow any Affiliate that is an Ikaria Competitor to exercise any rights or perform any obligations under this Agreement, and subject to such restriction, each Party's Affiliates will have the benefit of all rights (including all licenses) of such Party under this Agreement. Accordingly, and subject to the above restriction, in this Agreement "Baylor" will be interpreted to mean "Baylor and/or its Affiliates" and "Bellerophon" will be interpreted to mean "Bellerophon and/or its Affiliates" where necessary to give each Party's Affiliates the benefit of the rights provided to the applicable Party in this Agreement; provided, however, that in any event each Party will remain responsible hereunder for the acts and omissions of its respective Affiliates. Baylor shall notify Ikaria and Bellerophon (email shall suffice) of the identity of each of its Affiliates that exercised or will exercise Baylor's rights or performed Baylor's obligations under this Agreement within thirty (30) days of appointing such Affiliate to exercise such rights or perform such obligations.
- 17.9 **Rights of Third Parties.** Unless expressly provided to the contrary in this Agreement (including in Section 2.4), a person who is not a Party has no right to enforce or to enjoy the benefit of any term of this Agreement. Notwithstanding any term of this Agreement, the consent of any Person who is not a Party is not required to rescind or vary this Agreement at any time.
- 17.10 **Expenses.** Each Party will be responsible for its own costs and expenses associated with its negotiation, execution, delivery and performance of this Agreement.
-

17.11 **Waiver of Rule of Construction.** Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement shall be construed against the drafting Party shall not apply.

17.12 **Counterparts.** This Agreement may be executed in any number of counterparts, and by each Party hereto on separate counterparts. Each counterpart is an original, but all counterparts shall together constitute one and the same instrument. Delivery of an executed counterpart signature page of this Agreement by e-mail attachment (PDF) or telecopy shall be an effective mode of delivery. The Parties irrevocably and unreservedly agree that this Agreement may be executed by way of electronic signatures and that this Agreement, or any part thereof, shall not be challenged or denied any legal effect, validity and/or enforceability solely on the ground that it is in the form of an electronic record.

[Signature Pages to Follow]

IN WITNESS WHEREOF, the Parties and BTI have executed this TECHNOLOGY LICENSE AGREEMENT by their duly authorized representatives effective as of the Effective Date.

Baylor Biosciences, Inc.

/s/ Theodore Wang
Authorized Signature/Company Seal

Theodore Wang
Print Name

Chairman
Title

Bellerophon Pulse Technologies LLC

/s/ Peter Fernandes
Authorized Signature/Company Seal

Peter Fernandes
Print Name

Chief Executive Officer
Title

Bellerophon Therapeutics, Inc.

/s/ Peter Fernandes
Authorized Signature/Company Seal

Peter Fernandes
Print Name

Chief Executive Officer
Title

IN WITNESS WHEREOF, the Parties and BTI have executed this TECHNOLOGY LICENSE AGREEMENT by their duly authorized representatives effective as of the Effective Date.

Baylor Biosciences, Inc.

/s/ Theodore Wang
Authorized Signature/Company Seal

Theodore Wang
Print Name

Chairman
Title

Bellerophon Pulse Technologies LLC

/s/ Peter Fernandes
Authorized Signature/Company Seal

Peter Fernandes
Print Name

Chief Executive Officer
Title

Bellerophon Therapeutics, Inc.

/s/ Peter Fernandes
Authorized Signature/Company Seal

Peter Fernandes
Print Name

Chief Executive Officer
Title

IN WITNESS WHEREOF, the Parties and BTI have executed this TECHNOLOGY LICENSE AGREEMENT by their duly authorized representatives effective as of the Effective Date.

Baylor Biosciences, Inc.

/s/ Theodore Wang
Authorized Signature/Company Seal

Theodore Wang
Print Name

Chairman
Title

Bellerophon Pulse Technologies LLC

/s/ Peter Fernandes
Authorized Signature/Company Seal

Peter Fernandes
Print Name

Chief Executive Officer
Title

Bellerophon Therapeutics, Inc.

/s/ Peter Fernandes
Authorized Signature/Company Seal

Peter Fernandes
Print Name

Chief Executive Officer
Title

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: May 15, 2023

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

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

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

- (1) the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 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: May 15, 2023

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