
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of report (Date of earliest event reported): May 15, 2023

Bellerophon Therapeutics, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction of
Incorporation)

001-36845
(Commission
File Number)

47-3116175
(IRS Employer
Identification No.)

20 Independence Boulevard, Suite 402
Warren, New Jersey
(Address of Principal Executive Offices)

07059
(Zip Code)

Registrant's telephone number, including area code: **(908) 574-4770**

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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 is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

- Emerging growth company
 - If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.
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Item 2.02. Results of Operations and Financial Condition.

On May 15, 2023, Bellerophon Therapeutics, Inc. issued a press release announcing its financial and operational results for the quarter ended March 31, 2023. The full text of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Current Report on Form 8-K (including Exhibit 99.1) shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits:

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated May 15, 2023 (furnished and not filed for purposes of Item 2.02)
104	Cover Page Interactive Data File (Formatted as Inline XBRL)

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 hereunto duly authorized.

BELLEROPHON THERAPEUTICS, INC.

Date: May 15, 2023

By: /s/ Peter Fernandes

Name: Peter Fernandes

Title: Chief Executive Officer



Bellerophon Provides Clinical Program Update and Reports First Quarter 2023 Financial Results

- *Last Patient Completed Blinded Treatment in REBUILD Phase 3 Trial for INOpulse®; Pivotal Top-line Data Expected in Mid-2023*

WARREN, N.J., May 15, 2023 – Bellerophon Therapeutics, Inc. (Nasdaq: BLPH) (“Bellerophon” or the “Company”), a clinical-stage biotherapeutics company focused on developing treatments for cardiopulmonary diseases, today provided a clinical program update and reported financial results for the first quarter ended March 31, 2023.

“We are pleased with the progress we have made to date in 2023, highlighted by the completion of the blinded treatment phase of our ongoing pivotal Phase 3 REBUILD trial,” said Peter Fernandes, Bellerophon’s Chief Executive Officer. “We expect to report top-line results from the study in the middle of this year, a critical milestone for the Company. Importantly, following the recent license agreement with Baylor Bioscience and having successfully completed a \$5 million equity financing, we are well-capitalized through this critical milestone.”

Clinical Program Highlights:

Fibrotic Interstitial Lung Disease (fILD)

- **REBUILD Phase 3 Study:** The Company completed the blinded treatment phase of their pivotal Phase 3 REBUILD trial evaluating the safety and efficacy of INOpulse® for the treatment of patients with fILD and anticipates the availability of top-line results in mid-2023. A total of 145 fILD patients were enrolled and treated with either INOpulse at a dose of iNO45 or placebo. The Phase 3 program builds on positive top-line results from the Company’s previously reported Phase 2 studies for INOpulse® for the treatment of fILD which showed benefits in multiple cardiopulmonary parameters, including pulmonary vascular resistance and improvement in Moderate to Vigorous Physical Activity (MVPA) as measured by actigraphy after 16 weeks of chronic treatment. With a total of 145 patients enrolled, the study is powered >90%, (p-value of 0.01) for the primary endpoint of a change in MVPA measured by actigraphy. If approved, INOpulse would become the first therapy to treat a broad fILD population, including patients at low-, intermediate- and high-risk pulmonary hypertension.

Pulmonary Hypertension-Sarcoidosis (PH-Sarc)

- **Phase 2 Clinical Study:** In December 2021, Bellerophon reported positive top-line data from the completed Phase 2 dose escalation study of INOpulse® evaluating the acute hemodynamic benefit of INOpulse® via right heart catheterization for the treatment of pulmonary hypertension associated with sarcoidosis (PH-Sarc). Based on the benefits demonstrated in hemodynamic parameters and favorable safety profile, Bellerophon designed and submitted to the FDA a proposed exploratory Phase 2 double-blinded placebo-controlled study to investigate the safety and efficacy of iNO45 dosed chronically for six months in patients with PH-Sarc. Subsequently, the Company received FDA clearance to conduct the study and Bellerophon is currently assessing the next steps for the study.

First Quarter Ended March 31, 2023, Financial Results:

Total licensing revenue for the three months ended March 31, 2023, was \$5.6 million, which is related to the licensing agreement with Baylor BioSciences, Inc.

For the first quarter ended March 31, 2023, the Company reported net income of \$2.8 million, or \$0.27 per basic and diluted share, compared to a net loss of \$5.6 million, or \$(0.59) per basic and diluted share, in the first quarter ended March 31, 2022.

Research and development expenses for the first quarter ended March 31, 2023, were \$2.6 million, compared to \$4.4 million in the first quarter of 2022. The decrease was due to the completion of enrollment in the ongoing Phase 3 REBUILD trial in January 2023.

General and administrative expenses for the first quarter ended March 31, 2023, were \$1.6 million, compared to \$1.2 million in the first quarter of 2022. The increase was primarily due to an increase in general consulting costs and an increase in stock-based compensation.

Balance Sheet:

As of March 31, 2023, the Company had unrestricted cash and cash equivalents of \$15.2 million, compared to unrestricted cash and cash equivalents of \$6.9 million as of December 31, 2022. Bellerophon's capital position as of March 31, 2023, is reflective of the transactions which closed in the first quarter of 2023. These transactions included \$1.7 million net proceeds from the sale of the Company's net operating losses and research and development credits under the State of New Jersey's Technology Business Tax Certificate Transfer Program in January 2023, net proceeds of approximately \$5 million related to the licensing agreement with Baylor BioSciences, and net proceeds of approximately \$5 million from the registered direct offering, which closed in March 2023.

About Bellerophon

Bellerophon Therapeutics is a clinical-stage biotherapeutics company focused on developing innovative therapies that address significant unmet medical needs in the treatment of cardiopulmonary diseases. The Company is currently developing multiple product candidates under its INOpulse® program, a proprietary pulsatile nitric oxide delivery system. For more information, please visit www.bellerophon.com.

Forward-looking Statements

Any statements in this press release about Bellerophon's future expectations, plans, and prospects, including statements about the clinical development of its product candidates, regulatory actions with respect to the Company's clinical trials, and expectations regarding the sufficiency of the Company's cash balance to fund clinical trials, operating expenses and capital expenditures, and other statements containing the words "anticipate," "believe," "continue," "contemplate," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," "would," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: risks and uncertainties relating to INOpulse®, the uncertainties inherent in the initiation of future clinical trials, availability and timing of data from ongoing and future clinical trials and the results of such trials, whether preliminary or interim results from a clinical trial will be predictive of the final results of that trial or whether results of early clinical trials will be indicative of the results of later clinical trials, expectations for regulatory approvals, the FDA's substantial discretion in the approval process, availability of funding

sufficient for our foreseeable and unforeseeable operating expenses and capital expenditure requirements and other factors discussed in the “Risk Factors” section of the Company’s most recent Annual Report on Form 10-K and in subsequent filings with the Securities and Exchange Commission. In addition, any forward-looking statements included in this press release represent Bellerophon’s views only as of the date of this release and should not be relied upon as representing the Company’s views as of any subsequent date. The Company specifically disclaims any obligation to update any forward-looking statements included in this press release.

Contacts

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BELLEROPHON THERAPEUTICS, INC.
Consolidated Balance Sheets
(Amounts 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	15,771	7,563
Restricted cash, non-current	—	—
Right of use assets, net	8	184
Property and equipment, net	1	2
Other non-current assets	186	186
Total assets	\$ 15,966	\$ 7,935
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 current liabilities	5,364	5,401
Long term operating lease liabilities	—	—
Common stock warrant liability	—	—
Total liabilities	5,364	5,401
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	10,602	2,534
Total liabilities and stockholders' equity	\$ 15,966	\$ 7,935

BELLEROPHON THERAPEUTICS, INC.
Consolidated Statement of Operations and Comprehensive Income (Loss)
(Unaudited)

(Amounts 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)