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 11, 2022

Bellerophon Therapeutics, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware	**001-36845**	**47-3116175**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

184 Liberty Corner Road, Suite 302 **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.

Item 2.02. Results of Operations and Financial Condition.

On May 11, 2022, Bellerophon Therapeutics, Inc. issued a press release announcing its financial and operational results for the quarter ended March 31, 2022. 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:

Exhibit No.	Description
99.1	Press Release dated May 11, 2022 (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 11, 2022

By: /s/ Nicholas Laccona
Name: Nicholas Laccona
Title: Principal Financial Officer and Principal Accounting Officer

Bellerophon Provides Clinical Program Update and Reports First Quarter 2022 Financial Results

WARREN, N.J., May 11, 2022 – 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, 2022.

"We remain focused on the continued advancement of our late-stage INOpulse® inhaled nitric oxide therapy platform for the treatment of fibrotic interstitial lung disease, or fILD, and pulmonary hypertension associated with sarcoidosis, or PH-Sarc," said Naseem Amin, M.D., Chairman of Bellerophon's Board of Directors. "Enrollment is progressing in our pivotal Phase 3 REBUILD study, following the recent moderation of the COVID-19 pandemic. In PH-Sarc, subsequent to the announcement of positive top-line results from our Phase 2 proof-of-concept study of INOpulse, we are working with key pulmonary disease experts on the design of a follow-up Phase 2 chronic treatment trial to evaluate the long-term benefits of INOpulse in PH-Sarc patients, and intend to discuss this potential study shortly with the U.S. Food and Drug Administration. We believe that our balance sheet, with $20 million in cash and cash equivalents, positions us to progress our planned clinical and regulatory activities."

Clinical Program Highlights:

Fibrotic Interstitial Lung Disease (fILD)

- **REBUILD Phase 3 Study**: Enrollment is continuing in Bellerophon's Phase 3 REBUILD registrational study of INOpulse for the treatment of fILD. The REBUILD study plans to enroll 300 fILD patients who will be treated with either INOpulse at a dose of iNO45 or placebo. The primary endpoint is change in moderate to vigorous physical activity (MVPA). If approved, INOpulse would become the first therapy to treat a broad fILD population that includes patients at low-, intermediate- and high-risk of pulmonary hypertension.

  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. Acute treatment with INOpulse showed benefit in multiple cardiopulmonary parameters, including pulmonary vascular resistance, which improved by 21%, and mean pulmonary arterial pressure, which improved by 12%. Chronic treatment with INOpulse at a dose of iNO45 assessed over four months showed an average improvement in MVPA of 20% as compared to placebo. The improvements in MVPA were supported by benefits in overall activity, as well as two patient reported questionnaires, the University of California, San Diego Shortness of Breath Questionnaire and the St. George's Respiratory Questionnaire.

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). PH-Sarc is an unmet medical need with no approved therapies, and a median survival of approximately five years after diagnosis. The Phase 2 trial was designed as a proof-of-concept study to determine if iNO could demonstrate hemodynamic benefit in PH-Sarc.

All eight subjects demonstrated decreases in mean pulmonary arterial pressure (mPAP) and pulmonary vascular resistance (PVR) across the doses of INOpulse utilized in the study. The dose of iNO45 (45 mcg/kg IBW/hr) resulted in a median drop of 20% (-54% to +22%) in PVR, compared to a median baseline PVR of 329 dyne/cm.sec-5; a reduction of 20% or more in PVR is generally considered to be clinically meaningful. Along with the improvements in PVR, mPAP decreased by a median of 6-10% across the doses of iNO30 to iNO125, compared to a median baseline mPAP of 37.2 mmHg. No treatment-emergent adverse events (TEAEs) or serious adverse events (TESAEs) occurred during the acute hemodynamic dose escalation phase of the study.

First Quarter Ended March 31, 2022 Financial Results:
For the first quarter ended March 31, 2022, the Company reported a net loss of $5.6 million, or $(0.59) per share, compared to a net loss of $5.5 million, or $(0.58) per share, in the first quarter ended March 31, 2021.

Research and development expenses for the first quarter ended March 31, 2022 were $4.4 million, compared to $3.6 million in the first quarter of 2021. The increase was primarily due to costs related to the ongoing Phase 3 fILD trial.

General and administrative expenses for the first quarter ended March 31, 2022 were $1.2 million, compared to $2.3 million in the first quarter of 2021. The decrease was primarily due to lower consulting, labor and stock-based compensation costs.

Balance Sheet
As of March 31, 2022, the Company had cash and cash equivalents of $20.0 million, compared to cash and cash equivalents of $24.7 million at December 31, 2021.

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

LifeSci Advisors:
Brian Ritchie
(212) 915-2578
britchie@lifesciadvisors.com

BELLEROPHON THERAPEUTICS, INC.
Consolidated Balance Sheets
(Amounts in thousands, except share and per share data)

	March 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 20,000	$ 24,736
Restricted cash	103	103
Prepaid expenses and other current assets	413	620
Total current assets	20,516	25,459
Restricted cash, non-current	300	300
Right of use assets, net	697	863
Property and equipment, net	46	67
Other non-current assets	186	186
Total assets	$ 21,745	$ 26,875
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,193	$ 1,192
Accrued research and development	1,857	1,397
Accrued expenses	751	1,711
Current portion of operating lease liabilities	765	752
Total current liabilities	5,566	5,052
Long term operating lease liabilities	8	203
Common stock warrant liability	1	1
Total liabilities	5,575	5,256
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.01 par value per share; 200,000,000 shares authorized and 9,545,451 and 9,545,451 shares issued and outstanding at March 31, 2022 and December 31, 2021, respectively	95	95
Preferred stock, $0.01 par value per share; 5,000,000 shares authorized, zero shares issued and outstanding at March 31, 2022 and December 31, 2021	—	—
Additional paid-in capital	253,963	253,771
Accumulated deficit	(237,888)	(232,247)
Total stockholders' equity	16,170	21,619
Total liabilities and stockholders' equity	$ 21,745	$ 26,875

BELLEROPHON THERAPEUTICS, INC.
Consolidated Statement of Operations and Comprehensive Loss
(Amounts in thousands, except share and per share data)

	Three Months Ended March 31,	
	2022	2021
Operating expenses:		
Research and development	$ 4,409	$ 3,584
General and administrative	1,233	2,275
Total operating expenses	5,642	5,859
Loss from operations	(5,642)	(5,859)
Change in fair value of common stock warrant liability	—	397
Interest and other income, net	1	1
Pre-tax loss	(5,641)	(5,461)
Net loss and comprehensive loss	$ (5,641)	$ (5,461)
Weighted average shares outstanding:		
Basic	9,545,451	9,491,281
Diluted	9,545,451	9,491,281
Net loss per share:		
Basic	$ (0.59)	$ (0.58)
Diluted	$ (0.59)	$ (0.58)