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): March 31, 2023

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 March 31, 2023, Bellerophon Therapeutics, Inc. issued a press release announcing its financial and operational results for the year ended December 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:

Exhibit No.	Description
99.1	Press Release dated March 31, 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: March 31, 2023

By: /s/ Peter Fernandes
Name: Peter Fernandes
Title: Chief Executive Officer

Bellerophon Provides Clinical Program Update and Reports Full-Year 2022 Financial Results

- *Completed Enrollment in INOpulse® REBUILD Phase 3 trial; Pivotal Top-line Data Expected in Mid-2023*
- *Signed License Agreement with Baylor BioSciences to Commercialize INOpulse® in Greater China*
- *Strengthened Balance Sheet Through $5 Million Registered Direct Offering with Life Sciences-focused Institutional Investor*

WARREN, N.J., March 31, 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 year ended December 31, 2022.

"We have achieved significant recent progress throughout our business, including advancing the INOpulse® clinical program, enhancing our regulatory and commercial prospects in China, and strengthening the balance sheet," said Peter Fernandes, Bellerophon's Chief Executive Officer. "With the INOpulse® REBUILD Phase 3 study fully enrolled, we anticipate treating the last patient in the second quarter of 2023, followed by pivotal top-line data readout in mid-2023. Moreover, the recent license agreement established with Baylor BioSciences and the IND clearance from China NMPA to conduct a Phase 3 clinical trial in fibrotic interstitial lung disease (fILD) position us well to access one of the largest commercial markets globally. Importantly, following the license agreement with Baylor and successfully completed $5 million financing, we are now well-capitalized through top-line data from the pivotal Phase 3 REBUILD trial."

Clinical Program Highlights:

Fibrotic Interstitial Lung Disease (fILD)

- **REBUILD Phase 3 Study**: The Company completed the planned enrollment of 145 patients in the pivotal Phase 3 trial evaluating the safety and efficacy of INOpulse® for the treatment of fILD and anticipates treating the last patients in the second quarter of 2023. The pivotal top-line data readout from patients treated with either INOpulse® at a dose of iNO45 or placebo is expected in mid-2023. 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). If approved, INOpulse would become the first therapy to treat a broad fILD population, including patients at low-, intermediate- and high-risk pulmonary hypertension.

- **IND Clearance from China NMPA:** The Center for Drug Evaluation of China's National Medical Products Administration (NMPA) cleared the Company's Investigational New Drug (IND) application to conduct a Phase 3 clinical trial to support the registration of INOpulse® for the treatment of fILD in China. The study will utilize MVPA as the primary endpoint and be conducted in collaboration with Baylor BioSciences, a life sciences company dedicated to the development and commercialization of innovative medical products for Greater China.

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.

Corporate Update:

- **License Agreement with Baylor BioSciences:** On January 4, 2023, the Company entered into a license agreement with Baylor BioSciences, a life sciences company dedicated to the development and commercialization of innovative medical products in Greater China. 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 PH-Sarcoidosis and PH-COPD. Under the terms of the license agreement, Bellerophon will receive a license payment of $6 million subject to taxes and closing costs. Additionally, the Company is entitled to royalties of 5% on net sales resulting from all of the licensed INOpulse® indications within Greater China.

- **Registered Direct Offering:** On March 3, 2023, Bellerophon entered into a subscription agreement with a life sciences-focused institutional investor to issue and sell in a registered direct offering, 718,474 shares of common stock at a price of $2.00 per share and 1,781,526 prefunded warrants at a price of $1.99 per pre-funded warrant for total gross proceeds of approximately $5 million, before deducting estimated offering expenses. The Company intends to use the proceeds of this $5 million offering to complete the ongoing REBUILD Phase 3 study and for working capital and general corporate purposes.

2022 Year-End Financial Results:

For the year ended December 31, 2022, the Company reported a net loss of $19.8 million, or $(2.08) per basic and diluted share, compared to a net loss of $17.8 million, or $(1.87) per basic and diluted share, in the year ended December 31, 2021.

Research and development expenses for the year ended December 31, 2022, were $16.4 million, compared to $13.0 million in the prior year period. The increase was primarily due to the ongoing Phase 3 REBUILD trial.

General and administrative expenses for the year ended December 31, 2022, were $6 million, as compared to $7.1 million in the prior year period. The decrease was primarily due to reduced labor, stock-based compensation and general consulting costs.

Balance Sheet:

As of December 31, 2022, the Company had unrestricted cash and cash equivalents of $6.9 million, compared to unrestricted cash and cash equivalents of $24.7 million on December 31, 2021. The Company's capital position as of December 31, 2022 is not reflective of the subsequent transactions which closed in the first quarter of 2023. These transactions include the $1.7 million net proceeds from the sale of 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, the $6 million license payment, subject to tax closing costs, due from Baylor BioSciences and the net proceeds of approximately $5 million from the registered direct offering 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 December 31, 2022	As of December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 6,924	$ 24,736
Restricted cash	405	103
Prepaid expenses and other current assets	234	620
Total current assets	7,563	25,459
Restricted cash, non-current	—	300
Right of use assets, net	184	863
Property and equipment, net	2	67
Other non-current assets	186	186
Total assets	$ 7,935	$ 26,875
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,230	$ 1,192
Accrued research and development	2,655	1,397
Accrued expenses	1,313	1,711
Current portion of operating lease liabilities	203	752
Total current liabilities	5,401	5,052
Long term operating lease liabilities	—	203
Common stock warrant liability	—	1
Total liabilities	5,401	5,256
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.01 par value per share; 200,000,000 shares authorized and 9,645,711 and 9,545,451 shares issued and outstanding at December 31, 2022 and December 31, 2021, respectively	96	95
Preferred stock, $0.01 par value per share; 5,000,000 shares authorized, zero shares issued and outstanding at December 31, 2022 and December 31, 2021	—	—
Additional paid-in capital	254,516	253,771
Accumulated deficit	(252,078)	(232,247)
Total stockholders' equity	2,534	21,619
Total liabilities and stockholders' equity	$ 7,935	$ 26,875

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

	Year Ended December 31,	
	2022	2021
Operating expenses:		
Research and development	$ 16,362	$ 13,015
General and administrative	6,022	7,146
Total operating expenses	22,384	20,161
Loss from operations	(22,384)	(20,161)
Change in fair value of common stock warrant liability	1	600
Interest income and financing expenses, net	135	5
Pre-tax loss	(22,248)	(19,556)
Income tax benefit	2,417	1,800
Net loss and comprehensive loss	$ (19,831)	$ (17,756)
Weighted average shares outstanding:		
Basic	9,550,872	9,502,793
Diluted	9,550,872	9,502,793
Net loss per share:		
Basic	$ (2.08)	$ (1.87)
Diluted	$ (2.08)	$ (1.87)