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): January 18, 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 8.01. Other Events.

On January 18, 2023, Bellerophon Therapeutics, Inc. issued a press release announcing the completion of enrollment in the Phase 3 REBUILD study for INOpulse® in fibrotic interstitial lung disease. A copy of this press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

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Item 9.01. Financial Statements and Exhibits.

(d) Exhibits:

Exhibit No.	Description
99.1	Press Release dated January 18, 2023
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: January 18, 2023

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

Bellerophon Therapeutics Announces Completion of Enrollment in Phase 3 REBUILD Study for INOpulse® in Fibrotic Interstitial Lung Disease

Enrollment concludes earlier than anticipated; pivotal top-line data now expected mid-2023

WARREN, N.J., January 18, 2023 – Bellerophon Therapeutics, Inc. (Nasdaq: BLPH) ("Bellerophon" or the "Company"), a clinical-stage biotherapeutics company focused on developing treatments for cardiopulmonary diseases, today announced that the last patient has been enrolled in the ongoing Phase 3 REBUILD study of INOpulse®, a proprietary pulsatile nitric oxide delivery system, for the treatment of fibrotic interstitial lung disease (fILD). The Company now expects to report pivotal top-line results in mid- 2023.

"We are pleased to have completed enrollment in this important study sooner than previously anticipated, which represents a significant milestone for Bellerophon, our INOpulse clinical development program, and the fILD patient community. Based on the earlier than expected enrollment completion, we now expect to report top-line results from REBUILD in mid-2023," said Naseem Amin, M.D., Chairman of Bellerophon's Board of Directors.

"This study will provide the randomized dataset to evaluate the change in moderate to vigorous physical activity (MVPA) following treatment with INOpulse in patients with fILD. These patients struggle to perform basic activities of daily living, such as walking, climbing stairs, or showering. The ability to monitor changes in their level of physical activity, specifically the difference in MVPA as the novel endpoint, which correlates to household tasks and activities of daily living, has the potential to inform directly on the patient's overall health, well-being, and quality of life. We are extremely grateful to our clinical sites for their support in the expeditious enrollment of this study and look forward to the availability of top-line results from REBUILD later this year," said Peter Fernandes Bellerophon's Chief Executive Officer.

The REBUILD study is a pivotal Phase 3, randomized, double-blind, placebo-controlled dose escalation and verification clinical trial evaluating the safety and efficacy of pulsed inhaled nitric oxide (iNO) in patients at risk for pulmonary hypertension associated with pulmonary fibrosis on long-term oxygen therapy. 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, based on the results from Phase 2, and will be the basis for the submission of our NDA for approval in fILD.

For more information on the REBUILD Phase 3 study of INOpulse for the treatment of fILD, please visit ClinicalTrials.gov and reference Identifier NCT0326710.

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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