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, 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.)

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.

Item 8.01. Other Events.

On May 11, 2023, Bellerophon Therapeutics, Inc. issued a press release announcing that the last patient has completed the blinded treatment 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits:

Exhibit No.	Description
99.1	Press Release dated May 11, 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: May 11, 2023

By: /s/ Peter Fernandes

Name: Peter Fernandes
Title: Chief Executive Officer

Exhibit 99.1

Bellerophon Therapeutics Announces Last Patient Has Completed Blinded Treatment in Phase 3 REBUILD Study for INOpulse® in Fibrotic Interstitial Lung Disease

Pivotal top-line data readout expected in mid-2023

WARREN, N.J., May 11, 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 completed blinded treatment 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 expects to report top-line results from this study in mid-2023.

"The successful and timely completion of the blinded treatment phase of our pivotal Phase 3 REBUILD trial represents a key milestone in our INOpulse® development program and we look forward to the availability of top-line results from this important study in the middle of this year," said Peter Fernandes, Bellerophon's Chief Executive Officer.

The REBUILD study is a Phase 3, randomized, double-blind, placebo-controlled 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. 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 the results from the Company's previously reported Phase 2 studies which showed improvement in multiple cardiopulmonary parameters, including pulmonary vascular resistance after acute treatment and benefit 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.

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.

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