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): September 27, 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 8.01. Other Events.

On September 27, 2022, Bellerophon Therapeutics, Inc. issued a press release announcing the U.S. Food and Drug Administration's acceptance of a change to its ongoing Phase 3 REBUILD study of INOpulse® for treatment of fibrotic interstitial lung disease that reduces the study's sample size from 300 to 140 patients. 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 September 27, 2022
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: September 27, 2022

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

Bellerophon Announces FDA Acceptance of Change to Ongoing Phase 3 REBUILD Study of INOpulse® for Treatment of Fibrotic Interstitial Lung Disease

- *New study size of 140 patients for the REBUILD Study, without modifying trial objective or endpoints and maintaining power of >90% for the primary endpoint*
- *Independent Data Monitoring Committee agreed that the new targeted study size is appropriate*
- *Enrollment now expected to conclude in Q1 2023, with pivotal top-line data readout anticipated in Q3 2023*

WARREN, N.J., September 27, 2022 – Bellerophon Therapeutics, Inc. (Nasdaq: BLPH) ("Bellerophon" or the "Company"), a clinical-stage biotherapeutics company focused on developing treatments for cardiopulmonary diseases, announced today that the U.S. Food and Drug Administration (FDA) has accepted the Company's proposal to reduce the study size for its ongoing registrational REBUILD Phase 3 trial of INOpulse® for the treatment of fibrotic Interstitial Lung Disease (fILD). The new study size of 140 subjects does not impact the trial's principal objective or endpoints and maintains power of >90% (p-value < 0.01) for the primary endpoint of Moderate to Vigorous Physical Activity (MVPA) based on the effect size observed in Phase 2.

Following the evaluation of baseline MVPA characteristics, as measured by actigraphy, compliance to treatment and review of safety data of the randomized subjects in the ongoing Phase 3 REBUILD study, the trial's independent Data Monitoring Committee (DMC) supported reducing the target study size from 300 to 140 subjects.

"With this study size change, we believe that we are well-positioned to accelerate the completion of our Phase 3 REBUILD study," said Naseem Amin, M.D., Chairman of Bellerophon's Board of Directors. "With over 100 subjects randomized to date, we expect to complete enrollment in the first quarter of 2023, and anticipate the availability of pivotal top-line data in the third quarter of 2023."

"The target of 140 subjects maintains a statistical power of greater than 90% for MVPA, which has been accepted by the FDA as the primary endpoint for the Phase 3 REBUILD study," said Peter Fernandes, Bellerophon's Principal Executive Officer.

Dr. Steven D. Nathan, M.D., F.C.C.P., Medical Director of the Advanced Lung Disease and Lung Transplant Program at Inova Fairfax Hospital and Chair of Bellerophon's REBUILD Steering Committee, said, "The revised study size is based on an effect size generated from Phase 2 study data in 44 patients with the same primary endpoint being evaluated in the Phase 3 study, MVPA. The analysis presented to the FDA indicated that the trial remains adequately powered to demonstrate a statistically significant result on MVPA. We look forward to working with the Company to get this study over the finish line soon and build upon and validate the existing body of clinical evidence generated to date for INOpulse."

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 subjects on long-term oxygen therapy who are at risk for pulmonary hypertension associated with pulmonary fibrosis. The study plans to enroll 140 fILD subjects who will be treated with either INOpulse at a dose of iNO45 (45 mcg/kg ideal body weight/hr) or placebo. The trial's primary endpoint is the placebo corrected change in MVPA, as measured by actigraphy.

For further details regarding the protocol and additional 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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