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): December 1, 2020

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)	**7059** (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):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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).

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**

x Emerging growth company

x 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.

Bellerophon Therapeutics, Inc. (the "Company") issued a press release on December 1, 2020, to announce the enrollment of the first patient in the Company's Phase 3 REBUILD study evaluating INOpulse® for the treatment of fibrotic interstitial lung disease.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits:

Exhibit No.	Description
99.1	Press Release dated December 1, 2020

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: December 1, 2020

By: /s/ Fabian Tenenbaum
Name: Fabian Tenenbaum
Title: Chief Executive Officer

Exhibit 99.1

Bellerophon Therapeutics Announces First Patient Enrolled in Phase 3 REBUILD Study Evaluating INOpulse® for the Treatment of Fibrotic Interstitial Lung Disease

WARREN, N.J., Dec. 1, 2020 – Bellerophon Therapeutics, Inc. (Nasdaq: BLPH) ("Bellerophon" or the "Company"), a clinical-stage biotherapeutics company focused on developing treatments for cardiopulmonary and infectious diseases, today announced that the first patient has been enrolled in its REBUILD Phase 3 registrational clinical study evaluating INOpulse®, a pulsed inhaled nitric oxide therapy, as a potential treatment for fibrotic interstitial lung disease (fILD).

"Fibrotic ILD is a severe disease where patients face debilitating functional impairment, poor quality of life and limited life expectancy. Patients with fILD suffer severe mobility restrictions and often lack the ability to perform the most basic tasks such as walking, ascending stairs and managing daily housework," said Jeremy Feldman, MD, Director Pulmonary Hypertension Program, Arizona Pulmonary Specialists and a lead investigator for the Phase 3 study. "Nitric Oxide is a pulmonary vasodilator that improves ventilation-perfusion matching, which can be impaired by systemic vasodilators. The benefits we observed in the Phase 2 study and into open-label extension, including activity levels and patient reported outcomes, underscore INOpulse's potential to address this significant unmet medical need. I am excited to advance the Phase 3 study with the enrollment of the first patient, and look forward to the continued development of the promising INOpulse therapy for fILD."

REBUILD is a Phase 3 randomized, double-blind, placebo-controlled clinical study to assess the safety and efficacy of pulsed inhaled nitric oxide (iNO) [at a dose of 45 mcg/kg ideal body weight (IBW)/hour] versus placebo in fILD patients at risk of pulmonary hypertension (PH) on long-term oxygen therapy. The REBUILD trial is planned to enroll 300 patients who will receive either INOpulse or placebo for a 16-week blinded treatment period, after which patients are eligible to rollover into an open-label extension. The primary endpoint is change in moderate to vigorous physical activity (MVPA), as previously agreed upon with the U.S. Food and Drug Administration.

"We are pleased to have enrolled the first patient in our Phase 3 REBUILD study, as it marks an important milestone in our efforts to develop the first potential therapy to treat a broad fILD population that includes patients at risk of pulmonary hypertension," said Fabian Tenenbaum, Chief Executive Officer of Bellerophon. "The REBUILD study builds on the positive results from our Phase 2 trial that demonstrated the safety and efficacy of INOpulse in improving MVPA, multiple quality of life measures and key hemodynamic parameters. Importantly, our current balance sheet provides us with the resources to continue advancing this program through the availability of these Phase 3 data and we look forward to sharing top-line results from this important study in 2022."

Bellerophon previously reported positive top-line results from its iNO-PF Phase 2 study, a randomized, double-blind, placebo-controlled clinical study of INOpulse for the treatment of fILD. The Phase 2 studies established iNO45 as the preferred dose for the REBUILD Phase 3 study, with patients who received iNO45 over 16 weeks demonstrating clinically meaningful and statistically significant improvement in MVPA of 20% over baseline compared to placebo (p=0.02). Improvements in MVPA were further supported by placebo-corrected benefits in other key parameters, as measured by two patient-reported questionnaires, the University of California, San Diego Shortness of Breath Questionnaire, and the St.

George's Respiratory Questionnaire. The safety and tolerability profile of INOpulse in the double-blind period of iNO-PF has been maintained in the ongoing open-label extension period.

The Company also previously reported positive top-line data from PHPF-002, an ancillary dose escalation study assessing the acute hemodynamic effect of INOpulse in fILD via right heart catheterization. The study demonstrated that acute treatment with INOpulse provided clinically meaningful and statistically significant improvements in pre-specified hemodynamic parameters, including a 21% reduction in pulmonary vascular resistance, with increased benefit ($p<0.01$) on dose escalation from iNO30 to iNO45, and a 12% reduction in mean pulmonary arterial pressure. The acute hemodynamic benefits underpin the chronic benefit in exercise capacity demonstrated in the iNO-PF study and further support utilizing the iNO45 dose in the REBUILD Phase 3 study.

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 and infectious lung 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® not proving to be an effective treatment for COVID-19 or approved for marketing by the FDA, 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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