

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 10, 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)

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))

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

☒ 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.

Bellerophon Therapeutics, Inc. (the "Company") issued a press release on March 10, 2020, to announce agreement with the FDA on its planned pivotal Phase 3 study for the treatment of Pulmonary Hypertension Associated with Pulmonary Fibrosis. 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
<u>99.1</u>	<u>Press Release dated March 10, 2020</u>

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 10, 2020

By: /s/ Fabian Tenenbaum

Name: Fabian Tenenbaum

Title: Chief Executive Officer

Bellerophon Announces Agreement with the FDA on its Planned Pivotal Phase 3 Study for the Treatment of Pulmonary Hypertension Associated with Pulmonary Fibrosis

WARREN, N.J., Mar. 10, 2020 - Bellerophon Therapeutics, Inc. (Nasdaq: BLPH) ("Bellerophon" or the "Company"), a clinical-stage biotherapeutics company, today announced the successful completion of its End-of-Phase 2 Meetings with the U.S. Food and Drug Administration (FDA) for INOpulse® for the treatment of Pulmonary Hypertension associated with Pulmonary Fibrosis (PH-PF).

The Company, in consultation with the FDA, has finalized the key elements of its planned pivotal Phase 3 study, including the use of moderate to vigorous physical activity (MVPA) as the primary endpoint for approval, the patient population of pulmonary fibrosis subjects at risk of PH, as well as the dose of iNO45 (45 mcg/kg IBW/hr). Importantly, the primary endpoint, patient population, and the iNO45 dose have recently been evaluated in a Phase 2 clinical trial in which iNO45 achieved a statistically significant improvement ($p=0.02$) in MVPA versus placebo.

"We are very pleased with the alignment reached with the FDA on the design of our pivotal Phase 3 trial which allows us to move confidently towards the initiation of this important study," said Fabian Tenenbaum, Chief Executive Officer of Bellerophon. "There is a pressing need to develop a safe and effective treatment for patients with PH-PF, a disease with no approved therapies and a median life expectancy of approximately 18 months. INOpulse, with its targeted pulmonary vasodilation, would potentially become the first therapy to treat a broad PH-PF population that includes patients at low, intermediate and high risk of pulmonary hypertension. We look forward to initiating our pivotal Phase 3 study in PH-PF shortly."

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: 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

At Bellerophon:

Fabian Tenenbaum, Chief Executive Office
(908) 574-4767

At LifeSci Advisors:

Brian Ritchie
(212) 915-2578
britchie@lifesciadvisors.com