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): April 8, 2019

Bellerophon Therapeutics, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware	**001-36845**	**47-3116175**
	(Commission	(IRS Employer
(State or Other Jurisdiction of Incorporation)	File Number)	Identification No.)

184 Liberty Corner Road, Suite 302 **Warren, New Jersey**	**07059**
(Address of Principal Executive Offices)	(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).

☒ 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 April 8, 2019, to announce an agreement with FDA on regulatory approval pathway for INOpulse® for treatment of Pulmonary Hypertension Associated with 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 April 8, 2019

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: April 8, 2019

By: /s/ Fabian Tenenbaum

Name: Fabian Tenenbaum
Title: Chief Executive Officer

Bellerophon Announces Agreement with FDA on Regulatory Approval Pathway for INOpulse® for Treatment of Pulmonary Hypertension Associated with Interstitial Lung Disease

FDA Agrees to Primary Endpoint of Change in Moderate to Vigorous Physical Activity from Baseline to Week 16, Measured by Actigraphy

FDA Also Agrees on Modification of Ongoing Phase 2b Study into a Phase 2/3 Trial, with Cohort 3 Serving as the Pivotal Phase 3 Study

Completion of Cohort 2 and Initiation of Cohort 3 Expected in Second Half of 2019

Warren, NJ, April 8, 2019 - Bellerophon Therapeutics, Inc. (Nasdaq: BLPH) ("Bellerophon" or the "Company"), a clinical-stage biotherapeutics company, today announced that it has reached agreement with the U.S. Food and Drug Administration ("FDA" or the "Agency") on the regulatory approval pathway for INOpulse® in patients with Pulmonary Hypertension associated with Interstitial Lung Disease (PH-ILD).

In January 2019, the Company reported positive results from Cohort 1 of its ongoing Phase 2b randomized, double-blind, placebo-controlled clinical study (iNO-PF) of INOpulse for the treatment of PH-ILD. Subjects on active treatment demonstrated a statistically significant improvement of 34% in moderate to vigorous physical activity (MVPA) as compared to subjects on placebo, as well as improvements in overall activity, oxygen saturation and additional functional measures. Based on these data and INOpulse's safety profile, the FDA agreed with Bellerophon on the use of MVPA as the primary endpoint in the pivotal Phase 3 study, as measured by a medical wearable continuous activity monitor (actigraphy). In addition, the Agency agreed with the Company's proposal that the Phase 2b study be amended to a Phase 2/3 trial. This agreement allows a seamless transition into Cohort 3 of iNO-PF, which will serve as the pivotal Phase 3 trial.

"Reaching this critical agreement with the FDA for INOpulse in PH-ILD represents a significant milestone for Bellerophon as it confirms the validity of MVPA as a clinically meaningful endpoint, enables us to build upon the robust data generated to date from iNO-PF and substantially shortens the regulatory pathway for our therapy in a disease with a serious unmet need," said Fabian Tenenbaum, Chief Executive Officer of Bellerophon. "We appreciate the FDA's support and their agreement on both the primary endpoint and the seamless pivotal Phase 2/3 design, creating the opportunity for INOpulse to become the first approved therapy in PH-ILD. We expect to complete Cohort 2 and initiate the pivotal Phase 3 trial in the second half of this year."

"Compared to surrogate endpoints, such as six-minute walk distance or patient reported outcomes, change in MVPA provides a direct and continuous measure of physical activity in PH-ILD patients, who have limited ability to perform even the most basic daily tasks," said 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 Steering Committee. "INOpulse is a selective vasodilator that can improve both cardiopulmonary circulation and oxygenation, increasing the ability to perform physical activities. The improvements in MVPA seen to date in iNO-PF support INOpulse's potential to address this unmet

medical need. I am excited by the acceleration of this program into Phase 3 and look forward to the further evaluation of this promising therapy in the clinic."

PH-ILD is a life threatening and debilitating disease that places a significant burden on daily life. Patients describe severe limits on their mobility and difficulty with moderate daily activities, such as walking and housework, with serious negative implications on their physical and emotional well-being. Actigraphy continuously measures real-world physical activity, allowing for an objective and clinically meaningful assessment of the therapeutic benefit. This is a well-established methodology utilized in a range of clinical applications, including in late-stage trials in cardiopulmonary indications, such as heart failure and Chronic Obstructive Pulmonary Disease.

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

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