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): August 1, 2019

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**	**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):

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))

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 Global 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).

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 August 1, 2019, to announce the enrollment completion of Cohort 2 of ongoing Phase 2/3 randomized, double-blinded, placebo-controlled clinical study of its INOpulse® for the 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 August 1, 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: August 1, 2019

By: /s/ Fabian Tenenbaum

Name: Fabian Tenenbaum
Title: Chief Executive Officer

Bellerophon Completes Enrollment in Cohort 2 of Ongoing Phase 2/3 Study of INOpulse® for Treatment of Pulmonary Hypertension Associated with Interstitial Lung Disease

Initiation of Pivotal Cohort 3 Anticipated in Q1 2020

WARREN, N.J., August 1, 2019 -- Bellerophon Therapeutics, Inc. (Nasdaq: BLPH) ("Bellerophon" or the "Company"), a clinical-stage biotherapeutics company, today announced that it has completed enrollment for Cohort 2 of its ongoing Phase 2/3 randomized, double-blind, placebo-controlled clinical study (iNO-PF) of INOpulse® for the treatment of Pulmonary Hypertension associated with Interstitial Lung Disease (PH-ILD).

"We have been extremely pleased with the rate of enrollment in Cohort 2, and are thankful for the continued support and enthusiasm from our sites. We look forward to study completion by year-end 2019," said Fabian Tenenbaum, Chief Executive Officer of Bellerophon. "Top-line data from Cohort 1 showed that INOpulse demonstrated clinically and statistically significant improvement in moderate to vigorous physical activity, or MVPA, as well as other physical activity parameters measured by continuous activity monitoring. Subsequently, the U.S. Food and Drug Administration agreed with Bellerophon's proposal that MVPA serve as the primary endpoint and that iNO-PF be amended from a Phase 2b study to a Phase 2/3 trial, providing a seamless transition into Cohort 3, which will serve as the pivotal Phase 3 trial. The results from Cohorts 1 and 2 will be used to determine the optimal dose between iNO30 and iNO45 to progress into Cohort 3, which we expect to initiate in the first quarter of 2020. PH-ILD is a debilitating and life threatening disease where patients suffer severe functional impairment that limit their capacity to perform even the most basic daily tasks. The capability of INOpulse to improve MVPA would directly benefit a patient's ability to function and provides the potential for the first approved therapy in this unmet medical need."

Cohort 2 of iNO-PF includes 44 subjects randomized 2:1 to either iNO45 (45 mcg/kg IBW/hr) or placebo. Subjects will complete 16 weeks of blinded treatment on iNO45 vs placebo, and then continue onto open-label treatment.

In January 2019, Bellerophon reported top-line data from Cohort 1 of iNO-PF, which included 41 subjects randomized 1:1 to either iNO30 (30 mcg/kg IBW/hr) or placebo for 8 weeks of blinded treatment. Cohort 1 showed clinically meaningful improvements in multiple activity parameters, as well as oxygen saturation:

- MVPA (walking, stairs, yardwork, etc.) improved by 34% (8% increase on iNO vs. 26% decrease on placebo; p=0.04)
    - 23% of subjects on iNO had a clinically significant improvement in MVPA, compared to 0% of subjects on placebo (placebo corrected difference of 23%)
    - 39% of subjects on iNO had a clinically significant decline in MVPA, compared to 71% of subjects on placebo (placebo corrected difference of 32%)
- Overall activity improved by 12% (stable on iNO vs. 12% decrease on placebo; p=0.05)
- Calorie expenditure improved by 12% (6% decrease on iNO vs. 18% decrease on placebo p=0.05)
- Oxygen saturation improved by 20% (9% improvement on iNO vs. 11% deterioration on placebo)

Cohort 3 of iNO-PF is the pivotal Phase 3 study for approval, with MVPA as the primary endpoint. The study is expected to include approximately 300 subjects randomized 1:1 to active or placebo for 16 weeks of blinded treatment.

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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