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 16, 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 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).

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 September 16, 2019, to announce that the U.S. Food and Drug Administration (FDA) has granted the Company an Orphan Drug Designation to nitric oxide for the treatment of idiopathic pulmonary fibrosis (IPF). 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 16, 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: September 16, 2019

By: /s/ Fabian Tenenbaum

Name: Fabian Tenenbaum
Title: Chief Executive Officer

Bellerophon Receives Orphan Drug Designation for Nitric Oxide in the Treatment of Idiopathic Pulmonary Fibrosis

WARREN, N.J., September 16, 2019 -- Bellerophon Therapeutics, Inc. (Nasdaq: BLPH) ("Bellerophon" or the "Company"), a clinical-stage biotherapeutics company, announced today the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation to nitric oxide for the treatment of Idiopathic Pulmonary Fibrosis (IPF).

IPF is a progressive, irreversible and fatal interstitial lung disease characterized by thickening and scarring of the air sacs in the lungs affecting approximately 100,000 people in the U.S. and reducing their life expectancy to between two and five years from diagnosis. IPF patients suffer from severe functional impairment that limits their ability to perform basic daily tasks, resulting in a significant deterioration in their quality of life. Pulsed nitric oxide, delivered via Bellerophon's patented INOpulse® device and delivery algorithm, is the first therapy with the potential to improve a patient's physical activity levels, cardiac output and oxygen saturation by treating both the ventilation perfusion mismatch driven by the fibrosis, as well as pulmonary hypertension, a common comorbidity in the IPF patient population.

Bellerophon is currently conducting a Phase 2/3 (iNO-PF) study of nitric oxide and its proprietary INOpulse system to treat patients with IPF, as well as other pulmonary fibrotic diseases.

"The receipt of orphan drug designation represents a significant milestone for our INOpulse clinical development program," said Fabian Tenenbaum, Chief Executive Officer of Bellerophon. "We are encouraged by the Cohort 1 results of our iNO-PF study, which demonstrated that treatment with INOpulse provided clinically and statistically significant improvement in activity levels. We recently completed enrollment in Cohort 2, which is assessing a higher dose, as well as longer treatment duration, and expect to report top-line results before the end of the year. Moreover, we have FDA agreement on our pivotal Phase 3 Cohort, which we anticipate initiating in the first quarter of 2020. IPF is a debilitating life threatening disease and we believe that INOpulse is well-positioned to potentially become a first-in class therapy for this serious unmet medical need."

The mission of the FDA's Office of Orphan Products Development (OOPD) is to advance the evaluation and development of products that demonstrate promise for the diagnosis and/or treatment of rare diseases or conditions that affect fewer than 200,000 people in the U.S. In fulfilling that task, the OOPD evaluates scientific and clinical data submissions from sponsors to identify and designate products as promising for rare diseases and to further advance scientific development of such promising medical products. Orphan drug designation provides the sponsor access to various development incentives, including tax credits for qualified clinical trial expenditures and waivers for certain FDA user fees. Orphan Drug Designation also provides up to seven years of marketing exclusivity if regulatory approval is received.

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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