

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): June 16, 2016

Bellerophon Therapeutics, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware

001-36845

47-3116175

(State or Other Jurisdiction of Incorporation)

(Commission

(IRS Employer

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):

- 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))

Item 7.01. Regulation FD Disclosure.

Bellerophon Therapeutics, Inc. (the “Company”) issued a press release on June 16, 2016 announcing that the first subject has been enrolled in the Phase 3 INOvation-1 clinical trial for patients with Pulmonary Arterial Hypertension. The first patient was enrolled by Jeremy Feldman, MD., Principal Investigator at Arizona Pulmonary Associates, Ltd. The Company has also enrolled the first subject in a Phase 2 trial evaluating the safety and efficacy of the INOpulse delivery system in patients with pulmonary hypertension associated with Idiopathic Pulmonary Fibrosis in collaboration with Professor W. DeBacker, MD, Director Department of Pulmonary Medicine, University Hospital and University of Antwerp. A copy of this press release is attached hereto as Exhibit 99.1. The information included in Exhibit 99.1 shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits:

Exhibit No.	Description
99.1	Press Release dated June 16, 2016 (furnished and not filed for purposes of Item 7.01)

SIGNATURE

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: June 16, 2016

By: /s/ Fabian Tenenbaum
Fabian Tenenbaum
Chief Financial Officer and Chief Business Officer

Bellerophon Therapeutics Announces Enrollment of the First Patient in the INOvation-1 Phase 3 Clinical Trial for Pulmonary Arterial Hypertension (PAH)

Warren, NJ, June 16, 2016 -Bellerophon Therapeutics, Inc. (Nasdaq: BLPH), a clinical-stage biotherapeutics company, announced today that the first subject has been enrolled in the Phase 3 INOvation-1 clinical trial. The first patient was enrolled by Jeremy Feldman, MD., Principal Investigator at Arizona Pulmonary Associates, Ltd.

INOvation-1 is a clinical trial evaluating the efficacy and safety of the INOpulse® delivery system for the treatment of patients with Pulmonary Arterial Hypertension (PAH) with an anticipated enrollment of 188 subjects in 17 countries. The INOpulse delivery system utilizes a proprietary technology to deliver pulsatile inhaled nitric oxide allowing for use in a portable chronic setting.

Bellerophon has also enrolled the first subject in a Phase 2 trial evaluating the safety and efficacy of the INOpulse delivery system in patients with pulmonary hypertension associated with Idiopathic Pulmonary Fibrosis (PH-IPF) in collaboration with Professor W. DeBacker, MD, Director Department of Pulmonary Medicine, University Hospital and University of Antwerp.

Jonathan Peacock, Chairman and Chief Executive Officer of Bellerophon Therapeutics, stated, “The initiation of enrollment in INOvation-1, Bellerophon’s first Phase 3 trial in PAH, marks an important milestone for the company and offers a new potential treatment to patients who continue to suffer poor outcomes. Additionally, with the initiation of the clinical trial in IPF and a planned clinical trial in pulmonary hypertension associated with COPD, we are positioned to gain additional insight in 2016 for our future development programs for INOpulse.”

INOpulse Clinical Program Focus

The focus of the company’s INOpulse clinical program is the continued development of its nitric oxide therapy for patients with pulmonary hypertension (PH). The lead indication for INOpulse is Pulmonary Arterial Hypertension (PAH), for which FDA issued Special Protocol Assessment for the Phase 3 program and agreement was reached with European Medicines Agency (EMA) through its Scientific Advice Working Party (SAWP) process. The Phase 3 program will include 2 confirmatory trials in approximately 450 patients. The primary endpoint for each trial is Six Minute Walk Distance (6MWD), with Time to Clinical Worsening (TTCW) as a secondary endpoint, pooled across both trials. In February 2016, Bellerophon released encouraging results from the long-term extension of the company’s Phase 2 PAH clinical trial demonstrating benefit for patients on long-term oxygen therapy whose disease is progressing despite taking one or more existing PAH therapies. Bellerophon also plans to continue with Phase 2 testing in PH associated with Chronic Obstructive Pulmonary Disease (PH-COPD) and PH associated with Idiopathic Pulmonary Fibrosis (PH-IPF) for which results are anticipated by the end of 2016.

About Bellerophon

Bellerophon Therapeutics is a clinical-stage biotherapeutics company focused on developing innovative therapies at the intersection of drugs and devices that address significant unmet medical needs in the treatment of cardiopulmonary diseases. The Company is currently developing three product candidates under its INOpulse platform, a proprietary pulsatile nitric oxide delivery system. The first is for the treatment of pulmonary arterial hypertension (PAH), for which the Company intends to commence Phase 3 clinical trials in 2016. The second is for the treatment of pulmonary hypertension associated with chronic obstructive pulmonary disease (PH-COPD), which is in Phase 2 development and the third candidate is for the treatment of pulmonary hypertension associated with Idiopathic Pulmonary Fibrosis (PH-IPF). The Company’s plans also call for the completion of further work on the use of INOpulse to treat PH-COPD and PH-IPF during 2016. For more information, please visit www.bellerophon.com.

Forward-looking Statements

Any statements in this press release about our future expectations, plans and prospects, including statements about clinical development of our product candidates and expectations regarding the sufficiency of our cash balance to fund clinical trials, operating expenses and capital expenditures, and other statements containing the words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “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 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, 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 our most recent filings with the Securities and Exchange Commission. In addition, any forward-looking statements included in this press release represent our views only as of the date of this release and should not be relied upon as representing our views as of any subsequent date. We specifically disclaim any obligation to update any forward-looking statements included in this press release.

Contact

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