

**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): July 25, 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 July 25, 2016 announcing that it has received health authority approval in Belgium to commence a Phase 2 trial for INOpulse, its patented and proprietary pulsatile nitric oxide [NO] delivery device, to treat pulmonary hypertension in chronic obstructive pulmonary disease, or PH-COPD. This follows results from the Company’s Phase 2a study and proof of mechanism work, which indicated that INOpulse could be both safe and effective in PH-COPD. Bellerophon expects to enroll the first patient in the third quarter of 2016 with results of the trial expected before year end. 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 July 25, 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: July 27, 2016

By: /s/ Fabian Tenenbaum

Fabian Tenenbaum

Chief Financial Officer and Chief Business Officer

## **Bellerophon Receives Approval to Commence Phase 2 Trial in PH-COPD**

-- Trial expected to commence in third quarter; Results to be reported by year end 2016 --

-- Previous data supporting testing long-term benefits of pulsed inhaled nitric oxide (iNO) reported in peer-reviewed International Journal of COPD --

**Warren, NJ, July 25, 2016** -Bellerophon Therapeutics, Inc. (Nasdaq: BLPH), a clinical-stage biotherapeutics company, today announced it has received health authority approval in Belgium to commence a Phase 2 trial for INOpulse, its patented and proprietary pulsatile nitric oxide [NO] delivery device, to treat pulmonary hypertension in chronic obstructive pulmonary disease, or PH-COPD. This follows results from the Company's Phase 2a study and proof of mechanism work, which indicated that INOpulse could be both safe and effective in PH-COPD. Bellerophon expects to enroll the first patient in the third quarter of 2016 with results of the trial expected before year end.

Approximately 12 million people in the United States suffer from COPD of which approximately 700,000 are PH-COPD patients. Severe COPD is often associated with secondary pulmonary hypertension, which worsens its prognosis, is associated with high hospitalization rates, impaired exercise capacity and carries with it a median life expectancy of four years. Earlier Phase 2a data showed that in an acute setting, Bellerophon's INOpulse safely reduced PH for COPD patients and increased blood volume in the vessels within the lung.

### **Trial Protocol**

The Phase 2 study of INOpulse for PH-COPD is designed to demonstrate the potential benefit of INOpulse on exercise capacity for patients suffering from PH-COPD and will enroll 10 COPD patients with PH on LTOT. The trial is an open-label study of iNO 30 mcg/kg IBW (Ideal Body Weight)/hour for four weeks with a follow up visit two weeks after discontinuation of iNO. After four weeks of treatment, patients' vasodilation in pulmonary arteries will be measured by high resolution CT scanning (HRCT), with a key secondary endpoint of 6MWD at four weeks.

"This study builds on the results of earlier work by the Vonbank group in Austria, our own Phase 2a acute dose ranging study as well as the results of a trial conducted in the Department of Respiratory Medicine at the University Hospital Antwerp, by Professor Wilfried De Backer and Bellerophon, published in the peer-reviewed International Journal of COPD (Hajian et al., Pulmonary vascular effects of pulsed inhaled nitric oxide in COPD patients with pulmonary hypertension, International Journal of COPD, 2016, 11:1533-1541)," stated Jonathan Peacock, Chairman and Chief Executive Officer of Bellerophon Therapeutics.

"The prognosis of COPD patients with severe PH is very poor and there is currently no approved therapy to treat this condition. We look forward to developing a therapy for this serious unmet medical need and reporting results by year end 2016," concluded Mr. Peacock.

### **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](http://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," "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 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 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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