# **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): January 3, 2018

# **Bellerophon Therapeutics, Inc.**

(Exact Name of Registrant as Specified in Charter) 001-36845

(Commission

File Number)

(State or Other Jurisdiction of Incorporation)

Delaware

184 Liberty Corner Road, Suite 302

Warren, New Jersey

(Address of Principal Executive Offices)

07059

(Zip Code)

47-3116175

(IRS Employer

Identification No.)

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))

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 7.01 Regulation FD Disclosure

Bellerophon Therapeutics, Inc. (the "Company") issued a press release on January 3, 2018, to announce that the first patient has been randomized into a Phase 2b study evaluating INOpulse® in patients with Pulmonary Hypertension associated with Interstitial Lung Disease (PH-ILD). 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
<u>99.1</u>	Press Release dated January 3, 2018 (furnished and not filed for purposes of Item 7.01)

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#### 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: January 3, 2018

By: /s/ Fabian Tenenbaum

Name: Fabian Tenenbaum Title: Chief Executive Officer

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# Bellerophon Announces First Patient Enrolled in Phase 2b Study Evaluating INOpulse® for Treatment of Pulmonary Hypertension Associated with Interstitial Lung Disease

**Warren, NJ, January 3, 2018** - Bellerophon Therapeutics, Inc. (Nasdaq: BLPH), a clinical-stage biotherapeutics company, today announced that the first patient has been randomized into a Phase 2b study evaluating INOpulse® in patients with Pulmonary Hypertension associated with Interstitial Lung Disease (PH-ILD). The first patient was treated at The Lung Research Center in Chesterfield, MO, by Neil A. Ettinger, M.D.

The iNO-PF Phase 2b, randomized, double-blind, placebo-controlled clinical study will assess the safety and efficacy of pulsed, inhaled nitric oxide (iNO) versus placebo in patients with PH-ILD, including patients with idiopathic pulmonary fibrosis (PH-IPF). A total of 40 subjects will be enrolled in this clinical trial. The study design includes a 1-week run-in period, followed by an 8-week double-blinded treatment period. The primary endpoint of the study is the change in 6 Minute Walk Distance from baseline to week 8. The trial will include several additional endpoints, including the change in Right Ventricular Function.

"The initiation of our iNO-PF study represents an important milestone in our INOpulse development program," said Fabian Tenenbaum, Chief Executive Officer of Bellerophon. "PH associated with ILD, including PH-IPF, are devastating conditions with no approved therapies. Patients suffering from these conditions represent an orphan population with a mean survival of only two years from diagnosis and for whom systemic vasodilators have proven to be ineffective. The proprietary and targeted INOpulse mechanism of action, and the positive data generated from our previously completed Phase 2a study, suggest that INOpulse has the potential to become the first approved therapy to address this critical treatment void. We look forward to working with our Steering Committee and investigators to continue the development of INOpulse for PH-ILD."

Top-line results from this study are expected to be available by the end of 2018. Additional details of the trial can be found at <u>www.clinicaltrials.gov</u> (NCT 03267108).

#### **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 program, a proprietary pulsatile nitric oxide delivery system. The first is for the treatment of pulmonary arterial hypertension (PAH), for which the Company has commenced Phase 3 clinical trials. The second is for the treatment of pulmonary hypertension associated with chronic obstructive pulmonary disease (PH-COPD) and the third candidate is for the treatment of pulmonary hypertension associated with Interstitial Lung Disease (PH-ILD), both of which are in Phase 2 development. For more information, please visit <u>www.bellerophon.com</u>.

### **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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