

**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): May 8, 2018

**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**

(Address of Principal Executive Offices)

**07059**

(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):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- 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).

Emerging growth company

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

Bellerophon Therapeutics, Inc. (the "Company") issued a press release on May 8, 2018, to announce that the Company has reached agreement with the US Food and Drug Administration on all key aspects of its planned Phase 2b study of INOpulse® for the treatment of Pulmonary Hypertension Associated with Chronic Obstructive Pulmonary Disease (PH-COPD).

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:

<u>Exhibit No.</u>	<u>Description</u>
<a href="#"><u>99.1</u></a>	<a href="#"><u>Press Release dated May 8, 2018 (furnished and not filed for purposes of Item 7.01)</u></a>

**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: May 8, 2018

By: /s/ Fabian Tenenbaum  
Name: Fabian Tenenbaum  
Title: Chief Executive Officer



## **Bellerophon Reaches Agreement with FDA on Study Design of Phase 2b Trial of INOpulse® for Treatment of Pulmonary Hypertension Associated with Chronic Obstructive Pulmonary Disease**

**Warren, NJ, May 8, 2018** - Bellerophon Therapeutics, Inc. (Nasdaq: BLPH) (“Bellerophon” or the “Company”), a clinical-stage biotherapeutics company, today announced that, following the receipt of minutes from a recent meeting with the U.S. Food and Drug Administration (FDA), the Company has reached agreement with FDA on all key aspects of its planned Phase 2b study of INOpulse® for the treatment of Pulmonary Hypertension Associated with Chronic Obstructive Pulmonary Disease (PH-COPD).

The U.S. based Phase 2b study will be a double-blind, placebo-controlled, clinical trial in approximately 90 PH-COPD patients assessing the benefit of pulsed inhaled nitric oxide (iNO) delivered by the INOpulse system. The primary end point will be six-minute walking distance (6MWD) and the study will also assess multiple secondary endpoints including right ventricular function.

“Reaching agreement with the FDA on the Phase 2b study design in PH-COPD represents an important achievement for our INOpulse development program,” said Fabian Tenenbaum, Chief Executive Officer of Bellerophon. “Based on the data generated to date and INOpulse’s dual mechanism of action, to provide targeted vasodilation as well as improve ventilation-perfusion matching, we believe INOpulse has the potential to be the first treatment approved for PH-COPD and we look forward to advancing our INOpulse therapy in this serious and unmet medical condition.”

The FDA meeting followed positive Phase 2a data, reported in September 2017 that showed statistically significant and clinically meaningful increases in 6MWD after both 2 and 4 weeks of treatment on INOpulse (+50.7m; p=0.04), as compared to baseline. In addition, the trial results demonstrated a statistically significant increase (average 4.2%; p=0.03) in blood vessel volume and a statistically significant correlation in Ventilation-Vasodilation (p=0.01), indicating targeted delivery to the well-ventilated alveoli, as well as clinically meaningful decrease of 19.9% (p=0.02) in systolic pulmonary arterial pressure. The therapy was well-tolerated with no related safety concerns.

COPD is a common, but potentially life-altering disease with a diagnosed prevalence greater than 12 million in the U.S. Approximately 25-30% of COPD patients have associated pulmonary hypertension. Although there are multiple therapies indicated for the treatment of COPD, there are no approved therapies for the treatment of PH associated with COPD.

### **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 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 [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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