

**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 29, 2018

**Bellerophon Therapeutics, Inc.**

(Exact Name of Registrant as Specified in Charter)

<b>Delaware</b>	<b>001-36845</b>	<b>47-3116175</b>
(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 Regulation FD Disclosure

Bellerophon Therapeutics, Inc. (the "Company") issued a press release on January 29, 2018, to announce that enrollment in its Phase 3 INOvation-1 study evaluating INOpulse® in patients with pulmonary arterial hypertension (PAH) now exceeds 100 patients, representing more than half of the anticipated enrollment. 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
<a href="#"><u>99.1</u></a>	Press Release dated January 29, 2018 (furnished and not filed for purposes of Item 7.01)

## 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 29, 2018

By: /s/ Fabian Tenenbaum

Name: Fabian Tenenbaum

Title: Chief Executive Officer

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## **Bellerophon Therapeutics Announces Enrollment Exceeds 100 Patients in Phase 3 INOvation-1 Study Evaluating INOpulse® for Treatment of Pulmonary Arterial Hypertension**

**Warren, NJ, January 29, 2018** — Bellerophon Therapeutics, Inc. (Nasdaq: BLPH), a clinical-stage biotherapeutics company, today announced that enrollment in its Phase 3 INOvation-1 study evaluating INOpulse® in patients with pulmonary arterial hypertension (PAH) now exceeds 100 patients, representing more than half of the anticipated enrollment. As previously agreed with the U.S. Food and Drug Administration (FDA), an interim analysis of this trial will be performed by the Data Monitoring Committee when half of the subjects complete the 16-week blinded treatment phase. The interim analysis will determine if the study should be stopped early for efficacy or futility, continued as planned, or if the trial size should be increased. The Company anticipates the readout of the interim analysis in mid-2018, and the availability of top-line data from the full study toward the end of 2018.

“I am excited to be participating in the INOvation-1 study, and pleased to see strong momentum in recruitment,” said Dr. Marion Delcroix, Professor of Medicine and of Respiratory Physiology at the KU Leuven in Belgium, an investigator and member of the PAH Steering Committee. “PAH remains an underserved disease with poor quality of life and no cure. INOpulse’s unique mechanism of action delivers a precise dose of pulsatile nitric oxide, a potent and well validated vasodilator, and has the potential to become an important new therapy in the management of PAH patients.”

“We are pleased with the progress achieved to date in this Phase 3 study,” said Fabian Tenenbaum, President and Chief Executive Officer of Bellerophon. “We believe this speaks to the desire for PAH patients to seek more effective and tolerable treatment alternatives, as well as the enthusiasm and dedication of our investigators and clinical development team. We look forward to the interim analysis in mid-2018, and the continued advancement of our INOvation-1 trial over the remainder of the year.”

The INOpulse PAH Phase 3 program consists of two studies, the INOvation-1 study, and a confirmatory randomized withdrawal study with approximately 40 patients who will cross over from the INOvation-1 study.

- The INOvation-1 study is evaluating the safety and efficacy of the INOpulse delivery system for the treatment of patients with PAH on long-term oxygen treatment (LTOT). The INOpulse delivery system utilizes a proprietary technology to deliver pulsatile inhaled nitric oxide (iNO), allowing for use in a portable chronic setting. The primary endpoint of the study is Six Minute Walk Distance (6MWD), with Time to Clinical Worsening as a secondary endpoint.
- The INOvation-1 trial includes an interim analysis after approximately half the patients have completed the 16-week blinded phase on either iNO at a dose of 75 mcg/kg IBW/hr (iNO75) or placebo. The interim analysis will be conducted by the independent Data

Monitoring Committee, which will provide the Company with one of four predetermined decisions, including allowing the trial to be stopped early if efficacy has been demonstrated, continuing the trial to the planned size, increasing the trial size to reach a threshold of conditional powering, or halting the trial for futility.

As agreed with the FDA, the INOvation-1 and withdrawal studies can serve as the two adequate and well-controlled studies required to support a New Drug Application filing for INOpulse in PAH subjects on LTOT.

### **About Pulmonary Arterial Hypertension**

Pulmonary arterial hypertension is one form of a broader condition known as pulmonary hypertension, which means high blood pressure in the lungs. PAH occurs when the very small arteries throughout the lungs narrow in diameter, which increases the resistance to blood flow through the lungs. Over time, the increased blood pressure can damage the heart. A number of diseases and conditions can cause PAH, and symptoms are similar to the symptoms often seen in more common diseases, such as asthma, chronic obstructive pulmonary disease (COPD), and heart failure.

### **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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