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): October 9, 2018

Bellerophon Therapeutics, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware	**001-36845**	**47-3116175**
	(Commission	(IRS Employer
(State or Other Jurisdiction of Incorporation)	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):

☐ 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 October 9, 2018, to provide an update on its INOpulse® Phase 2b clinical program for the treatment of pulmonary hypertension associated with interstitial lung disease. 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 October 9, 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: October 9, 2018

By: /s/ Fabian Tenenbaum

Name: Fabian Tenenbaum
Title: Chief Executive Officer

Bellerophon Provides Update on INOpulse® Phase 2b Clinical Program for Treatment of Pulmonary Hypertension Associated with Interstitial Lung Disease

Enrollment of the Planned 40 Subjects Completed, with Top-line Data Expected in January 2019

Warren, NJ, October 9, 2018 - Bellerophon Therapeutics, Inc. (Nasdaq: BLPH) ("Bellerophon" or the "Company"), a clinical-stage biotherapeutics company, today provided an update on the Company's ongoing Phase 2b randomized, double-blind, placebo-controlled clinical study (iNO-PF) evaluating INOpulse® in patients with Pulmonary Hypertension associated with Interstitial Lung Disease (PH-ILD), as well as updated interim results from the Pulmonary Arterial Hypertension (PAH) Phase 3 trial, INOvation-1.

Bellerophon has completed enrollment of the planned 40 subjects in the iNO-PF trial, with top-line results for this cohort expected in January 2019. These subjects are randomized (1:1) to iNO 30 (30 mcg/kg IBW/hr) vs. placebo, with a one-week run-in period, followed by an eight-week double-blinded treatment period. Following completion of the blinded treatment period, subjects are offered open-label access. The study is evaluating multiple endpoints, including change in six-minute walk distance (6MWD), oxygen saturation, right ventricular function, activity monitoring, patient reported outcomes, as well as several composite endpoints.

In order to support a potential registration package, the Company will expand the iNO-PF study to assess higher doses of iNO and duration of treatment through the addition of two further cohorts. Cohort 2 will include approximately 20 subjects randomized (2:1) to receive either iNO 45 or placebo. Cohort 3 will include approximately 20 subjects randomized (2:1) to receive either iNO 75 or placebo. In addition to evaluating higher doses, cohorts 2 and 3 will increase the blinded treatment period from 8 weeks to 16 weeks. Enrollment in these additional cohorts is expected to begin later this year, with top-line data anticipated in 2019. In addition to the further cohorts, the study is also being modified to allow dose escalation during the open-label period.

"We are pleased with the enthusiasm for our iNO-PF Phase 2b study from investigators and the strong recruitment observed throughout the study. The completion of enrollment in cohort 1 represents an important milestone for our INOpulse clinical development program and we look forward to the availability of these results early next year," said Fabian Tenenbaum, Chief Executive Officer of Bellerophon. "The expansion of the study to include two additional cohorts will allow us to assess higher doses of iNO with longer duration of treatment. PH-ILD is a significant unmet medical need, with approximately 200,000 patients in the U.S. suffering from this disease that has a mean survival of only two years from diagnosis. There are no approved therapies to treat PH in these patients as the underlying lung disease results in systemic vasodilators causing ventilation-perfusion mismatch and hypoxemia. INOpulse's unique targeted vasodilation provides the potential for it to be the first approved therapy for patients with PH-ILD."

Importantly, the interim results from INOvation-1, evaluating INOpulse for the treatment of PAH, verified the INOpulse mechanism of action and support its potential in treating PH-ILD patients. Specifically, following 16 weeks of blinded therapy, subjects on iNO demonstrated clinically meaningful improvement consistent with currently marketed PAH drugs in the following key areas:

- Pulmonary vascular resistance (PVR) improved by 75 dyne/sec/cm as compared to placebo, which worsened by 111 dyne/sec/cm
- Cardiac output (CO) improved by 0.5 L/min as compared to placebo, which worsened by 0.2 L/min
- NT-ProBNP, a peptide biomarker for right ventricular failure, improved by 48 pmol/L compared to placebo, which worsened by 20 pmol/L
- Clinically meaningful decline in 6MWD (>15%) was twice as high in the placebo arm as compared to INOpulse
- 6MWD improved 41 meters (mono PAH therapy) and 25 meters (excluding prostanoids)

"The collective results of INOvation-1 supports the vasodilatory performance of iNO, as well as its clinical benefits in improving hemodynamics, reducing right ventricular failure and preventing decline in 6MWD. In addition, subjects that were not on prostanoids or multiple background therapies showed improvement in 6MWD that is consistent with currently marketed PAH therapies," continued Mr. Tenenbaum. "These results support the potential benefit that INOpulse can provide for PH-ILD patients, where there are no approved PH therapies and patients are not on any background PAH medications."

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 multiple product candidates under its INOpulse program, a proprietary pulsatile nitric oxide delivery system. For more information, please visit 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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