

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): September 5, 2017

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. Regulation FD Disclosure.

Bellerophon Therapeutics, Inc. (the “Company”) issued a press release on September 5, 2017 announcing positive top line data from a Phase 2 clinical trial evaluating INOpulse® in patients with 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:

Exhibit No.	Description
99.1	Press Release dated September 5, 2017 (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: September 5, 2017

By: /s/ Megan Schoeps
Megan Schoeps
Controller and Principal Financial Officer

Bellerophon Announces Positive Top Line Phase 2 Data of INOpulse® for Treatment of Pulmonary Hypertension Associated with Chronic Obstructive Pulmonary Disease

Study Met its Primary and Secondary Endpoints Demonstrating Statistically Significant Improvements in Six-Minute Walking Distance, Hemodynamics and Blood Vessel Volume

Warren, NJ, September 5, 2017 - Bellerophon Therapeutics, Inc. (Nasdaq: BLPH), a clinical-stage biotherapeutics company, today announced positive top line data from a Phase 2 clinical trial evaluating INOpulse® in patients with Pulmonary Hypertension Associated with Chronic Obstructive Pulmonary Disease (PH-COPD).

The Phase 2 study was designed to assess the acute effect of pulsed inhaled nitric oxide (iNO) on targeted vasodilation and the chronic effect (4 weeks) of iNO on hemodynamics and exercise capacity. The study enrolled 10 subjects and used a dose of 30 mcg/kg IBW/hr (iNO 30). The acute results showed a statistically significant increase (average 4.2%) in blood vessel volume on iNO compared to baseline ($p=0.03$), and a statistically significant correlation in Ventilation-Vasodilation ($p=0.01$), indicating targeted delivery to the well-ventilated alveoli. The chronic results demonstrated statistically significant and clinically meaningful increases in six-minute walking distance (6MWD) at both 2 weeks and 4 weeks (+50.7m; $p=0.04$), as compared to baseline. In addition, the study demonstrated a statistically significant and clinically meaningful decrease of 19.9% in systolic pulmonary arterial pressure (sPAP) at 4 weeks ($p=0.02$), as compared to baseline. The therapy was well tolerated with no related safety concerns.

“COPD patients with associated pulmonary hypertension have a poor prognosis with an approximately 4-year life expectancy and high hospitalization rates, which represents a significant unmet medical need for a safe and effective long-term treatment,” said Dr. Raymond L. Benza of the Cardiovascular Institute at Allegheny General Hospital, Pittsburgh, PA and Chairman of Bellerophon’s PH-COPD steering committee. “Collectively, these Phase 2 data demonstrate the promising potential of INOpulse to safely deliver pulsatile nitric oxide in a targeted manner to achieve medically and statistically significant improvements in exercise capacity and hemodynamics.”

“These compelling data confirm and build upon the results from our previous acute studies, and reaffirm INOpulse’s potential role as a first-in-class therapy for PH-COPD patients,” said Fabian Tenenbaum, Chief Executive Officer of Bellerophon. “We believe INOpulse’s ability to provide targeted vasodilation to the well-ventilated areas of the lung could allow it, if approved, to become a safe and effective treatment for over 700,000 PH-COPD patients in the U.S. for whom there are currently no marketed therapies. We now have an experienced steering committee in place chaired by Dr. Benza to help guide our next clinical studies and the regulatory pathway towards the potential approval of INOpulse in PH-COPD.”

In addition to PH-COPD, Bellerophon is currently conducting a Phase 3 trial for INOpulse for the treatment of pulmonary arterial hypertension (PAH), with interim and top-line data expected in 2018, and recently completed a Phase 2 clinical trial that investigated INOpulse in idiopathic pulmonary fibrosis patients with pulmonary hypertension (PH-IPF). The results of the PH-IPF trial were recently presented at the American Thoracic Society meeting and the next step in this program will be to conduct a larger Phase 2b study to inform the design of a pivotal registration trial.

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 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

At Bellerophon:

Fabian Tenenbaum, Executive Officer
(908) 574-4767

At LifeSci Advisors:

Bob Yedid
(646) 597-6989
bob@lifesciadvisors.com