

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 22, 2017

Bellerophon Therapeutics, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware

001-36845

47-3116175

(State or Other Jurisdiction of Incorporation)

(Commission

(IRS Employer

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 May 22, 2017 announcing the presentation of new clinical data from a Phase 2 clinical trial that investigated INOpulse in idiopathic pulmonary fibrosis patients with pulmonary hypertension (PH-IPF) at the American Thoracic Society (ATS) 113th International Conference. The Company also presented preliminary data from a second, ongoing study evaluating INOpulse in COPD patients with Pulmonary Hypertension (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 May 22, 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: May 22, 2017

By: /s/ Megan Schoeps

Megan Schoeps

Controller and Principal Financial Officer

Positive Clinical Data on INOpulse® Presented at the American Thoracic Society 113th International Conference

Acute and Chronic Benefits Demonstrated with INOpulse in Patients with PH-IPF; Patients Achieved Statistically Significant Increases in Blood Vessel Volume; Consistent Improvements were Observed in Hemodynamics, 6MWD and Composite Endpoints of Oxygen Saturation and 6MWD

Preliminary Results from an Ongoing Study in PH-COPD Support a Consistent Improvement in Vasodilation and Meaningful Reduction in Pulmonary Artery Pressures with 4 Weeks of INOpulse Treatment

Warren, NJ, May 22, 2017 - Bellerophon Therapeutics, Inc. (Nasdaq: BLPH), a clinical-stage biotherapeutics company, today announced the presentation of new clinical data from a Phase 2 clinical trial that investigated INOpulse in idiopathic pulmonary fibrosis patients with pulmonary hypertension (PH-IPF) at the American Thoracic Society (ATS) 113th International Conference, currently taking place in Washington DC. The company also presented preliminary data from a second, ongoing study evaluating INOpulse in COPD patients with Pulmonary Hypertension (PH-COPD).

“Pulmonary Hypertension with IPF or COPD has no approved therapies and has been associated with increased hospitalizations and mortality. The therapies used in other pulmonary hypertension populations, which act systemically, have failed to show a benefit for these patients, creating a critical unmet need for effective and safe long-term treatment options,” said Prof. W. De Backer MD, Director in the Department of Pulmonary Medicine, University Hospital and University of Antwerp. “Pulsed iNO has a potentially unique and distinguishing advantage as the data from these trials shows that it can provide selective vasodilation to the well-functioning parts of the lung, allowing for improvement in hemodynamic measures as well as increased exercise capacity without worsening oxygenation.”

The PH-IPF study was a proof of concept study (n=4) designed to evaluate the ability of pulsed inhaled nitric oxide (iNO) to provide selective vasodilation as well as assess the potential for improvement in hemodynamics and exercise capacity in PH-IPF patients. The study met its primary endpoint showing an average of 15.3% increase in blood vessel volume ($p < 0.001$) during acute inhalation of iNO as well as showing a significant association between ventilation and vasodilation, demonstrating the ability of INOpulse to provide selective vasodilation to the better ventilated areas of the lung. The study showed consistent benefit in hemodynamics with a clinically meaningful average reduction of 14% in systolic pulmonary arterial pressure (sPAP) with acute exposure to iNO. The study also assessed the chronic effects of iNO on exercise capacity showing an average 75 meter improvement in 6MWD and consistent improvement of approximately 80 m% in composite endpoints of 6MWD and oxygen saturation with four weeks of treatment. The study assessed both the iNO 75 and iNO 30 dose, supporting iNO 30 as a potentially safe and effective dose.

The next step in this program will be to conduct a larger Phase 2b study to inform the design of a pivotal registration trial.

The company also shared preliminary results of an ongoing PH-COPD study (n=10) designed to evaluate the acute effects of pulsed iNO on vasodilation as well as the chronic effect on hemodynamics and exercise tolerance. The interim data results from the first four patients showed a significant association between ventilation and vasodilation on acute treatment with iNO, suggesting that regions with better

ventilation experience greater vasodilation. In addition, a meaningful reduction in sPAP (average 17.4%) was seen on all patients with chronic treatment of iNO. The full study results are expected around the middle of 2017.

About the American Thoracic Society

The American Thoracic Society (ATS) improves global health by advancing research, patient care, and public health in pulmonary disease, critical illness, and sleep disorders. Founded in 1905 to combat TB, the ATS has grown to tackle asthma, COPD, lung cancer, sepsis, acute respiratory distress, and sleep apnea, among other diseases. The ATS 113th International Conference is taking place at the Walter E. Washington Convention Center in Washington DC, May 19-24, 2017. Additional information on the ATS 113th International Conference can be found at <http://conference.thoracic.org>.

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 in 2016. 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 Idiopathic Pulmonary Fibrosis (PH-IPF), both of which are in Phase 2 development. For more information, please visit www.bellerophon.com.

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