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 21, 2019

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).

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.01 par value per share	**BLPH**	**The Nasdaq Global Market**

☒ 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 8.01 Other Events.

Bellerophon Therapeutics, Inc. (the "Company") issued a press release on May 21, 2019, to publish additional positive data from Cohort 1 of its ongoing Phase 2/3 randomized, double-blind, placebo controlled clinical study of INOpulse® for the treatment of pulmonary hypertension associated with interstitial lung disease as a late-breaking oral presentation at the American Thoracic Society (ATS) 115th International Conference in Dallas. A copy of this press release is attached hereto as Exhibit 99.2 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits:

Exhibit No.	Description
99.1	Press Release dated May 21, 2019

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 21, 2019

By: /s/ Fabian Tenenbaum

Name: Fabian Tenenbaum
Title: Chief Executive Officer

Bellerophon Presents Additional Positive Data from Cohort 1 of Ongoing Phase 2/3 Study of INOpulse® for Treatment of Pulmonary Hypertension Associated with Interstitial Lung Disease at American Thoracic Society 115th International Conference

Results Presented in Late-Breaking Abstract as an Oral Presentation

WARREN, N.J., May 21, 2019 -- Bellerophon Therapeutics, Inc. (Nasdaq: BLPH) ("Bellerophon" or the "Company"), a clinical-stage biotherapeutics company, presented additional data from Cohort 1 of its ongoing Phase 2/3 randomized, double-blind, placebo-controlled clinical study (iNO-PF) of INOpulse® for the treatment of Pulmonary Hypertension associated with Interstitial Lung Disease (PH-ILD) as a late-breaking oral presentation at the American Thoracic Society (ATS) 115th International Conference in Dallas. The data were presented by Steven D. Nathan, M.D., F.C.C.P., Medical Director of the Advanced Lung Disease and Lung Transplant Program at Inova Fairfax Hospital and Chair of Bellerophon's Steering Committee.

"PH-ILD patients have limited ability to perform even the most basic daily tasks. The ability of INOpulse to improve moderate to vigorous physical activity, or MVPA, as well as other activity parameters, such as overall activity and caloric expenditure, is a significant finding," said Dr. Nathan. "Importantly, subjects receiving iNO improved their oxygen saturation as compared to the placebo group, which saw a decrease. Subjects on open-label extension saw continued benefit on treatment, with subjects who transitioned from placebo to active treatment experiencing a change from deterioration to improvement in both MVPA and overall activity. I am excited by the meaningful improvements seen to date and look forward to the continued evaluation of this promising therapy in the clinic."

"We continue to be extremely pleased with the collective results from Cohort 1 of the iNO-PF study, which served as the basis for an agreement with the U.S. Food and Drug Administration (FDA) on the regulatory approval pathway for INOpulse in PH-ILD," said Fabian Tenenbaum, Chief Executive Officer of Bellerophon. "The FDA agreed with Bellerophon's proposal that MVPA serve as the primary endpoint and that iNO-PF be amended from a Phase 2b study to a Phase 2/3 trial, providing a seamless transition into Cohort 3, which will serve as the pivotal Phase 3 trial. Of significance, INOpulse demonstrated clinical and statistical significance on MVPA in Cohort 1. We are actively recruiting patients in Cohort 2, which will assess a higher dose (iNO45), as well as a longer duration of treatment to 16 weeks. We continue to see strong recruitment activity and support from clinical sites, with half of the target 40 patients in Cohort 2 already recruited. We anticipate top-line data from Cohort 2 and initiation of Cohort 3 in the second half of 2019."

The top-line data reported in January 2019 from Cohort 1 included 41 subjects randomized 1:1 to either iNO30 (30 mcg/kg IBW/hr) or placebo for a period of 8 weeks of blinded treatment. Data highlights included:

- MVPA (Minutes of MVPA, such as walking, stairs, yardwork, etc.) improved by 34% (8% increase on iNO vs. 26% decrease on placebo; p=0.04)
- Overall activity improved by 12% (stable on iNO vs. 12% decrease on placebo; p=0.05)
- NT-ProBNP improved by 27% (15% increase on iNO vs. 42% increase on placebo). NT-ProBNP is a peptide marker of right ventricular failure, with higher levels indicative of disease worsening.
- Oxygen saturation improved by 20% (9% improvement on iNO vs. 11% deterioration on placebo)

The ATS presentation included additional activity parameters that were supportive of the previously announced top-line results, as well as new data from subjects on open-label extension. Presentation highlights included:

- The 34% placebo corrected improvement in MVPA was supported by strong separation between subjects on iNO and subjects on placebo:
  - 23% of subjects on iNO had a clinically significant improvement in MVPA, compared to 0% of subjects on placebo (placebo corrected difference of 23%)

    - 39% of subjects on iNO had a clinically significant decline in MVPA, compared to 71% of subjects on placebo (placebo corrected difference of 32%)
    - Clinically significant improvement is >15% increase in MVPA from baseline; clinically significant decline is >15% decrease in MVPA from baseline
- Proportion of awake time spent in MVPA improved by 38% (16% increase on iNO vs. 22% decrease on placebo; p=0.04)
- Calorie expenditure improved by 12% (6% decrease on iNO vs. 18% decrease on placebo; p=0.05)
- Subjects on open-label extension demonstrated consistent improvements in MVPA and overall activity, with subjects transitioning from placebo to open-label experiencing a reversal from worsening to improving:
    - Subjects on placebo had an average weekly decrease of 3 minutes per day of MVPA during blinded treatment, which reversed to an average weekly increase of 1 minute per day during open-label
    - Subjects on placebo had an average weekly decrease of 22 counts per minute in overall activity during blinded treatment, which reversed to an average weekly increase of 15 counts per minute during open-label
    - Subjects on active treatment remained stable for both MVPA and overall activity during blinded treatment, both of which improved during open-label, with an average weekly increase of 1 minute per week in MVPA and 15 counts per minute in overall activity

The ATS presentation and poster can be found at investors.bellerophon.com.

About Bellerophon

Bellerophon Therapeutics is a clinical-stage biotherapeutics company focused on developing innovative therapies 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," "contemplate," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," "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 Annual Report on Form 10-K and in subsequent 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.

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