

**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): November 7, 2019

**Bellerophon Therapeutics, Inc.**

(Exact Name of Registrant as Specified in Charter)

<b>Delaware</b>  (State or Other Jurisdiction of Incorporation)	<b>001-36845</b>  (Commission File Number)	<b>47-3116175</b>  (IRS Employer Identification No.)
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<b>184 Liberty Corner Road, Suite 302</b> <b>Warren, New Jersey</b>  (Address of Principal Executive Offices)	<b>07059</b>  (Zip Code)
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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
<b>Common Stock, \$0.01 par value per share</b>	<b>BLPH</b>	<b>The Nasdaq Capital Market</b>

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.

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**Item 8.01 Other Events.**

Bellerophon Therapeutics, Inc. (the "Company") issued a press release on November 7, 2019, to publish new data from Cohort 1 of the ongoing phase 2/3 study of INOpulse® for treatment of Pulmonary Hypertension Associated with Interstitial Lung Disease at the Pulmonary Fibrosis Foundation Summit 2019. A copy of this press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits:

<u>Exhibit No.</u>	<u>Description</u>
<a href="#"><u>99.1</u></a>	<a href="#"><u>Press Release dated November 7, 2019</u></a>

**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: November 7, 2019

By: /s/ Fabian Tenenbaum  
Name: Fabian Tenenbaum  
Title: Chief Executive Officer

**Bellerophon Presents New Data from Cohort 1 of Ongoing Phase 2/3 Study of INOpulse® for Treatment of Pulmonary Hypertension Associated with Interstitial Lung Disease at Pulmonary Fibrosis Foundation Summit 2019**

*Data Include New Results from Subgroup Analysis of Cohort 1 Further Demonstrating Benefits of INOpulse*

**WARREN, N.J., November 7, 2019** -- Bellerophon Therapeutics, Inc. (Nasdaq: BLPH) (“Bellerophon” or the “Company”), a clinical-stage biotherapeutics company, is presenting 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) at the Pulmonary Fibrosis Foundation (PFF) Summit 2019, being held November 7-9, 2019, in San Antonio, TX.

“The new data further substantiate the significant improvement previously demonstrated in Cohort 1 of our ongoing iNO-PF study,” said Fabian Tenenbaum, Chief Executive Officer of Bellerophon. “In this analysis, INOpulse demonstrated a consistent and clinically meaningful benefit in moderate to vigorous physical activity (MVPA) across both low and intermediate/high probability of pulmonary hypertension groups. These results highlight INOpulse’s proprietary mechanism of action, which improves both pulmonary hemodynamics, as well as ventilation/perfusion matching. The improvements in MVPA, 6 minute walk distance (6MWD) and distance saturation product in the group with reduced exercise capacity were especially encouraging as it directly addresses the physical limitations that critically impact the overall quality of life in this patient population. The collective data from Cohort 1 support the potential for INOpulse to become the first approved therapy to treat patients with PH-ILD and we look forward to reporting top-line results from Cohort 2 by the end of the year.”

Cohort 1, the first of 3 cohorts, included 41 subjects randomized 1:1 to either iNO 30 (30 mcg/kg IBW/hr) or placebo, for a period of 8 weeks of blinded treatment. Highlights from the newly presented subgroup analysis included:

- Placebo corrected benefit of 33% in MVPA for intermediate/high probability of PH
- Placebo corrected benefit of 28% in MVPA for low probability of PH
- Placebo corrected benefit of 40% in MVPA for subjects with baseline 6MWD  $\leq$ 300 meters as well as 33 meters in 6MWD and 39 meter% in distance saturation product (6MWD  $\times$  SpO2 Nadir)

The Company previously presented positive data from Cohort 1 that included:

- MVPA (walking, stairs, yardwork, etc.) improved by 34% (8% increase on iNO vs. 26% decrease on placebo; p=0.04)
    - 23% of subjects on INOpulse had a clinically significant improvement in MVPA, compared to 0% of subjects on placebo (placebo corrected difference of 23%)
    - 39% of subjects on INOpulse had a clinically significant decline in MVPA, compared to 71% of subjects on placebo (placebo corrected difference of 32%)
    - Proportion of awake time spent in MVPA improved by 38% (16% increase on INOpulse vs. 22% decrease on placebo; p=0.04)
  - Overall activity improved by 12% (stable on iNOpulse vs. 12% decrease on placebo; p=0.05)
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Details of the presentations are as follows:

Presentation Title: A Subgroup analysis from the randomized, double-blind, placebo-controlled study of inhaled nitric oxide (iNO) in subjects at risk of Pulmonary Hypertension associated with Pulmonary Fibrosis (PH-PF)

Presenter: Steven D. Nathan, M.D., F.C.C.P., Inova Fairfax Hospital

Date/Time: Thursday, November 7, 2019, from 5:30 PM - 8:30 PM Central Time

Presentation Title: Actigraphy as a clinically meaningful endpoint to detect change after treatment with inhaled NO (30mcg/kg-IBW/hr) in patients at risk of Pulmonary Hypertension associated with Pulmonary Fibrosis

Presenter: Lisa Lancaster, M.D., Vanderbilt University Medical Center

Date/Time: Thursday, November 7, 2019, from 5:30 PM - 8:30 PM Central Time

### **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](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," "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.

### **Contacts**

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