# 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): January 7, 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**<br>**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 8.01 Other Events.**

Bellerophon Therapeutics, Inc. (the "Company") issued a press release on January 7, 2019, to provide an update on its INOpulse® Phase 2b clinical trial for the treatment of pulmonary hypertension associated with interstitial lung disease. 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:

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release dated January 7, 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: January 7, 2019

By: /s/ Fabian Tenenbaum

Name: Fabian Tenenbaum
Title: Chief Executive Officer

**Bellerophon Announces Top-line Results from Cohort 1 of the INOpulse® Phase 2b Clinical Trial for Treatment of Pulmonary Hypertension Associated with Interstitial Lung Disease**

*Statistically Significant Improvements in Multiple Clinically Meaningful Activity Parameters Demonstrated*

**Warren, NJ, January 7, 2019 -** Bellerophon Therapeutics, Inc. (Nasdaq: BLPH) ("Bellerophon" or the "Company"), a clinical-stage biotherapeutics company, today announced top-line results from Cohort 1 of 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).

Statistically significant improvements in multiple clinically meaningful activity parameters as measured by a wearable medical-grade activity monitor (actigraphy) were observed:

- Subjects on pulsed inhaled nitric oxide (iNO) demonstrated an increase of 8% in moderate activity versus a 26% decrease for subjects on placebo (p=0.04)
- Subjects on iNO showed no decline in their overall activity levels versus a 12% decline for subjects on placebo (p=0.05)

Wearable activity monitoring is designed to provide continuous objective real-world physical activity data and is scientifically validated to assess patient outcomes. Actigraphy is currently being utilized as the primary endpoint in multiple late-stage clinical programs in pulmonary hypertension and other cardiopulmonary diseases.

Clinically meaningful improvements were also demonstrated in the following key areas:

- Subjects on iNO showed an increase of 15% in NT-ProBNP versus a 42% increase for subjects on placebo. NT-ProBNP is a peptide marker of right ventricular failure, with higher levels indicative of disease worsening.
- Subjects on iNO demonstrated improved oxygen saturation by 9% versus a worsening of 11% for placebo.

In addition, iNO was well-tolerated with no safety concerns.

"The results from Cohort 1 confirm the potential of INOpulse® to effectively treat PH-ILD, a disease with a serious unmet medical need. Notably, the results were seen following only eight weeks of treatment in both patients at high and low risk of pulmonary hypertension," said Fabian Tenenbaum, Chief Executive Officer of Bellerophon. "We are continuing with the remaining planned dose escalation Cohorts in the iNO-PF study, and in parallel, based on these compelling top-line results, intend to initiate discussions with the U.S. Food and Drug Administration to formalize a streamlined and efficient regulatory approval path for INOpulse in PH-ILD."

"PH associated with interstitial lung disease has profound implications for patients as it is typically accompanied by severe functional impairment and a limited life expectancy. These patients may suffer

from significant right ventricular dysfunction that limits their ability to perform even the most basic daily tasks," said 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. "These results are especially exciting because they represent the first time such benefits have been observed in this difficult to treat patient population. I look forward to continuing with the clinical development of INOpulse in PH-ILD with a focus on these meaningful patient-centric endpoints."

Cohort 1 of the iNO-PF trial consisted of 41 subjects who were 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. Cohorts 2 and 3, which are ongoing, will assess higher doses, iNO 45 and iNO 75, as well as a longer 16-week treatment period.

**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," "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 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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