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): December 17, 2021

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))

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 Capital Market**

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. issued a press release on December 17, 2021 announcing positive top-line data from a Phase 2 acute does escalation study of INOpulse® for treatment of Pulmonary Hypertension associated with Sarcoidosis. 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 December 17, 2021
104	Cover Page Interactive Data File (Formatted as Inline XBRL)

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: December 17, 2021

By: /s/ Nicholas Laccona
Name: Nicholas Laccona
Title: Principal Financial Officer and Principal Accounting Officer

Bellerophon Reports Positive Top-Line Data from Phase 2 Acute Dose Escalation Study of INOpulse® for Treatment of Pulmonary Hypertension Associated with Sarcoidosis

Phase 2 results provide clinically meaningful reduction in pulmonary vascular resistance; Company intends to design multi-dose Phase 2b trial

Treatment was safe and well-tolerated, with no treatment-emergent adverse events observed during the acute hemodynamic dose escalation phase of the study

WARREN, N.J., December 17, 2021 – Bellerophon Therapeutics, Inc. (Nasdaq: BLPH) ("Bellerophon" or the "Company"), a clinical-stage biotherapeutics company focused on developing treatments for cardiopulmonary diseases, today announced positive top-line data from a recently completed Phase 2 dose escalation study (PULSE-PHPF-002) evaluating the acute hemodynamic benefit of INOpulse® via right heart catheterization for the treatment of pulmonary hypertension associated with sarcoidosis (PH-Sarc).

The Phase 2 trial was designed as a proof of concept study to determine if iNO could demonstrate hemodynamic benefit in PH-Sarc. Key results included:

- All 8 subjects demonstrated decreases in mean pulmonary arterial pressure (mPAP) and pulmonary vascular resistance (PVR) across the doses of INOpulse utilized in the study.
- The dose of iNO45 (45 mcg/kg IBW/hr) resulted in a median drop of 20% (-54% to +22%) in PVR, compared to a median baseline PVR of 329 dyne/cm.sec-5; a reduction of 20% or more in PVR is generally considered to be clinically meaningful.
    - Increasing to the highest dose, iNO125 (125 mcg/kg IBW/hr), demonstrated further improvement in PVR, with a median drop of 29% (-43% to -5%), achieving statistical significance from baseline (p=0.02) and from the preceding lower dose of iNO75 (75 mcg/kg IBW/hr) (p=0.02). During the study, 7 out of 8 patients escalated to the highest dose, iNO125.
- Along with the improvements in PVR, mPAP decreased by a median of 6-10% across the doses of iNO30 to iNO125, compared to a median baseline mPAP of 37.2 mmHg.
- No treatment-emergent adverse events (TEAEs) or serious adverse events (TESAEs) occurred during the acute hemodynamic dose escalation phase of the study.

"Sarcoidosis associated pulmonary hypertension has a median survival of approximately five years after development of the pulmonary hypertension. I am encouraged by the positive changes observed in multiple hemodynamic parameters in patients with sarcoidosis associated pulmonary hypertension being treated with long-term oxygen therapy and then acutely treated with INOpulse," said Robert Baughman, M.D., Professor of Medicine at the University of Cincinnati and one of the Principal Investigators for Study PULSE-PHPF-002. "These clinically meaningful improvements in PVR started at the iNO45 dose and were well tolerated with no clinically relevant deterioration in pulmonary capillary wedge pressure or other hemodynamic parameters, even at the higher iNO doses. The results from this cohort of patients support further evaluation of the potential of iNO to treat PH-Sarc patients who are in urgent need of safe and effective therapies."

“We are pleased with the positive top-line data from this proof-of-concept study,” said Naseem Amin, M.D., Chairman of Bellerophon’s Board of Directors. “Based on these results, Bellerophon is working with its steering committee, which is comprised of multiple pulmonary disease experts, to assess next steps for this program, including the design of a multi-dose Phase 2b study to assess the chronic benefit of iNO in PH-Sarc patients. We look forward to continuing our development program in PH-Sarc, a rare disease with significant morbidity and mortality for which there are no approved treatment options. Bellerophon will continue to provide additional updates on our clinical activities in the coming year, including our ongoing Phase 3 program in fibrotic interstitial lung disease, the REBUILD study.”

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: risks and uncertainties relating to INOpulse®, 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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