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): February 9, 2023

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.

On February 9, 2023, Bellerophon Therapeutics, Inc. issued a press release announcing the clearance from China NMPA to conduct a Phase 3 clinical trial in China for INOpulse® in fibrotic interstitial lung disease. A copy of this press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

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Item 9.01. Financial Statements and Exhibits.

(d) Exhibits:

Exhibit No.	Description
99.1	Press Release dated February 9, 2023
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: February 9, 2023

By: /s/ Peter Fernandes
Name: Peter Fernandes
Title: Chief Executive Officer

Bellerophon Therapeutics Receives IND Clearance from China NMPA to Conduct Phase 3 Clinical Trial in China for INOpulse® in Fibrotic Interstitial Lung Disease

China NPMA accepts the use of Moderate to Vigorous Physical Activity (MVPA) as the primary endpoint

WARREN, N.J., February 9, 2023 – Bellerophon Therapeutics, Inc. (Nasdaq: BLPH) ("Bellerophon" or the "Company"), a clinical-stage biotherapeutics company focused on developing treatments for cardiopulmonary diseases, today announced clearance of its Investigational New Drug (IND) application from the Center for Drug Evaluation of China's National Medical Products Administration (NMPA) to conduct a Phase 3 clinical trial to support the registration of INOpulse® for the treatment of fibrotic interstitial lung disease (fILD) in China. The study will utilize Moderate to Vigorous Physical Activity (MVPA) as the primary endpoint and be conducted in collaboration with Bellerophon's regional partner, Baylor BioSciences, a life sciences company dedicated to the development and commercialization of innovative medical products for Greater China.

"We are delighted to expand our clinical program with the aim of bringing INOpulse to patients in need in Greater China," said Peter Fernandes, Bellerophon's Chief Executive Officer. "INOpulse has the potential to become the first therapy to treat an fILD population that includes patients at low-, intermediate- and high-risk of pulmonary hypertension. This IND clearance further underscores the potential of INOpulse to improve activities of daily living and quality of life in patients with fILD, and supports the use of our novel primary endpoint, MVPA, which we are also utilizing in our ongoing Phase 3 REBUILD study in the U.S."

"We are excited to continue strengthening our partnership with Baylor BioSciences," said Naseem Amin, Chairman of Bellerophon Therapeutics. "INOpulse has significant potential in treating various diseases associated with pulmonary hypertension and the clearance of this IND brings us one step closer to a new treatment option for the underserved fILD patient community in Greater China."

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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