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): June 5, 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.)

20 Independence Boulevard, Suite 402 **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))

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 June 5, 2023, Bellerophon Therapeutics, Inc. (the "Company") issued a press release announcing top-line data of its Phase 3 REBUILD clinical trial of INOpulse® for the treatment of fibrotic interstitial lung disease. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated by reference herein. The Company also provided slides to be presented on an investor conference call to review these results, a copy of which is furnished as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated by reference herein.

The Company will conduct the conference call to review these results on June 5, 2023, at 8:30 a.m., Eastern Time.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits:

Exhibit No.	Description
99.1	Press Release dated June 5, 2023.
99.2	Slide Presentation dated June 5, 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: June 5, 2023

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

Exhibit 99.1

Bellerophon Announces Top-Line Data from Phase 3 REBUILD Clinical Trial of INOpulse® for Treatment of Fibrotic Interstitial Lung Disease

- *Trial did not meet its primary endpoint related to the change in moderate to vigorous physical activity*
- *INOpulse® was safe and well-tolerated, consistent with the overall safety profile demonstrated in Phase 2 and other INOpulse® programs in PH-COPD and PH-Sarcoidosis*
- *Company to host conference call and webcast with slides today at 8:30 AM ET*

WARREN, N.J., June 5, 2023 – Bellerophon Therapeutics, Inc. (Nasdaq: BLPH) ("Bellerophon" or the "Company"), a clinical-stage biotherapeutics company focused on developing treatments for cardiopulmonary diseases, today announced top-line results from its pivotal Phase 3 REBUILD clinical trial evaluating the safety and efficacy of INOpulse® for the treatment of fibrotic Interstitial Lung Disease (fILD).

The REBUILD clinical trial was designed as a randomized, double-blind, placebo-controlled Phase 3 study evaluating the safety and efficacy of INOpulse® for the treatment of patients with fILD. A total of 145 fILD patients were enrolled and treated with either INOpulse® at a dose of iNO45 or a placebo. The primary endpoint was the change in moderate to vigorous physical activity (MVPA) as measured by actigraphy after 16 weeks of chronic treatment.

The trial did not meet its primary endpoint, with iNO45 performing worse than placebo by 5.49 minutes per day (p=0.2646). The secondary endpoints demonstrated minimal difference between the two groups with none approaching statistical significance. Overall, INOpulse® was well-tolerated with no safety concerns, consistent with what has been observed in the prior Phase 2 studies.

Key REBUILD clinical trial secondary endpoints and safety outputs assessed over 16 weeks of blinded treatment included:

- Overall Activity showed 3.51 count/min benefit in favor of iNO45 (p=0.8572)
- 6 Minute Walk Distance showed 0.19 meter benefit in favor of iNO45 (p=0.9866)
- Patient reported outcomes (St. George's Respiratory Questionnaire and UCSD Shortness of Breath) were slightly in favor of placebo, while time to event assessments (Clinical Worsening, Clinical Deterioration and Clinical Improvement) showed little difference and none were statistically significant
- Subjects with treatment emergent adverse events was slightly in favor of placebo (84.0% vs 74.3%)
- Subjects with serious treatment emergent adverse events was balanced (20% vs 21.4%)
- Deaths were balanced (4.0% vs 4.3%)

"The REBUILD study did not match the outcomes we saw in the exploratory Phase 2 study in this patient population; however, the overall outcome of this pivotal validation study is conclusive and we do not see a path forward for continuing the REBUILD trial," said Peter Fernandes, Bellerophon's Chief Executive Officer. "On behalf of Bellerophon, I would like to thank all the patients, clinical trial sites, and investigators for participating and supporting the conduct of this pivotal study, allowing us to bring closure to the REBUILD clinical study."

For more information on the REBUILD Phase 3 clinical study of INOpulse for the treatment of fILD, please visit ClinicalTrials.gov and reference Identifier NCT0326710.

Conference Call and Webcast Information

Bellerophon management will host a conference call and webcst with slides today at 8:30 AM ET. The dial-in number for the conference call is 877-407-0792 (U.S./Canada) or 201-689-8263 (international). The conference ID for all callers is 13739289. The live webcast and replay may be accessed at https://viavid.webcasts.com/starthere.jsp?ei=1619849&tp_key=d528204b2c.

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.

Contacts
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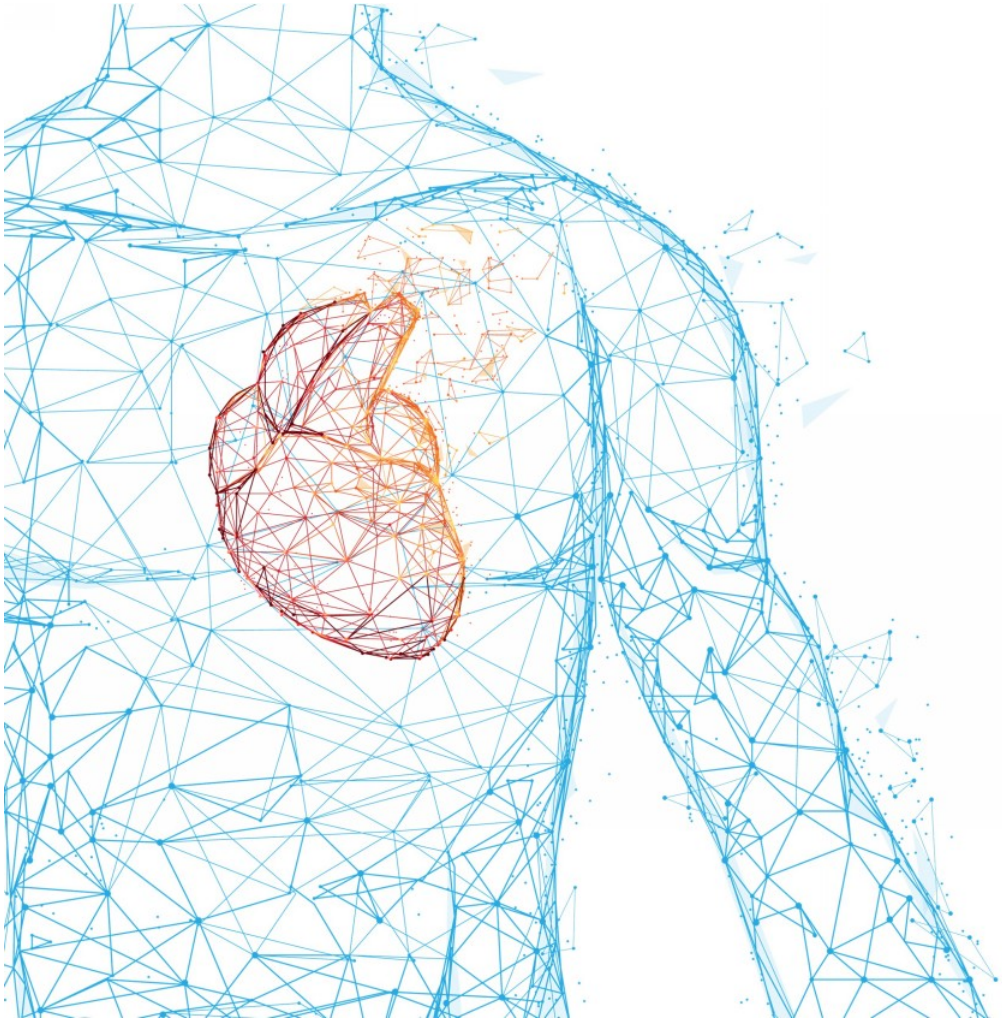
Exhibit 99.2



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Conference Call I June 5, 202

Forward Looking Statements

This presentation contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of hist in this presentation, including statements regarding our strategy, future operations, future financial position, future revenues, projected costs, objectives of management, are forward-looking statements. The words “anticipate,” “believe,” “estimate,” “expect,” “intend,” “may,” “plan,” “predi “potential,” “will,” “would,” “could,” “should,” “continue,” and similar expressions are intended to identify forward-looking statements, although n statements contain these identifying words. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and e in the forward-looking statements we make due to a number of important factors, including risks and uncertainties relating to: INOpulse® not prov treatment or approved for marketing by the FDA, the timing and outcomes of our ongoing and expected clinical trials for our product can successfully develop, commercialize and market any of our product candidates; our ability to obtain, maintain and enforce intellectual property ri reliance on third parties; our ability to obtain necessary financing; and those risk factors discussed in the “Risk Factors” section and elsewhere in 10-K and other periodic filings we make with the SEC.

All forward-looking statements contained in this presentation reflect our current views with respect to future events. We assume no obligation, applicable law, to update any forward-looking statements publicly, or to update the reasons why actual results could differ materially from tho forward-looking statements, even if new information becomes available in the future.

Pivotal Phase 3 Trial Design

REBUILD Demographics

REE

Demographics were balanced between the arms

	INO45	Placebo
Total Patients	75	70
• **Intermediate/High Probability of PH**	31 (41.3%)	29 (41.4%)
• **Low Probability of PH**	44 (58.7%)	41 (58.6%)
Age – Mean (SD)	67.8 (9.5)	68.7 (9.4)
Male (%)	64.0%	60.0%
Race (%)		
• **White**	81.3%	80.0%
• **Black or African American**	10.7%	14.3%
• **Asian**	2.7%	2.9%
• **Other**	5.3%	2.9%
BMI – Mean (SD)	29.20 (4.87)	29.41 (4.36)
Baseline MVPA – Mean (SD)	66.3 (46.8)	67.9 (53.4)
Baseline 6 minute walk distance – Mean (SD)	267.3 (69.2)	266.3 (75.9)

MVPA in minutes per day; 6 minute walk distance in meters

REBUILD Primary Endpoint (MVPA)

REB

Trial did not meet its primary endpoint of change in MVPA (moderate to vigorous physical a

		iNO45	Placebo	Placebo Co
Change from Baseline	LS Mean (SE)	-9.22 (3.51) min/day	-3.74 (3.76) min/day	m (p=

Analysis based on all randomized subjects who received at least one dose of study treatment (defined as minimum use of 12 hours); Statistical analysis are calc
(mixed model repeat measures) including the treatment group, visit, treatment-by-visit interaction, stratification factors (PH, CTD, PDE5) and baseline as fixed e

*p-value calculated based MMRM analysis of log-transformed MVPA as specified in statistical analysis plan

REBUILD Secondary Endpoints

REE

Minimal difference between the two groups

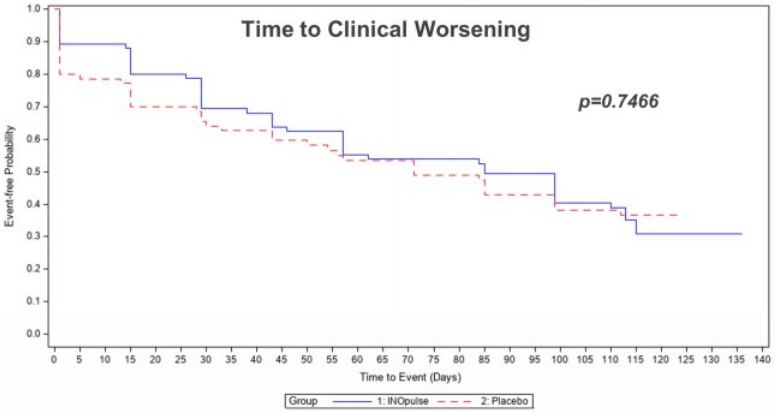
Endpoint	INO45	Placebo	Placebo Corrected Change	p
Overall Activity	-74.36 counts/min	-77.88 counts/min	+3.51 count/min	0
UCSD SOBQ	+4.27 points	-0.25 points	+4.52 points	0
SGRQ – Total	+4.83 points	+3.97 points	+0.86 points	0
SGRQ – Activity	+4.77 points	+1.97 points	+2.79 points	0
SGRQ – Impacts	+5.21 points	+4.12 points	+1.09 points	0
6 minute walk distance	-12.36 meters	-12.54 meters	+0.19 meters	0

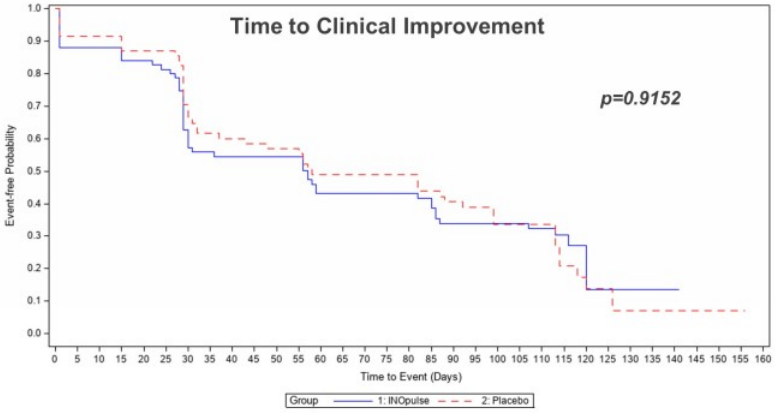
Analysis based on all randomized subjects who received at least one dose of study treatment (defined as minimum use of 12 hours); Statistical analysis are calc
(mixed model repeat measures) including the treatment group, visit, treatment-by-visit interaction, stratification factors (PH, CTD, PDE5) and baseline as fixed ef

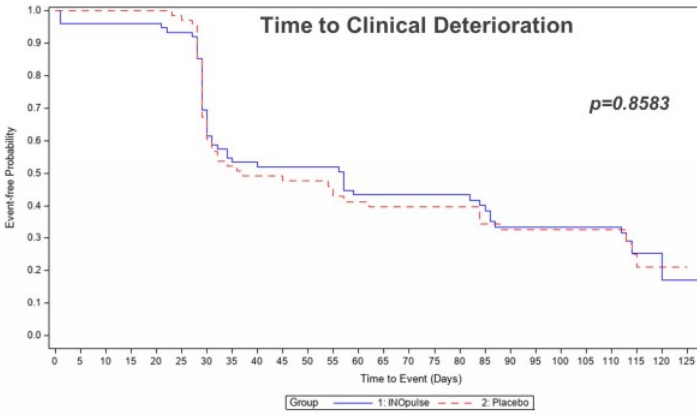
*p-value calculated based MMRM analysis of log-transformed MVPA as specified in statistical analysis plan

UCSD SOBQ (University of California Shortness of Breath Questionnaire); SGRQ (St. George's Respiratory Questionnaire); higher scores indicate deterioration

REBUILD Secondary Endpoints (time to event)







Time to event, defined as first event, otherwise censored to the end date
Log-Rank p-value is calculated from log rank test comparing INOpulse tre

REBUILD Safety Assessment

REE

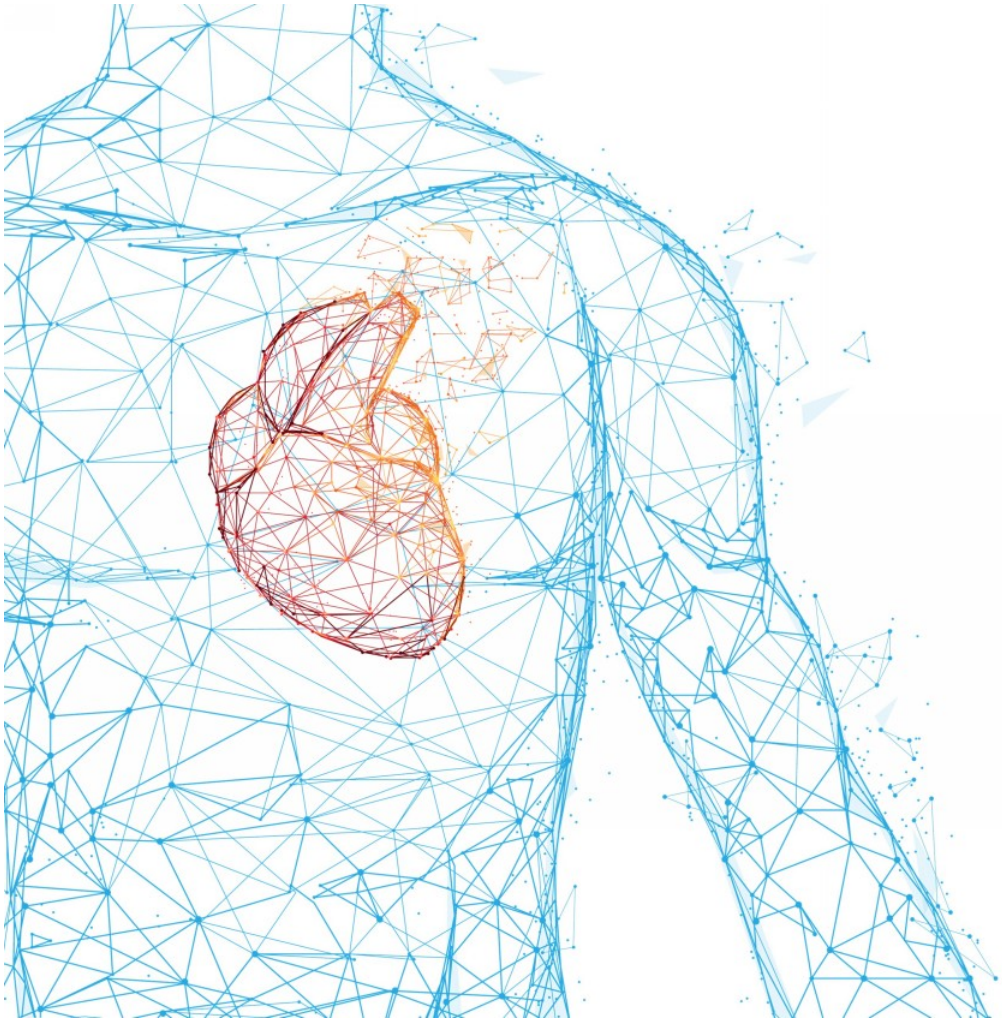
Overall Safety profile was balanced

	INO45	Placebo
Subjects with TEAE	84.0%	74.3%
Subject with Serious TEAE	20.0%	21.4%
Death	4.0%	4.3%

Safety analysis based on all subjects who received at least one dose post randomization (defined as exposure to INOpulse of any duration) of treatment interver

TEAE (treatment emergent adverse event) is defined as an AE with onset after the administration of treatment intervention through the end of the study or any e at baseline but worsened in intensity or was subsequently considered drug-related by the investigator through the end of the study.

If a subject experienced more than 1 event in a given category, that subject is counted only once in that category.



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