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 14, 2022

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 2.02. Results of Operations and Financial Condition.

On November 14, 2022, Bellerophon Therapeutics, Inc. issued a press release announcing its financial and operational results for the three and nine months ended September 30, 2022. The full text of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Current Report on Form 8-K (including Exhibit 99.1) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits:

Exhibit No.	Description
99.1	Press Release dated November 14, 2022 (furnished and not filed for purposes of Item 2.02)
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: November 14, 2022

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

Bellerophon Provides Clinical Program Update and Reports Third Quarter 2022 Financial Results

- *Ongoing INOpulse® REBUILD Phase 3 trial enrollment completion expected in the first quarter of 2023, with pivotal top-line data readout anticipated in the third quarter of 2023*

WARREN, N.J., November 14, 2022 – Bellerophon Therapeutics, Inc. (Nasdaq: BLPH) ("Bellerophon" or the "Company"), a clinical-stage biotherapeutics company focused on developing treatments for cardiopulmonary diseases, today provided a clinical program update and reported financial results for the third quarter ended September 30, 2022.

"We continue to achieve important progress in advancing the ongoing REBUILD Phase 3 trial of INOpulse® for the treatment of fibrotic Interstitial Lung Disease (fILD)," said Naseem Amin, M.D., Chairman of Bellerophon's Board of Directors.

"With the recent U.S. Food and Drug Administration (FDA) acceptance of the reduction in the study sample size, we are well positioned to accelerate the completion of the REBUILD study, which is now approximately 85% enrolled. We expect that enrollment will conclude in the first quarter of 2023, with the reporting of pivotal top-line data in third quarter of 2023," said Peter Fernandes, Bellerophon's Principal Executive Officer.

Clinical Program Highlights:

Fibrotic Interstitial Lung Disease (fILD)

- **REBUILD Phase 3 Study**: Phase 3 REBUILD registrational study enrollment of INOpulse for the treatment of fILD is approaching completion. The reduced study size is 140 fILD patients who will be treated with either INOpulse at a dose of iNO45 or a placebo. The new study size does not impact the trial's principal objective or endpoints and maintains power of >90% (p-value < 0.01) for the primary endpoint of Moderate to Vigorous Physical Activity (MVPA) based on the effect size observed in Phase 2. If approved, INOpulse would become the first therapy to treat a broad fILD population that includes patients at low-, intermediate- and high-risk of pulmonary hypertension. Following the evaluation of baseline MVPA characteristics, as measured by actigraphy, compliance to treatment, and review of safety data of randomized subjects in the ongoing Phase 3 REBUILD study, the trial's independent Data Monitoring Committee (DMC) supported reducing the target study size from 300 to 140 subjects.

  The Phase 3 program builds on positive top-line results from the Company's previously reported Phase 2 studies for INOpulse for the treatment of fILD which showed benefits in multiple cardiopulmonary parameters, including pulmonary vascular resistance and improvement in MVPA.

Pulmonary Hypertension-Sarcoidosis (PH-Sarc)

- **Phase 2 Clinical Study:** In December 2021, Bellerophon reported positive top-line data from the completed Phase 2 dose escalation study of INOpulse evaluating the acute hemodynamic benefit of INOpulse via right heart catheterization for the treatment of pulmonary hypertension associated with sarcoidosis (PH-Sarc). PH-Sarc is an unmet medical need with no approved therapies and a median survival of approximately five years after diagnosis. The Phase 2 trial was designed as a proof-of-concept study to determine if iNO could demonstrate hemodynamic benefit in PH-Sarc.

All eight 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. 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.

Based on the results of the acute dose escalation study, Bellerophon designed and submitted to the FDA a proposed exploratory Phase 2 double-blinded placebo-controlled study to investigate the safety and efficacy of iNO45 dosed chronically for six months in patients with PH-Sarc. Subsequently, the Company received FDA clearance to conduct the study and the Company is currently assessing the next steps for the study.

Third Quarter Ended September 30, 2022, Financial Results:
For the three months ended September 30, 2022, the Company reported a net loss of $5.1 million, or $(0.53) per basic and diluted share, compared to a net loss of $4.6 million, or $(0.49) per basic and diluted share, for the three months ended September 30, 2021.

Research and development expenses for the three months ended September 30, 2022, were $3.8 million, compared to $3.0 million in the prior year period. The increase was primarily due to the ongoing Phase 3 fILD trial.

General and administrative expenses for the three months ended September 30, 2022, were $1.4 million, as compared to $1.8 million in the prior year period. The decrease was primarily due to due to fewer labor, and stock-based compensation costs.

Nine Months Ended September 30, 2022, Financial Results:
For the nine months ended September 30, 2022, the Company reported a net loss of $14.8 million, or $(1.55) per basic and diluted share, compared to a net loss of $13.5 million, or $(1.42) per basic and diluted share, in the nine months ended September 30, 2021.

Research and development expenses for the nine months ended September 30, 2022 were $12.6 million, compared to $9.9 million in the prior year period. The increase was primarily due to the ongoing Phase 3 fILD trial.

General and administrative expenses for the nine months ended September 30, 2022 were $4.7 million, compared to $6.0 million in the prior year period. The decrease was primarily due to lower consulting, labor, and stock-based compensation costs.

Balance Sheet
As of September 30, 2022, the Company had unrestricted cash and cash equivalents of $11.3 million, compared to unrestricted cash and cash equivalents of $24.7 million on December 31, 2021.

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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BELLEROPHON THERAPEUTICS, INC.
Condensed Consolidated Balance Sheets
(Amounts in thousands, except share and per share data)

	September 30, 2022 (Unaudited)	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 11,317	$ 24,736
Restricted cash	404	103
Prepaid expenses and other current assets	338	620
Total current assets	12,059	25,459
Restricted cash, non-current	—	300
Right of use assets, net	357	863
Property and equipment, net	6	67
Other non-current assets	186	186
Total assets	$ 12,608	$ 26,875
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,525	$ 1,192
Accrued research and development	1,888	1,397
Accrued expenses	1,370	1,711
Current portion of operating lease liabilities	396	752
Total current liabilities	5,179	5,052
Long term operating lease liabilities	—	203
Common stock warrant liability	1	1
Total liabilities	5,180	5,256
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.01 par value per share; 200,000,000 shares authorized and 9,545,451 and 9,545,451 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	95	95
Preferred stock, $0.01 par value per share; 5,000,000 shares authorized, zero shares issued and outstanding at September 30, 2022 and December 31, 2021	—	—
Additional paid-in capital	254,395	253,771
Accumulated deficit	(247,062)	(232,247)
Total stockholders' equity	7,428	21,619
Total liabilities and stockholders' equity	$ 12,608	$ 26,875

BELLEROPHON THERAPEUTICS, INC.
Condensed Consolidated Statement of Operations and Comprehensive Loss (Unaudited)
(Amounts in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 3,750	$ 3,030	$ 12,646	$ 9,853
General and administrative	1,366	1,773	4,653	6,035
Total operating expenses	5,116	4,803	17,299	15,888
Loss from operations	(5,116)	(4,803)	(17,299)	(15,888)
Change in fair value of common stock warrant liability	—	167	—	600
Interest and other income, net	47	2	67	4
Pre-tax loss	(5,069)	(4,634)	(17,232)	(15,284)
Income tax benefit	—	—	2,417	1,800
Net loss and comprehensive loss	$ (5,069)	$ (4,634)	$ (14,815)	$ (13,484)
Weighted average shares outstanding:				
Basic	9,545,451	9,506,419	9,545,451	9,501,428
Diluted	9,545,451	9,506,419	9,545,451	9,501,428
Net loss per share:				
Basic	$ (0.53)	$ (0.49)	$ (1.55)	$ (1.42)
Diluted	$ (0.53)	$ (0.49)	$ (1.55)	$ (1.42)