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): August 15, 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 August 15, 2022, Bellerophon Therapeutics, Inc. issued a press release announcing its financial and operational results for the three and six months ended June 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 August 15, 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: August 15, 2022

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

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

WARREN, N.J., August 15, 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 second quarter ended June 30, 2022.

"The Bellerophon team continues to advance our late-stage INOpulse® inhaled nitric oxide therapy platform for the treatment of fibrotic interstitial lung disease, or fILD, and pulmonary hypertension associated with sarcoidosis, or PH-Sarc," said Naseem Amin, M.D., Chairman of Bellerophon's Board of Directors. "Enrollment is steadily proceeding in our Phase 3 REBUILD study in fILD, which is evaluating the change in moderate to vigorous physical activity following treatment with INOpulse. In addition, we recently received clearance from the U.S. Food and Drug Administration (FDA) to conduct a follow-up exploratory Phase 2 chronic treatment clinical trial to evaluate the safety and efficacy of INOpulse in PH-Sarc patients."

Clinical Program Highlights:

Fibrotic Interstitial Lung Disease (fILD)

- **REBUILD Phase 3 Study**: Enrollment is continuing in Bellerophon's Phase 3 REBUILD registrational study of INOpulse for the treatment of fILD. The REBUILD study plans to enroll 300 fILD patients who will be treated with either INOpulse at a dose of iNO45 or placebo. The primary endpoint is change in moderate to vigorous physical activity (MVPA). 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.

  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. Acute treatment with INOpulse showed benefit in multiple cardiopulmonary parameters, including pulmonary vascular resistance, which improved by 21%, and mean pulmonary arterial pressure, which improved by 12%. Chronic treatment with INOpulse at a dose of iNO45 assessed over four months showed an average improvement in MVPA of 20% as compared to placebo. The improvements in MVPA were supported by benefits in overall activity, as well as two patient reported questionnaires, the University of California, San Diego Shortness of Breath Questionnaire and the St. George's Respiratory Questionnaire.

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 inhaled nitric oxide/INOpulse dosed chronically for six months in patients with PH-Sarc. Subsequently, the Company received FDA clearance to conduct the study.

Corporate Update:

- Dr. Robert Baughman M.D., Professor of Medicine at the University of Cincinnati, was the lead author for a poster presented at the American Thoracic Society 2022 International Conference summarizing the 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 PH-Sarc.

Second Quarter Ended June 30, 2022 Financial Results:
For the three months ended June 30, 2022, the Company reported a net loss of $4.1 million, or $(0.43) per basic and diluted share, compared to a net loss of $3.4 million, or $(0.36) per basic and diluted share, for the three months ended June 30, 2021.

Research and development expenses for the three months ended June 30, 2022 were $4.5 million, compared to $3.2 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 June 30, 2022 were $2.1 million, essentially flat as compared to $2.0 million in the prior year period.

Six Months Ended June 30, 2022 Financial Results:
For the six months ended June 30, 2022, the Company reported a net loss of $9.7 million, or $(1.02) per basic and diluted share, compared to a net loss of $8.9 million, or $(0.93) per basic and diluted share, in the six months ended June 30, 2021.

Research and development expenses for the six months ended June 30, 2022 were $8.9 million, compared to $6.8 million in the prior year period. The increase was primarily due to the ongoing Phase 3 fILD trial.

General and administrative expenses for the six months ended June 30, 2022 were $3.3 million, compared to $4.3 million in the prior year period. The decrease was primarily due to lower consulting, labor and stock-based compensation costs.

Balance Sheet
As of June 30, 2022, the Company had cash and cash equivalents of $16.3 million, compared to cash and cash equivalents of $24.7 million at 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.
Consolidated Balance Sheets
(Amounts in thousands, except share and per share data)

	June 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 16,328	$ 24,736
Restricted cash	403	103
Prepaid expenses and other current assets	257	620
Total current assets	16,988	25,459
Restricted cash, non-current	—	300
Right of use assets, net	529	863
Property and equipment, net	27	67
Other non-current assets	186	186
Total assets	$ 17,730	$ 26,875
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,007	$ 1,192
Accrued research and development	1,512	1,397
Accrued expenses	1,344	1,711
Current portion of operating lease liabilities	586	752
Total current liabilities	5,449	5,052
Long term operating lease liabilities	—	203
Common stock warrant liability	1	1
Total liabilities	5,450	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 June 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 June 30, 2022 and December 31, 2021	—	—
Additional paid-in capital	254,178	253,771
Accumulated deficit	(241,993)	(232,247)
Total stockholders' equity	12,280	21,619
Total liabilities and stockholders' equity	$ 17,730	$ 26,875

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 4,488	$ 3,239	$ 8,897	$ 6,823
General and administrative	2,053	1,987	3,286	4,262
Total operating expenses	6,541	5,226	12,183	11,085
Loss from operations	(6,541)	(5,226)	(12,183)	(11,085)
Change in fair value of common stock warrant liability	—	36	—	433
Interest and other income, net	19	1	20	2
Pre-tax loss	(6,522)	(5,189)	(12,163)	(10,650)
Income tax benefit	2,417	1,800	2,417	1,800
Net loss and comprehensive loss	$ (4,105)	$ (3,389)	$ (9,746)	$ (8,850)
Weighted average shares outstanding:				
Basic	9,545,451	9,506,419	9,545,451	9,498,892
Diluted	9,545,451	9,506,419	9,545,451	9,498,892
Net loss per share:				
Basic	$ (0.43)	$ (0.36)	$ (1.02)	$ (0.93)
Diluted	$ (0.43)	$ (0.36)	$ (1.02)	$ (0.93)