
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 15, 2021

Bellerophon Therapeutics, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction of
Incorporation)

001-36845
(Commission
File Number)

47-3116175
(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.
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Item 2.02. Results of Operations and Financial Condition.

On November 15, 2021, Bellerophon Therapeutics, Inc. issued a press release announcing its financial and operational results for the three and nine months ended September 30, 2021. 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:

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated November 15, 2021 (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 15, 2021

By: /s/ Nicholas Laccona

Name: Nicholas Laccona

Title: Principal Financial Officer and Principal
Accounting Officer



Bellerophon Provides Clinical Program Update and Reports Third Quarter 2021 Financial Results

WARREN, N.J., November 15, 2021 – 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, 2021.

“We remain focused on advancing the development of our INOpulse® inhaled nitric oxide therapy in fibrotic interstitial lung disease, or fILD, and sarcoidosis, or PH-Sarc, which are two areas of severe unmet medical need,” said Naseem Amin, M.D., Chairman of Bellerophon’s Board of Directors. “Our pivotal Phase 3 REBUILD study in fILD is continuing to enroll. Importantly, INOpulse is the first potential therapy to treat a broad fILD population that includes patients at low, intermediate, and high risk of associated pulmonary hypertension. In addition, we are pleased to have concluded enrollment in our PH-Sarc Phase 2 dose escalation study and expect the availability of top-line results before the end of this year. Finally, with \$28.7 million in cash and cash equivalents, we believe that we are in a strong financial position to continue advancing our late-stage development programs.”

Clinical Program Highlights:

fILD

- **REBUILD Phase 3 Study:** In December 2020, Bellerophon announced that the first patient had been enrolled in its 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:** Bellerophon has concluded enrollment in a Phase 2 dose escalation study in PH-Sarc and anticipates the availability of top-line data by the end of this year. The safety and efficacy study is assessing the acute hemodynamic benefit of INOpulse via right heart catheterization. PH-Sarc is an unmet medical need with no approved therapies, and a median survival of approximately five years after diagnosis.

Corporate Update:

- In September 2021, the Company presented at the H.C. Wainwright 23rd Annual Global Investment Conference.

Third Quarter Ended September 30, 2021 Financial Results:

For the three months ended September 30, 2021, the Company reported an operating loss of \$4.8 million, compared to \$8.3 million in the three months ended September 30, 2020.

For the three months ended September 30, 2021, the Company reported a net loss of \$4.6 million, or \$(0.49) per basic and diluted share, compared to a net loss of \$7.9 million, or \$(0.84) per basic and diluted share, for the three months ended September 30, 2020.

Research and development expenses for the three months ended September 30, 2021 were \$3.0 million, compared to \$6.1 million for the three months ended September 30, 2020. The decrease was primarily due to the close-out of activities related to the development of INOpulse for the treatment of COVID-19.

General and administrative expenses for the three months ended September 30, 2021 were \$1.8 million, compared to \$2.2 million for the three months ended September 30, 2020. The decrease was primarily due to a decrease in consulting and stock-based compensation costs.

Nine Months Ended September 30, 2021 Financial Results:

For the nine months ended September 30, 2021, the Company reported an operating loss of \$15.9 million, compared to \$18.1 million in the nine months ended September 30, 2020.

For the nine months ended September 30, 2021, the Company reported a net loss of \$13.5 million, or \$(1.42) per basic and diluted share, compared to a net loss of \$16.7 million, or \$(2.31) per basic and diluted share, for the nine months ended September 30, 2020.

Net loss for the nine months ended September 30, 2021 included an income of \$0.6 million due to a change in fair value of the Company's common stock warrant liability, as compared to an expense of \$0.8 million for the nine months ended September 30, 2020.

Research and development expenses for the nine months ended September 30, 2021 were \$9.9 million, compared to \$11.8 million for the nine months ended September 30, 2020. The decrease was primarily due to the close-out of activities related to the development of INOpulse for the treatment of COVID-19.

General and administrative expenses for the nine months ended September 30, 2021 were \$6.0 million, compared to \$6.4 million for the nine months ended September 30, 2020. The decrease was primarily due to a decrease in consulting and stock-based compensation costs.

Balance Sheet

As of September 30, 2021, the Company had cash and cash equivalents of \$28.7 million, compared to \$47.6 million at December 31, 2020.

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

	<u>September 30, 2021</u>	<u>December 31, 2020</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 28,714	\$ 47,557
Restricted cash	103	103
Prepaid expenses and other current assets	898	420
Total current assets	<u>29,715</u>	<u>48,080</u>
Restricted cash, non-current	300	300
Right of use assets, net	1,026	1,504
Property and equipment, net	88	169
Other non-current assets	186	186
Total assets	<u>\$ 31,315</u>	<u>\$ 50,239</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 1,278	\$ 3,725
Accrued research and development	1,314	3,699
Accrued expenses	1,795	2,305
Current portion of operating lease liabilities	740	704
Total current liabilities	<u>5,127</u>	<u>10,433</u>
Long term operating lease liabilities	396	956
Common stock warrant liability	1	601
Total liabilities	<u>5,524</u>	<u>11,990</u>
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.01 par value per share; 200,000,000 shares authorized and 9,506,419 and 9,491,111 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	95	95
Preferred stock, \$0.01 par value per share; 5,000,000 shares authorized, zero shares issued and outstanding at September 30, 2021 and December 31, 2020	—	—
Additional paid-in capital	253,671	252,645
Accumulated deficit	(227,975)	(214,491)
Total stockholders' equity	<u>25,791</u>	<u>38,249</u>
Total liabilities and stockholders' equity	<u>\$ 31,315</u>	<u>\$ 50,239</u>

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	\$ 3,030	\$ 6,065	\$ 9,853	\$ 11,754
General and administrative	1,773	2,196	6,035	6,376
Total operating expenses	4,803	8,261	15,888	18,130
Loss from operations	(4,803)	(8,261)	(15,888)	(18,130)
Change in fair value of common stock warrant liability	167	319	600	(768)
Interest and other income, net	2	9	4	50
Pre-tax loss	(4,634)	(7,933)	(15,284)	(18,848)
Income tax benefit	—	—	1,800	2,125
Net loss	\$ (4,634)	\$ (7,933)	\$ (13,484)	\$ (16,723)
Weighted average shares outstanding:				
Basic	9,506,419	9,491,111	9,501,428	7,228,349
Diluted	9,506,419	9,491,111	9,501,428	7,228,349
Net loss per share:				
Basic	\$ (0.49)	\$ (0.84)	\$ (1.42)	\$ (2.31)
Diluted	\$ (0.49)	\$ (0.84)	\$ (1.42)	\$ (2.31)