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): March 11, 2021

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 March 11, 2021, Bellerophon Therapeutics, Inc. issued a press release announcing its financial and operational results for the year ended December 31, 2020. 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 March 11, 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: March 11, 2021

By: /s/ Assaf Korner
Name: Assaf Korner
Title: Chief Financial Officer

Bellerophon Provides Clinical Program Update and Reports Fourth Quarter and Full-Year 2020 Financial Results

WARREN, N.J., March 11, 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 fourth quarter and year ended December 31, 2020.

"Bellerophon continues to make significant progress in advancing its INOpulse® inhaled nitric oxide therapy in multiple indications," said Fabian Tenenbaum, Chief Executive Officer of Bellerophon. "In December 2020, we announced that the first patient had been enrolled in our pivotal Phase 3 REBUILD study for fibrotic interstitial lung disease (fILD) patients at risk of associated pulmonary hypertension. In addition, we expect top-line results from our Phase 2 dose escalation study of INOpulse in sarcoidosis (PH-Sarc) this year."

"Our balance sheet continues to be strong and provides us with the resources to support our ongoing clinical programs in fILD and PH-Sarc," concluded Mr. Tenenbaum.

Clinical Program Highlights:

fILD

- **REBUILD Phase 3 Study**: In December, 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 will 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 is continuing enrollment in a Phase 2 dose escalation study in PH-Sarc and anticipates the availability of top-line data during 2021. 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 a median survival of approximately five years after diagnosis. Similar to PH associated with fILD, there are currently no approved therapies to treat PH-Sarc.

COVID-19 (Coronavirus)

- **COViNOX Phase 3 Study:** The randomized, placebo-controlled COViNOX study evaluated the efficacy and safety of the investigational INOpulse therapy in patients diagnosed with COVID-19 who require supplemental oxygen. In November 2020, the Company announced the results of a pre-specified interim analysis conducted by

an independent Data Monitoring Committee (DMC). Based on the recommendation of the DMC, the COViNOX study was placed on clinical hold. Upon completion of the protocol defined monitoring period, the safety and efficacy analysis of the full 191 patients was reviewed by the DMC, and the DMC determined that there were no safety concerns attributed to INOpulse. However, based on the absence of an efficacy signal and the availability of multiple vaccines, the Company will not be continuing the COViNOX trial.

Corporate Update:

- In 2020, a patent covering the shape of the nitric oxide pulse and valve configuration of our proprietary INOpulse drug delivery device was issued in the U.S. with an expiry date of June 2039. The issued patent builds upon the Company's portfolio of over 100 issued and pending patent applications and the Orphan Drug Designation for nitric oxide for the treatment of idiopathic pulmonary fibrosis in the U.S., which can provide up to 7 years of exclusivity if the product is approved.
- In November 2020, the Company presented at the H.C. Wainwright 6th Annual Israel Conference.
- In January 2021, Belleophon presented at the H.C. Wainwright Virtual BioConnect 2021 Conference.

Fourth Quarter Financial Results:

For the fourth quarter ended December 31, 2020, the Company reported a net loss of $8.0 million, or $(0.84) per share, compared to a net loss of $4.1 million, or $(0.89) per share in the fourth quarter ended December 31, 2019.

Net loss for the three months ended December 31, 2020 included income of $0.4 million due to a change in fair value of the Company's common stock warrant liability, as compared to $0.2 million in the fourth quarter of 2019.

Research and development expenses for the fourth quarter ended December 31, 2020 were $6.1 million, compared to $2.8 million in the prior year period. The increase was primarily due to costs related to the Phase 3 COVID-19 and fILD trials.

General and administrative expenses for the fourth quarter ended December 31, 2020 were $2.0 million, compared to $1.5 million in the prior year period. The increase was primarily due to intellectual property, consulting, and labor costs.

2020 Year End Financial Results:

For the year ended December 31, 2020, the Company reported a net loss of $24.7 million, or $(3.17) per share, compared to net loss of $13.3 million, or $(2.95) per share, in the year ended December 31, 2019.

Net loss for the year ended December 31, 2020 included an expense of $0.3 million due to a change in fair value of the Company's common stock warrant liability, as compared to an income of $2.7 million in the year ended December 31, 2019.

Research and development expenses for the year ended of December 31, 2020 were $17.9 million, compared to $11.0 million in the year ended December 31, 2019. The increase was primarily due to costs related to the Phase 3 COVID-19 and fILD trials.

General and administrative expenses for the year ended December 31, 2020 were $8.4 million, compared to $6.4 million for the year ended December 31, 2019. The increase was primarily due to intellectual property, consulting, and labor costs.

Balance Sheet

As of December 31, 2020, the Company had cash and cash equivalents of $47.6 million, compared to cash and cash equivalents of $9.9 million at December 31, 2019.

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)

	December 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 47,557	$ 9,874
Restricted cash	103	103
Prepaid expenses and other current assets	420	405
Total current assets	48,080	10,382
Restricted cash, non-current	300	300
Right of use assets, net	1,504	2,110
Property and equipment, net	169	316
Other non-current assets	186	—
Total assets	$ 50,239	$ 13,108
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,725	$ 3,106
Accrued research and development	3,699	2,117
Accrued expenses	2,305	1,703
Current portion of operating lease liabilities	704	658
Total current liabilities	10,433	7,584
Long term operating lease liabilities	956	1,659
Common stock warrant liability	601	274
Total liabilities	11,990	9,517
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.01 par value per share; 200,000,000 shares authorized and 9,491,111 and 4,580,127 shares issued and outstanding at December 31, 2020 and December 31, 2019, respectively	95	46
Preferred stock, $0.01 par value per share; 5,000,000 shares authorized, zero shares issued and outstanding at December 31, 2020 and December 31, 2019	—	—
Additional paid-in capital	252,645	193,308
Accumulated deficit	(214,491)	(189,763)
Total stockholders' equity	38,249	3,591
Total liabilities and stockholders' equity	$ 50,239	$ 13,108

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

	Year Ended December 31,	
	2020	2019
Operating expenses:		
Research and development	$ 17,890	$ 11,032
General and administrative	8,386	6,441
Total operating expenses	26,276	17,473
Loss from operations	(26,276)	(17,473)
Change in fair value of common stock warrant liability	(327)	2,682
Warrant amendment charge	—	(674)
Interest income and financing expenses, net	(250)	397
Pre-tax loss	(26,853)	(15,068)
Income tax benefit	2,125	1,801
Net (loss) income	$ (24,728)	$ (13,267)
Weighted average shares outstanding:		
Basic	7,797,130	4,503,375
Diluted	7,797,130	4,503,375
Net (loss) income per share:		
Basic	$ (3.17)	$ (2.95)
Diluted	$ (3.17)	$ (2.95)