# 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): May 9, 2019

# 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**<br>**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):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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).

x Emerging growth company

x 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.

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 Global Market** |

**Item 2.02. Results of Operations and Financial Condition.**

On May 9, 2019, Bellerophon Therapeutics, Inc. issued a press release announcing its financial and operational results for the three months ended March 31, 2019. 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:

The following exhibit relating to Item 2.02 shall be deemed to be furnished, and not filed:

99.1 Press Release dated May 9, 2019.

## EXHIBIT INDEX

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release dated May 9, 2019 (furnished and not filed for purposes of Item 2.02) |

## 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: May 9, 2019

By: /s/ Assaf Korner

Name: Assaf Korner
Title: Chief Financial Officer

# Bellerophon Provides Business Update and Reports First Quarter 2019 Financial Results

**WARREN, N.J., May 9, 2019** -- Bellerophon Therapeutics, Inc. (Nasdaq: BLPH) ("Bellerophon" or the "Company"), a clinical-stage biotherapeutics company, today provided a business update and reported financial results for the first quarter ended March 31, 2019.

"Bellerophon has achieved substantial progress in the beginning of 2019 with additional important milestones expected later this year," said Fabian Tenenbaum, Chief Executive Officer of Bellerophon. "We reported positive results from Cohort 1 of our ongoing Phase 2b randomized, double-blind, placebo-controlled clinical study (iNO-PF) of INOpulse® in patients with Pulmonary Hypertension associated with Interstitial Lung Disease (PH-ILD). The study demonstrated a clinically and statistically significant improvement in moderate to vigorous physical activity (MVPA), supporting an agreement with the U.S. Food and Drug Administration ("FDA") on the regulatory approval pathway for INOpulse in PH-ILD. Importantly, the FDA agreed with our proposal that MVPA will serve as the primary endpoint and that the ongoing Phase 2b study will be amended to a Phase 2/3 trial, providing a seamless transition into Cohort 3, which will serve as the pivotal Phase 3 trial for an efficient development program."

"Cohort 2 will assess a higher dose and longer duration of treatment, allowing us to select the optimal dose to be used in the pivotal Cohort 3. Cohort 2 is enrolling well, reflective of the significant interest from physicians in this study, and we expect to report top-line results and initiate the pivotal Phase 3 trial in the second half of 2019," continued Mr. Tenenbaum. "PH-ILD represents a significant unmet need as there are currently no approved therapies for this condition which is characterized by progressive and substantial worsening of outcomes such as physical activity, quality of life and life expectancy. Based on the data generated to date and the alignment with the FDA on the regulatory path forward, we believe INOpulse has the potential to be the first approved drug for this debilitating disease."

"We recently initiated our Phase 2 study to assess the effect of iNO in PH-Sarcoidosis, another debilitating condition with no approved therapies. We also successfully completed a $7 million follow-on offering in January that was anchored by a leading healthcare-focused institutional investor and included significant participation from several members of the Company's Board of Directors. This financing will allow us to complete Cohort 2 and initiate the pivotal Cohort 3 in PH-ILD, as well as support our planned activities through the readout of the ongoing Phase 2 PH-Sarcoidosis study," concluded Mr. Tenenbaum.

**Key Recent Highlights**

- **PH-ILD**: The Company announced positive results from Cohort 1 of its ongoing iNO-PF trial. Cohort 1 included 41 subjects randomized 1:1 to either iNO 30 (30 mcg/kg IBW/hr) or placebo, for a period of 8 weeks of blinded treatment. Subjects on iNO demonstrated improvements in key parameters, including statistically significant improvements in physical activity, as measured by an autonomous wearable activity monitor (actigraphy):
  - MVPA (Minutes of moderate to vigorous physical activity, such as walking, stairs, yardwork, etc.) improved by 34% (8% increase on iNO vs. 26% decrease on placebo; p=0.04).
  - Overall activity improved by 12% (0% change on iNO vs. 12% decrease on placebo; p=0.05).
  - NT-ProBNP improved by 27% (15% increase on iNO vs. 42% increase on placebo). NT-ProBNP is a peptide marker of right ventricular failure, with higher levels indicative of disease worsening.
  - Oxygen saturation improved by 20% (9% improvement on iNO vs. 11% deterioration on placebo).

- Based on these results, Bellerophon reached an agreement with the FDA on the use of MVPA as the primary endpoint in the pivotal Phase 3 study. In addition, the FDA agreed with the Company's proposal that the ongoing Phase 2b study be amended to a seamless Phase 2/3 trial, allowing Bellerophon to continue directly into the final third cohort required for approval.
- Bellerophon is actively recruiting patients in Cohort 2 of its INO-PF trial, which will assess a higher dose (iNO45), as well as a longer duration of treatment to 16 weeks. The Company continues to see strong recruitment activity and support from clinical sites, and top-line data from Cohort 2 are anticipated in the second half of 2019. Bellerophon also expects to initiate Cohort 3 in the second half of 2019.

- **PH-Sarcoidosis:** Bellerophon has initiated a Phase 2 dose escalation study that will assess safety, as well as the hemodynamic benefit of iNO via right heart catheterization in subjects with PH associated with Sarcoidosis. PH-Sarcoidosis is an unmet medical need with a median survival of approximately five years after diagnosis. Similar to PH-ILD and PH-COPD, PH-Sarcoidosis cannot be treated with currently available systemic vasodilators. Top-line results from the study are expected later this year.

- **PH-COPD:** Following positive results from its Phase 2 study for INOpulse in PH-COPD and an agreement with the FDA, Bellerophon finalized the design of a Phase 2b study in PH-COPD. This trial will be a randomized, double-blind, placebo-controlled study that will evaluate multiple clinically relevant endpoints.

**First Quarter Ended March 31, 2019 Financial Results**
For the three months ended March 31, 2019, the Company reported a net loss of $0.8 million, or $(0.01) per share, compared to a net income of $4.1 million, or $0.07 per share, in the three months ended March 31, 2018. On a diluted basis, the Company reported a loss of $(0.01) per share for the three months ended March 31, 2019, compared to a loss of $(0.04) per share in the three months ended March 31, 2018.

Net loss for the three months ended March 31, 2019 included an adjustment of $1.6 million due to a change in fair value of common stock warrant liability, as compared to an adjustment of $7.1 million for the three months ended March 31, 2018.

Research and development expenses for the three months ended March 31, 2019 were $2.3 million compared to $6.4 million in the prior year period. The decrease was primarily due to the conclusion of the INOvation-1 PAH trial, which was partially offset by increased activity in the PH-ILD Phase 2b program.

General and administrative expenses for the three months ended March 31, 2019 were $2.0 million, flat as compared to the prior year period.

**Balance Sheet**
As of March 31, 2019, the Company had cash and cash equivalents of $20.7 million, compared to $16.6 million at December 31, 2018. Cash as of March 31, 2019 included the net proceeds from the $7 million public offering of common stock completed in January 2019, and an additional $1.7 million received in January 2019 from the sale of the Company's tax net operating losses in the State of New Jersey.

**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: 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.**

**Condensed Consolidated Balance Sheets**

(in thousands except share and per share data)

| | As of March 31, 2019 (Unaudited) | As of December 31, 2018 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 20,679 | $ 16,645 |
| Restricted cash | 101 | 101 |
| Prepaid expenses and other current assets | 948 | 650 |
| Total current assets | 21,728 | 17,396 |
| Restricted cash, non-current | 300 | 300 |
| Right of use asset, net | 2,189 | — |
| Property and equipment, net | 576 | 664 |
| Total assets | $ 24,793 | $ 18,360 |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 2,638 | $ 2,755 |
| Accrued research and development | 3,187 | 3,771 |
| Accrued expenses | 885 | 1,031 |
| Current portion of operating lease liability | 547 | — |
| Total current liabilities | 7,257 | 7,539 |
| Long-term operating lease liability | 1,882 | — |
| Common stock warrant liability | 5,349 | 6,965 |
| Total liabilities | 14,488 | 14,504 |
| Commitments and contingencies | | |
| Stockholders' equity: | | |
| Common stock, $0.01 par value per share; 200,000,000 shares authorized, 68,906,765 and 58,679,492 shares issued and outstanding at March 31, 2019 and December 31, 2018 respectively | 689 | 587 |
| Preferred stock, $0.01 par value per share; 5,000,000 shares authorized, zero shares issued and outstanding at March 31, 2019 and December 31, 2018 | — | — |
| Additional paid-in capital | 186,907 | 179,765 |
| Accumulated deficit | (177,291) | (176,496) |
| Total stockholders' equity | 10,305 | 3,856 |
| **Total liabilities and stockholders' equity** | $ 24,793 | $ 18,360 |

**Bellerophon Therapeutics, Inc.**

**Condensed Consolidated Statement of Operations (Unaudited)**

(in thousands except share and per share data)

| | Three Months Ended March 31, | |
|---|---|---|
| | **2019** | **2018** |
| Operating expenses: | | |
| Research and development | $ 2,305 | $ 6,380 |
| General and administrative | 2,037 | 2,112 |
| Total operating expenses | 4,342 | 8,492 |
| Loss from operations | (4,342) | (8,492) |
| Change in fair value of common stock warrant liability | 1,616 | 7,050 |
| Interest income and other, net | 130 | 99 |
| Pre-tax loss | (2,596) | (1,343) |
| Income tax benefit | 1,801 | 5,439 |
| Net (loss) income | $ (795) | $ 4,096 |
| Weighted average shares outstanding: | | |
| Basic | 65,191,635 | 57,059,686 |
| Diluted | 65,191,635 | 72,100,690 |
| Net loss income per share: | | |
| Basic | $ (0.01) | $ 0.07 |
| Diluted | $ (0.01) | $ (0.04) |