# 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 6, 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):

☐ 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 6, 2019, Bellerophon Therapeutics, Inc. issued a press release announcing its financial and operational results for the three and nine months ended September 30, 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 November 6, 2019.

**EXHIBIT INDEX**

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release dated November 6, 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: November 6, 2019

By: /s/ Assaf Korner

Name: Assaf Korner
Title: Chief Financial Officer

Exhibit 99.1

**Bellerophon Provides Business Update and Reports Third Quarter 2019 Financial Results**

**WARREN, N.J., November 6, 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 three and nine months ended September 30, 2019.

"We are encouraged by the clinical and regulatory progress achieved with our INOpulse® program over the past several months, and look forward to reporting top-line results by the end of the year from Cohort 2 of our ongoing Phase 2/3 iNO-PF trial for the treatment of pulmonary hypertension associated with Interstitial Lung Disease (PH-ILD)," said Fabian Tenenbaum, Chief Executive Officer of Bellerophon. "Cohort 1 of iNO-PF, which assessed the lowest dose of 30 mcg/kg IBW/hr (iNO30), previously demonstrated clinically and statistically significant improvements in moderate to vigorous physical activity (MVPA), as well as other actigraphy parameters. Cohort 2, which is fully enrolled, will assess a higher dose of iNO45 over a 16-week treatment evaluation period. We have reached agreement with the U.S. Food and Drug Administration (FDA) on the use of the results from Cohorts 1 and 2 to determine the optimal dose between iNO30 and iNO45 to progress into the pivotal Cohort 3, as well as on the use of MVPA as the study's primary endpoint for approval. We anticipate initiating this pivotal Cohort during the first quarter of 2020."

"In addition, we were pleased to receive Orphan Drug Designation in the third quarter from the FDA for nitric oxide in the treatment of idiopathic pulmonary fibrosis (IPF), a progressive, irreversible and fatal interstitial lung disease. With the clinically meaningful results observed to date in iNO-PF we remain committed to bringing INOpulse to market as the first approved therapy in PH-ILD, a serious unmet medical need," concluded Mr. Tenenbaum.

**Key Recent Highlights**

**PH-ILD:**

**Cohort 1:** Bellerophon presented results from Cohort 1 of iNO-PF, a randomized, double-blind, placebo-controlled clinical study of INOpulse for the treatment of PH-ILD, as a late-breaking abstract oral presentation at the American Thoracic Society 115th International Conference. Additional data from Cohort 1, including (OLE) data, were presented as a late-breaking oral presentation at the CHEST 2019 Annual Meeting.

Cohort 1, the first of 3 cohorts, 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. Top-line data from Cohort 1 demonstrated clinically and statistically significant improvement in MVPA, as well as other physical activity parameters measured by actigraphy, and was safe and well tolerated.

- MVPA (walking, stairs, yardwork, etc.) improved by 34% (8% increase on iNO vs. 26% decrease on placebo; p=0.04)
  - 23% of subjects on INOpulse had a clinically significant improvement in MVPA, compared to 0% of subjects on placebo (placebo corrected difference of 23%)
  - 39% of subjects on INOpulse had a clinically significant decline in MVPA, compared to 71% of subjects on placebo (placebo corrected difference of 32%)
  - Proportion of awake time spent in MVPA improved by 38% (16% increase on INOpulse vs. 22% decrease on placebo; p=0.04)
- Overall activity improved by 12% (stable on INOpulse vs. 12% decrease on placebo; p=0.05)
- Responder analysis:
  - 85% of subjects on placebo declined in MVPA, overall activity and non-sedentary activity
  - 46% of subjects on INOpulse improved in MVPA, 62% in overall activity and 39% in non-sedentary activity (compared to only 15% of subjects on placebo in each category)
- OLE:
  - Collectively, subjects (with an average of 27 weeks of OLE data) demonstrated maintenance of MVPA, overall activity and non-sedentary activity
  - Subjects randomized to active treatment in the blinded portion of the trial continued to maintain their activity levels when transitioning to OLE over 27 weeks of open-label treatment
  - Subjects randomized to placebo in the blinded portion of the trial transitioned from a decline during blinded treatment to stabilization of activity levels (MVPA, overall activity and non-sedentary activity) over 27 weeks of open-label treatment

**Cohort 2:** The Company completed recruitment in Cohort 2, which includes 44 subjects randomized 2:1 to either iNO45 (45 mcg/kg IBW/hr) or placebo. Subjects will complete 16 weeks of blinded treatment on iNO45 vs. placebo, and then continue onto open-label treatment. The Company expects to report top-line results from Cohort 2 by year-end 2019.

**Cohort 3:** The results from Cohorts 1 and 2 will be evaluated to determine the optimal dose between iNO30 and iNO45 to progress into pivotal Phase 3, with MVPA serving as the primary endpoint. The Company anticipates initiating the Phase 3 study in the first quarter of

2020, with approximately 300 subjects randomized 1:1 to active or placebo for a period of 16 weeks of blinded treatment.

**Orphan Drug Designation:** The FDA granted Bellerophon Orphan Drug Designation for nitric oxide in the treatment of IPF, a progressive, irreversible and fatal interstitial lung disease characterized by thickening and scarring of the air sacs in the lungs. IPF patients suffer from severe functional impairment that limits their ability to perform basic daily tasks, resulting in a significant deterioration in their quality of life and reducing their life expectancy to between two and five years from diagnosis. INOpulse is the first therapy with the potential to improve a patient's physical activity levels, cardiac output and oxygen saturation by treating both the ventilation perfusion mismatch driven by the fibrosis, as well as pulmonary hypertension, a common comorbidity in the IPF patient population.

**PH-Sarcoidosis:** Bellerophon has initiated a Phase 2 dose escalation study in PH associated with sarcoidosis. The study is a dose escalation safety and efficacy study that will assess the acute hemodynamic benefit of INOpulse via right heart catheterization. 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.

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

**Third Quarter Ended September 30, 2019 Financial Results**
For the three months ended September 30, 2019, the Company reported a net loss of $4.3 million, or $(0.06) per basic and diluted share, compared to net income of $11.1 million, or $0.19 per share, for the three months ended September 30, 2018.

Net income for the three months ended September 30, 2018 included income of $17.8 million related to a change in fair value of common stock warrant liability, as compared to $0.2 million for the three months ended September 30, 2019. On a diluted basis, the Company reported a loss of $(0.06) per share for the three months ended September 30, 2019, compared to a loss of $(0.10) per share for the three months ended September 30, 2018.

Research and development expenses for the three months ended September 30, 2019 were $3.3 million, compared to $5.2 million for the three months ended September 30, 2018. 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 2/3 program.

General and administrative expenses were $1.3 million for the three months ended September 30, 2019, compared to $1.6 million for the three months ended September 30, 2018. The decrease was primarily due to a decrease in stock-based compensation expenses.

**Nine Months Ended September 30, 2019 Financial Results**
For the nine months ended September 30, 2019, the Company reported a net loss of $9.2 million, or $(0.14) per share, compared to net income of $3.7 million, or $0.06 per share, for the nine months ended September 30, 2018.

Net income for the nine months ended September 30, 2018 included income of $21.2 million related to a change in fair value of common stock warrant liability, as compared to $2.5 million for the nine months ended September 30, 2019. On a diluted basis, the Company reported a loss of $(0.14) per share for the nine months ended September 30, 2019, compared to a loss of $(0.27) per share for the nine months ended September 30, 2018.

Research and development expenses for the nine months ended September 30, 2019 were $8.2 million, compared to $17.4 million for the nine months ended September 30, 2018. 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 2/3 program.

General and administrative expenses for the nine months ended September 30, 2019 were $5.0 million, compared to $5.8 million for the nine months ended September 30, 2018. The decrease was primarily due to lower consulting expenses, as well as a decrease in stock-based compensation expenses.

**Balance Sheet**
As of September 30, 2019, the Company had cash and cash equivalents of $12.8 million, compared to $16.6 million at December 31, 2018.

**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.

**Contacts**
**At Bellerophon:**
Fabian Tenenbaum
Chief Executive Officer
(908) 574-4767

**At LifeSci Advisors:**
Brian Ritchie
(212) 915-2578
britchie@lifesciadvisors.com

**Bellerophon Therapeutics, Inc.**

**Condensed Consolidated Balance Sheets**

(in thousands except share and per share data)

| | As of September 30, 2019 | As of December 31, 2018 |
|---|---|---|
| | (Unaudited) | |
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 12,838 | $ 16,645 |
| Restricted cash | 102 | 101 |
| Prepaid expenses and other current assets | 712 | 650 |
| Total current assets | 13,652 | 17,396 |
| Restricted cash, non-current | 300 | 300 |
| Right of use asset, net | 2,256 | — |
| Property and equipment, net | 401 | 664 |
| Total assets | $ 16,609 | $ 18,360 |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 2,264 | $ 2,755 |
| Accrued research and development | 2,581 | 3,771 |
| Accrued expenses | 1,488 | 1,013 |
| Current portion of operating lease liability | 647 | — |
| Total current liabilities | 6,980 | 7,539 |
| Long-term operating lease liability | 1,828 | — |
| Common stock warrant liability | 452 | 6,965 |
| Total liabilities | 9,260 | 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 September 30, 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 June 30, 2019 and December 31, 2018 | — | — |
| Additional paid-in capital | 192,343 | 179,765 |
| Accumulated deficit | (185,683) | (176,496) |
| Total stockholders' equity | 7,349 | 3,856 |
| **Total liabilities and stockholders' equity** | $ 16,609 | $ 18,360 |

**Bellerophon Therapeutics, Inc.**

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

(in thousands except share and per share data)

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | **2019** | **2018** | **2019** | **2018** |
| Operating expenses: | | | | |
| Research and development | $ 3,259 | $ 5,247 | $ 8,193 | $ 17,442 |
| General and administrative | 1,332 | 1,584 | 4,965 | 5,754 |
| Total operating expenses | 4,591 | 6,831 | 13,158 | 23,196 |
| Loss from operations | (4,591) | (6,831) | (13,158) | (23,196) |
| Change in fair value of common stock warrant liability | 215 | 17,840 | 2,504 | 21,201 |
| Warrant amendment charge | — | — | (674) | — |
| Interest income and other, net | 89 | 92 | 340 | 282 |
| Pre-tax (loss) income | (4,287) | 11,101 | (10,988) | (1,713) |
| Income tax benefit | — | — | 1,801 | 5,439 |
| Net (loss) income | $ (4,287) | $ 11,101 | $ (9,187) | $ 3,726 |
| Weighted average shares outstanding: | | | | |
| Basic | 68,303,027 | 57,710,251 | 67,229,585 | 57,356,445 |
| Diluted | 68,303,027 | 64,544,504 | 67,229,585 | 65,854,903 |
| Net (loss) income per share: | | | | |
| Basic | $ (0.06) | $ 0.19 | $ (0.14) | $ 0.06 |
| Diluted | $ (0.06) | $ (0.10) | $ (0.14) | $ (0.27) |