

Bellerophon Therapeutics, Inc.
Form 8-K
April 13, 2015

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): **April 13, 2015**

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.)

53 Frontage Road, Suite 301
Hampton, New Jersey
(Address of Principal Executive Offices)

08827
(Zip Code)

Registrant's telephone number, including area code: **(908) 574-4770**

(Former Name or Former Address, if Changed Since Last Report)

Edgar Filing: Bellerophon Therapeutics, Inc. - Form 8-K

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))
-

Item 7.01. Regulation FD Disclosure.

INOpulse PH-COPD Exploratory Study Results

In April, Bellerophon Therapeutics, Inc. (the Company) received preliminary results from Part 1 of a Company sponsored exploratory clinical study of its product candidate INOpulse for PH-COPD. This study was conducted to assess the effect of pulsed inhaled nitric oxide using high resolution computed tomography (HRCT) in subjects with pulmonary hypertension associated with chronic obstructive pulmonary disease (PH-COPD).

This study, conducted by FLUIDDA, a Belgium based company specializing in functional respiratory imaging, was performed in six patients with PH-COPD who were also on long-term oxygen therapy. The primary endpoint in this study was the change from baseline in blood volume of each lobe of patients' lungs after dosing with INOpulse using a 30 mcg/kg IBW/hr, or 30 mcg, dose as measured by HRCT. Safety endpoints of the study included device deficiencies, elevated methemoglobin levels ($>7\%$), signs of rebound pulmonary hypertension, left heart failure or pulmonary edema and any clinically significant decrease in blood oxygenation levels of arterial blood measured by pulse oximetry (SpO_2). In this study, two key variables were measured using HRCT: one, the percent distribution of airflow, or ventilation, in each of the five lobes for each patient, and two, change in blood volume in each of these lobes before and after treatment with INOpulse, which is a measure of the vasodilation caused by the treatment. Measurement of these values was done at an initial baseline with the patients on LTOT and room air for at least 20 minutes, at a retest with patients on LTOT and room air for at least 20 minutes and at treatment with patients on LTOT, room air and 30 mcg of INOpulse, delivered using our INOpulse DS device, for at least 20 minutes. The purpose of the study was to test the utility of HRCT in evaluating if vasodilation and improved blood flow caused by INOpulse treatment would be greater in lobes of the lung with better ventilation and less in lobes of the lung with worse ventilation.

The results of this exploratory study show a statistically significant correlation between ventilation and vasodilation after treatment with INOpulse ($p = 0.002$ and $r^2 = 0.32$ for treatment versus the initial baseline and $p = <0.001$ and $r^2 = 0.47$ for treatment versus the retest), indicating that the lobes of the lungs with better ventilation were likely to experience more vasodilation when treated with the 30 mcg dose of INOpulse as compared to LTOT and room air. In addition, comparing changes in vasodilation and ventilation between the test and retest without the INOpulse dose showed no correlation ($p = 0.476$ and $r^2 = 0.02$), suggesting that the increased vasodilation was caused by the INOpulse dose rather than measurement variations. Evaluation of the safety parameters indicated no significant adverse events including no change in blood oxygenation levels as measured by pulse oximetry (SpO_2).

Forward-Looking Statements. Any statements in this Form 8-K about our future expectations, plans and prospects, including statements about exploratory clinical study results and the clinical development of our product candidates, and other statements containing the words anticipate, believe, continue, could, estimate, expect, intend, may, plan, potential, predict, project, should, target, would, and, are 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 uncertainty of the utility of results from any exploratory clinical study, whether preliminary results from a clinical study will be predictive of the final results of such study or whether results of early clinical studies will be predictive of any future trial results, expectations for regulatory approvals and other factors discussed in the Risk Factors section of our most recent filings with the Securities and Exchange Commission. In addition, any forward-looking statements included in this Form 8-K represent our views only as of the date hereof and should not be relied upon as representing our views as of any subsequent date. We specifically disclaim any obligation to update any of these forward-looking statements.

The information in this Form 8-K 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.

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: April 13, 2015

By:

/s/ Jonathan M. Peacock

Name: Jonathan M. Peacock

Title: Chairman, President and Chief Executive
Officer