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): January 7, 2019

Bellerophon Therapeutics, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware

001-36845

(Commission File Number) **47-3116175** (IRS Employer Identification No.)

(State or Other Jurisdiction of Incorporation)

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):

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)

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))

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.

Item 7.01. Regulation FD Disclosure.

Bellerophon Therapeutics, Inc. has prepared an investor presentation to be presented to members of the investment community, a copy which is attached to this Current Report on Form 8-K as Exhibit 99.1.

In accordance with General Instruction B.2 on Form 8-K, the information set forth in this Item 7.01 and the investor presentation attached to this report as Exhibit 99.1 is "furnished" and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section, nor shall such information be deemed incorporated by reference in any filing under the Securities Exchange Act of 1934, as amended, or the Securities Act of 1933, as amended.

The investor presentation attached hereto as Exhibit 99.1 contains certain statements that may be deemed to be "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. In some cases, these forward-looking statements can be identified by the use of forward-looking terminology, including the terms "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should," "approximately" or, in each case, their negative or other variations thereon or comparable terminology, although not all forward-looking statements contain these words.

By their nature, forward-looking statements involve risks and uncertainties because they relate to events, competitive dynamics, and healthcare, regulatory and scientific developments and depend on the economic circumstances that may or may not occur in the future or may occur on longer or shorter timelines than anticipated. Although we believe that we have a reasonable basis for each forward-looking statement contained in the presentation, we caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in the presentation as a result of, among other factors, the factors referenced in the "Risk Factors" section of our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 15, 2018, and as amended on May 17, 2018, and the "Risk Factors" sections of our Quarterly Reports on Form 10-Q filed with the Securities and Exchange Commission on May 10, 2018, August 1, 2018 and November 7, 2018, respectively. In addition, even if our results of operations, financial condition and liquidity, and the development of the industry in which we operate are consistent with the forward-looking statements contained in the presentation, they may not be predictive of results or developments in future periods. Any forward-looking statements that we make in the presentation speak only as of the date of such statement, and we undertake no obligation to update such statements to reflect events or circumstances after the date of the presentation, except as required by law.

You should read carefully our "Cautionary Note Regarding Forward-Looking Statements" and the factors described in the "Risk Factors" sections of our Annual Report on Form 10-K and Quarterly Reports on Form 10-Q to better understand the risks and uncertainties inherent in our business.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits:

Exhibit No. Description
99.1 Investor Presentation

2

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: January 7, 2019

By: /s/ Fabian Tenenbaum

Name: Fabian Tenenbaum Title: Chief Executive Officer

3



Forward Looking Statements

This presentation contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this presentation, including statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "wull," "would," "could," "should," "continue," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make due to a number of important factors, including risks and uncertainties relating to: the timing and outcomes of our ongoing and expected clinical trials for our product candidates; our ability to successfully develop, commercialize and market any of our product candidates; our ability to obtain, maintain and enforce intellectual property rights; competition; our reliance on third parties; our ability to obtain necessary financing; and those risk factors discussed in the "Risk Factors" section and elsewhere in our most recent Form 10-K and other periodic filings we make with the SEC.

All forward-looking statements contained in this presentation reflect our current views with respect to future events. We assume no obligation, except as required by applicable law, to update any forward-looking statements publicly, or to update the reasons why actual results could differ materially from those anticipated in the forward-looking statements, even if new information becomes available in the future.



Bellerophon Therapeutics (BLPH)

Company Profile

| Clinical-Stage Biotherapeutics Company | Company spun-off from Ikaria Focused on developing inhaled nitric oxide (iNO) based therapies for outpatient management of chronic pulmonary diseases Portable, lightweight delivery system allows for chronic home use |
|---|--|
| Novel Therapy Addressing Unmet Medical Needs | PH-ILD Phase 2b study ongoing with positive results for first cohort reported PH-COPD Phase 2b study design finalized with FDA PH-Sarc Phase 2 study to be initiated in 1Q2019 Simplified regulatory approval pathway via existing nitric oxide NDA |
| Financial Summary Notes: (1) Amounts as of September 30, 2018 p | IPO on Nasdaq in February 2015 Cash & Equivalents: \$20.6M ^(1,2) , No Debt ⁽¹⁾ Shares Outstanding = 58.7 million ⁽¹⁾ ; Fully Diluted = 97.7 million ⁽¹⁾ er Quarterly Report on Form 10-Q filed November 7, 2018 (2) Includes cash, cash equivalents and marketable securities |
| Bellerophon | January 2019 3 |

Highly Experienced Leadership Team

| Jonathan Peacock Chairman | 10 years experience as CFO at Amgen and Novartis Pharma | AMGEN McKinse | v&Company 🔥 NOV | ARTIS PWC |
|---|--|--------------------|-------------------|-------------------------|
| Fabian Tenenbaum Chief Executive Officer | 15 years of executive-level experience in finance, BD and operations | anterios | Uniferen | SYNERON CANDELA |
| Hunter Gillies, M.D. Acting Chief Medical Officer | 20 years experience in clinical research specializing in cardiometabolic and pulmonary vascular diseases | Pfizer | 💋 GILEAD | ACTELION |
| Peter Fernandes Chief Regulatory & Safety Officer | 25 years experience in global regulatory affairs specializing in respiratory products | IKARIA | U NOVARTIS | Boehringer Ingelheim |
| Assaf Korner Chief Financial Officer | 15 years of financial experience in medical device and consumer product companies | SYNERON CANDELA | КРМБ | Unilawar |
| Parag Shah, PhD VP, Business Operations | 12 years experience in pharmaceutical product development | IKA | RIA | Pfizer |
| Amy Edmonds VP, Clinical Operations & Administration | 20 years experience global clinical operations and training | IKARIA | Pfizer | Celgene |
| Martin Dekker VP, Device Engineering & Manufacturing | 17 years experience in new product development and launch | | SPACE LABS | |



Development Pipeline

| Indication Market | | Development Stage | | | Key Milestones |
|--------------------------|--|-------------------|--------------|--------------|--|
| | | 2018 | 2019 | 2020 | Rey Milestones |
| | 220,000 with ILD in US | | | | Phase 2a Trial completed Results presented in May 2017 |
| PH-ILD (WHO Group 3) | 35-40% with associated PH Unmet medical need \$2B+ potential market | iNO-PF Ph 2b C1 | C2 C3 | | Phase 2b Trial: iNO-PF Cohort 1 positive results presented in Jan 2019 Cohort 2 & 3 ongoing with TLR in 2019 |
| PH-COPD (WHO Group 3) | 1.2 million PH-COPD in US Unmet medical need Multi billion dollar potential market | | PH | 1-COPD Ph 2b | Phase 2a Trial completed Trial completed in Sept 2017 Phase 2b Trial: iNO-COPD Trial design finalized Timing TBD |
| PH-Sarc (WHO Group 5) | 200,000 with sarcoidosis in US Up to 30% with associated PH Unmet medical need \$1B+ potential market | | PH-Sarc Ph 2 | | Phase 2 Trial To be initiated in 1Q2019 |



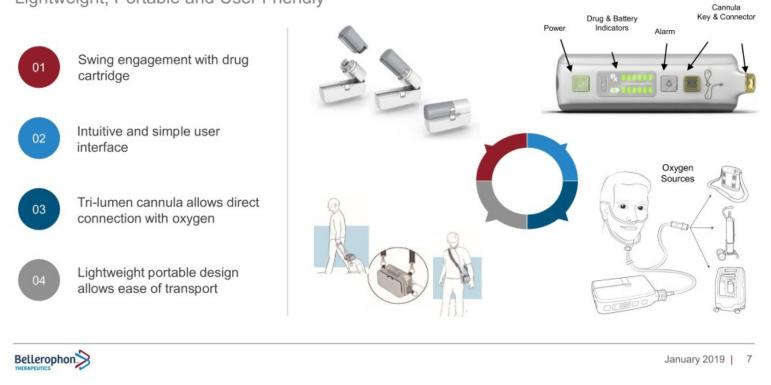
INOpulse Delivery System Overview

Portable Delivery System Allows Chronic iNO Therapy

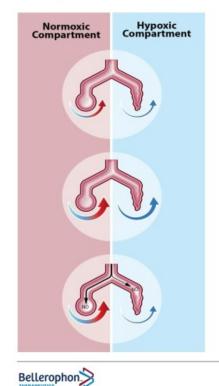


INOpulse Delivery System

Lightweight, Portable and User Friendly



INOpulse Provides a Unique and Differentiating Mechanism of Action



Baseline

Hypoxic pulmonary vasoconstriction prevents oxygen desaturation

Systemic Vasodilators

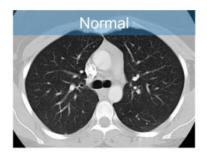
Systemic vasodilators can reverse hypoxic vasoconstriction leading to ventilation/perfusion (V/Q) mismatch and arterial O2 desaturation

INOpulse

Providing iNO early in the inspiratory phase allows for targeted vasodilation of only the well ventilated alveoli thereby preventing V/Q mismatch and O2 desaturation

Interstitial Lung Disease (PH-ILD)

A Significant Unmet Medical Need



Interstitial Lung Disease (ILD) is a broad category of diffuse lung diseases characterized by variable amounts of inflammation and fibrosis

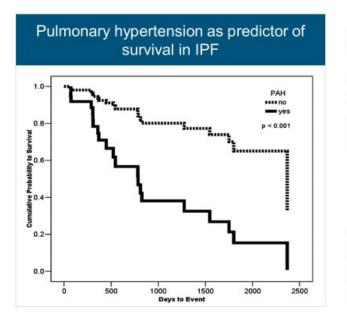
Idiopathic Pulmonary Fibrosis (IPF) is the largest and most serious of the many fibrotic subsets of ILDs



Patients with pulmonary fibrosis have thickening and scarring of the air sacs in the lungs, and often require supplemental oxygen to maintain adequate oxygen saturation



PH-ILD Significantly Reduces Survival



Rivera-Lebron, Advances in Pulmonary Hypertension, 2013



Approximately 40% of IPF patients exhibit symptoms of pulmonary hypertension at rest, including elevated pulmonary pressures

Prognosis and survival are significantly worse for patients with pulmonary hypertension

PH-IPF associated with a 3-fold increase in risk of death compared to IPF alone

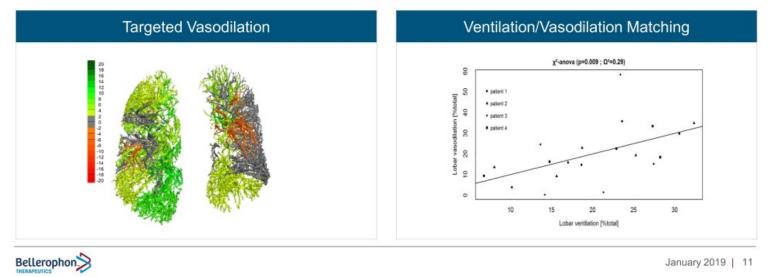
No approved therapy for treating PH in these patients

INOpulse has the potential to provide targeted vasodilation while avoiding concerns of V/Q mismatch which have prevented current PAH systemic vasodilators to be approved for this unmet medical need

Phase 2a Study PH-IPF

Acute Phase Data Showed Immediate Benefit of iNO on Vasodilation and Hemodynamics

- Significant correlation between ventilation and vasodilation, demonstrating selective vasodilation to better ventilated areas
 of the lung (p=0.009)
- · Consistent and clinically meaningful reduction of 14% in systolic pulmonary arterial pressure (sPAP)
- · Clinically meaningful improvement oxygen desaturation of 28.5% and SpO2 nadir of 5.5%

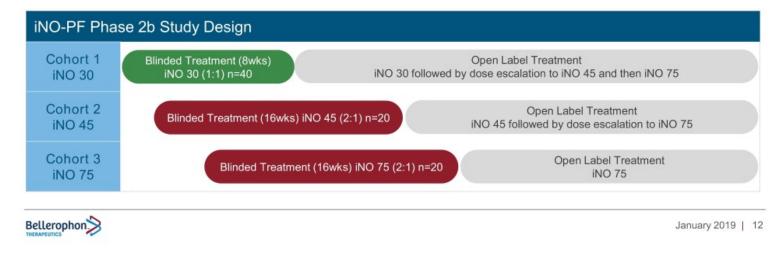


Phase 2b (iNO-PF) Study Allows Assessment of Multiple Doses and Duration of Treatment

Double-blind placebo controlled study will assess 80 subjects with pulmonary fibrosis at low or intermediate/high risk of associated pulmonary hypertension

- · Endpoints include actigraphy, oxygen saturation, right ventricular function, and others
 - Multiple Cohorts allows for evaluation of higher doses and longer duration of treatment
 - Enrollment in Cohort 1 is complete with study positive study results presented in January 2019
 - · Cohorts 2 and 3 expected to readout later in 2019

٠



Summary of Key Outputs from iNO-PF Phase 2b Trial (Cohort 1)

| | iNO | Placebo | |
|---|--------------|---------------|---|
| Actigraphy (% change) | | | |
| Moderate Activity (walking, stairs, yardwork, etc.) | +8% | -26% | Statistically significant reduction in moderate activity for placebo (p=0.04) |
| Overall Activity | +0% | -12% | Statistically significant reduction in overall activity for placebo (p=0.05) |
| NT-ProBNP (% change) | +15% | +42% | Peptide marker indicator of cardiac failure Larger increase in placebo indicative of disease worsening |
| Oxygen Saturation | | | |
| Oxygen DesaturationSpO2 Nadir | -9% +0.3% | +11% -1.4% | Lower desaturation for iNO=better saturation Higher nadir for iNO=better saturation |

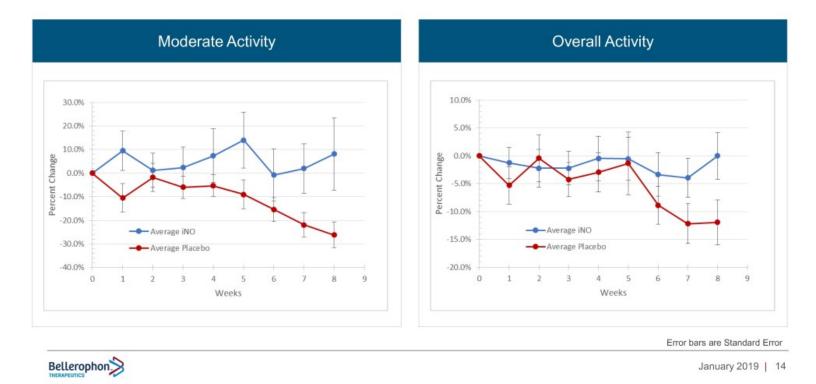
 Results show iNO provides statistically significant improvement in activity as measured by a wearable medical-grade activity monitor (Actigraph GT9X)

· Changes in NT-ProBNP are consistent with activity results, showing greater worsening for placebo subjects

· Unlike other approved PAH systemic vasodilators; INOpulse targeted delivery improves oxygen saturation during exercise



iNO Demonstrated Consistent and Sustained Benefit in Activity Parameters



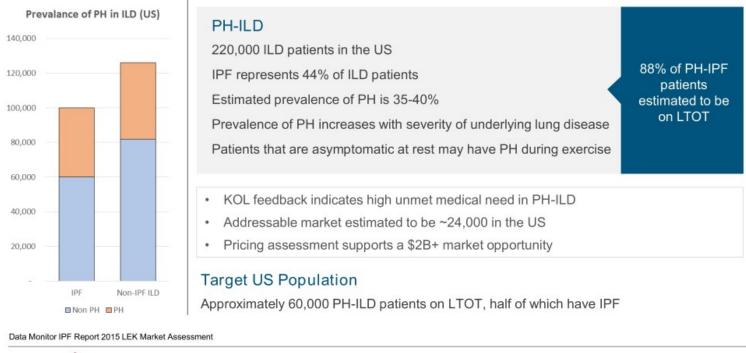
Actigraphy in Clinical Trials

- · Actigraphy utilizes a wearable medical-grade activity monitor to continuously measure activity
- · Multiple late stage trials in cardiopulmonary disease are using actigraphy as the primary endpoint
- · Strong KOL support for activity monitoring to assess patient outcomes

| Phase | Indication | Sponsor | Primary Endpoint | Secondary Endpoints |
|-----------|--|-----------------|------------------|--|
| Phase IV | PAH (selexipeg vs placebo) | Actelion | Actigraphy | WHO Functional Class 6MWD Borg Dyspnea NT-ProBNP PAH-Sympact Questionnaire |
| Phase III | COPD (portable oxygen concentrator vs standard of care) | Resmed & Inogen | Actigraphy | St George Respiratory Questionnaire Oxygen Usage Hospital & Depression Scale |
| Phase II | Heart Failure with Preserved Ejection Fraction (HFpEF) (macitentan vs placebo) | Actelion | NT-ProBNP | Actigraphy Kansas City Cardiomyopathy Questionnaire Time to Worsening |



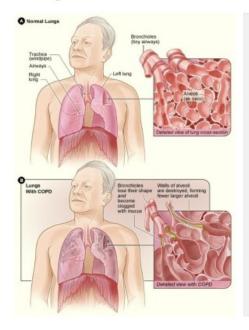
PH-ILD Market Opportunity in the US





Chronic Obstructive Pulmonary Disease (PH-COPD)

A Large Unmet Medical Need



Chronic obstructive pulmonary disease (COPD) which includes chronic bronchitis and emphysema is a group of lung diseases characterized by progressive airflow obstruction and chronic airway inflammation

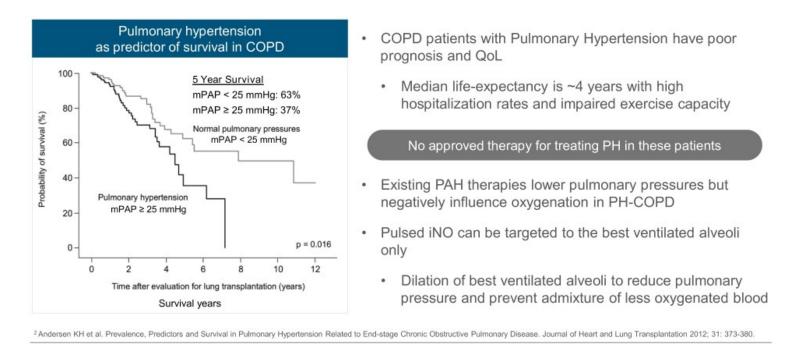
COPD is typically associated with smoking or exposure to other pollutants such as dust or chemicals

Obstruction of the bronchioles and alveoli reduces the ability to get oxygen and ultimately leads to hypoxemia

Hypoxemia and inflammation in COPD are thought to contribute to the development of associated pulmonary hypertension



Pulmonary Hypertension Independently Predicts Reduced Survival in Moderateto-Severe COPD



Bellerophon

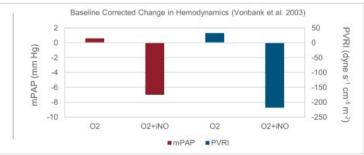
Demonstrated Benefit of Pulsed iNO on Vasodilation and Hemodynamics for COPD Patients

Vonbank et al, 2003

Sustained hemodynamic benefits, at three months, of pulsed $\mathrm{iNO+O}_2$

 Reduced mPAP¹ and PVRI¹ and increased cardiac output² as compared to O₂ alone without negative impact on hypoxemia
 Acute results replicated with INOpulse in a PH-COPD Phase 2 study (COPD-201)

1. p-value <0.001; 2. p-value = 0.025

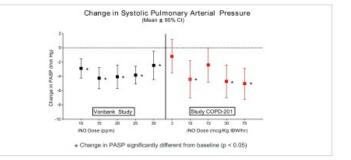


COPD-201 Study

seen at iNO 75

Statistically significant change from baseline for PASP at iNO 30 and iNO 75 dose

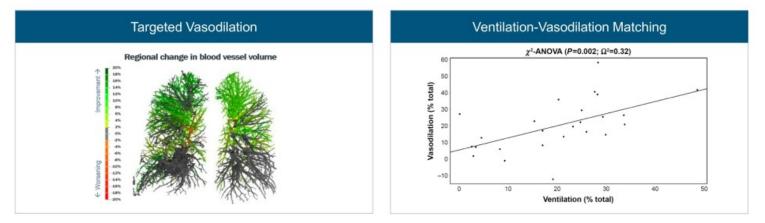
Improvement in PASP is similar to results from Vonbank study Verified iNO 30 as optimal dose with no further improvement



Bellerophon

High-Resolution Computed Tomography Imaging Study

Demonstrated iNO targets pulmonary vessels in PH-COPD patients



- Acute Treatment with iNO 30 mcg/kg IBW/hr for at least 20 minutes (n=6)
- No significant drop in blood oxygenation (SpO₂)
- · All six patients showed increases in the blood volume in the vessel, a surrogate for vasodilation
- · Patients reported significant improvement in symptoms for up to 24 hours

| Bellerophon |
|-------------|
|-------------|

Haijan et al., Int J of COPD, 2016

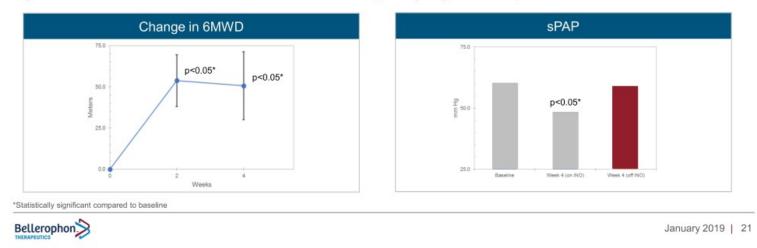
COPD-007 Phase 2a Study

Showed Benefit of Chronic iNO Treatment on Exercise Capability and Hemodynamics

Subjects who completed 4 week chronic phase on iNO 30 showed:

- Statistically significant increase in 6MWD at 2 weeks and 4 weeks (+50.7m)
- Statistically and clinically significant decrease in sPAP at 4 weeks (-12.0 mmHg; 19.9% reduction)
- sPAP increased to near baseline upon stopping treatment with iNO

Acute phase results showed a statistically significant increase of 4.2% in blood vessel volume compared to baseline and significant correlation between ventilation and vasodilation supporting targeted delivery to well ventilated alveoli

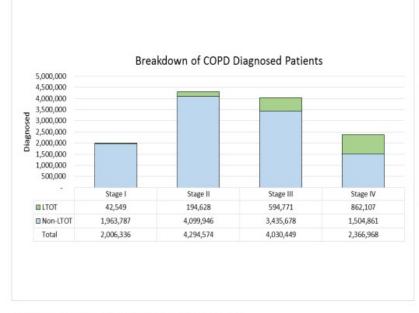


Next Steps in PH-COPD





PH-COPD Market Opportunity in the US



Data Monitor COPD Report 2010 LEK Opportunity Assessment



COPD in US

Prevalence: 27.8 million Diagnosed: 12.7 million (45.6%) Estimated prevalence of pulmonary hypertension (PH) in COPD is 27%

- KOL feedback indicates high unmet medical need in PH-COPD
- Addressable market estimated to be ~350,000 patients in the US
- · Multi-billion dollar market opportunity

Target US Population

PH-COPD on LTOT Overall: 1,200,000 Severe (Stage III/IV COPD): 900,000

Pulmonary Hypertension associated with Sarcoidosis (PH-Sarc)

An Orphan Unmet Medical Need

Sarcoidosis is characterized by the growth of inflammatory cells (granulomas) most commonly in the lungs or lymphatic tissues

Prevalence of sarcoidosis is estimated at 200,000 in the US with up to 30% with associated pulmonary hypertension



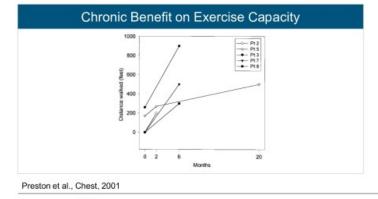
| | Patients with associated PH have | ve significantly reduced surviva | |
|---------|----------------------------------|----------------------------------|-----------------|
| | 1 year survival | 3 year survival | 5 year survival |
| PH-Sarc | 84% | 74% | 59% |
| Sarc | 100% | 96% | 96% |



INOpulse MoA has the Potential to Provide Benefit to PH-Sarc Patients

Inhaled nitric oxide has been shown to improve hemodynamics and exercise capacity in PH-Sarc

| Acute Hemodynamic Benefit on iNO | | |
|----------------------------------|----------|--|
| Parameter | % Change | |
| mPAP | -18 ± 4 | |
| PVR | -31 ± 5 | |
| CO | 12 ± 4 | |



Systemic vasodilators exacerbate hypoxic vasoconstriction and cause hypoxemia

No approved therapy for treating PH in these patients

Phase 2 study designed to verify hemodynamic effect of INOpulse in PH-Sarc

- Acute dose escalation study with right heart catheterization
- Primary endpoint: change in mean PAP, PCWP, cardiac output and PVR
- Study to be initiated in 1Q2019

INOpulse Intellectual Property Protection

| Patent | Status | Expiration | Description |
|---|--|------------|--|
| Method of NO administration | US/EU: Issued Other Territories: Issued/Pending | Jan 2027 | Covers consistent delivery of prescribed dose independent of respiratory rate |
| Breath Skipping & Pulse Volume Variation | US: Issued | Sept 2025 | Covers skipping breaths or modifying pulse volume to ensure consistent dose independent of respiratory rate |
| Method of Administering High Concentration NO | US/EU: Pending Other Territories: Pending | Mar 2033 | Limits delivery rate of high concentration iNO to preven safety concerns |
| Optimized Pulse Shape | US: Pending | Oct 2035 | Covers key parameters of pulse shape |
| INOpulse Design | US: Issued | Apr 2028 | Covers design of the INOpulse device |
| Tip Purge | US: Issued EU/Other Territories: Pending | Apr 2033 | Covers the use tip purge to ensure purity of iNO within the cannula |
| Triple-Lumen Cannula | US/ EU: Issued Other Territories: Pending | Dec 2033 | Covers accurate dose delivery and reduced $\ensuremath{NO_2}$ formation |
| Index valve | US/EU: Issued Other Territories: Issued/Pending | May 2029 | Ensures other cartridges cannot be used with INOpulse |

• Orphan Drug designation for PH-IPF/PH-ILD would provide potential exclusivity for 7 years (US) and 10 years (EU)

• Multiple provisional patent applications filed in 2017 and 2018 that can extend patent coverage into 2038

Bellerophon

Financial Summary

| Cash and Cash Equivalents and Marketable Securities | \$20.6(1) |
|---|----------------------|
| Restricted Cash | \$0.6 ⁽¹⁾ |
| Debt | \$0 ⁽¹⁾ |
| Shares Outstanding | 58.7 ⁽¹⁾ |
| Fully Diluted | 97.7(1) |

1) Amounts as of September 30, 2018 per Quarterly Report on Form 10-Q filed November 7, 2018



January 2019 | 27

Amount (in millions)

Investment Highlights

| | persistent pulmonary hypertension ase 2 studies support INOpulse MoA and ber | nefit in PH-ILD, PH-COPD and PH- |
|---|---|--|
| Sarcoidosis | | |
| Advanced Clinical Stage P | roduct | |
| • | veral unmet and orphan indications, each wit | th multi-billion dollar market potential |
| PH-ILD | PH-COPD | PH-Sarc |
| Successful Phase 2a study in PH-IPF completed in May 2017 | Successful Phase 2 study completed in September 2017 | Phase 2 study to be initiated in 1Q2019 |
| Positive results for Phase 2b study in Cohort 1 | Phase 2b study design finalized in agreement w/ FDA | |
| Remaining Phase 2b Cohorts expected to readout later in 2019 | | |
| Proprietary INOpulse Tech | nology | |
| Strong IP protection on core program | ms through 2033 and ability to extend covera | ae into 2038 |

Investor Contacts

Fabian Tenenbaum Chief Executive Officer BTInvestorRelations@bellerophon.com

> Brian Ritchie LifeSci Advisors britchie@lifesciadvisors.com 212-915-2578

