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): September 5, 2018

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**	**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.

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 and August 1, 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

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: September 5, 2018

By: /s/ Fabian Tenenbaum

Name: Fabian Tenenbaum
Title: Chief Executive Officer

Company Presentation

September 2018

Nasdaq: BLPH

Bellerophon®
THERAPEUTICS

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,” “will,” “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 readout around end of 2018
- PH-COPD Phase 2b study design finalized with FDA
- PH-Sarc Phase 2 study to be initiated in 4Q2018
- Simplified regulatory approval pathway via existing nitric oxide NDA

Financial Summary

- IPO on Nasdaq in February 2015
- Cash & Equivalents: $25.9M[1,2], No Debt[1]
- Shares Outstanding = 57.8 million[1]; Fully Diluted = 96.8 million[1]

Notes: (1) Amounts as of June 30, 2018 per Quarterly Report on Form 10-Q filed August 1, 2018
(2) Includes cash, cash equivalents and marketable securities

Investment Highlights

- Therapeutic benefit of inhaled nitric oxide (iNO) has been demonstrated
  - Approved for acute treatment of persistent pulmonary hypertension
- Proprietary INOpulse technology enables advanced clinical stage product candidate targeting several unmet indications, including multiple orphan opportunities, with simplified approval pathway due to existing iNO NDA
  - Pulmonary hypertension associated with interstitial lung disease (PH-ILD)
    - Successful Phase 2 study in PH-IPF completed in May 2017
    - Phase 2b study initiated with top line results expected around the end of 2018
  - Pulmonary hypertension associated with chronic obstructive pulmonary disease (PH-COPD)
    - Successful Phase 2 study completed in September 2017
    - Phase 2b study design finalized in agreement with FDA
  - Pulmonary hypertension associated with sarcoidosis (PH-Sarc)
    - Phase 2 study to be initiated in 4Q2018
  - Learnings from PAH program support INOpulse mechanism of action and benefit in PH associated with ILD, COPD and Sarcoidosis
- Each indication represents multi-billion dollar potential market opportunity
- Strong IP protection on core programs through 2033

Development Pipeline

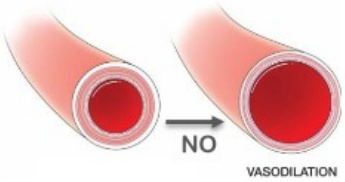
Indication	Market	Development Stage			Key Milestones
		2017	2018	2019	
PH-ILD (WHO Group 3)	• 220,000 with ILD in US • 35-40% with associated PH at rest • Unmet medical need • $2B+ potential market	PH-IPF Ph 2a	iNO-PF Ph 2b		**Phase 2 Trial completed** • Results presented in May 2017 **Phase 2b Trial: iNO-PF** • Trial underway • Top line around end of 2018
PH-COPD (WHO Group 3)	• 1.2 million PH-COPD in US • Unmet medical need • Multi billion dollar potential market	PH-COPD Ph 2		PH-COPD Ph 2b	**Phase 2 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 4Q2018

Highly Experienced Leadership Team

	**Jonathan Peacock** Chairman	10 years experience as CFO at Amgen and Novartis Pharma and 10+ years as partner in Strategy and Corporate Finance consulting	AMGEN, NOVARTIS, McKinsey&Company, PricewaterhouseCoopers
	**Fabian Tenenbaum** Chief Executive Officer	15 years of executive-level experience in finance, business development and operations	anterios, Syneron Candela, Unilever
	**Deborah Quinn, MD** Chief Medical Officer	15 years experience in clinical research specializing in PAH and heart failure	NOVARTIS, HARVARD MEDICAL SCHOOL, MASSACHUSETTS GENERAL HOSPITAL
	**Peter Fernandes** Chief Regulatory & Safety Officer	25 years experience in global regulatory affairs specializing in respiratory products	IKARIA, NOVARTIS, Boehringer Ingelheim
	**Assaf Korner** Chief Financial Officer	15 years of financial experience in medical device and consumer product companies	Syneron Candela, Unilever, KPMG
	**Parag Shah, PhD** VP, Business Operations	12 years experience in pharmaceutical product development	IKARIA, Pfizer
	**Amy Edmonds** VP, Clinical Operations & Administration	20 years experience global clinical operations and training	IKARIA, Celgene, Pfizer
	**Martin Dekker** VP, Device Engineering & Manufacturing	17 years experience in new product development and launch	SPACELABS HEALTHCARE

Bellerophon THERAPEUTICS

INOpulse Platform Overview

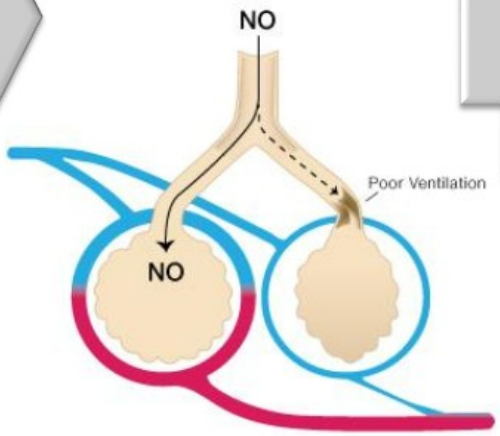


Nitric Oxide is a well established vasodilator approved for acute treatment of persistent pulmonary hypertension in hospitals

INOpulse® therapy allows for chronic use along with pulsatile targeted delivery to well ventilated sections of the lung

Novel drug-device combination therapy with dual mechanisms of action

- Targeted pulmonary vasodilation
- Ventilation/Perfusion (V/Q) matching



Potential to target multiple unmet and underserved chronic pulmonary diseases including areas where systemic vasodilators are ineffective or poorly tolerated

Current Programs:

PH-ILD
PH-COPD
PH-Sarc

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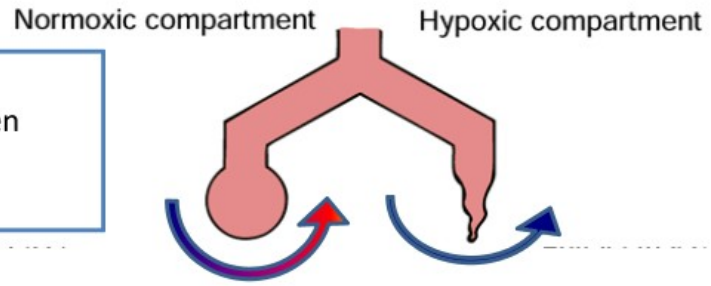
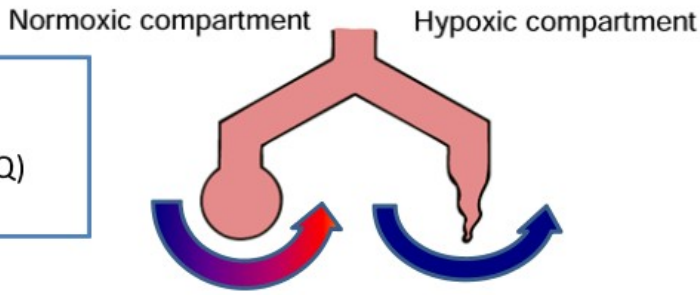
INOpulse Provides a Unique and Differentiating Mechanism of Action

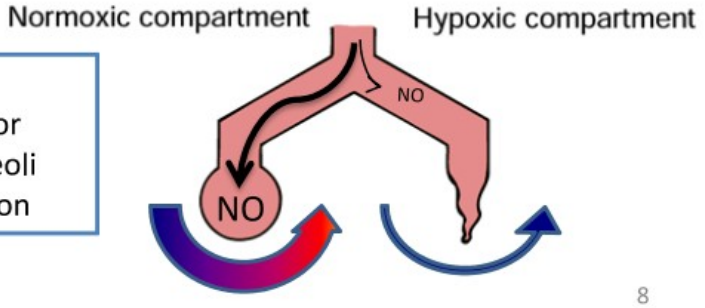
Baseline
Hypoxic pulmonary vasoconstriction prevents oxygen desaturation



Systemic Vasodilators
Systemic vasodilators can reverse hypoxic vasoconstriction leading to ventilation/perfusion (V/Q) mismatch and arterial O_2 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 O_2 desaturation



INOpulse: Portable Delivery System Allows Chronic iNO Therapy

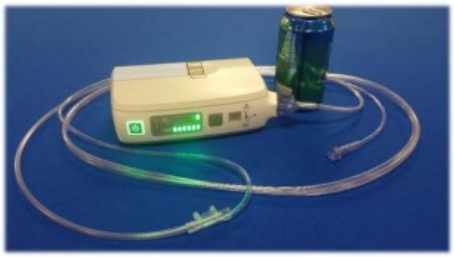
INOmax ⟵ IKARIA ⟶ INOpulse

Commercial platform sold to Mallinckrodt for $2.3B

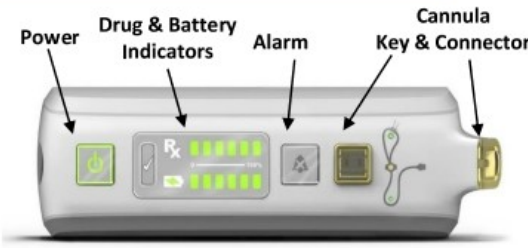
- Continuous flow iNO delivery system
- Approved for use in persistent pulmonary hypertension in neonates
- Bulky device with large cylinders designed for use in acute hospital settings

R&D Platform spun-out to form Bellerophon Therapeutics

- Pulsatile iNO delivery system
- Pulsed iNO can deliver equivalent dose as continuous delivery with 5% of the volume
- Dynamic pulse delivers the prescribed dose accurately throughout the day
- Small portable ~2.5 lbs. device allows ambulatory use in chronic in-home setting



INOpulse Delivery System: Lightweight, Portable and User Friendly

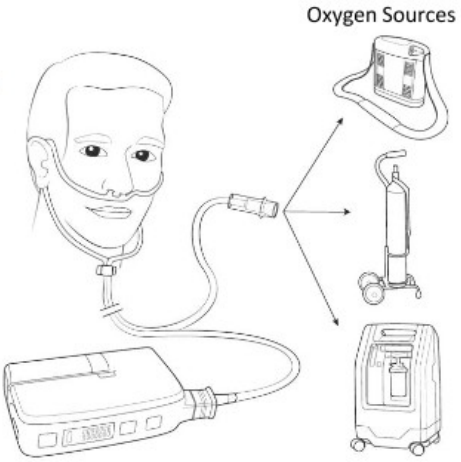


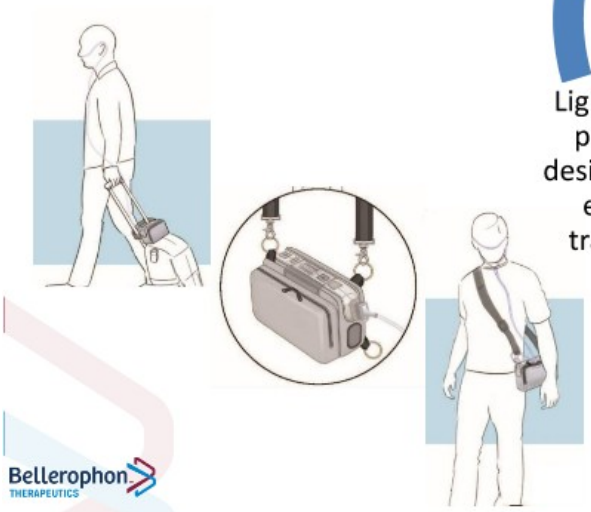
Swing engagement with drug cartridge

Intuitive and simple user interface

Tri-lumen cannula allows direct connection with oxygen

Lightweight portable design allows ease of transport





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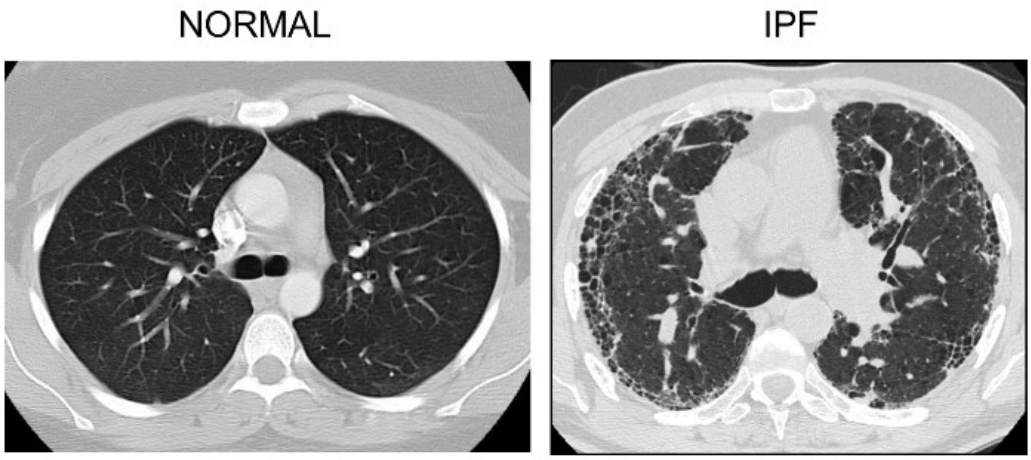
Differences in PH Pathology, Standard of Care, and INOpulse Mechanism of Action

	PH Group 1 (PAH)	PH Group 3 (PH-ILD & PH-COPD)	PH Group 5 (PH-Sarc)
Underlying Disease	• Vascular disease	• Pulmonary disease (obstructive, fibrotic, etc.)	• Inflammatory disease (granulomas)
PH Pathology	• Normal lung function • PH driven by narrowing of pulmonary arteries	• Reduced lung function • PH comorbidity is driven by lung structural and vascular changes	
Standard of Care	• 13 approved drugs to treat PAH • Most patients treated with multiple vasodilators	• No approved therapy to treat PH • PH Group 1 vasodilators ineffective	
INOpulse Mechanism of Action	Single MOA • Pulmonary vasodilation	Dual MOA • Targeted pulmonary vasodilation • Ventilation/Perfusion (V/Q) matching	
Clinical Findings	• Improvements in hemodynamics and cardiac function verifies pulmonary vasodilation • Improvement in composite of 6MWD & SpO2 confirms V/Q matching • Improvement in 6MWD limited due to endpoint variability and multiple background vasodilators	• Improvements in hemodynamics and 6MWD verifies pulmonary vasodilation • Improvements in composite of 6MWD & SpO2 confirms V/Q matching • Results support dual mechanism of action	• Improvements in hemodynamics and 6MWD supports pulmonary vasodilation

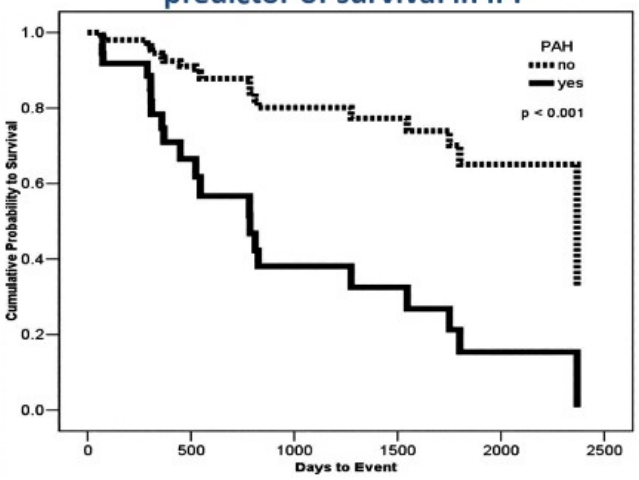
Interstitial Lung Disease (PH-ILD) Represents a Significant Unmet Medical Need

- 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 associated with Interstitial Lung Disease (PH-ILD) Significantly Reduces Survival

Pulmonary hypertension as predictor of survival in IPF



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 to while avoiding concerns of V/Q mismatch which have prevented current PAH systemic vasodilators to be approved for this unmet medical need

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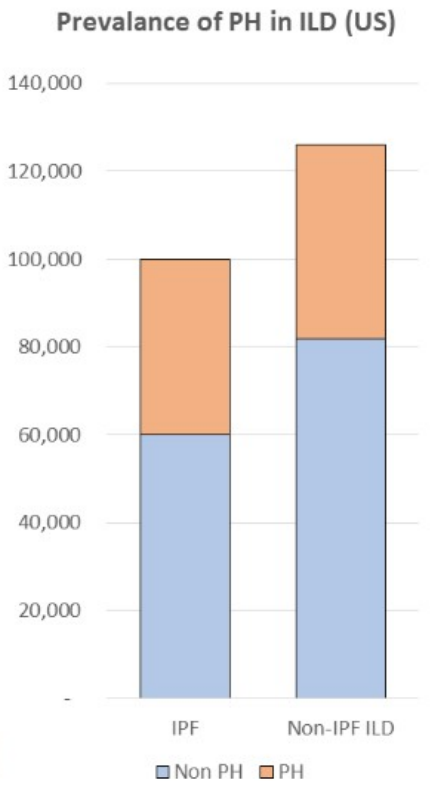
PH-ILD Market Opportunity in the US



PH-ILD

- 220,000 ILD patients in the US
- IPF represents 44% of ILD patients
- Estimated prevalence of PH is 35-40%
- Prevalence of PH increases with severity of underlying lung disease
- Patients that are asymptomatic at rest may have PH during exercise

88% of PH-IPF patients estimated to be on LTOT

Target US Population:

- Approximately 60,000 PH-ILD on LTOT half of which have IPF

- KOL feedback indicates high unmet medical need in PH-ILD
- Addressable market estimated to be ~24,000 in the US
- Pricing assessment supports a $2B+ market opportunity

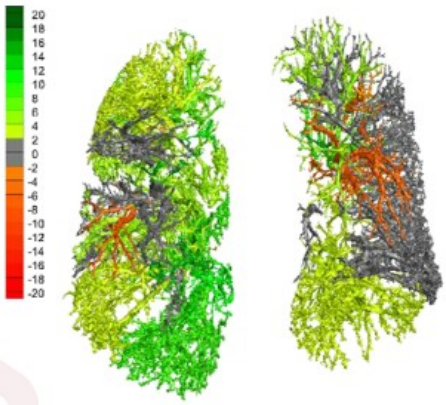
Data Monitor IPF Report 2015
LEK Market Assessment

Phase 2 Study Showed Immediate Benefit of iNO on Vasodilation and Hemodynamics

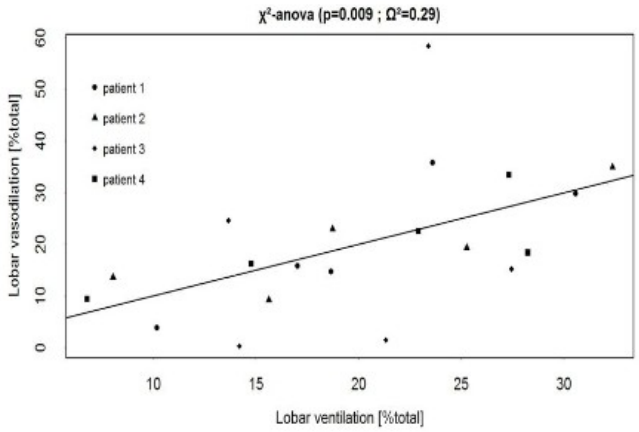
Acute phase data showed:

- Statistically significant (15.3%) increase blood vessel volume as compared to baseline
- Significant correlation between ventilation and vasodilation, demonstrating selective vasodilation to better ventilated areas of the lung
- Consistent and clinically meaningful reduction (14%) in systolic pulmonary arterial pressure (sPAP)

Targeted Vasodilation



Ventilation/Vasodilation Matching



Chronic iNO Treatment Provides Benefit on Oxygen Saturation and Exercise Capacity

Chronic phase data showed:

- Clinically meaningful improvement in exercise capacity and oxygen desaturation during 6MWT
- Composite endpoint of oxygen saturation and exercise capacity shows consistent improvement in DSP and IDSP

	iNO
Change in 6MWD	74.5 m
Improvement in Nadir SpO2	5.5 %
Improvement in Oxygen Desaturation	28.5 %
Change in Distance Saturation Product (DSP)	78.1 m%
Change in Integral Distance Saturation Product (IDSP)	85.9 m%

Composite endpoints, combining oxygen saturation and walk distance during 6MWT, is potentially a better predictor of mortality in IPF (Lettieri et al, 2006)

- DSP is the product of the distance walked and the lowest oxygen saturation (SpO2 nadir) during the 6MWT
- IDSP is the product of the distance walked and the integral average (representative of AUC) of the oxygen saturation during the 6MWT

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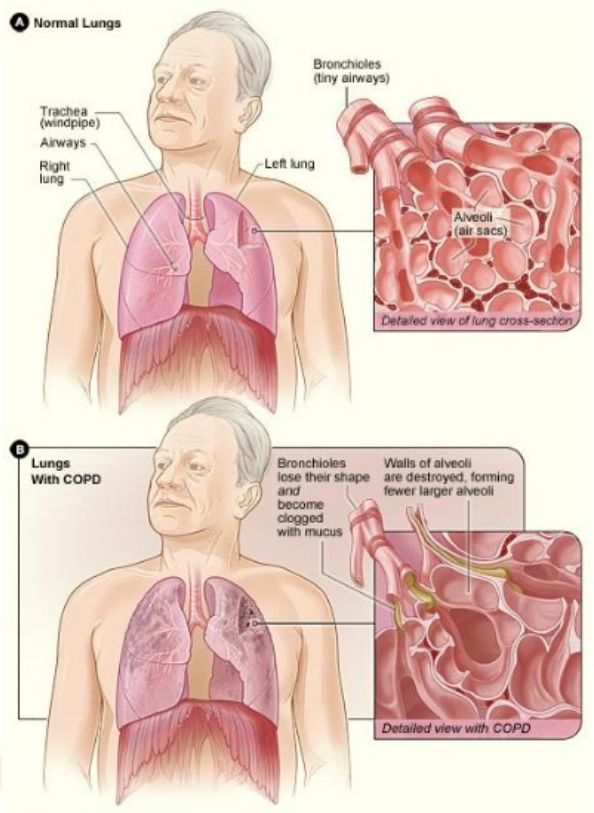
Next Steps in PH-ILD

- Phase 2b (iNO-PF) study initiated with Top Line Results around year end
  - 40 subjects with pulmonary fibrosis: assessing subjects at low or intermediate/high risk of associated pulmonary hypertension at rest
  - 8 weeks of blinded therapy (iNO 30 vs placebo) followed by open label treatment
  - Multiple endpoints to be evaluated including:
    - 6MWD
    - Right ventricular function
    - Activity level (via activity monitors)
    - Oxygen saturation
    - Composite endpoints of oxygen saturation and exercise capacity (DSP, IDSP)

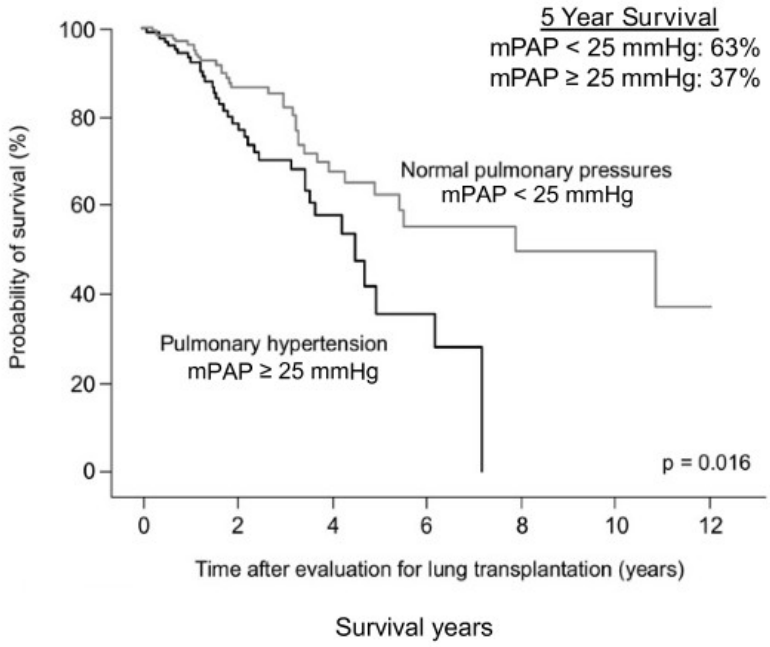
- Top line results will help finalize patient population, clinical endpoints and study size for Phase 3
- Potential for a single Phase 3 trial to support NDA in underserved patient population

Chronic Obstructive Pulmonary Disease (PH-COPD) Represents 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 leads 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 Moderate-to-Severe COPD



[2] Andersen KH et al. Prevalence, Predictors and Survival in Pulmonary Hypertension Related to End-stage Chronic Obstructive Pulmonary Disease. Journal of Heart and Lung Transplantation 2012; 31: 373-380.

- COPD patients with Pulmonary Hypertension have poor prognosis and QoL
  - Median life-expectancy is ~4 years with high hospitalization rates and impaired exercise capacity

No approved therapy for treating PH in these patients

- Existing PAH therapies lower pulmonary pressures but negatively influence oxygenation in PH-COPD
- Pulsed iNO can be targeted to the best ventilated alveoli only
  - Dilation of best ventilated alveoli to reduce pulmonary pressure and prevent admixture of less oxygenated blood

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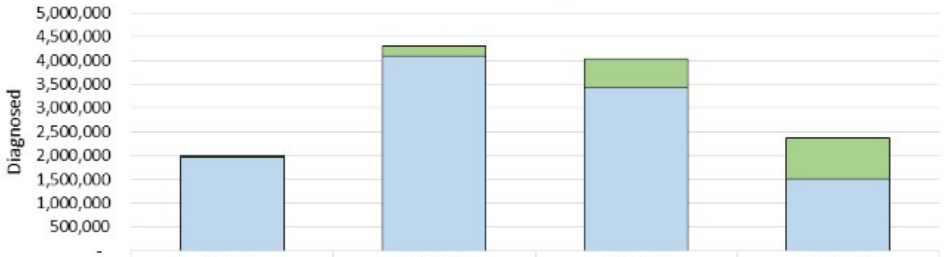
PH-COPD Market Opportunity in the US

COPD in US
Prevalence: 27.8 million
Diagnosed: 12.7 million (45.6%)

Breakdown of COPD Diagnosed Patients



	Stage I	Stage II	Stage III	Stage IV
LTOT	42,549	194,628	594,771	862,107
Non-LTOT	1,963,787	4,099,946	3,435,678	1,504,861
Total	2,006,336	4,294,574	4,030,449	2,366,968

Target US Population:
PH-COPD on LTOT
- Overall: 1,200,000
- Severe (Stage III/IV COPD): 900,00

- 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

Data Monitor COPD Report 2010
LEK Opportunity Assessment

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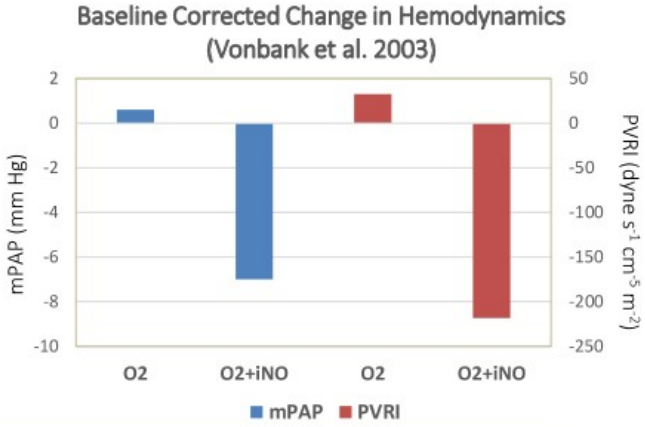
Demonstrated Benefit of Pulsed iNO on Vasodilation and Hemodynamics for PH-COPD Patients

Vonbank et al, 2003

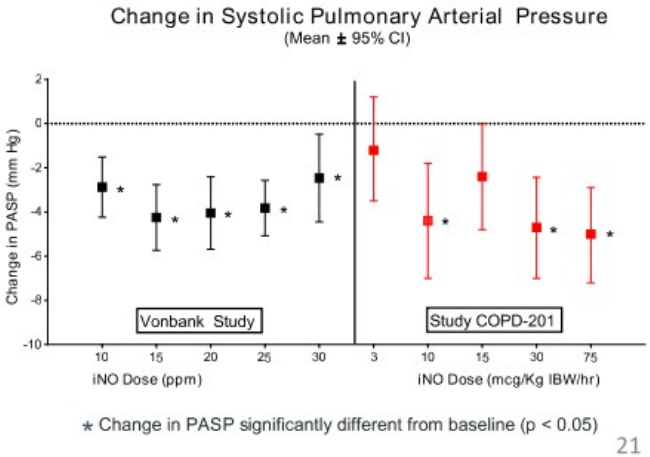
- Sustained hemodynamic benefits, at three months, of pulsed iNO+O_2
  - Reduced mPAP[1] and PVRI[1] and increased cardiac output[2] as compared to O_2 alone without negative impact on hypoxemia
- Acute results replicated with INOpulse in a PH-COPD Phase 2 study (COPD-201)

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



COPD-201 Study

- 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 seen at iNO 75

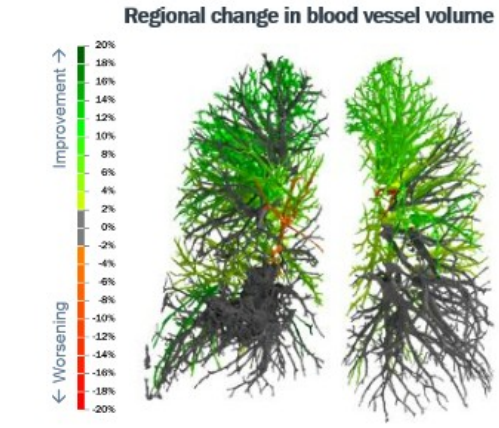


* Change in PASP significantly different from baseline ($p < 0.05$)

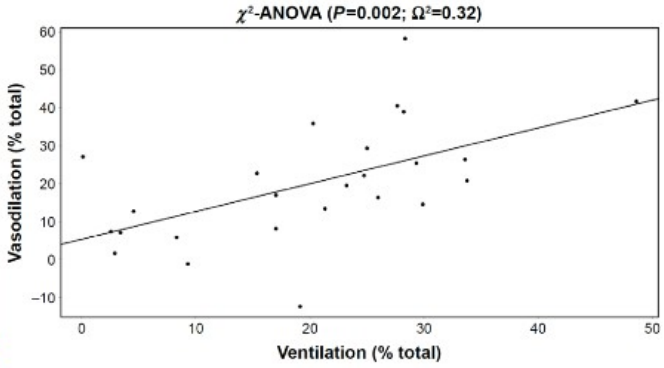
High-Resolution Computed Tomography Imaging Study

Demonstrated iNO effects on pulmonary vessels in PH-COPD patients

Targeted Vasodilation



Ventilation-Vasodilation Matching



- Acute Treatment with iNO 30 mcg/kg IBW/hr for at least 20 minutes (n=6)
- No significant drop in blood oxygenation (SpO_2)
- 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

Haijan et al., Int J of COPD, 2016

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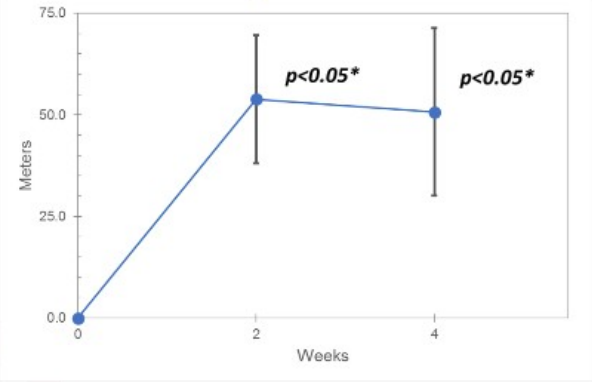
COPD-007 Phase 2 Study Showed Benefit of Chronic iNO Treatment on Exercise Capability and Hemodynamics

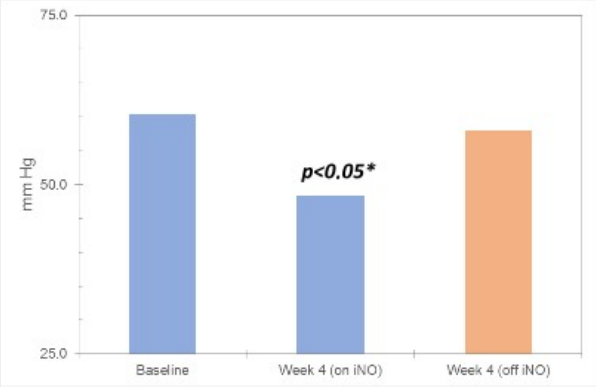
- Subjects who completed 4 week chronic phase on iNO 30 showed:
  - Statistically significant increase in 6MWD at 2 weeks and 4 weeks (+50.7m)
  - Statistically and clinically significant decrease in sPAP at 4 weeks (-12.0 mmHg; 19.9% reduction)
  - sPAP increased to near baseline upon stopping treatment 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

Change in 6MWD



sPAP



**Statistically significant compared to baseline*

Next Steps in PH-COPD

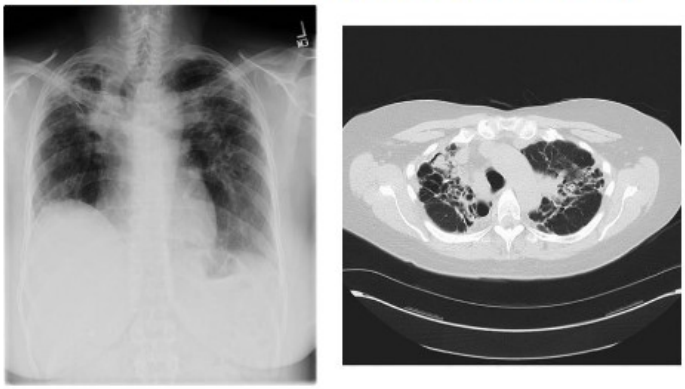
- Phase 2b study design reviewed and finalized with FDA
  - U.S. based double-blind, placebo-controlled, study in approximately 90 PH-COPD patients
  - Multiple endpoints to be evaluated including:
    - 6MWD
    - Right ventricular function
    - Time to clinical worsening
    - Time to clinical improvement
    - Oxygen saturation during 6MWT
    - Composite endpoints of oxygen saturation and 6MWT (distance saturation product)

- Target study start in 2019
- Phase 2b study results will help finalize patient population, clinical endpoints and study size for Phase 3

Pulmonary Hypertension associated with Sarcoidosis (PH-Sarc) Represents an Orphan Unmet Medical Need

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

Chest x-ray & CT of patient with PH-Sarc



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

Patients with associated PH have significantly reduced survival

	1 year survival	3 year survival	5 year survival
PH-Sarc	84%	74%	59%
Sarc	100%	96%	96%

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INOpulse Mechanism of Action has the Potential to Provide Benefit to PH-Sarc Patients

- Systemic vasodilators exacerbate hypoxic vasoconstriction and cause hypoxemia

No approved therapy for treating PH in these patients

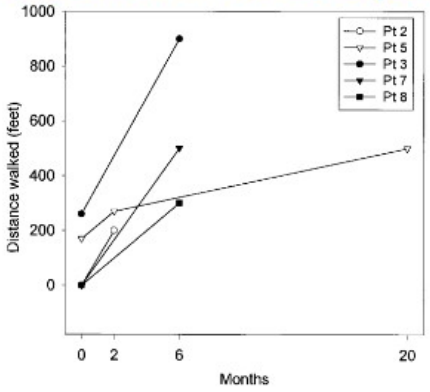
- Inhaled nitric oxide has been shown to improve hemodynamics and exercise capacity in PH-Sarc

Acute Hemodynamic Benefit on iNO

Parameter	% Change
mPAP	-18 ± 4
PVR	-31 ± 5
CO	12 ± 4

Preston et al., Chest, 2001

Chronic Benefit on Exercise Capacity



- 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 4Q2018

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INOpulse – Intellectual Property Protection

Patent	Status	Expiration	Notes
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 prevent 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 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**

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Financial Summary

	Amount (in millions)
Cash and Cash Equivalents and Marketable Securities	$25.9[(1)]
Restricted Cash	$0.6[(1)]
Debt	$0[(1)]
Shares Outstanding	57.8[(1)]
Fully Diluted	96.8[(1)]

- Current cash runway projected to cover cost of ongoing trials and key milestones into 2019, including top line results of Phase 2b Study in PH-PF

1) Amounts as of June 30, 2018 per Quarterly Report on Form 10-Q filed August 1, 2018

Investment Highlights

- Therapeutic benefit of inhaled nitric oxide (iNO) has been demonstrated
  - Approved for acute treatment of persistent pulmonary hypertension
- Proprietary INOpulse technology enables advanced clinical stage product candidate targeting several unmet indications, including multiple orphan opportunities, with simplified approval pathway due to existing iNO NDA
  - Pulmonary hypertension associated with interstitial lung disease (PH-ILD)
    - Successful Phase 2 study in PH-IPF completed in May 2017
    - Phase 2b study initiated with top line results expected around the end of 2018
  - Pulmonary hypertension associated with chronic obstructive pulmonary disease (PH-COPD)
    - Successful Phase 2 study completed in September 2017
    - Phase 2b study design finalized in agreement with FDA
  - Sarcoidosis associated pulmonary hypertension (SAPH)
    - Phase 2 study to be initiated in 4Q2018
  - Learnings from PAH program support INOpulse mechanism of action and benefit in PH associated with ILD, COPD and Sarcoidosis
- Each indication represents multi-billion dollar potential market opportunity
- Strong IP protection on core programs through 2033

Thank you

Investor Contacts:

Fabian Tenenbaum
Chief Executive Officer
BTInvestorRelations@bellerophon.com

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

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