

**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 9, 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)

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.

A copy of the presentation that the management of Bellerophon Therapeutics, Inc. intends to use from time to time during presentations to and discussions with investors, analysts and other interested parties is attached hereto as Exhibit 99.1. The information included in 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 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:

Exhibit No.	Description
99.1	Bellerophon Therapeutics, Inc. Presentation (furnished and not filed for purposes of Item 7.01)

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 9, 2015

By: /s/ Jonathan M. Peacock

EXHIBIT INDEX

Exhibit No.	Description
99.1	Bellerophon Therapeutics, Inc. Presentation (furnished and not filed for purposes of Item 7.01)

Company Presentation

September 2015



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 Highlights

- Focused on developing novel therapies for severe cardiopulmonary and cardiac diseases
- Product candidates address opportunities at the intersection of drugs and devices with high unmet need
- INOpulse: Extension of nitric oxide based therapy for Pulmonary Hypertension (PH) in chronic diseases
 - Nitric oxide approved for use in hospital in neonates; over 450,000 patients treated since launch
 - Novel delivery technology allows for use in serious chronic diseases
 - Several potential applications include:
 - PAH: Planning to initiate Phase 3 in 2015
 - PH-COPD: Completed early Phase 2 testing
 - PH-IPF: Proof of concept work planned
 - Other opportunities include CTEPH, PH-Sarcoidosis, and chronic high altitude sickness
- BCM: Novel injectable device designed to prevent congestive heart failure following a serious heart attack
 - Compelling animal data and encouraging, early open label study
 - Further exploratory work under consideration following results from recent Phase 2 study but no active development at this point
- Strong IP protection on core programs

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Major Institutional Stockholders

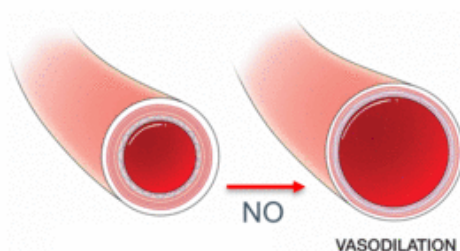


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INOpulse Platform



INOpulse Platform Overview



NO
as a
vasodilator



Small,
pulsed gas
delivery
device



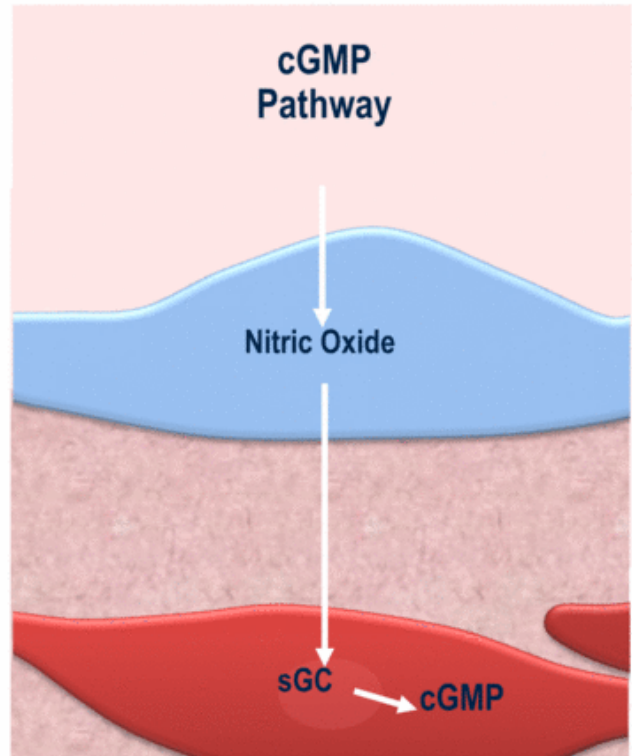
Opportunity in 6
indications:

- PAH
- PH-COPD
- PH-IPF
- CTEPH
- PH-Sarcoidosis
- Chronic High Alt. Sickness



Clinical Application of Inhaled NO

- Nitric oxide is an endogenous molecule integral to normal vasodilation
- Well understood pathophysiology with FDA approved use in Persistent Pulmonary Hypertension in the Newborn for 10+ years
- Inhaled NO has ultra-local effect when targeted to the pulmonary artery smooth muscle
 - Metabolized rapidly as it contacts blood
- INOpulse is being developed as a safe and effective add-on to existing therapies



Portable Delivery System Allows Outpatient Chronic Nitric Oxide Therapy

- Currently well established as a therapy for neonates in hospitals
- In-hospital device is bulky with large cylinders
- Continuous dosing is inefficient



- Pulsed iNO can deliver equivalent dose as continuous delivery with 5% of the volume; Allows for small portable ~2.5 lbs. device
- Dynamic pulse is designed to deliver the prescribed dose accurately throughout the day
- Triple-lumen cannula designed to support accurate dosing and for use, when needed, alongside Long Term Oxygen Therapy (LTOT)
- Pulsing minimizes NO release which is important for chronic at-home use



Images are not to scale relative to each other

Potential Indications for Chronic Use of Pulsed iNO

- Pulmonary Arterial Hypertension (PAH)
 - Several approved therapies but median survival still less than 5 years
 - Orphan disease
- PH associated with Chronic Obstructive Pulmonary Disease (PH-COPD)
 - No current drug therapies
- PH associated with Idiopathic Pulmonary Fibrosis (PH-IPF)
 - No current drug therapies
 - Orphan disease
- Chronic Thromboembolic Pulmonary Hypertension (CTEPH)
 - Riociguat recently approved for this condition
 - Orphan disease
- PH associated with Sarcoidosis
 - No current drug therapies
 - Orphan disease
- Chronic High Altitude Sickness
 - Currently treated with Oxygen therapy

INOpulse Scientific Advisory Board

Senior International Experts in PAH, PH-COPD and PH associated with other lung diseases

- **Greg Elliot, MD, Utah:** Professor of Medicine at the University of Utah and Chief of the Pulmonary and Critical Care Medicine Division at the LDS
- **Nazzareno Galie, MD, Italy:** Head of the Pulmonary Hypertension Center at the University of Bologna
- **Ardi Ghofrani, MD, Germany:** Associate Professor for Internal Medicine at University Hospital, Giessen
- **Fernando Martinez, MD, NYC:** Executive Vice Chair of Medicine, Weill Cornell Medical College and New York-Presbyterian Hospital/Weill Cornell Medical Center
- **Vallerie McLaughlin, MD, Detroit:** Director of the Pulmonary Hypertension Program at the University of Michigan and Attending Physician at the University of Michigan Health System in Ann Arbor, MI
- **Robert Naeije, MD, PhD, Belgium:** Professor and Chairman of the Department of Physiology and Pathophysiology at Erasme University Hospital, Brussels
- **Steve Rennard, MD, Omaha:** Larson Professor of Medicine in the Pulmonary and Critical Care Medicine, Department of Internal Medicine at the University of Nebraska Medical Center in Omaha
- **Lewis Rubin, MD, NYC:** Emeritus Professor of Medicine at the University of California in San Diego; now consultant out of NY
- **Olivier Sitbon, MD, France:** Professor of Respiratory Medicine at the South Paris University

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INOpulse Device Patents

Patent	Status	Expiration	Notes
Method of NO administration	Issued-US Pending in other territories	1-2027	Covers consistent delivery of prescribed dose independent of respiratory rate
Cannula	Issued-US	12-2033	Covers accurate dose delivery and reduced NO ₂ formation
Index valve	Pending-US Pending-EU	5-2029	Ensures other cartridges cannot be used with INOpulse

- In addition to patent protection, we will have 7 years of market exclusivity in the US from Orphan Drug status* for PAH
- Orphan status filing for PAH planned for EU where we expect orphan market exclusivity of 10 years*

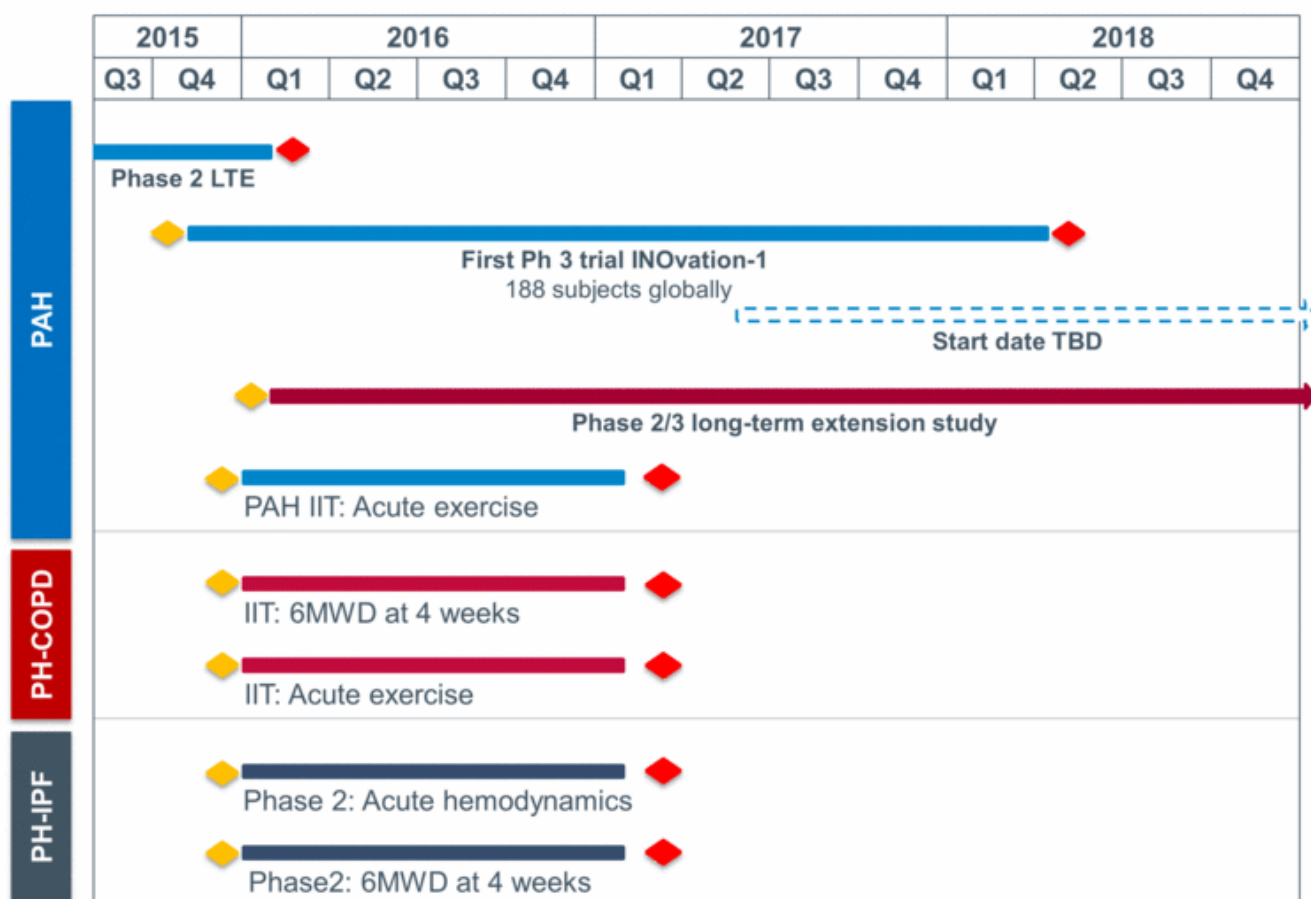
* Contingent on INOpulse being the first inhaled nitric oxide therapy to receive FDA approval or EMA marketing authorization, respectively, in this indication

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Expected Milestones

- Study start
- Top line results

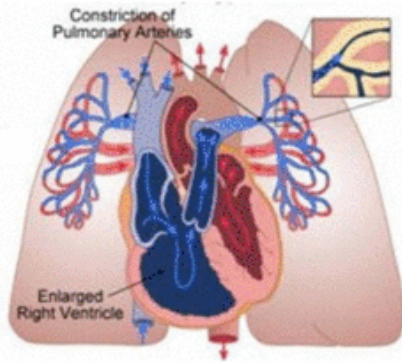


INOpulse: Primary Indication in Pulmonary Arterial Hypertension (PAH)

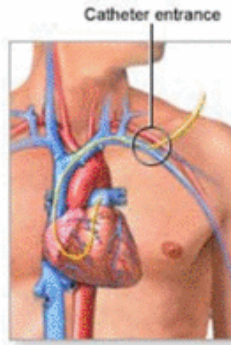


Pulmonary Arterial Hypertension (PAH)

Disease of the Pulmonary Arteries



Diagnosed by right heart catheterization



Under 30 group at PHA Meeting



They like going to karaoke at Disney World at PHA Meeting in Orlando



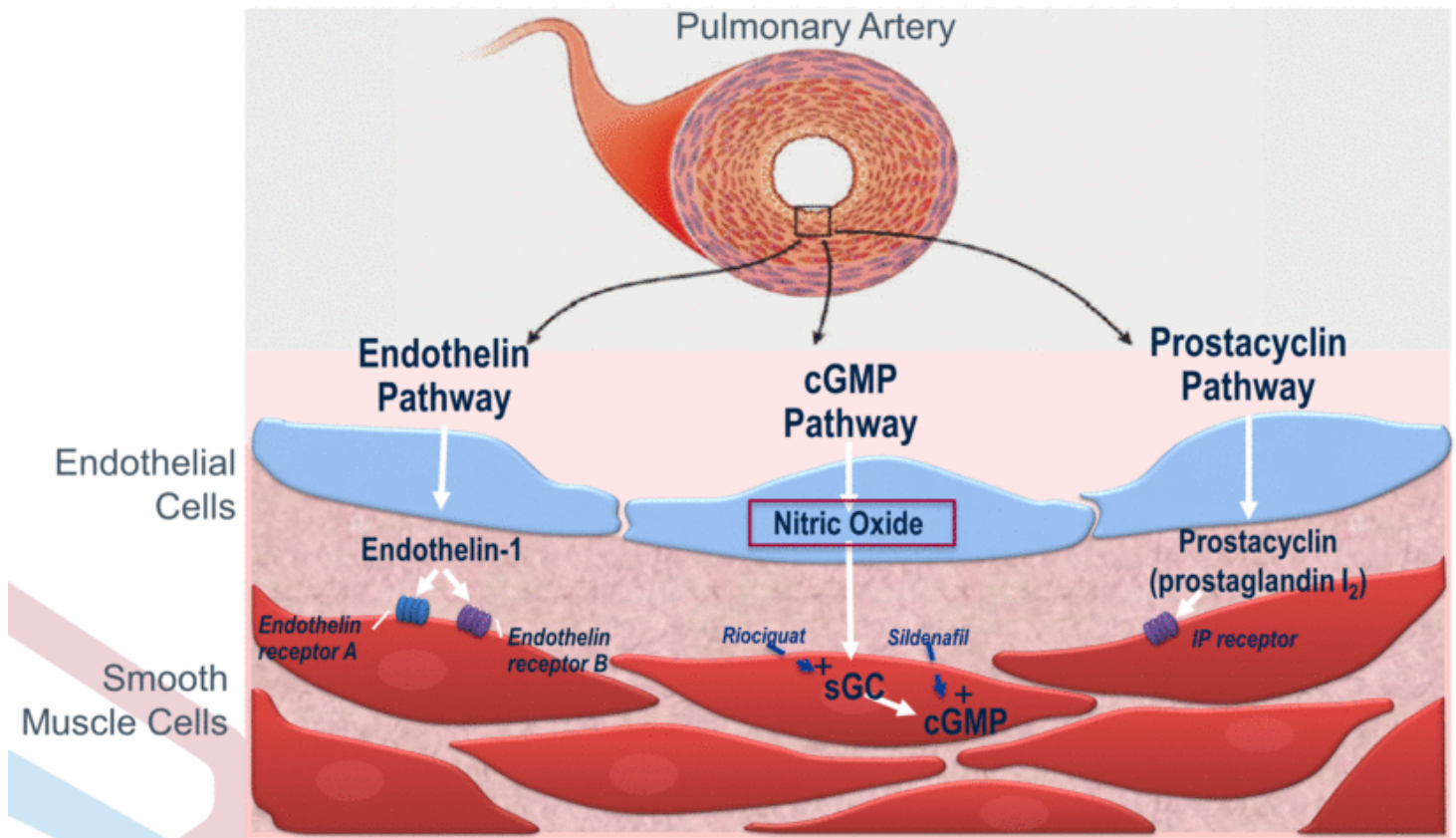
- Despite the available therapies, PAH patients have a poor prognosis with high mortality rates resulting in a median survival of less than 5 years
- Only cure is lung transplantation
- More common in young women
- Approximately 20,000 patients in the US and EU have severe to very severe disease and are treated with multiple therapies, including many who are on Long Term Oxygen Therapy (LTOT)
- Pricing for existing treatments are in the range of ~\$100K to \$150K per patient per year in the US

Many are children and teenagers



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INOpulse Targets a New Pathway to Treat PAH



Adapted from Humbert M et al. *N Engl J Med*. 2004;351:1425-1436.

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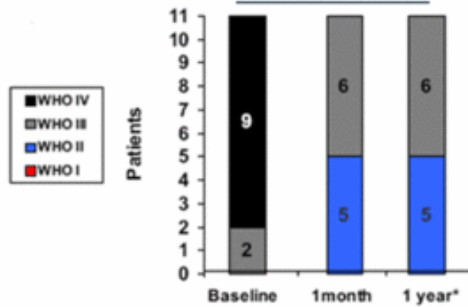
Pilot Study Indicated Efficacy of Pulsed iNO in PH

7 patients with severe PAH who declined i.v. prostacyclin

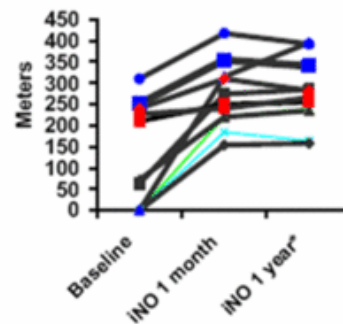
4 patients with severe CTEPH

Individualized pulsatile inhaled nitric oxide treatment administered for 8-12 months

Change in WHO Severity Classification



Change in Six Minute Walk Distance (6MWD)



* Two patients did not complete 1 year evaluation; data are from 6 months test assessed as last measurement carried forward

Perez-Penate et al. J Heart Lung Transplant 2008;27:1326
(Independent Study)

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INOpulse for PAH: Phase 2 Trial

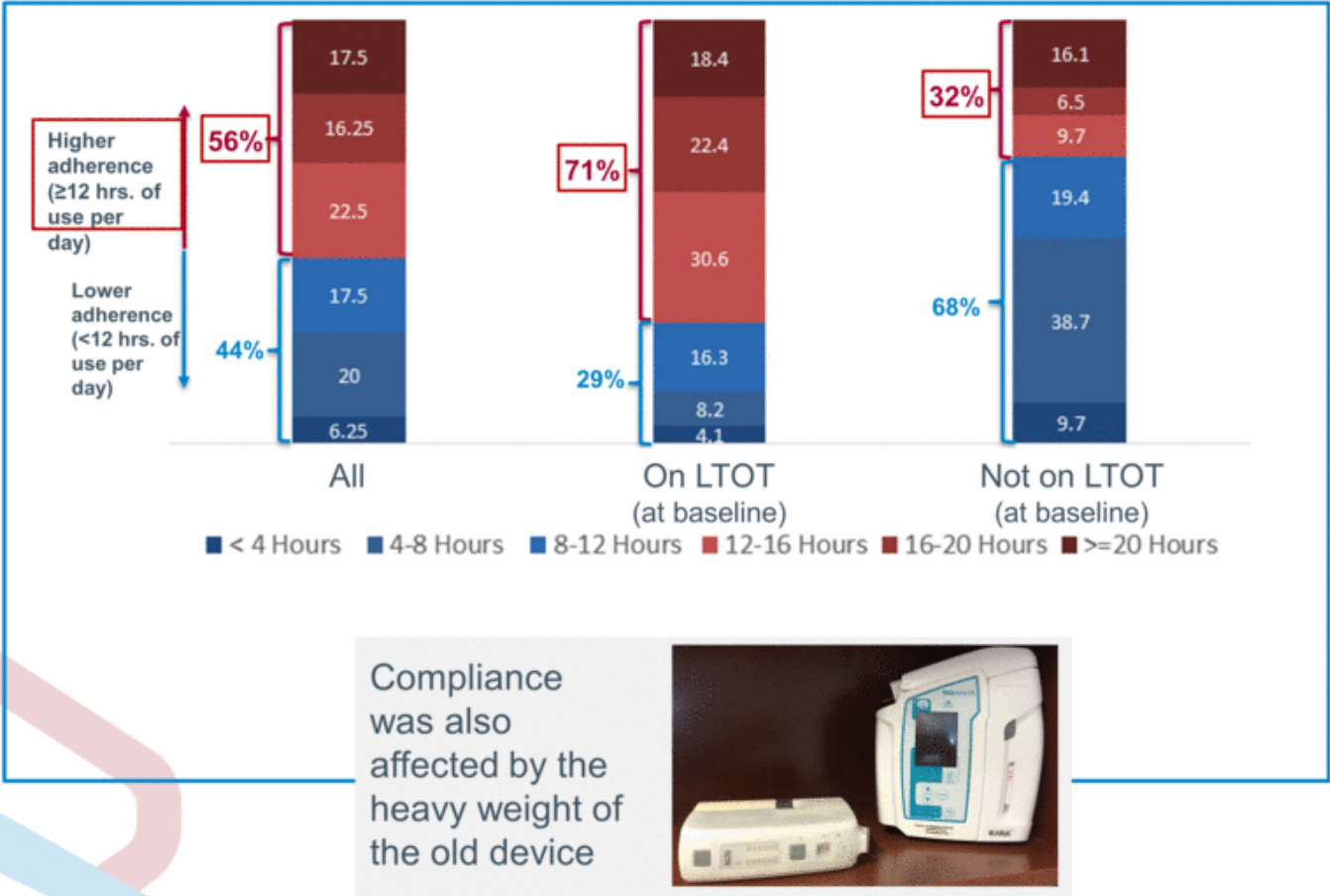
- **Purpose of trial:** Evaluate effect of iNO on hemodynamic measures and 6MWD in ambulatory patients with PAH on at least one approved therapy
- **Design:** Randomized, double-blind, placebo-controlled
 - 16-weeks study with 80 patients in 52 sites
 - Two active doses of 25 and 75 mcg/kg IBW/hr
- **Endpoints:**
 - Primary: change in pulmonary vascular resistance (PVR)
 - Secondary: change in 6MWD

Baseline Characteristics	Placebo	25 iNO	75 iNO
Number of patients	26	27	27
PVR (mean; dynes sec.cm ⁻⁵)	601.5	665.8	662.9
6MWD (mean; meters)	367.5	326.8	300.7

IBW: Ideal body weight; Majority of patients were in WHO FC III & IV

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LTOT Users Were More Compliant to INOpulse Therapy



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Data shown as percentage of patients in group; LTOT = long term oxygen use

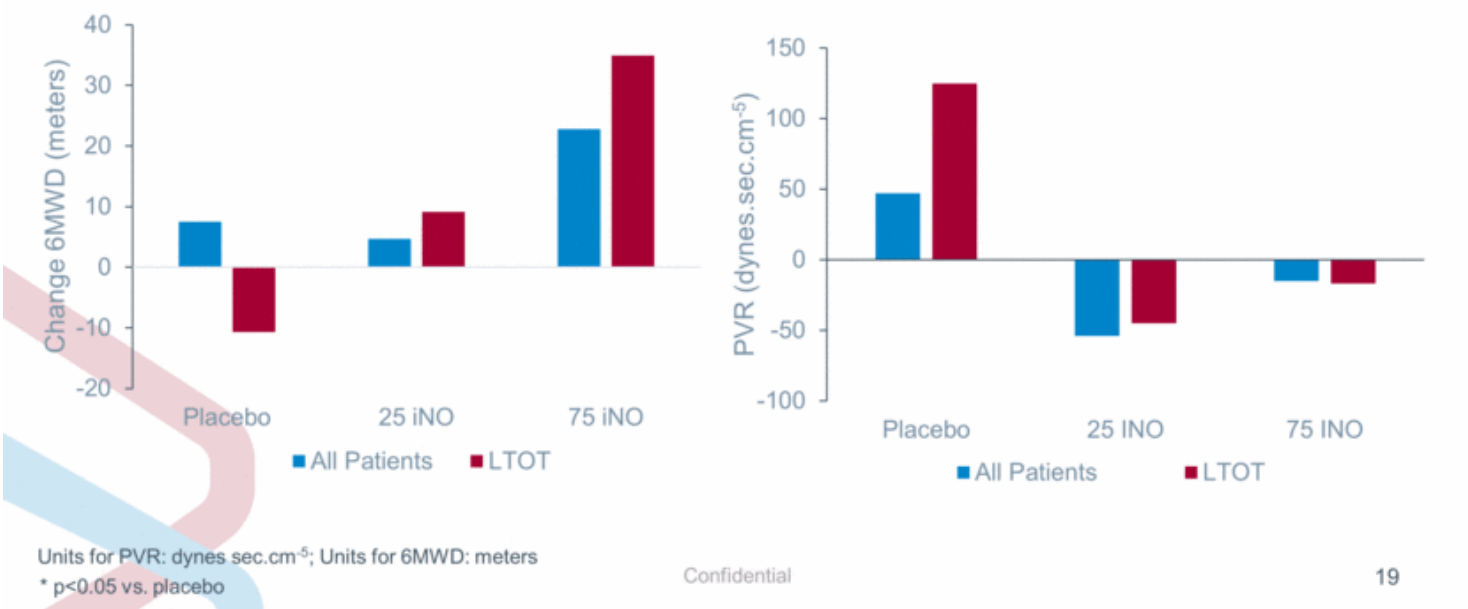
LTOT Patients Showed Clinically Significant Improvement in Exercise Tolerance with High Dose iNO

6MWD: Change vs. Baseline (Mean)

	N	Placebo	25 iNO	75 iNO
All patients	71	7.5	4.7	22.8
LTOT users	43	-10.7	9.1	34.9*

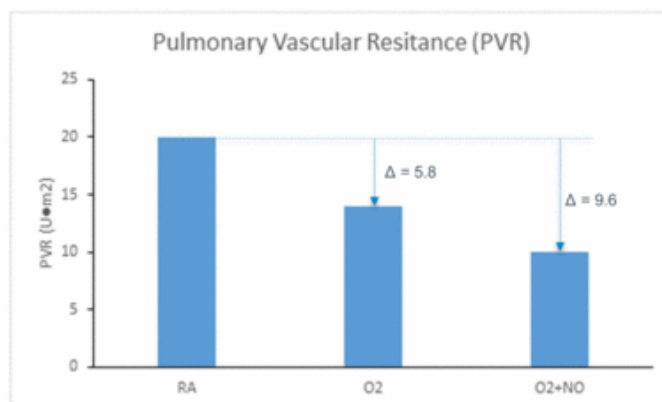
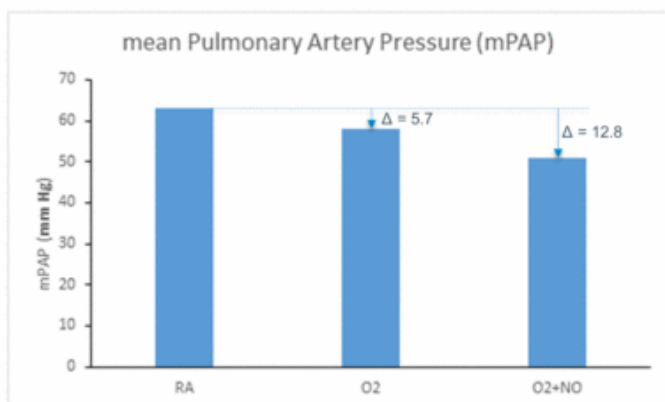
Resting PVR: Change vs. Baseline (Mean)

	N	Placebo	25 iNO	75 iNO
All patients	71	47.2	-54.1	-15.0
LTOT users	44	125.5	-47.1*	-17.5



Inhaled Nitric Oxide Has Demonstrated Additive Effects to Oxygen

Academic study of 25 patients with PH, ranging in age from 5 months to 69 years, to evaluate acute vasoreactivity testing with oxygen alone and with nitric oxide versus room air



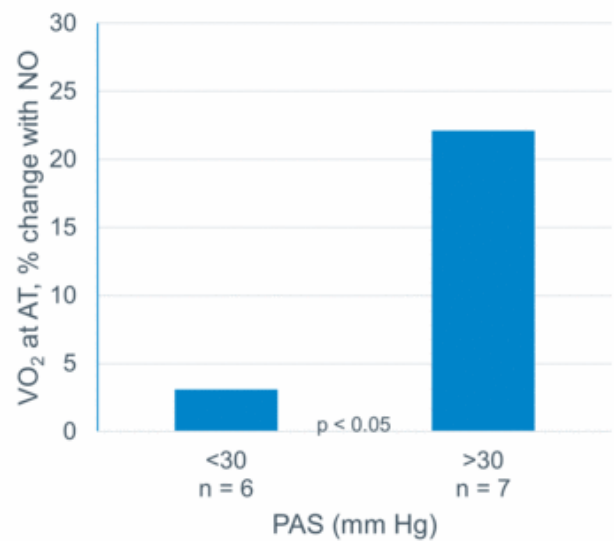
ANOVA p Value is 0.0002 for mPAP and < 0.0001 for PVR
mPAP and PVR for O2 + NO was different than for O2 and RA ($p < 0.05$)
PVR for O2 was different than for RA ($p < 0.05$)

Atz et al, J Am Coll Cardiol 1999; 33:813-9 (Independent Study)

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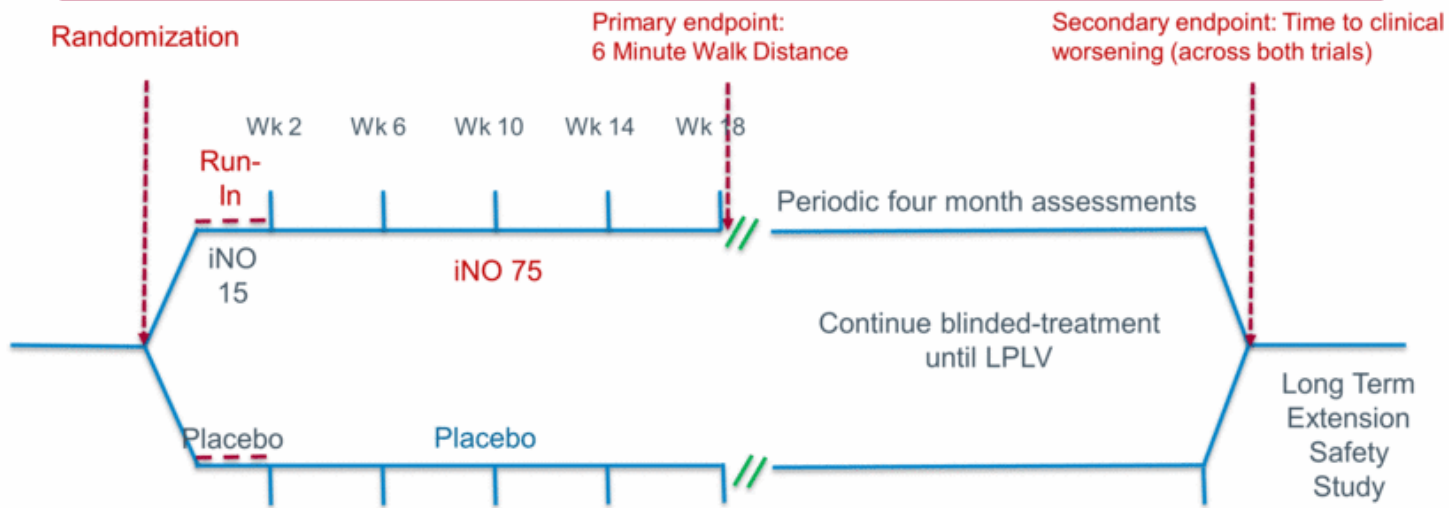
Inhaled Nitric Oxide Has Improved Exercise Capacity in Patients With Pulmonary Hypertension

- In a prior academic study, patients with heart failure were evaluated for exercise capacity, measured as oxygen consumption (VO_2) at peak exercise
- Exercise testing was performed with and without inhaled NO and patients were assessed by degree of PH
- Patients with high pulmonary artery pressures showed significant improvements in exercise capacity versus baseline



These results show the importance of pulmonary circulation during exercise and the potential for iNO to impact exercise capacity

- FDA and EMA are in agreement on Phase 3 protocol:
 - Two Phase III trials with change in 6MWD as primary endpoint
 - Secondary endpoint of Time to Clinical Worsening with analysis combining data across both trials
 - Population: PAH patients requiring LTOT
 - Two week run-in period to enrich for adherence
 - 6MWD will be measured at 16 weeks after the run-in period
- Regulated as a drug-device combination
- Orphan Drug Designation granted in US
 - Plan to apply for EU designation; Has been granted for other PAH drugs



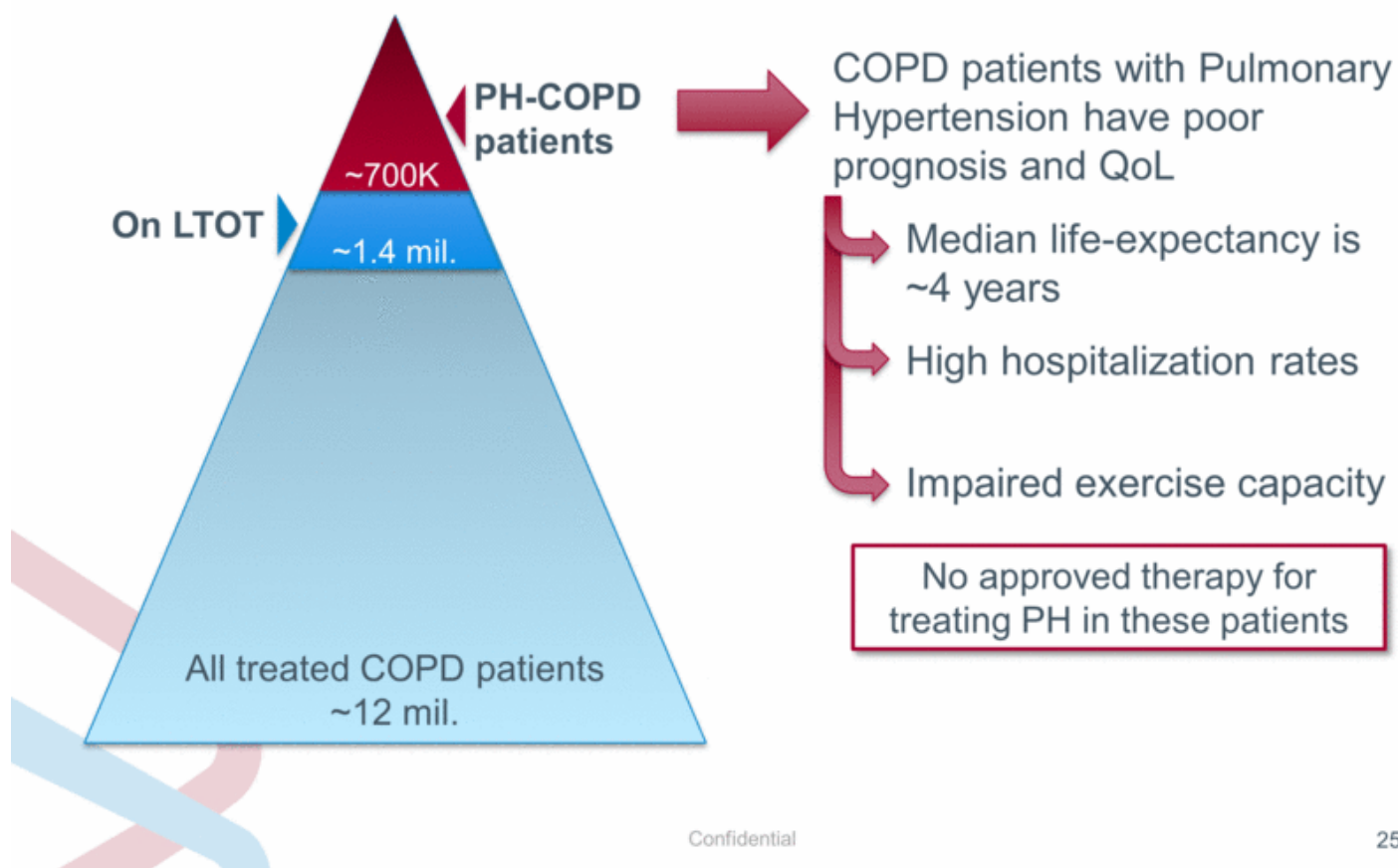
Screening	Run in period	Monthly visits	18 week visit	Four monthly visits	End of study
Right Heart Catheterization	Over 16 hrs of use / day	6 minute walk distance	6 minute walk distance	6 minute walk distance	6 minute walk distance
6 minute walk distance		Several secondary criteria	Several secondary criteria	Several secondary criteria	Time to clinical worsening
Several secondary criteria					Several secondary criteria

INOpulse: PH-COPD



PH-COPD Patients Constitute a Large and Sick Patient Group

US Patient Population

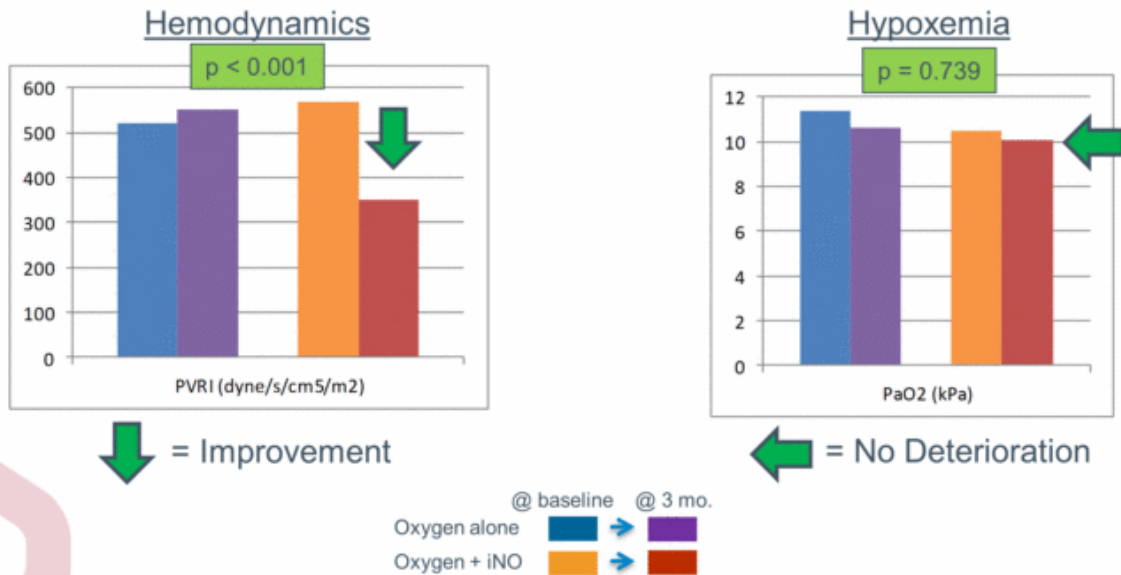


INOpulse May Offer Unique Benefits in Treating COPD Patients with PH

- Existing PAH therapy lowers pulmonary pressures but negatively influences oxygenation in PH-COPD
- Pulsed iNO can be targeted to the alveoli
 - Short pulse early in inspiration dilates vessels in best ventilated alveoli only, reduces pulmonary pressures, and prevents admixture of less oxygenated blood
 - Local and fast metabolism prevents delivery to non-targeted alveoli

Pilot Studies Support Testing Long Term Benefit of iNO in PH-COPD Patients

- iNO demonstrated sustained hemodynamic benefits in PH-COPD patients
 - 3 month, open-label trial of pulsed iNO delivered using a prototype device
 - Patients were randomized to LTOT alone (n=17) or LTOT + pulsed iNO (n=15)
 - At 3 months, iNO reduced PVRI and PASP and increased cardiac output without negative impact on hypoxemia



Vonbank K et al. *Thorax* 58:289-93,2003
PVRI = Pulmonary vascular resistance index
PASP = Pulmonary artery systolic pressure

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INOpulse Testing Confirmed Impact on Pulmonary Hemodynamics Without Hypoxemia in PH-COPD

- FDA asked us to establish a dose range with the INOpulse device and to confirm the efficacy and safety results seen in the open label study
- We have completed randomized placebo controlled acute test with 159 patients using the INOpulse device with doses ranging from 3 to 75 mcg/kg IBW/hr
 - Oxygenation levels were similar to placebo across all doses tested
 - PASP change vs. baseline was very similar to the open label study for doses ≥ 10 mcg/kg IBW/hr

PASP = Pulmonary artery systolic pressure

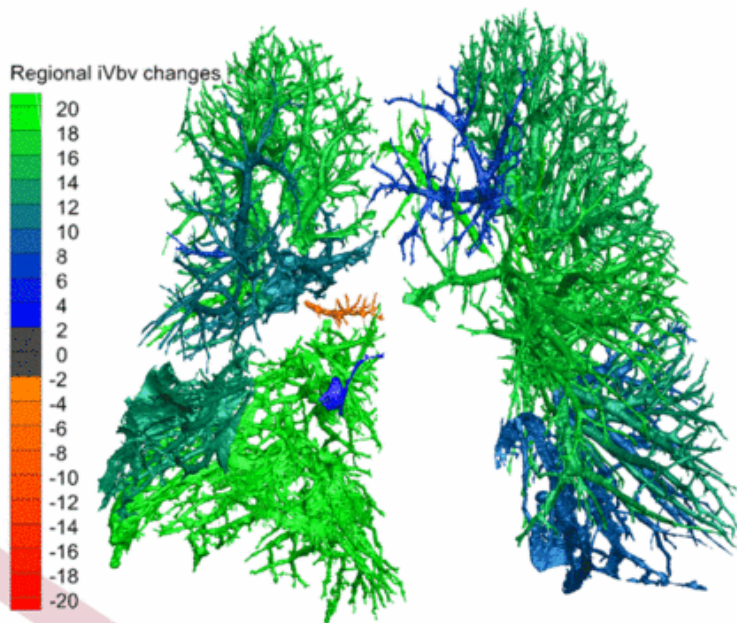
*PASP data consistently favor iNO at doses 10 – 75 mcg/kg IBW/hr, but statistical significance compared to placebo was not reached

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High-Resolution Computed Tomography Imaging Study

Demonstrated iNO effects on pulmonary vessels in PH-COPD patients



- The objective of this exploratory study was to further validate the potential benefits for COPD patients by measuring changes in pulmonary vessels (i.e. vasodilation) as a function of short term iNO administration using INOpulse in subjects with PH associated with COPD on LTOT
- Acute Treatment with iNO 30 mcg/kg IBW/hr for at least 20 minutes not to exceed 90 minutes (n=6)
- No significant drop in blood oxygenation (SpO₂) was observed during inhalation
- 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