

# Corporate Presentation

July 2020



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These forward-looking statements appear in a number of places throughout this presentation and include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, the patient market size and market adoption of our products by physicians and patients, the timing and cost of clinical trials for our products or whether such trials will be conducted at all, completion and receiving favorable results of clinical trials for our products, the development and approval of the use of nitric oxide for additional indications, FDA approval of, or other regulatory action with respect to, the timing, cost or other aspects of the commercial launch of our products and the commercial launch and future sales of our products or any other future products or product candidates. The extent to which the COVID-19 pandemic and global efforts to contain its spread will impact our operations, including the ability to conduct our preclinical studies and clinical trials or rely on our third-party manufacturing and supply chain, will depend on future developments, which are highly uncertain and cannot be predicted at this time, and include the duration, severity and scope of the pandemic and the actions taken to contain or treat the COVID-19 pandemic.

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# Beyond Air – A Paradigm Shift in Nitric Oxide Therapy

## LungFit™ devices generate nitric oxide (NO) from ambient air

- Allows for unlimited on-site generation of NO vs. fixed supply cylinder systems currently used in hospitals
- NO therapy can move safely into the home setting with self-administration for chronic infections

## Advantages over currently used NO cylinder systems in the hospital setting

- Smaller, lighter, easier to store and simple to use for staff while reducing safety concerns

## LungFit™ allows for the use of high concentration NO to treat a variety of lung infections

- Persistent pulmonary hypertension of the newborn (PPHN) is the only FDA approved indication at a concentration of 20 parts per million (ppm) of NO
- Beyond Air evaluating NO concentrations in the range of 150-250 ppm, which are challenging for cylinder systems
- “Intermittent” dosing allows for safe delivery of high concentration NO
- SARS CoV-2, bronchiolitis, nontuberculous mycobacteria (NTM) lung Infections in development, with COPD in preclinical
- Ultra-high concentration (10,000+ ppm) NO for solid tumors (without LungFit™) in preclinical development

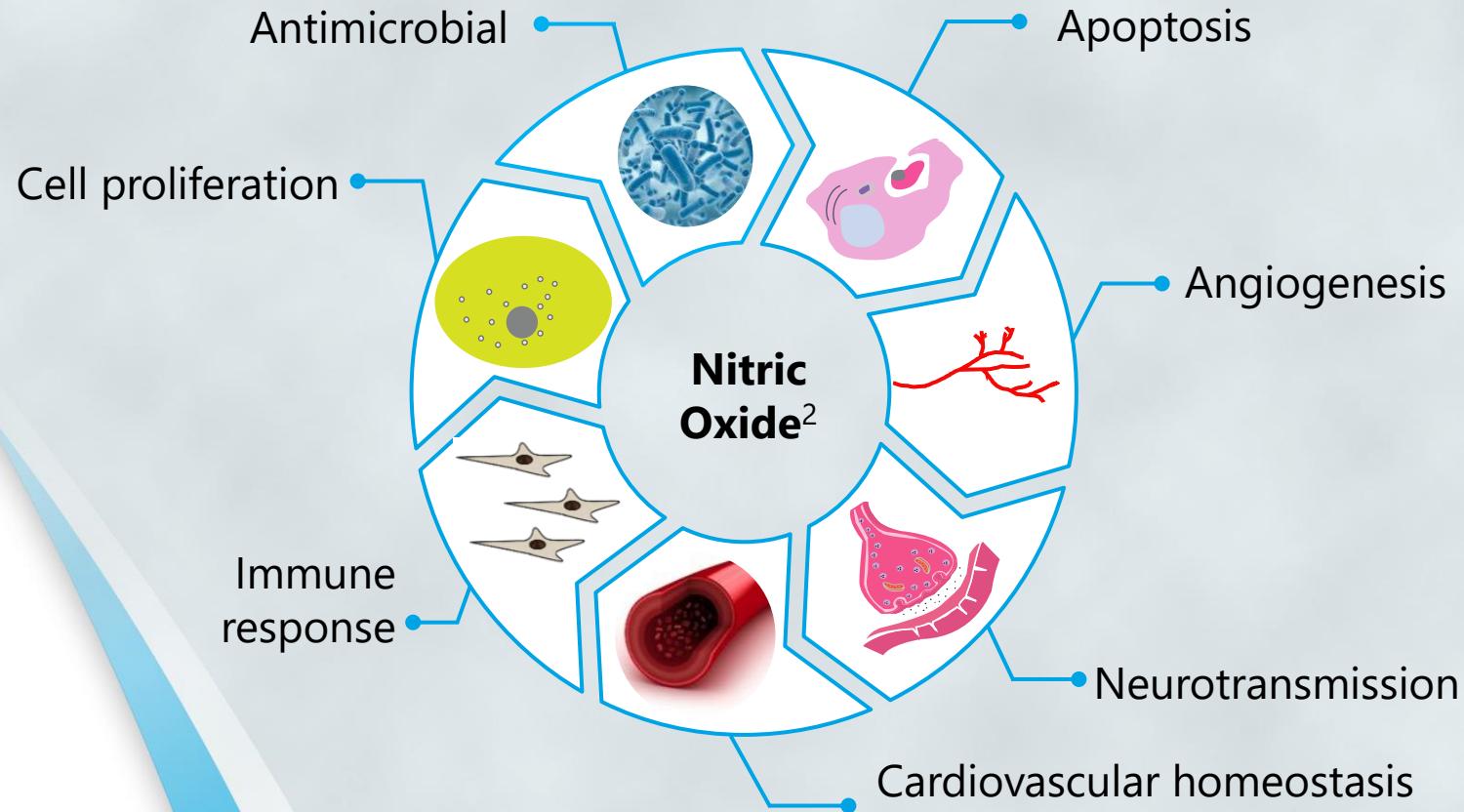
## Extensive intellectual property portfolio

## Upcoming events

- PMA for PPHN expected to be filed in 2H 2020
- COVID-19 pilot studies underway in the US and Canada with data expected by year end

# Late Stage, Active Pipeline

Product	Indication	Development Status	Key Dates <sup>(1)</sup>	US Sales Potential <sup>(2)</sup>	Worldwide Sales Potential <sup>(2)</sup>
LungFit™ PH ventilator compatible	In-hospital use for PPHN and cardiac surgery	Final preparations for PMA	PMA filing 2H 2020 US launch 1H 2021	>\$300 million	>\$600 million
	COVID-19	Pilot studies in progress	Pilot study data 2H 2020	N/A	N/A
LungFit™	Bronchiolitis	3 Pilot studies complete	Pivotal starts 4Q21 US launch 2023	>\$500 million Beyond Air to commercialize	>\$1.2 billion
	Nontuberculous mycobacteria (NTM) lung infection	Pivotal study-ready			
LungFit™ Home	Nontuberculous mycobacteria (NTM) lung infection	Pilot phase	4Q20 start for pilot Self-administration at home	>\$1 billion	>\$2.5 billion
	Severe exacerbations due to lung infections in COPD patients	Pre-clinical	Pilot study start 2H21	>\$2.5 billion	>\$6 billion
Solid Tumors	Multiple solid tumors	Pre-clinical	Initial data presented AACR June 2020	TBD	TBD



# The role of nitric oxide

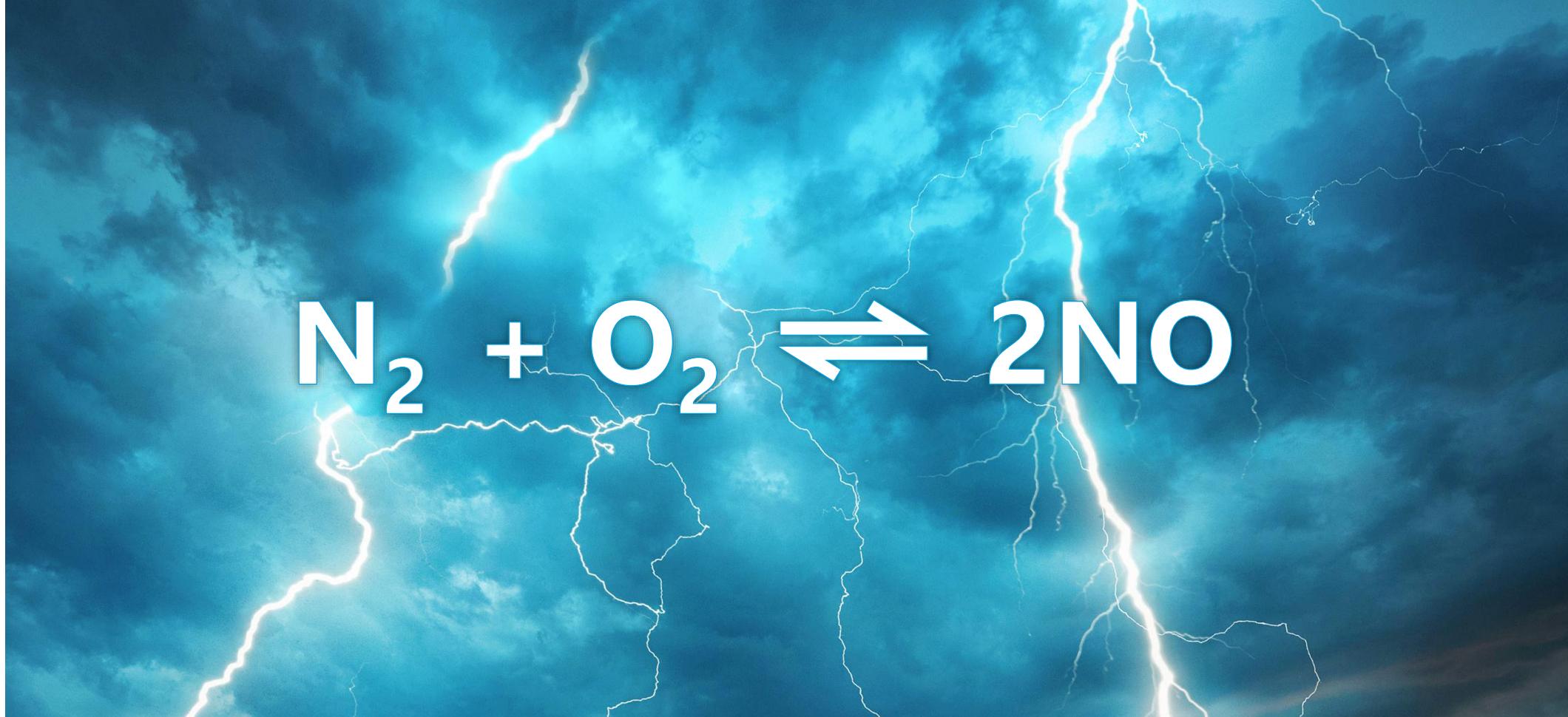
Nitric oxide market is currently > \$500M in the US<sup>1</sup>

1. MNK company reports

2. Image source: Bian K & Murad F. Nitric Oxide, (2014) | Bodgan C. Trends in Immunol, (2015)

# Generating NO From Ambient Air – High Barrier to Entry

During electric discharge in a lightning storm at 20,000°C, the nitrogen and oxygen in air react to produce nitric oxide



LungFit™ safely reproduces the reaction in a proprietary chamber without the extreme heat

# Nitric Oxide: Multiple Mechanisms of Action

## Pulmonary vasodilator

- Inhaled NO selectively dilates the pulmonary vasculature via relaxation of vascular smooth muscle
  - Any NO that passes from the pulmonary vascular wall into systemic circulation is rapidly and efficiently scavenged by hemoglobin which minimizes systemic vasodilation effects

## Immunomodulation

- Immunoregulatory functions
- Inhibition of T and B cell proliferation
- Leukocyte recruitment (adhesion, extravasation, chemotaxis)
- Antibody production by CD5+B cells, autoreactive T and B cell diversification<sup>[1]</sup>

## Antimicrobial

- Antiviral
  - Inhibition of viral enzymes<sup>[2]</sup>
  - Blocking of RNA synthesis<sup>[3]</sup>
  - Blocking of viral replication cycle by modifying target molecules essential for replication<sup>[3]</sup>
- Antibacterial
  - Broad-spectrum activity against multiple bacteria including *Pseudomonas*, *Staphylococcus*, *E. coli*, and MRSA
  - Mechanism attributed to DNA damage, bacterial enzyme inhibition, and induction of lipid peroxidation<sup>[4]</sup>

# NO Plays a Major Role in the Immune System

Source of NO (cell type)	Category	Effector function
Macrophages, microglia, neutrophils, eosinophils, fibroblasts, endothelial cells, epithelial cells	Antimicrobial activity	Killing or reduced replication of infectious agents (viruses, bacteria, protozoa, fungi and helminths)
Macrophages, eosinophils	Anti-tumor activity	Killing or growth inhibition of tumor cells
Macrophages, microglia, astroglia, keratinocytes, mesangial cells	Tissue-damaging effect (immunopathology)	Necrosis or fibrosis of the parenchyma
Macrophages ('suppressor phenotype')	Anti-inflammatory — immunosuppressive effect	Immunoregulatory functions Inhibition of T and B cell proliferation, leukocyte recruitment (adhesion, extravasation, chemotaxis), Antibody production by CD5+B cells, autoreactive T and B cell diversification
Macrophages, T cells, endothelial cells, fibroblasts	Modulation of the production and function of cytokines, chemokines and growth factors	Up- and downregulation, e.g., of: IL-1, IL-6, IL-8, IL-10, IL-12, IL-18, IFN- $\gamma$ , TNF TGF- $\beta$ , G-CSF, M-CSF, VEGF, MIP-1 $\alpha$ , MIP-2, MCP-1
Macrophages	T helper cell deviation	Induction and differentiation of TH1 cells Suppression of TH1 (and TH2) cell responses Suppression of tolerogenic T cell responses



## LungFit™ – Multiple Devices

*Nitric oxide generation from ambient air*



# Significant Advantages in the Hospital – Pulmonary Hypertension

Current SOC uses large, bulky, and heavy cylinders



	Cylinder System	LungFit™ PH	LungFit™ PH On Cart
Height	~60"	15"	60"
Width	~20"	18"	24"
Depth	~21"	14"	28"
Weight	175 lbs	32 lbs	65 lbs

## Simple, safe, and practical

- Ventilator compatible

## Easy to Use:

- Filter timer – signals when to change
- Simple, intuitive, and familiar user interface
- Convenient for all staff
- Alarms monitor performance
- Use with any electrical outlet 110/220V

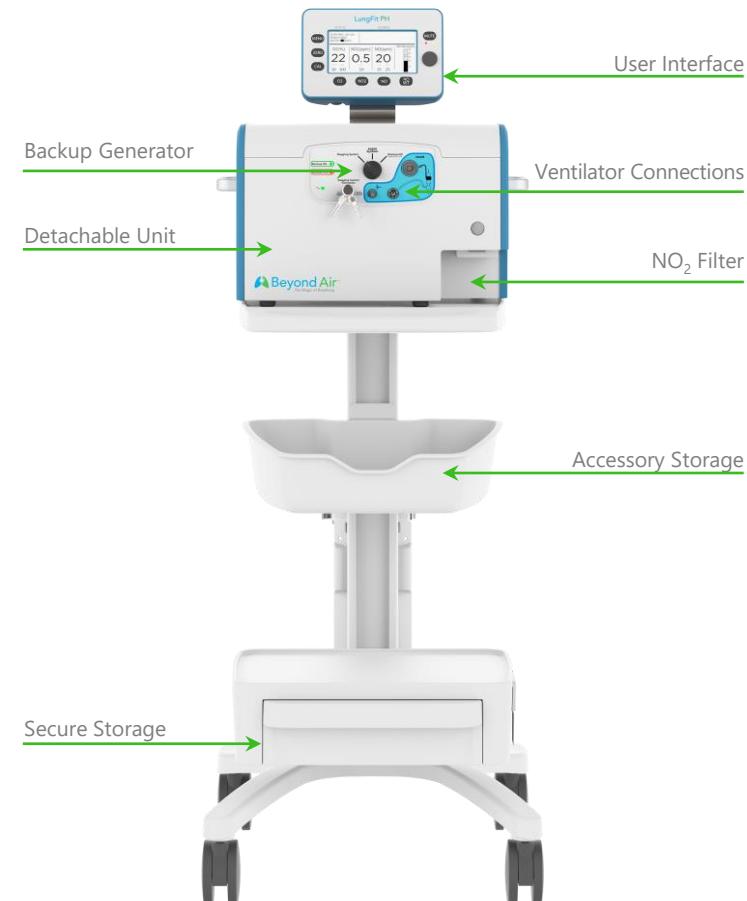
## Portable:

- Use with lightweight cart
- Detachable if desired – only 32 lbs.
- Ample accessory storage

## Built in back-up system

- No danger of sudden NO flow disruption
- Simple switch to flip to backup NO source
  - Keep ventilator or utilize “bagger”

LungFit™ PH generates NO from ambient air



# Beyond Air Smart Filter vs. Cylinder

45 pounds



Consummate “razor blade” financial model for NO Delivery

2.5 oz

**Proprietary smart filter removes toxic nitrogen dioxide (NO<sub>2</sub>) gas**

**Filters are a fraction of the cylinder size**

- No disposal requirements
- Easy to store, handle, and manage inventory

**Smart filter RFID chip**

- Measures time until filter change required
- Recognition – LungFit™ will not function without smart filter
  - Razor blade model
  - Safety – prevents NO<sub>2</sub> toxicity
  - Encryption prevents counterfeits
- Filter programs the system
  - Sets concentration and flow rate (not true for LungFit™ PH)

**Smart Filter ensures hospitals are only charged for what they use**

- Favorable economics for institutions



# LungFit™: For Treating Lung Infections



## Simple, safe, and practical

- Allows for both home and hospital use
- Supplemental oxygen can be utilized through the system

## Easy to Use

- Programmable by RFID on filter
- Convenient for all staff
- Self-administration for home use
- Use with any electrical outlet 110/220V

## Portable

- Only 20 lbs.

## One system can treat multiple patients

- Easy to change breathing circuit
- One circuit per patient
- Disposable filters

## One Respiratory Therapist (RT) can operate multiple systems

- Insert filter and press go
- Alarms monitor performance

# High Concentration NO – XAIR Demonstrated Safety in Humans

- Beyond Air has 9 years of experience with high concentration NO
- Concentrations as high as 250 ppm have been tested, with no SAE's
- Currently only 20 ppm NO approved by FDA

**2,500+**

Treatments  
administered

**140+**

Patients

**9**

Different  
clinical settings

**0**

Serious Adverse Events  
(SAEs) related to NO

Date	Study	Indication	Primary	Results
2011	Phase 1 Safety (n=10)	All comers	Safety	<ul style="list-style-type: none"><li>• No SAEs</li></ul>
2013 –2014	POC double blind randomized (n=43)	Bronchiolitis (due to any virus)	Safe & Eff	<ul style="list-style-type: none"><li>• No SAEs; 24hr reduction in hospital length of stay</li></ul>
2013 - 2014	Pilot open label (n=9)	Cystic Fibrosis (CF)	Safe & Eff	<ul style="list-style-type: none"><li>• No SAEs; Lowered bacterial load</li></ul>
2016	Compassionate use ISR (n=2)	NTM abscessus (CF)	Safe & Eff	<ul style="list-style-type: none"><li>• No SAEs; clinical &amp; surrogate endpoints improved</li></ul>
2017	Compassionate use National Institute of Health, US (n=1)	NTM abscessus (CF)	Safe & Eff	<ul style="list-style-type: none"><li>• No SAEs; Improvements in clinical endpoints</li></ul>
2017	Pilot open label (N=9)	NTM abscessus	Safe & Eff	<ul style="list-style-type: none"><li>• No SAEs; clinical &amp; surrogate endpoints improved</li></ul>
2018	Pilot: double blind randomized (n=67)	Bronchiolitis (due to any virus)	Safe & Eff	<ul style="list-style-type: none"><li>• No SAEs; 27hr reduction in hospital length of stay</li></ul>
2018	Compassionate use ISR (n=1)	NTM abscessus (CF)	Safety	<ul style="list-style-type: none"><li>• No SAEs at 250 ppm NO dose</li></ul>
2019 – 2020	Pilot: double blind randomized (n=89)	Bronchiolitis (due to any virus)	Safe & Eff	<ul style="list-style-type: none"><li>• No SAEs; 150 ppm treatment showed statistically significant improvements in primary and key secondary endpoints compared to both 85 ppm and control</li></ul>

# Intermittent Dosing – Safe Delivery of High Concentration NO

Demonstrated safety using intermittent dosing in preclinical animal toxicity studies and in humans (predictable methemoglobin)

## Preclinical Animal Studies

400 ppm

Rats: 30 days of intermittent treatments with LungFit™ at 400 ppm NO showed no macroscopic or microscopic findings

250 ppm

Rats: 12 weeks of intermittent treatments with LungFit™ at 250 ppm NO showed no macroscopic or microscopic findings

250 ppm

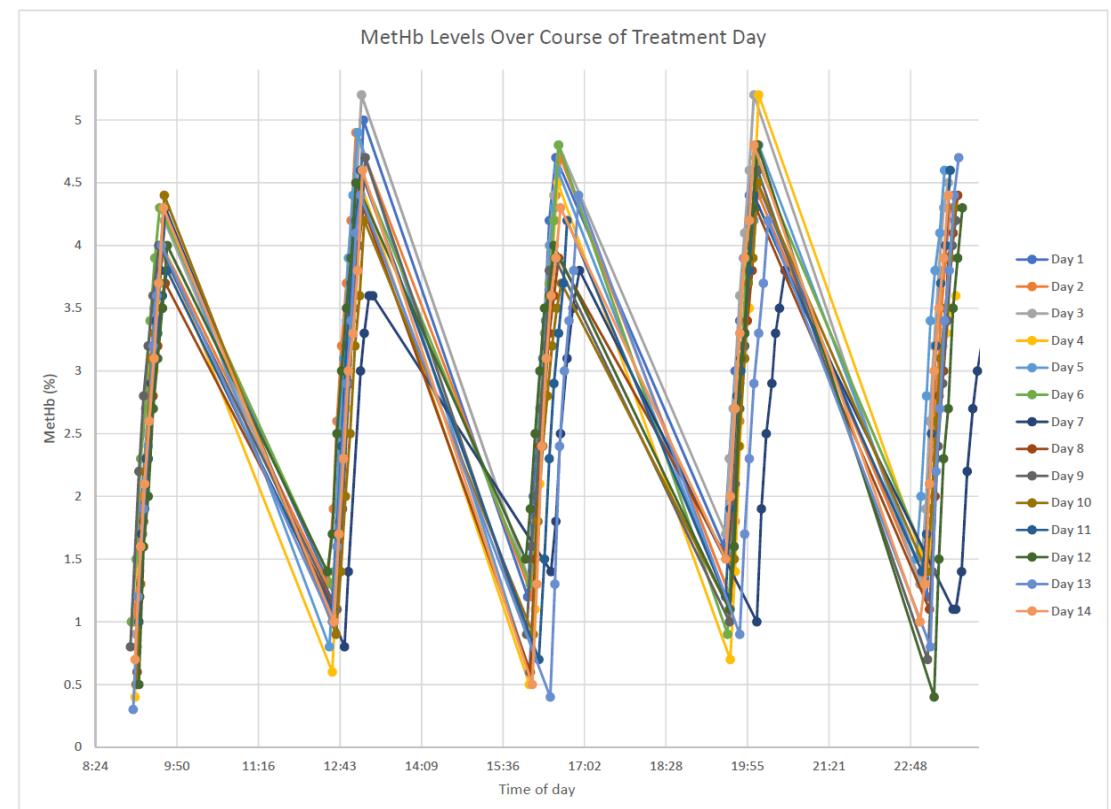
Dogs: 12 weeks of intermittent treatments with LungFit™ at 250 ppm NO showed no macroscopic or microscopic findings

200-400

Rats: Genotoxicology study of intermittent NO at 200 – 400 ppm showed a non-genotoxic response at all concentrations

## Clinical NTM Pilot Study – 160 PPM NO

Methemoglobin (MetHb) - well known biomarker for safety of NO  
Predictable peaks and troughs with intermittent delivery



Mean MetHb levels of 5 NO administrations (160 ppm every 4 hours) per day in 9 subjects for 14 days



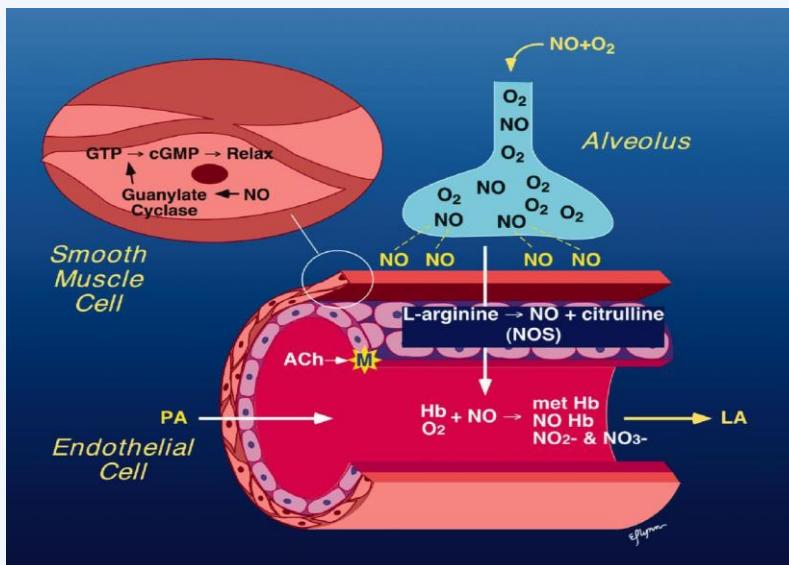
## Persistent pulmonary hypertension of the newborn (PPHN)

*LungFit™ has significant advantages over cylinders*



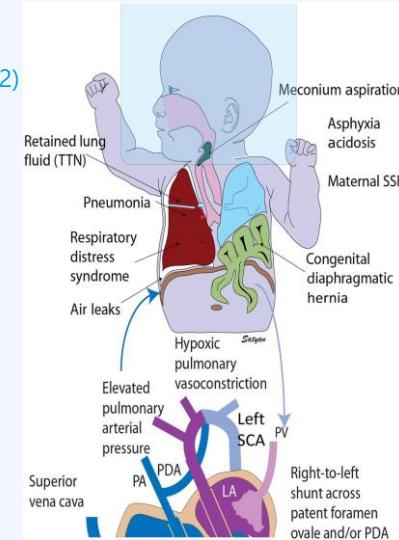
# Nitric Oxide for PPHN and Cardiac Surgery

Inhaled NO (iNO) causes smooth muscle relaxation, increasing blood flow to the lungs and decreasing right ventricular workload<sup>(1)</sup>



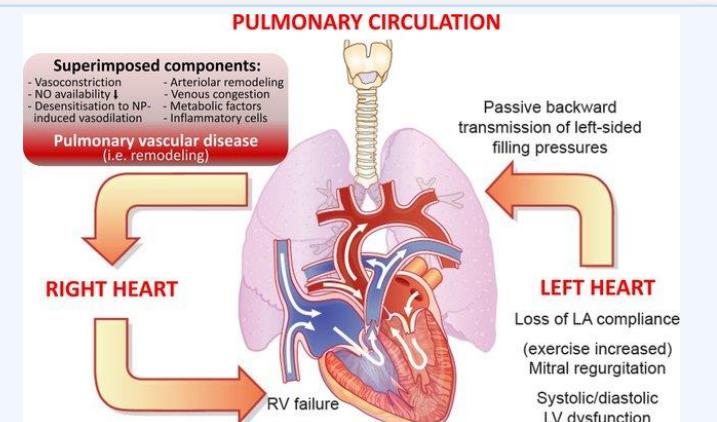
PPHN – Persistent Pulmonary Hypertension of the Neonate<sup>(2)</sup>

iNO reversal of pulmonary hypertension decreases Right-to-Left shunt through PDA and PFO, dramatically improving oxygenation



Perioperative Cardiac Surgery<sup>(3)</sup>

iNO reversal of pulmonary hypertension reduces RV workload and improves cardiac output pre- and post-cardiac surgery



# Current Nitric Oxide Market Dynamics

**Established as standard of care for >20 years for treating pulmonary hypertension in the hospital setting**

## Approved globally for decades

- Approved in the U.S. by the FDA in 1999 for PPHN
- Approved in the EU in 2001 for PPHN and subsequently cardiac surgery

## US market dynamics

- Cylinder systems have dominated since 1999
- 2<sup>nd</sup> player didn't enter the U.S. market until Q4 2019
- ~8% CAGR 2014-2019<sup>(1)</sup>
- >\$500M revenue market<sup>(1)</sup>
- ~800 hospitals use NO<sup>(1)</sup>
- Potential US label expansion to include cardiovascular patients

## International market dynamics

- Multiple players
- Significant opportunity for expansion with a generator-based system

# LungFit™ PH has Significant Advantages for Hospitals



Improved operating economics for the hospital



No burdensome inventory and storage requirements



NO supplied as a non-hypoxic gas mixture



No purging procedures or additional safety measures due to nitrogen dioxide (NO<sub>2</sub>) buildup



No significant capital investment required for hospitals new to NO



Reduced training burden



Greatly reduced risk for pregnant staff members



Reduced risk of NO<sub>2</sub> exposure



XAIR does not have any expenses associated with a manufacturing facility for nitric oxide

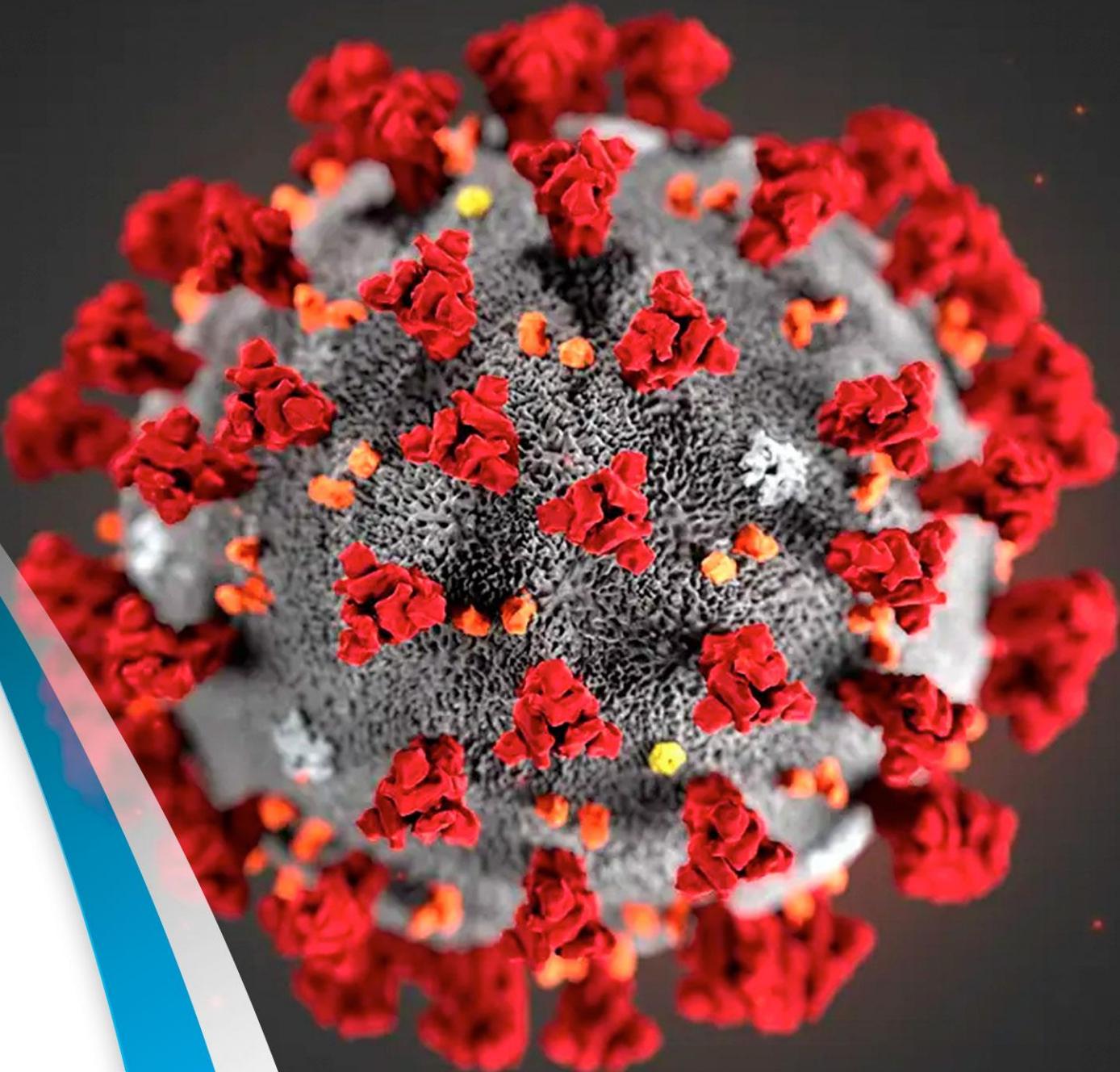


XAIR does not have any expenses associated with logistics related to nitric oxide cylinders



# COVID-19

*Nitric oxide has demonstrated antiviral activity*



# Nitric Oxide Inhibits SARS Coronavirus Replication Cycle

JOURNAL OF VIROLOGY, Feb. 2005, p. 1966–1969  
0022-538X/05/\$08.00+0 doi:10.1128/JVI.79.3.1966–1969.2005  
Copyright © 2005, American Society for Microbiology. All Rights Reserved.

Vol. 79, No. 3

## Nitric Oxide Inhibits the Replication Cycle of Severe Acute Respiratory Syndrome Coronavirus

Sara Åkerström,<sup>1</sup> Mehrdad Mousavi-Jazi,<sup>2</sup> Jonas Klingström,<sup>1,3</sup> Mikael Leijon,<sup>2</sup>  
Åke Lundkvist,<sup>1,3</sup> and Ali Mirazimi<sup>1\*</sup>

*Center for Microbiological Preparedness, Swedish Institute for Infectious Disease Control,  
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Stockholm,<sup>3</sup> Sweden*

Received 13 May 2004/Accepted 16 September 2004

Nitric oxide (NO) is an important signaling molecule between cells which has been shown to have an inhibitory effect on some virus infections. The purpose of this study was to examine whether NO inhibits the replication cycle of the severe acute respiratory syndrome coronavirus (SARS CoV) *in vitro*. We found that an organic NO donor, *S*-nitroso-*N*-acetylpenicillamine, significantly inhibited the replication cycle of SARS CoV in a concentration-dependent manner. We also show here that NO inhibits viral protein and RNA synthesis. Furthermore, we demonstrate that NO generated by inducible nitric oxide synthase, an enzyme that produces NO, inhibits the SARS CoV replication cycle.

# COVID-19 Pilot Study: Current Status and Timelines

## Human clinical testing

- Patient enrollment commenced in US pilot study in June 2020
- Expect to enroll 20 patients in the US
- Goal is to establish safety at 80 ppm
- Pivotal study will use higher concentration (150 ppm)
- Canadian study expected to start enrollment in 2H 2020
  - Expect to enroll 10 patients at 80 ppm, then 40 patients to establish efficacy at 150 ppm

## Pilot clinical trial design

- Multicenter open label US study of 20 adult patients hospitalized with COVID-19
- Subjects randomized 1:1 and treated intermittently with 80 ppm NO administered over 40 minutes, 4x/day, in addition to standard supportive therapy (SST) or SST alone
- Primary endpoint: time to clinical deterioration as measured by the need for: 1) non-invasive ventilation; or 2) high flow nasal cannula; or 3) intubation
- Secondary endpoints: reduction in viral load, need for supplemental oxygen, hospital LOS, mortality, safety, and various biomarkers
- Canadian trial design very similar to the US trial
- Data expected by year end



## Bronchiolitis

*Three successful pilot studies completed in infants*



# Bronchiolitis Disease Overview

## A leading cause of child mortality globally

### The disease

- Acute inflammatory injury of the bronchioles usually caused by viral infection
- Usually affects children <2 years<sup>(1)</sup>, with a peak in infants aged 3-6 months<sup>(1)</sup>
- Approximately 130,000 bronchiolitis admissions annually in the US at an estimated cost of \$1.73 Billion<sup>(2)</sup>
- Most common cause is respiratory syncytial virus (RSV)<sup>(3)</sup>

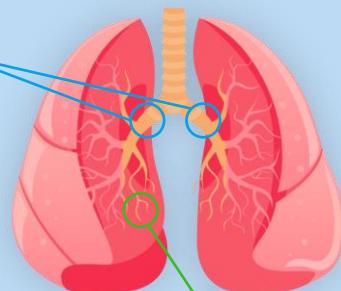
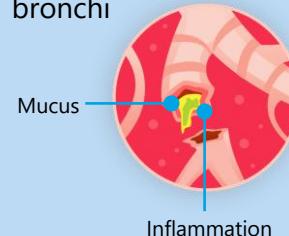
### Benefits of nitric oxide

- Antiviral and Antibacterial mechanisms
  - Preclinical studies show high dose NO has antibacterial and antiviral properties<sup>(4-7)</sup>
- Pulmonary vasodilatory properties
  - FDA/EMA approved for ~20 years

Bronchitis is different from bronchiolitis<sup>(8)</sup>

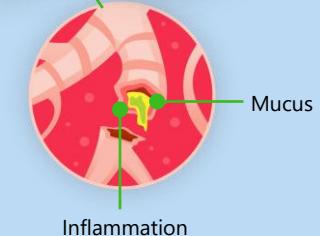
#### Bronchitis

Inflammation and swelling of the bronchi



#### Bronchiolitis

Inflammation and swelling of the bronchioles



No drugs approved for the treatment of bronchiolitis<sup>(9)</sup>

1) Hasegawa K, Tsugawa Y, Brown DF, Mansbach JM, Camargo CA, Jr.: Trends in bronchiolitis hospitalizations in the United States, 2000-2009. Pediatrics 2013; 132(1):28-36.

2) Hall CB, Weinberg GA, Iwane MK, Blumkin AK, Edwards KM, Staat MA, Auinger P, Griffin MR, Poehling KA, Erdman D et al: The burden of respiratory syncytial virus infection in young children. The New England journal of medicine 2009; 360(6):588-598.

3) Piedimonte G, et al. Respiratory syncytial virus infection and bronchiolitis. Pediatr Rev. 2014; 35(12):519-30

4) Ghaffari, A., et al. Efficacy of gaseous nitric oxide in the treatment of skin and soft tissue infections. Wound Repair Regen. 2007; 15(3):368-77.

5) Miller, C.C., et al. (2013) Inhaled nitric oxide decreases the bacterial load in a rat model of *Pseudomonas aeruginosa* pneumonia. J Cyst Fibros 12, 817-20.

6) Regev-Shoshani, G., et al. (2013) Prophylactic nitric oxide treatment reduces incidence of bovine respiratory disease complex in beef cattle arriving at a feedlot. Res Vet Sci 95, 606-611

7) Regev-Shoshani, G., et al. (2017) Non-inferiority of nitric oxide releasing intranasal spray compared to sub-therapeutic antibiotics to reduce incidence of undifferentiated fever and bovine respiratory disease complex in low to moderate risk beef cattle arriving at a commercial feedlot. Prev Vet Med 138, 162-169

8) <https://www.healthline.com/health/bronchiolitis-vs-bronchitis>

9) American Academy of Pediatrics

# Bronchiolitis Market

Bronchiolitis is the leading cause of hospitalization for infants worldwide <sup>(1)</sup>

## Bronchiolitis Overview & Market Dynamics

- ~130,000 infant hospitalizations per year in the US<sup>(2)</sup>
- Significant impact on the elderly with 177,000 hospitalizations per year in the US<sup>(3)</sup> for RSV alone
- No drugs approved for the treatment of bronchiolitis<sup>(4)</sup>
- Standard of care in the hospital is oxygen and hydration

## Market Size

- Beyond Air estimates the global market to be >\$1.2 billion (>\$2.5 Billion including adults)
- Beyond Air's goal would be to reduce duration of symptoms in infants and the length of hospitalization
- Elderly population trials to follow infants (condition is not termed bronchiolitis in adults)



# Two Completed and Published Pilot Bronchiolitis Trials

First two pilot bronchiolitis trials demonstrate reduction in hospital LOS



PEDIATRIC PULMONOLOGY

ORIGINAL ARTICLE: RESPIRATORY INFECTIONS

Nitric oxide inhalations in bronchiolitis: A pilot, randomized, double-blinded, controlled trial

Asher Tal✉, David Greenberg, Yossef Av-Gay, Inbal Golan-Tripto, Yael Feinstein, Shalom Ben-Shimol, Ron Dagan, Aviv D. Goldbart

First published: 27 November 2017 | <https://doi.org/10.1002/ppul.23905> | Citations: 1

*LOS did not differ between groups. However, in a post-hoc analysis of a subgroup of infants hospitalized for >24 h (n = 24), the median LOS was shorter in the nitric oxide (41.9 h) than in the control group (62.5 h) (P = 0.014).*

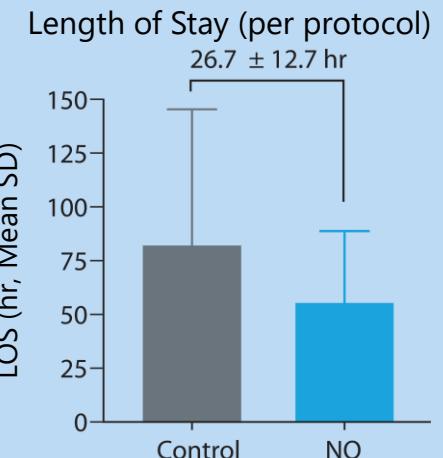
[Link](#)

SCIENTIFIC  
REPORTS

naturerresearch

Inhaled nitric oxide therapy in acute bronchiolitis: A multicenter randomized clinical trial

Aviv Goldbart<sup>1</sup>✉, Inbal Golan-Tripto<sup>1</sup>, Giora Pillar<sup>2</sup>, Galit Livnat-Levanon<sup>2</sup>, Ori Efrati<sup>3</sup>, Ronen Spiegel<sup>4</sup>, Ronit Lubetzky<sup>5</sup>, Moran Lavie<sup>5</sup>, Lior Carmon<sup>1</sup> & Amit Nahum<sup>1</sup>



SCIENTIFIC REPORTS | (2020) 10:9605 | <https://doi.org/10.1038/s41598-020-66433-8>

[Link](#)

# Third Bronchiolitis Pilot Study Top Line Data

Statistical significance on both the primary and secondary endpoint at 150 ppm vs. placebo and vs. 85 ppm

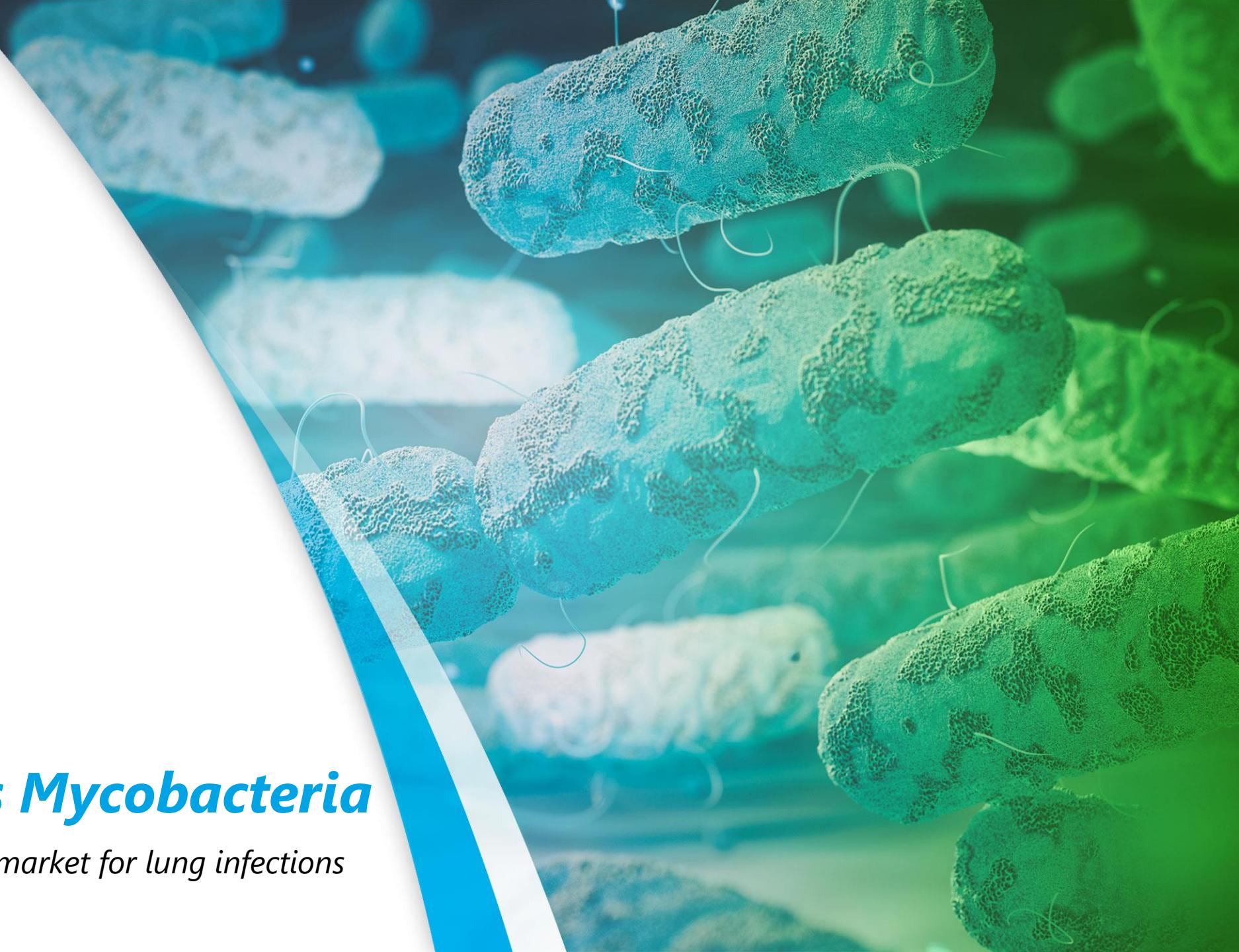
	150 ppm vs. 85 ppm	150 ppm vs. SST	85 ppm vs. SST
<i>Primary endpoint</i>			
<b>Time to Fit-to-Discharge (FTD)</b>			
Hazard Ratio	2.11	2.32	0.90
95% CI	1.03, 4.31	1.01, 5.33	0.44, 1.81
P-value	0.041	0.049	NS
<i>Secondary endpoint</i>			
<b>Hospital Length of Stay (LOS)</b>			
Hazard Ratio	2.01	2.28	0.77
95% CI	1.01, 3.99	1.03, 5.06	0.40, 1.48
P-value	0.046	0.043	NS

Pivotal study delayed due to COVID-19 – Beyond Air is prepared to initiate in the fourth quarter of 2021



## ***Nontuberculous Mycobacteria***

*Expanding NO into the home market for lung infections*



# Home Market: Nontuberculous Mycobacteria (NTM)

NTM is an FDA disease area of focus with limited treatment options

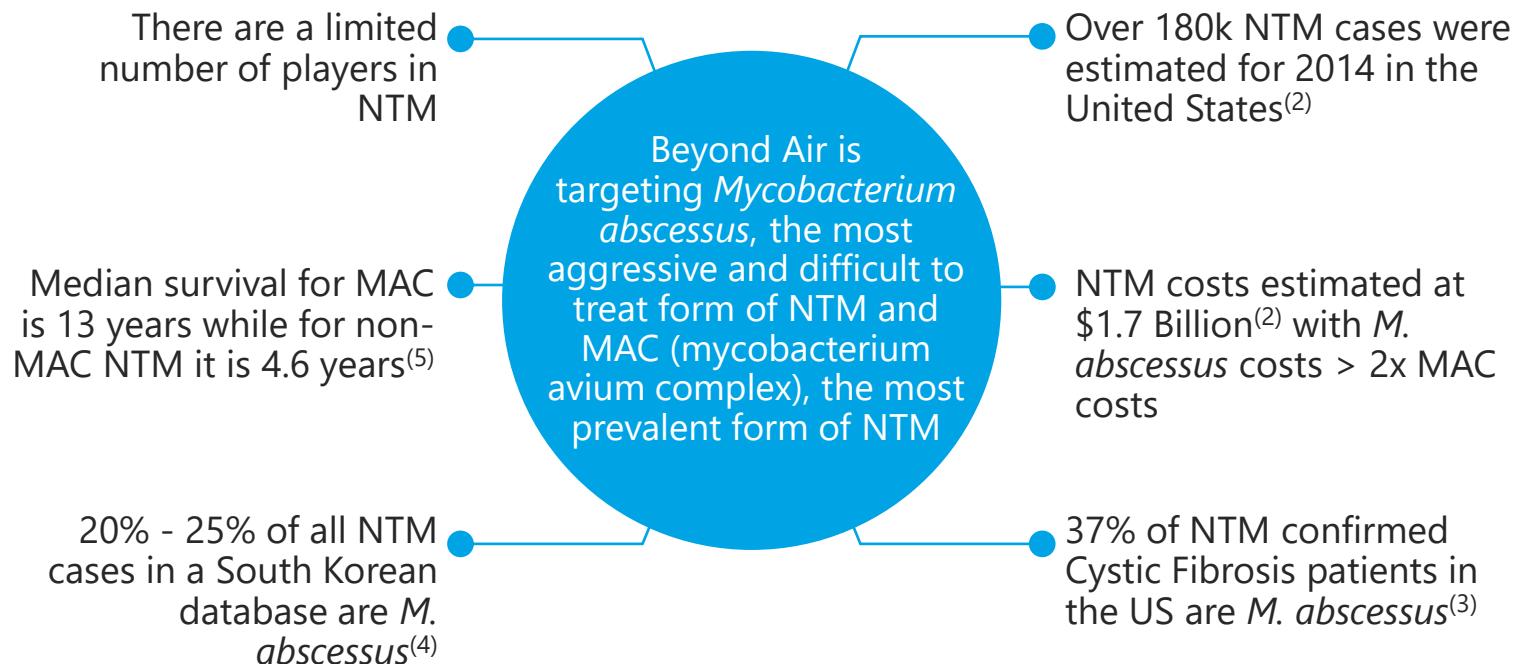
## How is NTM acquired?<sup>(1)</sup>

- Acquired by inhalation from the environment
- Water thought to be the main source
- Warmer climates have higher infection rates
- Patient to patient transmission possible

## Who is at risk?<sup>(1)</sup>

- Underlying lung disease and/or genetic predisposition
- Cystic Fibrosis (CF)
- COPD (chronic obstructive pulmonary disease)
- Bronchiectasis
- Receiving immunosuppressive therapy

## NTM Market Dynamics



1) Data: www.ntmfacts.com, FDA

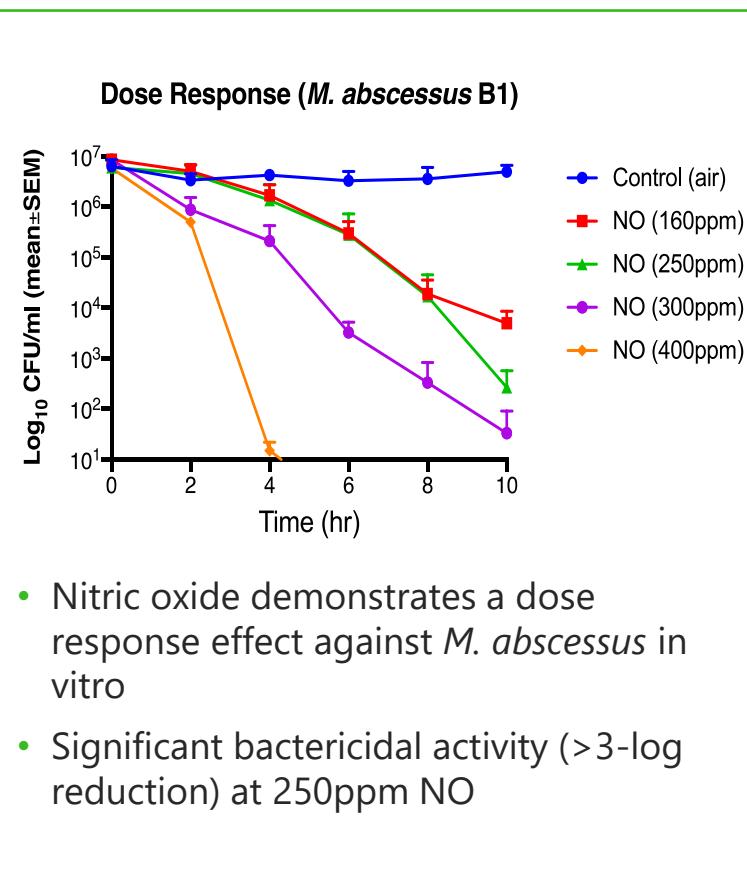
2) Strollo et al. The Burden of Pulmonary Nontuberculous Mycobacterial. Pub 27-July-2015

3) Data presented at ATS 2017 (Derek Low et al, Medical University of South Carolina)

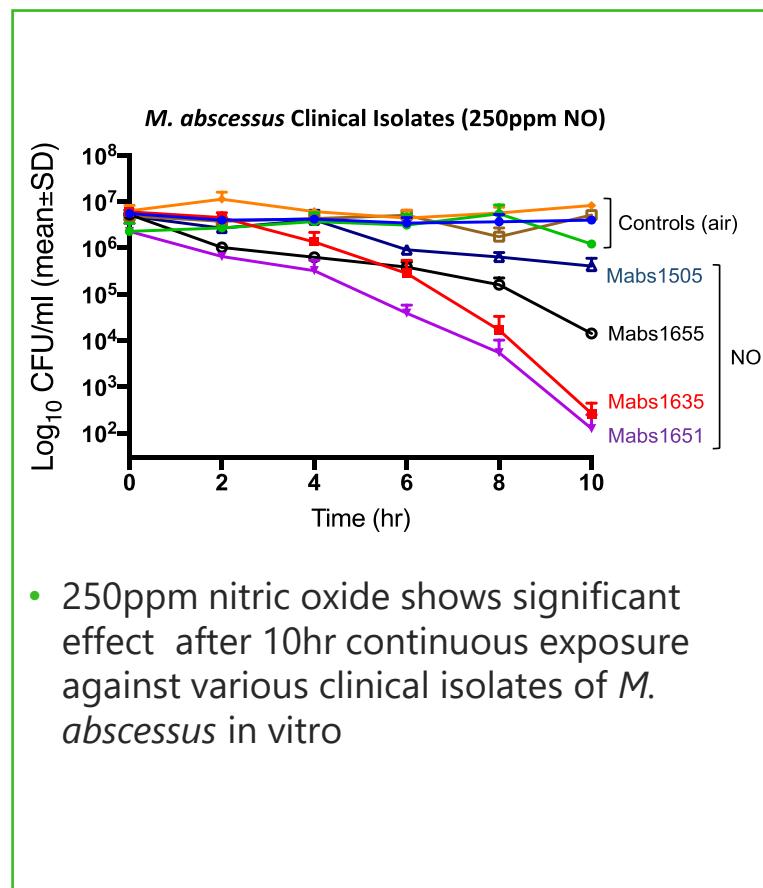
4) Data presented at ATS 2017 (Keun Burn Chung et al, Seoul National University College of Medicine) European Journal of Clinical Microbiology & Infectious Diseases 34.9 (2015)

# Pulmonary Infections: Nontuberculous Mycobacteria (NTM)

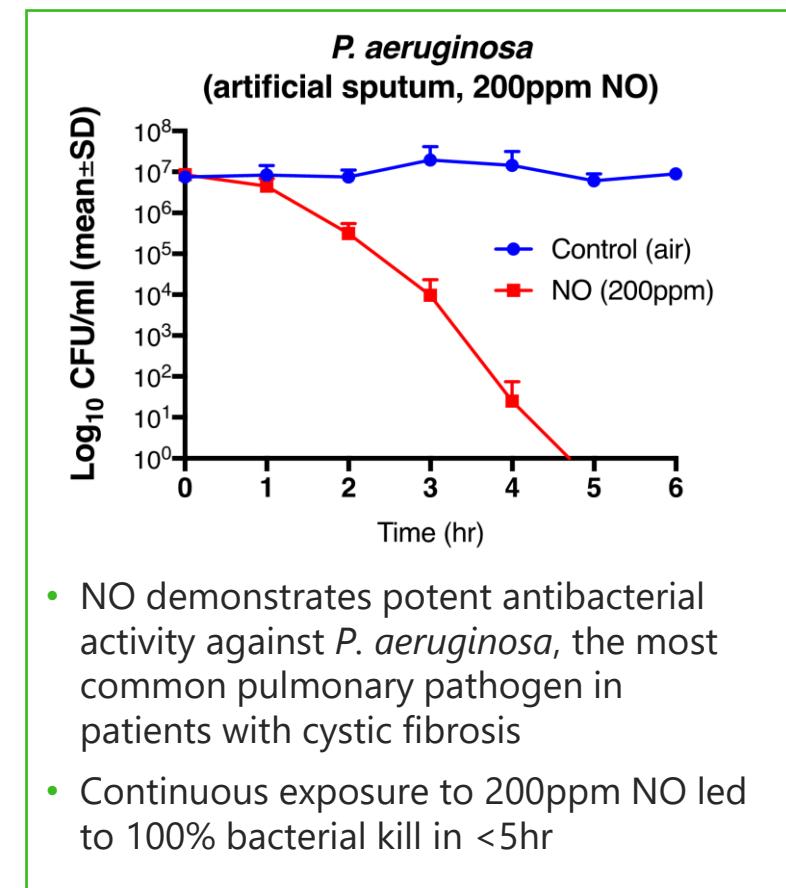
NO has direct killing effect on multi-drug resistant *M. abscessus* in vitro as well as common co-infections



- Nitric oxide demonstrates a dose response effect against *M. abscessus* in vitro
- Significant bactericidal activity (>3-log reduction) at 250ppm NO



- 250ppm nitric oxide shows significant effect after 10hr continuous exposure against various clinical isolates of *M. abscessus* in vitro



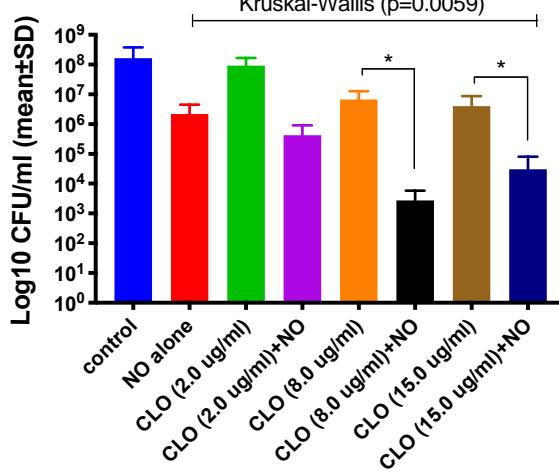
- NO demonstrates potent antibacterial activity against *P. aeruginosa*, the most common pulmonary pathogen in patients with cystic fibrosis
- Continuous exposure to 200ppm NO led to 100% bacterial kill in <5hr

Data Presented at the 3<sup>RD</sup> World Bronchiectasis Conference in 2018

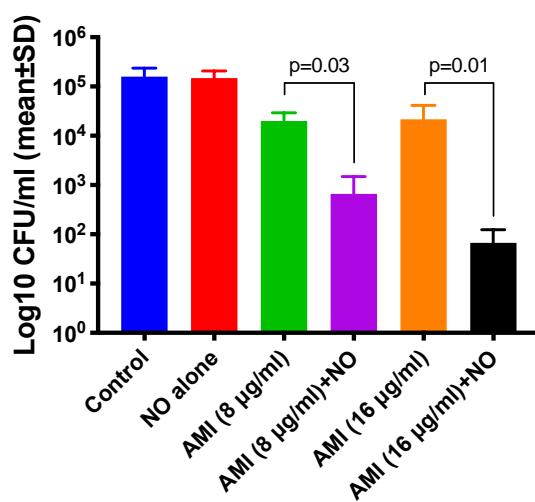
# Pulmonary Infections: Nontuberculous Mycobacteria (NTM)

NO synergy with clofazimine and amikacin against *M. abscessus* in vitro and kills when dosed intermittently

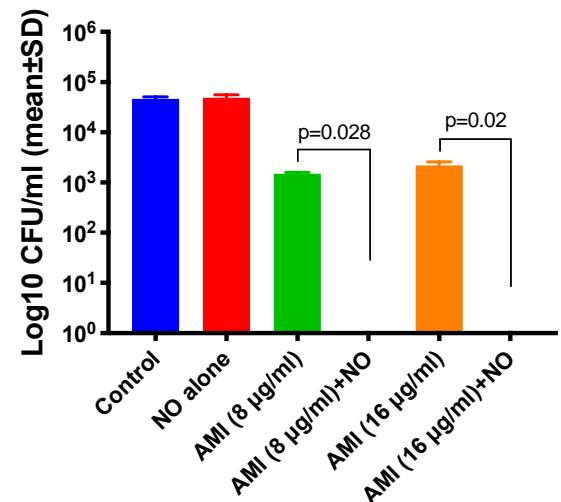
NO + CLO (*M. abscessus* ATCC 19777)



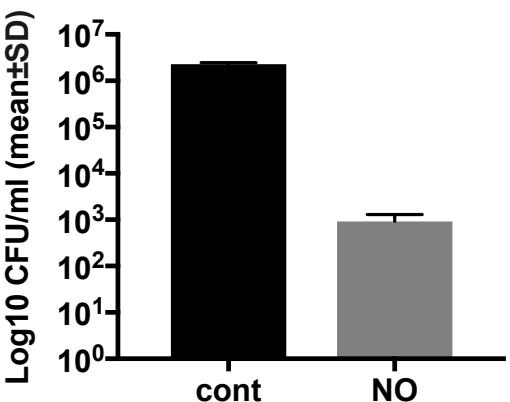
NO + AMI (*M. abscessus* 062600\_B1)



NO + AMI (*M. abscessus* 110917\_D1)



Intermittent 250 ppm NO  
(*M. abscessus* B1, 4 x40min, 48 hr)



NO synergistic effect seen with clofazimine (CLO) and amikacin (AMI)

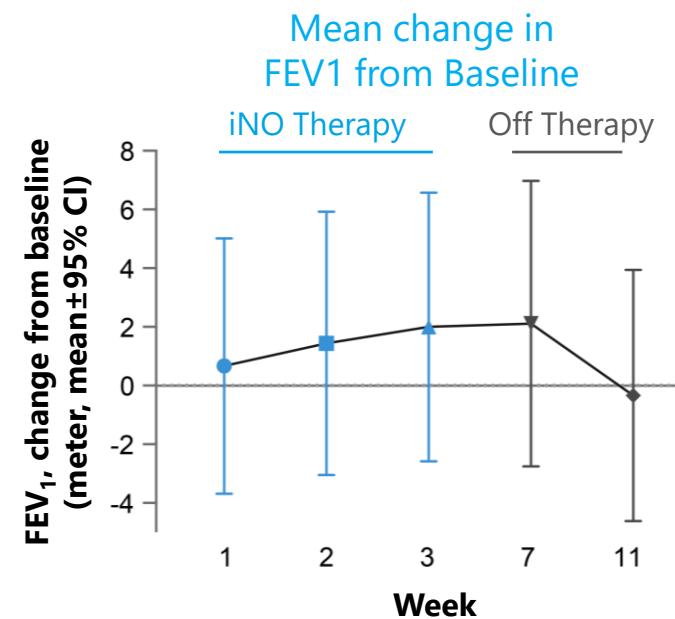
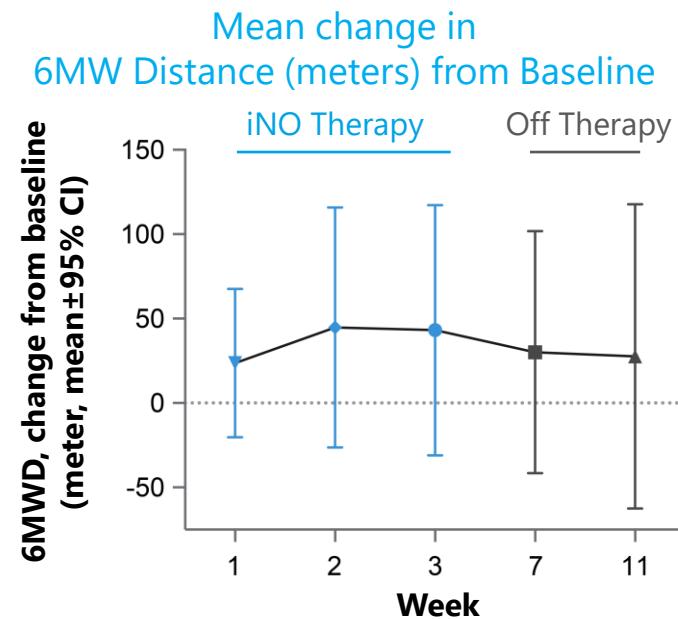
Each drug in combination with 3hr continuous exposure of NO demonstrates significant bactericidal activity against clinical isolates of *M. abscessus*.

Intermittent exposure to NO demonstrates anti-mycobacterium activity:  
4x40min regimen mimics anticipated human treatment regimen

Data Presented at ATS 2019 NTM Mini Symposium and ERS 2019

# Pilot Study in NTM infected CF Patients Demonstrates Safety and Efficacy

Single arm pilot study with 160 ppm NO showed a reduction in bacterial load and improvements in quality of life



- 9 CF patients with refractory MABSC were treated at 3 centers in Israel with NO added to background antibiotic therapy
  - 160 ppm NO was given via mask for 30 min 5x/day for 14 days and 3x/day for 7 days
  - Primary endpoint of safety was met, with no NO-related serious adverse events (SAEs) observed
  - Bacterial load, as measured by qPCR showed a 65% reduction at day 81 versus baseline
    - » One patient was culture negative at Day 51 and Day 81, two others had one negative culture
  - Quality-of-Life data showed positive trends on relevant questions
- 4 patients treated under compassionate use experienced similar results
  - 1 treated at NIH with LungFit™, 1 treated safely with 250 ppm NO, 1 culture conversion

# Pilot LungFit™ NTM Study Protocol Summary

- Open label pilot study with 12 weeks of treatment and 12 weeks of observation
- Approximately 20 subjects >18 years of age with NTM lung infection refractory to antibiotic therapy
  - Both MAC (*Mycobacterium avium* complex) and *Mycobacterium abscessus* will be included in CF and non-CF patients
- Study start fourth quarter 2020 with interim results expected 2Q21 and final results expected in 2H21
- Four doses of NO per day for 14 days followed by two doses of NO per day for 70 days (all patients will remain on background antibiotic therapy)
  - Each dose lasts 40 minutes and are 4-5 hours/at least 9 hours apart
  - Subjects will be titrated from 150 ppm up to 250 ppm in hospital with all subsequent administrations at home
- Primary endpoint is safety
- Key Secondary endpoints
  - Culture conversion/bacterial load
  - Quality of Life
  - Respiratory function
  - Physical function (activity tracker, 6MWT, etc.)



## Nitric Oxide for Solid Tumors

*Ultra high concentration nitric oxide has cytotoxic effects  
and immunostimulatory activity*



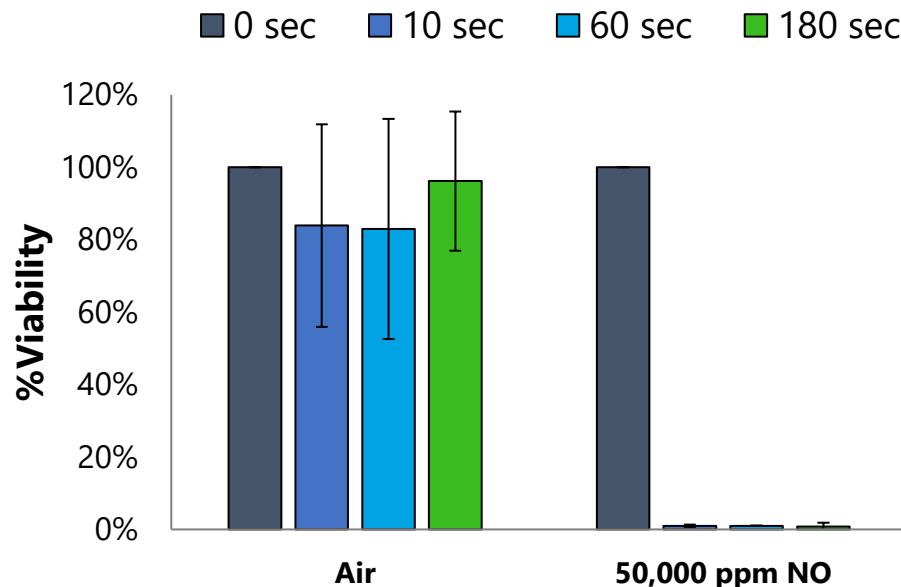
# Nitric Oxide is a Powerful Anti-Cancer Agent

- NO has shown anticancer properties at high concentrations
- Local tumor ablation resulting in tumor antigen release has been a goal in the fight against solid tumors
- Local tumor ablation using NO at concentrations >10,000 ppm may result in tumor antigen release
- Tumor antigen release is anticipated to trigger systemic anti-tumor immune response that could attack distal metastases



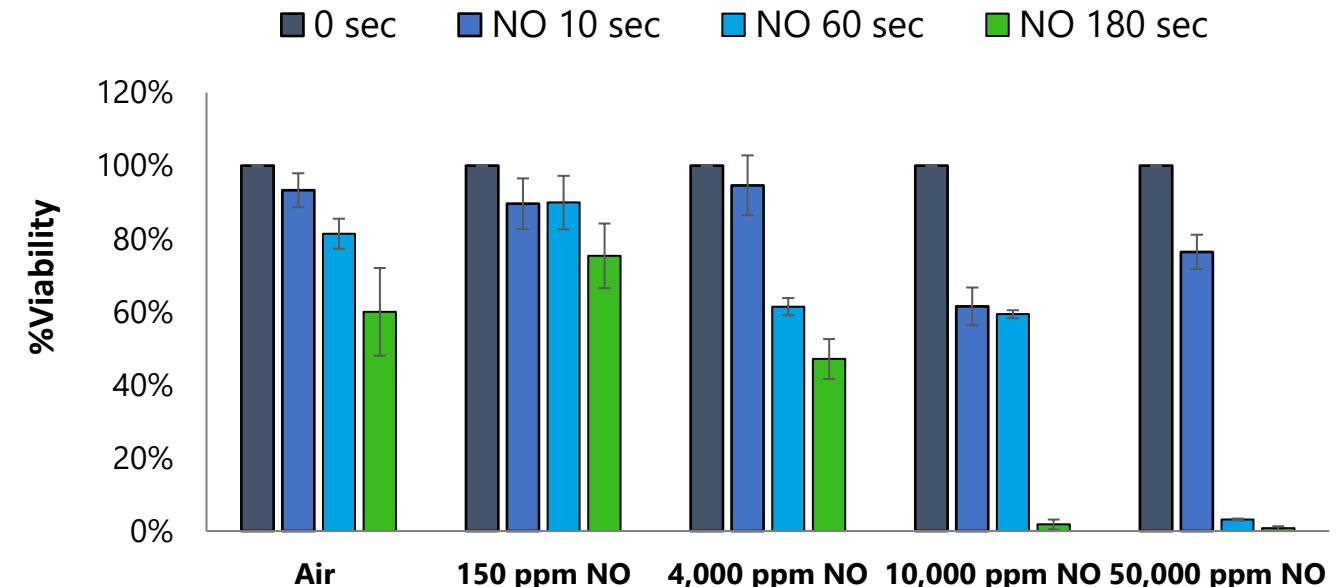
# Nitric Oxide Shows a Cytotoxic Effect on Colon and Breast Cancer Cells

## Colon Cancer Cells



Significant reduction in the viability of mouse colon cancer cells after exposure to 50,000ppm NO vs. air for 10-180 seconds.

## Breast Cancer Cells

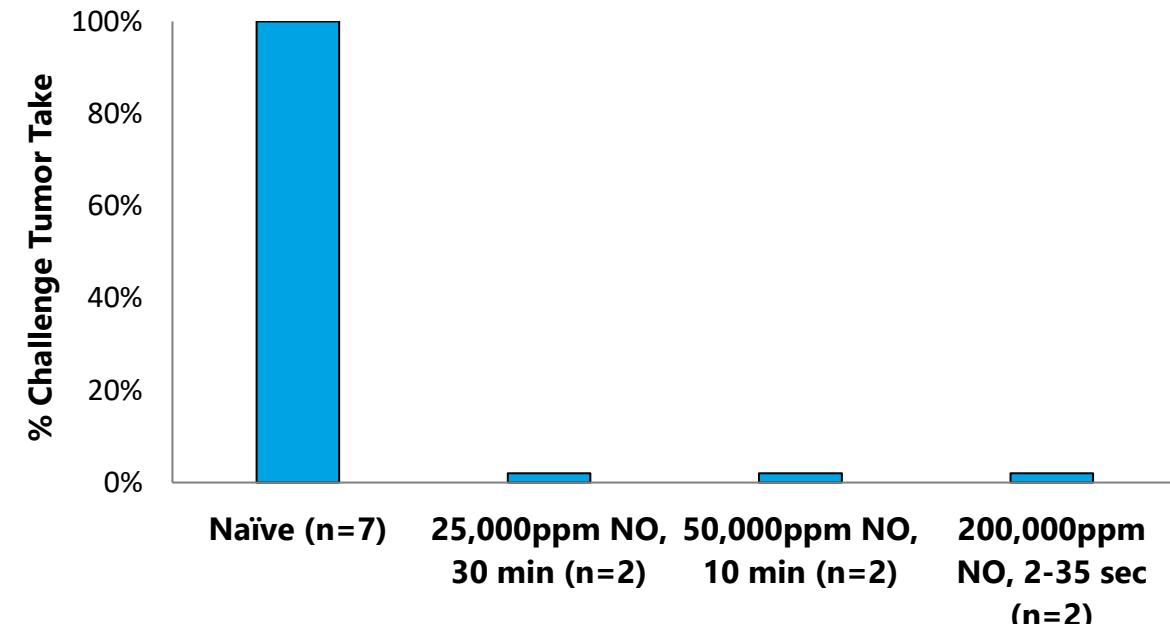
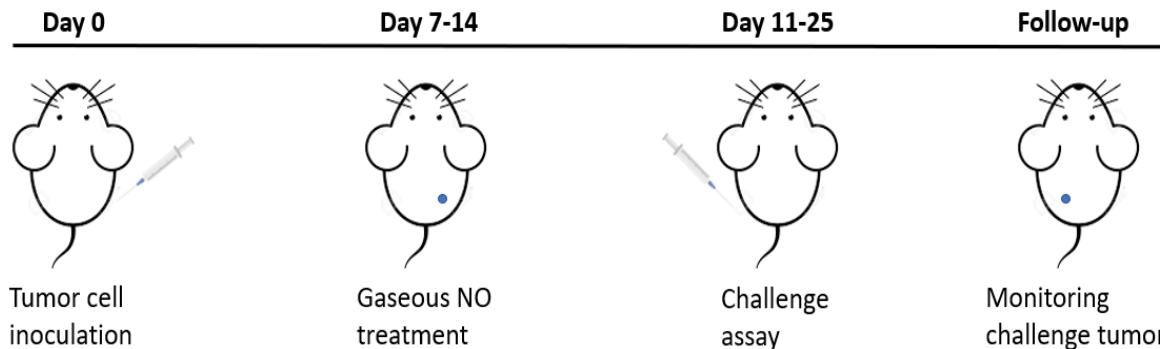


Significant time-dependent reductions in viability of mouse breast cancer cells after exposure to 150- 50,000 ppm NO or air for 10-180 seconds.

Data presented at the American Association for Cancer Research (AACR) June 22, 2020 via virtual AACR

# Nitric Oxide Stimulates an Anti-Tumor Immune Response

Nitric oxide mediates 100% prevention of tumor challenge



**Challenge assay:** The tumors of colon cancer tumor-bearing mice were treated with NO. Up to 14 days post NO treatment, mice were re-inoculated with colon cancer cells (CT26 cells) and the percentage of tumor take was monitored.

Data presented at the American Association for Cancer Research (AACR) June 22, 2020 via virtual AACR

# Financial and Patent Information

Ticker	XAIR
Exchange	NASDAQ
Share Price	\$7.24 (as of June 30, 2020)
Shares Outstanding	16.8 million

As of March 31, 2020

Cash & cash equivalents	\$25.5 million
Debt	\$5 million
Expected quarterly burn is approximately \$4-5M	

- > 20 issued patents expiring through 2033
- > 10 pending patents, if issued, may extend the last expiration through 2037
- Beyond Air believes that its patent portfolio is strong and broad
  - The generator
  - The breathing circuit
  - NO concentration
  - NO action in the body
  - NO dosing
  - NO<sub>2</sub> filter
  - Method of Use
  - Cancer
  - Coronavirus

# Upcoming Milestones

## Estimated timelines for pipeline progress and commercialization<sup>(1)</sup>

Program	1H20	2H20	1H21	2H21
LungFit™ PH Pulmonary Hypertension (PPHN & Heart Surgery <sup>(2)</sup> )	PMA submission to FDA delayed due to COVID-19 pandemic	Submit PMA to US FDA	US FDA approval anticipated: Commercial launch in the US and Israel	Continue to launch globally
LungFit™ COVID-19	Initiate US COVID-19 pilot study <b>ACHIEVED</b>	Report study data; discuss approval options with FDA & other regulatory agencies; manufacture product	Supply globally as needed	Supply globally as needed
LungFit™ Bronchiolitis	Report data from pilot study in Israel <b>ACHIEVED</b>	Pivotal study initiation delayed due to COVID-19 pandemic		Begin pivotal study in the US if pandemic conditions allow
LungFit™ Home NTM Lung Infection	Home study initiation delayed due to COVID-19 pandemic	Begin self-administration at home study	Report preliminary data from home study	Report full dataset from home study
LungFit™ Home Lung Infections in COPD Patients	Begin in vitro testing <b>ACHIEVED</b>		Report in vitro data	Begin pilot study (pending resource availability)
Multiple solid tumors	Preclinical data presented at virtual AACR in June 2020 <b>ACHIEVED</b>		Present pre-clinical data at a major medical conference	Potentially initiate human studies

# Beyond Air – A Paradigm Shift in Nitric Oxide Therapy

## LungFit™ devices generate nitric oxide (NO) from ambient air

- Allows for unlimited on-site generation of NO vs. fixed supply cylinder systems currently used in hospitals
- NO therapy can move safely into the home setting with self-administration for chronic infections

## Advantages over currently used NO cylinder systems in the hospital setting

- Smaller, lighter, easier to store and simple to use for staff while reducing safety concerns

## LungFit™ allows for the use of high concentration NO to treat a variety of lung infections

- Persistent pulmonary hypertension of the newborn (PPHN) is the only FDA approved indication at a concentration of 20 parts per million (ppm) of NO
- Beyond Air evaluating NO concentrations in the range of 150-250 ppm, which are challenging for cylinder systems
- “Intermittent” dosing allows for safe delivery of high concentration NO
- SARS CoV-2, bronchiolitis, nontuberculous mycobacteria (NTM) lung Infections in development, with COPD in preclinical
- Ultra-high concentration (10,000+ ppm) NO for solid tumors (without LungFit™) in preclinical development

## Extensive intellectual property portfolio

## Upcoming events

- PMA for PPHN expected to be filed in 2H 2020
- COVID-19 pilot studies underway in the US and Canada with data expected by year end

# Management Team

## Highly experienced and successful team of industry experts

	Steve Lisi Chairman and CEO	<ul style="list-style-type: none"><li>• 18 years experience as a Healthcare investor</li><li>• 3 years as SVP Head of Strategy and BD at Avadel (AVDL)</li><li>• Previously worked in HC investments at SAC Capital, Millennium Management, and was a partner at Deerfield</li></ul>
	Amir Avniel President & COO	<ul style="list-style-type: none"><li>• 15 years of executive-level experience in finance, business development and operations, including M&amp;A</li><li>• Previously worked at Rosetta Genomics (Founder) Rosetta Green (sold to Monsanto) and Monsanto</li></ul>
	Duncan Fatkis CCO	<ul style="list-style-type: none"><li>• 25+ years' experience across global medical device &amp; biopharma companies, including Becton Dickinson, Zimmer Biomet &amp; DePuy/J&amp;J</li><li>• Strong track record of commercialization, leading marketing &amp; sales</li><li>• Member of the Chartered Institute of Marketing for 30 years</li></ul>
	Giora Davidai CMO	<ul style="list-style-type: none"><li>• Prior to industry, was a pediatric nephrologist at Duke</li><li>• 23 years' experience in clinical research with &gt;10 drugs approved, including Phase 2-IV development of Spiriva</li><li>• Previously worked at Boehringer Ingelheim and Glaxo</li></ul>
	Douglas Beck CFO	<ul style="list-style-type: none"><li>• Over 10 years serving as CFO for 5 companies, including 3 Biotechs</li><li>• Has helped companies raise over \$100 million in equity &amp; debt</li><li>• Serves on the New York State Society of CPAs Chief Financial Officer &amp; SEC committee</li></ul>
	Frederick Montgomery VP, Medical Systems	<ul style="list-style-type: none"><li>• Developed all FDA approved NO systems used by Ino Therapeutics, Ikaria and Mallinckrodt</li><li>• Author on over 30 NO related patents including InoPulse</li><li>• Previously worked at Ikaria and NitricGen</li></ul>
	Rhona Shanker VP, Regulatory Affairs	<ul style="list-style-type: none"><li>• 35 years of FDA experience</li><li>• 22 years at the Device Division of FDA, with the final 10 years as an expert device reviewer</li></ul>
	Mike Gaul SVP, Operations	<ul style="list-style-type: none"><li>• 30+ years' in commercial and R&amp;D operations for medical devices at Sparton Corporation, SynCardia Systems and Robotic Vision Systems</li><li>• Proven track record in leading successful projects from concept to FDA approval and commercial success</li></ul>

DEERFIELD\*



LEVPHARMACEUTICALS



FDA



# Board of Directors

## Board of Directors with vast industry experience

	Steve Lisi Chairman and CEO	<ul style="list-style-type: none"><li>• 18 years experience as a Healthcare investor</li><li>• 3 years as SVP Head of Strategy and BD at Avadel (AVDL)</li><li>• Previously worked in HC investments at SAC Capital, Millennium Management, and was a partner at Deerfield</li></ul>
	Amir Avniel President & COO	<ul style="list-style-type: none"><li>• 15 years of executive-level experience in finance, business development and operations, including M&amp;A</li><li>• Previously worked at Rosetta Genomics (Founder) Rosetta Green (sold to Monsanto) and Monsanto</li></ul>
	Ron Bentsur Director	<ul style="list-style-type: none"><li>• Director since August 2015</li><li>• CEO and Director of UroGen Pharma since 2015</li><li>• Previous CEO and Director of Keryx Biopharmaceuticals</li><li>• Previous CEO of XTL Biopharmaceuticals</li></ul>
	Erick Lucera Director	<ul style="list-style-type: none"><li>• Director since August 2017</li><li>• CFO at Aveo</li><li>• Previous CFO of Valeritas, Viventia Bio</li><li>• Previous VP Corporate Development at Aratana</li></ul>
	Yoori Lee Director	<ul style="list-style-type: none"><li>• Director since January 2018</li><li>• Co-founder and President of Trio Health Advisory Group</li><li>• 15 years at Leerink Partners LLC</li><li>• Helped found the MEDACorp network</li></ul>
	Bill Forbes Director	<ul style="list-style-type: none"><li>• President and CEO of Vivelix Pharmaceuticals, Ltd.</li><li>• Former Chief Development Officer and Head of Medical and R&amp;D as Salix Pharmaceuticals</li><li>• Responsible for more than a dozen NDA/SNDA approvals</li></ul>
	Robert F. Carey Director	<ul style="list-style-type: none"><li>• Director since February 2019</li><li>• Served as Executive VP and Chief Business Officer at Horizon Pharma</li><li>• Previous Managing Director at JMP Securities</li></ul>





**For more information contact:**

Investor Relations

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[www.beyondair.net](http://www.beyondair.net)

